



A Pilot Randomised Controlled Trial of a Holistic Needs Assessment Questionnaire in a Supportive and Palliative Care Service

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Thesis submitted for the degree of Doctor of Philosophy

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September 2017



“The good physician treats the disease; the great physician treats the patient who has the disease” (William Osler, 1849 – 1919)

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Abbreviations

ADL:	Activities of Daily Living
AIDS:	Acquired Immune Deficiency Syndrome
BPI:	Brief Pain Inventory
BSc (Hons):	Bachelor of Science (Honours)
CNS:	Clinical Nurse Specialist
CONSORT:	Consolidated Standards of Reporting Trials
COPD:	Chronic Obstructive Pulmonary Disease
COREQ:	Consolidated Criteria for Reporting Qualitative Research
CRB:	Criminal Records Bureau
EAPC:	European Association for Palliative Care
EOL:	End of Life
EOLC:	End of Life Care
EQ-5D:	Standardised outcome measure of Health Related Quality of Life
EU:	European Union
GP:	General Practitioner
HADS:	Hospital Anxiety and Depression Scale
HCP:	Health Care Professional
HNA:	Holistic Needs Assessment
HRQoL:	Health Related Quality of Life
IHA:	Initial Health Assessment
ISRCTN:	International Standard Randomised Controlled Trial Number
LANNS:	Leeds Assessment of Neuropathic Symptoms and Signs
LCP:	Liverpool Care Pathway
M.Med.Sci:	Master of Medical Science
MacPaCC:	Macmillan Palliative Care Collaborative (Part of Macmillan Cancer Support)
MM:	Mixed Methods
MMR:	Mixed Methods Research
MMS:	Mixed Methods Study
MND:	Motor Neurone Disease
MPCU:	Macmillan Palliative Care Unit
MRC:	Medical Research Council
MREC:	Multi Centre Research Ethics Committee
MYCAW:	Measure Yourself Concerns and Wellbeing
MYMOP:	Measure Yourself Medical Outcome Profile
NCRI:	National Cancer Research Institute
NCSI:	National Cancer Survivorship Initiative
NEST:	Needs at the End-of-life Screening Tool
NHS:	National Health Service
NICE:	National Institute for Clinical Excellence/National Institute for Health and Care Excellence
NIHR:	National Institute for Health Research
OCPC:	Oncology Clinic Patient Checklist

PEI:	Patient Enablement Instrument
PhD:	Doctor of Philosophy
PNPC:	Problems and Needs in Palliative Care Instrument
PPI:	Patient and Public Involvement
R&D:	Research & Development
RCT:	Randomised Controlled Trial
REC:	Research Ethics Committee
RHH:	Royal Hallamshire Hospital
ScHARR:	School of Health & Related Research
SCNS:	Supportive Care Needs Survey
SIGLE:	System for Information on Grey Literature in Europe
SLH:	St Luke's Sheffield Hospice
SPARC:	Sheffield Profile for Assessment and Referral for Care
STH NHS FT:	Sheffield Teaching Hospitals NHS Foundation Trust
UK:	United Kingdom
USA:	United States of America
WHO:	World Health Organisation
WPH:	Weston Park Hospital

Dedication

In memory of my late dad, Mr Nur Mohammed, a learned man, and my greatest source of inspiration and motivation, who was always passionate about education and learning.

I am sure that he would have been so proud of my achievements.

Also dedicated to my mother Mrs Rehmat Bibi.

And

To my wife Fozia and children Bilal, Sofia, and Hifza for their love, patience and moral support throughout the duration of this study.

Declaration

I, Nisar Ahmed, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Copyright agreements have been obtained for published work arising from this thesis, including permission from co-authors to reproduce the work within this thesis. As a journal author, the licence signed when publishing the material means that I retain the rights to use the material for inclusion in a thesis or dissertation.

Acknowledgements

First and foremost, all praise is due the Almighty god and to my parents for their prayers which have enabled me to reach this all important milestone. It has always been my lifelong ambition to undertake a doctoral research study in a medical and health-related field.

It has been a great privilege for me to have undertaken this programme of work at The University of Sheffield, UK, which is recognised worldwide as an institute conducting high quality research, and more recently named as the UK University of the year 2011, in the Times Higher Education Awards.

During the course of this research, I have met people from all walks of life, who have shared interesting experiences with me. I also had the opportunity to attend national and international conferences to present my work and to network with other researchers from all around the world. The whole experience has been truly fascinating, and I feel a sense of immense personal satisfaction for completing this programme of work, an experience which will remain with me for the rest of my life.

I wish to acknowledge and thank numerous individuals and organisations for their continuous unfailing support and invaluable contributions to the study. There is no doubt that it would not have been possible to have completed this programme of work without their full co-operation and support.

Firstly, I would like to express my deepest gratitude and my sincerest of thanks to my academic supervisors: Professor Bill Noble; Professor Sam H. Ahmedzai; and Professor Karen Collins, for all their unwavering support, help, guidance and words of encouragement right from the conception of the original questions to the writing of the thesis. Your enormous contributions, generous giving of time, constructive criticism of my thesis and suggestions for improvement, mentorship and friendship will always be remembered and held in the highest of regard. Your insightful contributions from both an academic and clinical perspective proved extremely beneficial, and educational. Above all thank you for having the faith in me to deliver on this challenging piece of work.

I wish to extend my gratitude to my fellow researchers and co-workers: Ms Philippa Hughes; Dr Michelle Winslow; and Professor Peter Bath, for all the invaluable advice and support right from the word go.

I am extremely grateful to the patients who kindly and generously agreed to give their time and participate, and for sharing their experiences with me, often in the face of debilitating, advanced, progressive life threatening illnesses. I would like to extend my gratitude to patients' families and informal carers for supporting them in making this decision. I sincerely hope that this research has gone some way to fulfilling patients' expectations, and in helping future patients who may be in need of supportive and palliative care services.

I would also like to thank all the health care professionals (consultants, community nurses, managers, nurses, and clinical nurse specialists), who took ‘time-out’ from their busy work schedules to take part in the semi-structured interviews, and for their useful insights into patient assessment of needs from a ‘health care professional prospective’, that were very much valued and appreciated. A special thank you goes out to the senior management at the study sites for allowing me to undertake the study, and to all the staff members that supported this study at St.Luke’s Hospice (Sheffield) and across the various sites at the Sheffield Teaching Hospitals NHS Foundation Trust.

The administrative and secretarial support staff deserves special acknowledgement and great recognition for their supportive roles. I would particularly like to thank the following individuals for all the administrative support: Ms Pauline Hutchinson for transcription and secretarial support; the medical secretary, Ms Carolyn Sutton at the Central site of Royal Hallamshire Hospital (Sheffield); the medical secretary, Ms Kath Hibberd at the Northern General Hospital (Sheffield); the Medical Secretaries at St Luke’s Hospice, (Sheffield), Central Administration Team (Ms Jean Harland; Ms Sally Samavat; Ms Lisa Gash & Ms Celia Redmile). Thanks are also due to Ms Debbie Saunby (Lead Nurse) and Ms Louise McKay at St.Luke’s Hospice (Sheffield) for overseeing the administrative staff.

I would also like to thank the Macmillan Palliative Care Collaborative (MacPaCC; part of Macmillan Cancer Support) for advice and discussion of analysis, and the two consumer representatives: Ms Jacqui Gath; and Ms Alison Morton for their useful contributions to the study (Ahmed et al., 2015).

A special thank you is also due to our funders namely; Macmillan Cancer Support for funding all aspects of this important piece of work (Ahmed et al., 2015).

And last but not least, I am truly and greatly indebted to my family and some of my friends, including Wasim Ahmed (Information Science Specialist, Information School, The University of Sheffield) who provided practical, emotional and moral support throughout the duration of this study.

Thank you to everyone for all your contributions directly or indirectly, which have made this a truly memorable experience and helped immensely improve the quality of this research. I am grateful to all of you for sharing this wonderful and intellectually stimulating journey with me.

Preface

I am a health services researcher working in the Medical Care Research Unit, Health Services Research (Urgent and Emergency Care), School of Health & Related Research (ScHARR, The University of Sheffield). My employment with The University of Sheffield commenced in July 1999. I am currently a Project Manager for a study funded by Connected Yorkshire, part of the Connected Health Cities (CHC), a regional collaboration using local health data and advanced technology to improve health services for patients in Northern England.

I have over 16 years of experience of conducting research using both qualitative and quantitative methodologies, conducting systematic reviews, conducting surveys, experience in clinical trials methodology, undertaking all aspects of questionnaire development, preparing and submitting ethics and grant applications, analysing data and disseminating findings by writing papers for publication, and presenting work at meetings, conferences and seminars. I have successfully managed numerous research projects that have led to publications in peer-reviewed journals. I have previously worked in Palliative Medicine Unit (Academic Unit of Supportive Care) and Public Health at The University of Sheffield.

I undertook my PhD doctoral study while working in the Academic Unit of Supportive Care, Department of Oncology (formerly the Academic Palliative Medicine Unit), School of Medicine, at The University of Sheffield.

I graduated in 1995 with a BSc (Hons) degree in Pharmacology from the University of Leeds, and in 1997 with an M.Med.Sci. in Medical Science from The University of Sheffield. During my Master's degree, I undertook a research project entitled '*Altered ventricular repolarisation during hypoglycaemia invitro*'. The study involved collaboration with clinical colleagues in order to examine the relationship between hypoglycaemia and sudden death in diabetic patients, and to further explore the concept of 'dead in bed syndrome'. I have also worked as a Researcher (Systematic Reviewer) at Public Health Medicine, School of Health and Related Research (University of Sheffield), in the development of national clinical practice guidelines for the management and treatment of type 2 diabetes. It was during this time that I further developed an interest in medical and health services research. I have always had an interest in wanting to know more about how things work in the 'real world'.

I have worked on numerous research projects, and of particular relevance to this doctoral study, was my involvement with the early stages of development of a holistic needs assessment questionnaire in a supportive and palliative care service namely; the Sheffield Profile for Assessment and Referral for Care (SPARC).

SPARC is a multidimensional holistic needs assessment tool which provides a profile of needs (including physical, psychological, social, and spiritual issues) to identify patients who may benefit from additional supportive or palliative care regardless of diagnosis or stage of disease (Ahmed, 2010; Ahmed et al., 2014).

I was part of the team that developed SPARC over a period of five years. SPARC has undergone rigorous psychometric development, preliminary field-testing, and validation (Ahmed et al., 2004; Ahmed et al., 2009; Ahmed et al., 2014; Ahmed et al., 2015; Ahmedzai et al., 2004b; Bestall et al., 2004). SPARC has been shown to be acceptable to patients in various settings including those in support groups (Hughes et al., 2015) and at diagnosis (Wilcock et al., 2010). Since its inception, I have been involved with all aspects and stages of SPARC development (Ahmed, 2010; Ahmed et al., 2014).

There is evidence to indicate a lack of studies on the clinical utility of tools (Ahmed, 2010; Ahmed et al., 2014). Despite rigorous psychometric development, preliminary field-testing, and validation, the clinical utility of SPARC has yet to be established (Ahmed et al., 2015). The review I undertook as part of my doctoral study provided the evidence-base and the justification for a prospective randomised, controlled trial of the clinical utility of SPARC as an early holistic needs assessment, using the Medical Research Council framework for developing and evaluating complex interventions (Ahmed, 2010; Ahmed et al., 2014; Craig et al., 2008a; Craig et al., 2008b).

Having developed SPARC, the next step was to test its clinical utility, and we were rather fortunate to receive funding from Macmillan Cancer Support for a further four years, to undertake a pilot study to explore recruitment, data quality and follow up procedures in a prospective randomised controlled trial of the clinical utility of SPARC as an early holistic needs assessment (Ahmed, 2010; Ahmed et al., 2014). The four-year study commenced in January 2010 and was completed in January 2014. I was the trial manager and a co-applicant on the original grant application, and was involved with: protocol development; seeking of ethical approval; recruitment; data collection and analysis; drafting of the reports to the funder; and preparing papers for publication; as well as presenting the work at national and international conferences. It must however be stressed that although I managed the trial, I did not contribute to selecting the overall RCT design of the trial nor to selecting the outcome measures. The design of these elements preceded my involvement with the trial. The PhD and study hypothesis was that the use of a validated multidimensional holistic screening tool for supportive and palliative care needs namely; SPARC, would lead to improved recognition of supportive and palliative care needs and improved health care outcomes for patients (Ahmed, 2010; Ahmed et al., 2014).

Palliative care trials are complex, and in light of this, the trial was developed, piloted, evaluated, reported and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions (Ahmed, 2010; Ahmed et al., 2015; Craig et al., 2008a; Craig et al., 2008b). A complex intervention is described as having 'several interacting components' any of which could have an impact on the outcome. The control groups were placed on a 'waiting-list' and received the intervention at a later date (Craig et al., 2008a; Craig et al., 2008b; Higginson, 2005; Higginson et al., 2008). A multi-method research methodology was employed using both qualitative and quantitative techniques. It was anticipated that data generated from this pilot study would guide the

development of a further, and larger definitive multicentre study. This trial was the first step in a process that would define the clinical utility of SPARC. This study provided an opportunity to ‘test-drive’ SPARC with patients that have supportive and palliative care needs. It would contribute to recognising the best methods for identifying patients’ needs, and determine the extent to which these needs are addressed by following patients prospectively (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015). However, the results were counter intuitive, leading to concerns about the methodology and raising questions about the concept of holistic needs assessment (EAPC abstract, 2015), with the conclusion that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs a care plan (Ahmed et al., 2015).

The doctoral study in context

In summary, this doctoral study was conducted within the context of this pragmatic randomised controlled trial and nested within the MRC framework for evaluating complex interventions. An embedded (or nested) concurrent mixed methods design was considered the most appropriate design for this study. The rationale for this design is discussed further within this thesis. The primary objective was to design and undertake a pilot study to evaluate clinical outcomes associated with the use of SPARC. The trial itself focussed primarily on outcomes, not on the processes involved in implementing the intervention. An additional element of this PhD and a secondary objective was to undertake a process evaluation. From reviewing the literature, it became increasingly apparent of the importance of combining quantitative and qualitative research methods approaches in the development and evaluation of complex interventions in palliative care research. The use of qualitative and secondary quantitative analysis approaches alongside randomised controlled trials of complex healthcare interventions, in order to gain a better understanding of *‘whether and how an intervention works (or does not work) and inform the design of subsequent studies’* is highly recommended (Craig et al., 2008a; Craig et al., 2008b; Ellard et al., 2011; Ezendam et al., 2013; Farquhar et al., 2011; Flottorp et al., 2003; Francis et al., 2013; Grant et al., 2013; Hind et al., 2010; Moore et al., 2015; Toroyan et al., 2004; White, 2013).

List of publications arising from this thesis

Material from the following publications appears in this thesis.

Peer Reviewed Journal Papers

Ahmed, N., Hughes, P., Winslow, M., Bath, P., Collins, K., Noble, B. 2015. A pilot randomized controlled trial of a holistic needs assessment questionnaire in a supportive and palliative care service. *Journal of Pain and Symptom Management*. Volume 50, Issue 5, November. Pages 587–598.

Material from this paper (Appendix 1) appears in the following sections: Preface; Abstract; Background and Literature Review; Methodological Approach; Outcome Evaluation; Process Evaluation; Patient Interviews; HCP Interviews; Discussion.

Hughes, P., **Ahmed, N.**, Winslow, M., Walters, SJ., Collins, K., Noble, B. 2015. Consumer views on a new holistic screening tool for supportive and palliative care needs: Sheffield Profile for Assessment and Referral for Care (SPARC): A survey of self-help support groups in health care. *Health Expectations*. 18 (4), 562-577.

Material from this paper (Appendix 2) appears in the following sections: Preface; Process Evaluation; Patient Interviews; HCP Interviews; Discussion.

Ahmed, N., Ahmedzai, SH., Collins, K., Noble, B. 2014. Holistic assessment of supportive and palliative care needs: the evidence for routine systematic questioning. *BMJ Supportive & Palliative Care*. 4: 238-246.

Material from this paper (Appendix 3) appears in the following sections: Preface; Abstract; Background and Literature Review; Methodological Approach; Outcome Evaluation; Patient Interviews; HCP Interviews; Discussion.

Ahmed, N. 2010. Holistic assessment of supportive and palliative care needs. *MPhil to PhD Transfer Report Submitted to The University of Sheffield. December 2010.*

Material from this report appears in the following sections: Preface; Abstract; Background and Literature Review; Methodological Approach; Outcome Evaluation; Patient Interviews; HCP Interviews; Discussion.

Peer Reviewed Book Chapters

Ahmed, N., Noble, B., Ahmedzai, SH. 2010. The organisation of palliative care in England. (Book Chapter). Assessing organisations to improve palliative care in Europe. *Design and book production: Vantilt Publishers, Nijmegen, the Netherlands, and Martien Frijns, Doetinchem, the Netherlands (Appendix 4).*

Reports to Funding Bodies

Ahmed, N., Noble, B. 2014. Additional analysis of the Sheffield Profile for Assessment and Referral for Care (SPARC) feasibility trial. Process evaluation of a pragmatic randomised controlled trial of an holistic needs assessment questionnaire in a supportive and palliative care service. *Final Report to Macmillan Cancer Support*. 16th July 2014.

Ahmed, N., Hughes, P., Winslow, M., Bath, P., Collins, K., Noble B. 2013. A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC). *Final Report to Macmillan Cancer Support*. 31st January 2013.

Other publications relating to SPARC

Peer reviewed Journal Papers

Ahmed, N., Bestall, JC., Payne, SA., Noble, B., Ahmedzai, SH., 2009. The use of cognitive interviewing methodology in the design and testing of a screening tool for supportive and palliative care needs. *Supportive Care in Cancer*. 17 (6):665-673.

Material from this paper appears in the following sections: Process Evaluation; HCP Interviews.

Ahmed, N., Bestall, JC., Ahmedzai, SH., Payne, SA., Clark, D., Noble, B. 2004. Systematic review of the problems and issues of accessing specialist palliative care by patients, carers and health and social care professionals. *Palliative Medicine*. Volume 18, Number 6, 525-542. 1 September 2004, Arnold.

Bestall, JC., **Ahmed, N.**, Ahmedzai, SH., Payne, SA., Noble, B., Clark, D. 2004. Access and referral to specialist palliative care: patients' and professionals' experiences. *International Journal of Palliative Nursing*. Volume 10, Number 8, 381 -389.

Other Reports to Funding Bodies

Ahmedzai, SH., Payne, SA., Bestall, JC., **Ahmed, N.**, Dobson, K., Clark, D., Noble B. 2004. Developing a screening measure to assess the distress caused by advanced illness that may require referral to specialist palliative care. Academic Palliative Medicine Unit, Sheffield Palliative Care Studies Group, *Final Report 2004 (Elizabeth Clark Charitable Trust)*. The University of Sheffield.

Presentations: Conference and Seminar Papers (Selected published abstracts)

Oral Presentations

8th World Research Congress of the European Association for Palliative Care (EAPC) Lleida, Spain, 2015

- **Ahmed, N.**, Hughes, P., Winslow, M., Bath, P., Collins, K., Noble, B. 2015. A randomised controlled trial of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC): A mixed methods study. *Palliative Medicine*. Vol 28, Number 6. Oral, abstract number FC24.

Material from this abstract appears in the following sections: Preface; Outcome Evaluation; Process Evaluation; Patient Interviews; HCP Interviews; Discussion.

Third Year PhD Presentation. The Medical School. The University of Sheffield, September 2013

- **Ahmed, N.** 2013. Evaluation of an holistic needs assessment intervention in a supportive and palliative care service. Third Year PhD Presentations. Tuesday 10th September 2013 in Lecture Theatre 2, B Floor, Medical School. The University of Sheffield.

First Year PhD Presentation. The Medical School. The University of Sheffield, May 2010

- **Ahmed, N.** 2010. Holistic assessment of supportive and palliative care needs. First Year MPhil/PhD/MD Presentations. Thursday 6th May 2010. Medical School. The University of Sheffield.

The 11th Congress of EAPC in Vienna, Austria. Saturday, May 2009

- **Ahmed, N.**, Ahmedzai, SH., Engels, Y., Gomez-Batiste, X., Hasselaar, J., Jaspers, B., Mollard, JM., Klaschik, E., Leppert, W., Menten, J., Noble, B., Paz, S., Vanbeek, K., Woitha, K., Vissers, K. 2009. Access and referral to palliative care in seven European countries- an EU perspective. EAPC, Vienna, Austria, May 2009.

Trans-Pennine Palliative Care Research Network Meeting, Liverpool, United Kingdom, October 2005

- **Ahmed, N.** 2005. Trans-Pennine Palliative Care Research Network Meeting, The University of Liverpool, United Kingdom. Developing Sheffield Profile for Assessment and Referral for Care (SPARC). October 2005.

Poster Presentations

14th World Congress of the European Association for Palliative Care, Copenhagen, Denmark, 8 May-10th May 2015.

- **Ahmed, N., Collins, K., Noble, B.** 2015. A qualitative study to elicit the views of patients about their experience of completing an holistic needs assessment tool, the Sheffield Profile for Assessment and Referral for Care (SPARC): A qualitative study embedded in a RCT. *European Journal of Palliative Care*. 2015. Abstracts. Abstract Number P2-074, p188.

Material from this abstract appears in the following sections: Preface; Outcome Evaluation; Process Evaluation; Patient Interviews; HCP Interviews; Discussion.

First UK Clinical Trials Conference for Supportive Care in Cancer Research, Sheffield, June 2015

- **Ahmed, N., Collins, K., Noble, B.** 2015. A qualitative study to elicit the views of patients about their experience of completing an holistic needs assessment tool, the Sheffield Profile for Assessment and Referral for Care (SPARC): A qualitative study embedded in a RCT. 3rd June 2015.

13th EAPC World Congress, Prague, Czech Republic. 30th May 2013- 2nd June 2013

- **Ahmed, N., Winslow, M., Hughes, P., Bath, P., Collins, K., Noble, B.** 2013. Feasibility study of the Sheffield Profile for Assessment and Referral for Care (SPARC).

The 9th Palliative Care Congress: The Sage Gateshead, Newcastle Gateshead, UK, March 2012

- **Ahmed, N., Hughes, P., Winslow, M., Bath, P., Collins, K., Noble, B.** Feasibility study of the Sheffield Profile for Assessment and Referral for Care. 2012. The 9th Palliative Care Congress was held at: The Sage Gateshead, Newcastle Gateshead, UK, 14-16 March 2012. Published in *BMJ Supportive and Palliative Care* 2012. doi:10.1136/bmjspcare-2012-000196.126.

7th World Research Congress of the European Association for Palliative Care (EAPC), Trondheim, Norway, June 2012

- **Ahmed, N., Hughes, P., Winslow, M., Bath, P., Collins, K., Noble, B.** 2012. Feasibility study of the Sheffield Profile for Assessment and Referral for Care (SPARC): A holistic needs questionnaire. Abstracts of the 7th World Research Congress of the European Association for Palliative Care (EAPC), Trondheim, Norway, Published in *Palliative Medicine*. 7-9 June 2012.

12th Congress of the European Association for Palliative Care, Lisbon, Portugal, May 2011

- **Ahmed, N.**, Hughes, P., Winslow, M., Bath, P., Collins, K., Noble B. 2011. Feasibility Study of the Sheffield Profile for Assessment and Referral for Care (SPARC): A holistic needs questionnaire. 12th Congress of the European Association for Palliative Care, Lisbon, Portugal. May 18-21, 2011. Published in *Palliative Medicine*.

12th Congress of the European Association for Palliative Care, Lisbon, Portugal, May 2011

- Leppert, W., Stelcer, B., Ahmedzai, SH., **Ahmed N.** 2011. Preliminary experience with the use of the Polish version of the Sheffield Profile for Assessment and Referral for Care (SPARC). A new method of quality of life assessment in palliative care. Abstract Number P570. 12th Congress of the European Association for Palliative Care, Lisbon, Portugal. May 18-21, 2011. Published in *Palliative Medicine*.

Structure of the thesis

This programme of research comprises of two phases (outcome evaluation and process evaluation), both phases of the research were funded by Macmillan Cancer Support. This thesis will report on the findings from both phases of the research.

Phase 1: Outcome evaluation study: The main randomised controlled trial.

A pilot study of a holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC). The findings of the outcome evaluation together with some additional analysis undertaken are reported in full.

Phase 2: Process evaluation study: Qualitative study running alongside a RCT.

The process evaluation study comprising of three additional strands of work namely: 1) analysis of semi-structured interviews with patients; 2) analysis of semi-structured interviews with health care professionals; and 3) retrospective case note reviews (presented under findings and analysis of Phase I: outcome evaluation).

Project development

Professor Bill Noble was the principal investigator and project director. I was the trial manager and was responsible for the day to day management of the study, and I prepared applications for the relevant permissions, carried out the data collection, analysis and report writing. Professor Peter Bath carried out the major part of the statistical analysis (quantitative analysis: reported in **Chapter 4**). All team members were involved in design, planning and

implementing the study, as well as in the analysis and reporting. Some members were part of the internal project group, attending regular meetings and contributing to all stages of the study. Other personnel were co-opted as needed, and decisions were made consensually.

Study registration

The Trial was registered with the following organisations:

1. Sheffield Teaching Hospital (STH) NHS Foundation

2. Current Controlled Trials Register

'A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)'

International Standard Randomised Controlled Trial Number (ISRCTN):

ISRCTN25758268 <http://www.controlled-trials.com/ISRCTN25758268/> (Appendix 5).

3. Cancer Research UK

'A study testing a questionnaire to work out the care needs of people using a supportive or palliative care service in Sheffield (SPARC feasibility)'

<http://cancerhelp.cancerresearchuk.org/trials/a-study-testing-questionnaire-work-out-care-needs-people-using-supportive-or-palliative-care-service-sheffield-SPARC-feasibility>

Funding

This programme of research was funded by Macmillan Cancer Support under its Programme Grants made to the Macmillan Palliative Care Collaborative (MacPacc) and approved by the Commissioning Group, which comprises of research, service and healthcare expertise within Macmillan. The study was independently reviewed by academic and service user reviewers.

The research comprises of two phases (outcome and process evaluation), both phases of research were funded by Macmillan Cancer Support (**funding letters 1 and 2: Appendix 6 and Appendix 7** respectively), and I was a co-applicant on both of the successful grant applications.

Sponsor

The sponsor for the study was the Sheffield Teaching Hospitals (STH) NHS Foundation Trust. The trial insurance letter was issued on 28th October 2010 (**Appendix 8**).

Steering group

A research project steering group was convened to provide expertise and guidance and to ensure that project milestones were met. Steering group meetings were held twice a year over the study period. The following nine individuals from a range of backgrounds and with multidisciplinary skills were part of the steering group contributing to all stages of the study (Ahmed et al., 2015):

- Four health service researchers Mr Nisar Ahmed¹, Ms Philippa Hughes¹, Professor Karen Collins³, Dr Michelle Winslow¹;
- A Palliative Medicine Consultant and Senior Lecturer in Palliative Medicine: Professor Bill Noble¹;
- A health informatics specialist/statistician: Professor Peter Bath²;
- A Project Administrator: Ms Pauline Hutchinson¹;
- Two consumer representatives: Ms Jacqui Gath, and Ms Alison Morton.

¹ Academic Unit of Supportive Care, School of Medicine and Biomedical Sciences, University of Sheffield.

² Centre for Health Information Management Research, Information School, University of Sheffield.

³ Centre for Health and Social Care Research, Faculty of Health and Wellbeing, Sheffield Hallam University.

(Ahmed et al., 2015).

Consumer involvement

Consumer involvement particularly in the early stages of research development is viewed in the UK as both a medical and a political priority as a means of empowering patients (Ali et al., 2006; Allsop et al., 2004; Collins et al., 2005). The involvement of consumers and greater public involvement in shaping health care systems and delivery, particularly in the UK (Boote et al., 2006), and Western nations has gained momentum (Anderson, 1996). Some funders, for example, the Medical Research Council and the United Kingdom Co-ordinating Committee on Cancer Research have established consumer liaison groups (Hanley et al., 2001). Patient and public perspectives were integral to this research. The North Trent Cancer Network Consumer Research Panel has been a contributor to many projects at The University of Sheffield. Developed within the Academic Unit of Supportive Care, panel members now

have considerable experience in working with researchers on projects and studies. The panel comprises of 40 former and current cancer patients and carers (Caldon et al., 2010; Collins et al., 2005; Collins & Ahmedzai, 2005).

Representatives of the Consumer Research Panel (North Trent Cancer Network) were involved in earlier SPARC studies, including a research study to establish the acceptability and usability of the screening tool across a wide-range of conditions and at different stages of disease. The study demonstrated the acceptability of SPARC (Hughes et al., 2015).

Representatives from the panel were invited to consider the study and give comments. Two service user representatives who expressed an interest in the study were consulted during the research study; this was done by co-opting representatives onto the project steering group. This meant that all aspects of the study benefited from the comments and insights of people receiving services.

The two consumer representatives took part in ongoing discussions of the project, and were invited to be part of both the project group (consisting mainly of members of the research team), and the project steering group. This approach worked well during this study and in our previous work, and resulted in valuable and useful contributions to study design, documents, analysis and reporting. Project Group meetings involved members of the research team meeting on a much more regular basis than the Project Steering group meetings. The level and nature of user involvement is presented in **Table 1**.

Table 1: Level and nature of user involvement

	Consultation	Collaboration
Development of the grant application	✓	
Design and management of the research	✓	✓
Undertaking the research	✓	
Analysis	✓	
Dissemination of research findings (proposed)	✓	✓

The two consumer representatives were involved in all phases of the study including protocol design and assisted the research team particularly with writing patient information sheets and with the ethics application (Patient and Public Involvement: PPI. www.rcpch.ac.uk).

Researchers consulted the two consumer representatives about the research e.g. through individual contacts, and one-off meetings. The two service-user representatives were unable to attend the Steering Group Meetings, and made their contributions mainly via email/letter correspondence.

Abstract

Background: Studies suggest that cancer and non-cancer patients have needs (e.g. physical, psychological, religious, spiritual needs and information needs) that are not being adequately met. The review undertaken has presented a strong argument in favour of the case for a comprehensive holistic assessment of supportive and palliative care needs (Ahmed, 2010; Ahmed et al., 2014). At present, there is no widely used systematic, evidence-based, holistic approach to screening patients for supportive and palliative care needs. There is evidence to indicate a lack of studies on the clinical utility of tools (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015). The Sheffield Profile for Assessment and Referral for Care (SPARC) is a multidimensional screening tool which gives a profile of needs to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of disease. Despite rigorous psychometric development, preliminary field-testing, and validation, the clinical utility of SPARC has yet to be established (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015). This doctoral study was conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for evaluating complex interventions. From reviewing the literature, it became increasingly apparent of the importance of combining quantitative and qualitative research methods approaches in the development and evaluation of complex interventions in palliative care research. This study provides an opportunity to ‘test-drive’ SPARC with patients that have supportive and palliative care needs. The hypothesis was that the use of a validated multidimensional holistic screening tool for supportive and palliative care needs, namely; SPARC, would lead to improved recognition of supportive and palliative care needs, and improved health care outcomes for patients (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

Aims and Objectives: The primary objective was to design and undertake a pilot study to evaluate clinical outcomes associated with the use of SPARC. The trial itself focussed primarily on outcomes, not on the processes involved in implementing the intervention. An additional element of this doctoral study and a secondary objective was to undertake a process evaluation (comprising of retrospective case note reviews, semi-structured interviews with patients and health care professionals) (Ahmed et al., 2015).

Methods: This was an open, pragmatic, randomised controlled trial. Patients (n=182) referred to the palliative care service were randomised to receive SPARC at baseline (n=87) or after a period of two weeks (waiting-list control n=95). Primary outcome measure is the difference in score between Measure Yourself Concerns and Wellbeing (MYCAW) patient-nominated Concern 1 on the patient self-scoring visual analogue scale at baseline and the two-week follow-up. Secondary outcomes include difference in scores in the MYCAW, EuroQoL (EQ-5D), and Patient Enablement Instrument (PEI) scores at Weeks 2, 4, and 6. As part of a process evaluation, case notes were reviewed at week 8, and semi-structured interviews were undertaken with a sub-group of patients and health care professionals (Ahmed et al., 2015).

Results: There was a significant association between change in MYCAW score and whether the patients were in the intervention or control group (χ^2 trend = 5.51; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in the control group had an improvement in MYCAW score from baseline to Week 2: control (34 of 70 [48.6%]) vs. intervention (19 of 66 [28.8%]). There were no significant differences (no detectable effect) between the control and intervention groups in the scores for EQ-5D and Patient Enablement Instrument at 2, 4, or 6-week follow-up (Ahmed et al., 2015). Most patients interviewed [30/33], found SPARC either quite easy to complete, fairly straightforward, simple or had no problems in completing it. Only a small number of participants found questions on SPARC ‘too sensitive or upsetting’. A crucial finding in the context of the trial was the large proportion of patients interviewed [30/33] who did not experience or report any noticeable change, or beneficial effects after completing SPARC (EAPC abstract, 2015). Most health care professionals had something positive to say about SPARC and had previous experience of using SPARC, and most were considering using it at some point in the future. A number of barriers were identified to the relief of distress highlighted by SPARC. Only 5/164=3.0% patient notes made any direct reference to SPARC.

Conclusion: This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan (Ahmed et al., 2015). This is supported by review of case notes, and the interview data from patients that indicate that most patients felt that no particular action or benefit followed from the completion of SPARC (Ahmed et al., 2015). Only a few patients who had no recent contact with palliative care service and scored high for some SPARC items were recalled by the service and reassessed. Overall, participants and health care professionals considered SPARC an acceptable and relevant tool for the clinical assessment of supportive and palliative care needs (EAPC abstract, 2015). The potential negative effect of SPARC in a specialist palliative care service could be due to the failure of health care professionals to act on identified needs in a timely manner, or related to the raising of patients’ expectations that are not subsequently met. The qualitative study helps in the interpretation of the outcome results, and provides useful insights into how SPARC might be used in practice. Early identification of and monitoring of symptoms is only useful if effective treatment programs or systems are in place to address identified needs, and we must consider and evaluate new methods to achieve practice change. The effective integration of SPARC into routine care and standard operating systems requires further investigation (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

Key Words: Palliative care, holistic needs assessment, pilot randomised trial, SPARC, MYCAW, EQ-5D, PEI, process evaluation, semi-structured patient and health care professional interviews, qualitative study (Ahmed et al., 2015).

Trial registration: ISRCTN 25758268

Chapter 1

1 Background and Literature Review

1.1 Abstract

Background

Studies suggest that cancer and non-cancer patients have physical, psychological, religious, spiritual needs and information needs that are not being adequately met. At present, there is no widely used systematic, evidence-based, holistic approach to screening patients for supportive and palliative care needs (Ahmed et al., 2015). A review of the literature was undertaken to research the evidence base (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

Aims

The aim of the literature review was to provide an overview of holistic needs assessment in the fields of supportive and palliative care (Ahmed, 2010; Ahmed et al., 2014).

Methods

A comprehensive review of the literature was undertaken to identify both published and unpublished material (papers/research) on holistic needs assessment in supportive and palliative care. The following sources were searched: electronic databases; grey literature sources; hand-searching of key journals; and contacting experts in the field (Ahmed, 2010; Ahmed et al., 2014).

Results

A total of 63 papers were included in the review. There is evidence to suggest that patients with cancer and other non-malignant chronic progressive illnesses can experience some very distressing symptoms, issues and problems, which can often remain unrecognised. Assessing patients' holistic needs using routine systematic questioning ('done or acting according to a fixed plan or system; methodical') is useful in identifying symptoms, problems and issues, that would otherwise not be identified by other means, such as during a routine consultation, or by using open-ended questions. The need for systematic questioning is essential if holistic needs are to be identified and addressed. Recommendations for holistic needs assessment are also presented (Ahmed, 2010; Ahmed et al., 2014).

Conclusions

This review has presented a strong argument in favour of the need for a comprehensive holistic assessment of supportive and palliative care needs. There is evidence to indicate a lack of studies on the clinical utility of tools. Early identification of and monitoring of symptoms is only useful if effective treatment programs or systems are in place to address

identified needs, and we must consider and evaluate new methods to achieve practice change (Ahmed, 2010; Ahmed et al., 2014).

1.2 Review Procedure

Literature review methodology: search strategy for identification of studies

A detailed search strategy used to identify the literature and the evidence base is presented below (Ahmed et al., 2014). The review of the literature was conducted in the following stages (Ahmed et al., 2004):

- SEARCH STRATEGY
- INCLUSION AND EXCLUSION CRITERIA
- ASSESSMENT OF RELEVANCE AND VALIDITY OF STUDIES
- DATA EXTRACTION
- RESULTS OF SEARCHES
- DATA SYNTHESIS

1.21 Search strategy for identification of studies

The background literature review seeks to summarise present knowledge regarding patient holistic needs assessment in the fields of supportive and palliative care. The overall aim of the literature review was to add to the knowledge base by 1) providing an overview of patient holistic needs assessment in the fields of supportive and palliative care and reviewing the evidence of the value of routine systematic questioning; 2) identifying issues relating to access and referral to palliative care (barriers and timely referrals); 3) reviewing assessment tools and instruments currently used for assessing patients' holistic needs; 4) identifying studies examining the clinical utility of tools; and 5) identifying research gaps.

I undertook a narrative literature review (i.e. not a systematic review; methodologically speaking, no formal assessment of the quality of the studies was undertaken as would be the case in a systematic review, where only high quality RCTs or other forms of quantitative investigation would be eligible) including both published and unpublished materials. The literature was identified in a systematic manner using an all-inclusive approach (Ahmed et al., 2004; Ahmed et al., 2014; Hawker et al., 2002; Payne et al., 2002). Free text searches and medical subject headings were combined to identify papers (**Table 2**). Thus, this methodology ensured that the literature review was substantial, comprehensive, relevant and up to date.

Table 2: The terms used in the literature search strategy

Keywords used to search the literature
Palliative care OR Supportive care OR Specialist palliative care OR Terminal care OR Hospice care OR End of life care. AND
Access OR Assessment of need OR Assessment OR Care planning OR Case notes OR Clinical assessment OR Common approach to assessment OR Consultations OR Doctor-patient interaction OR Evaluation OR Evaluation tools OR Evaluation methods OR History taking OR Holistic assessment OR Holistic needs assessment OR Holistic self-assessment tools OR Interviews OR Measures OR Medical assessment OR Medical clerking OR Medical history OR Medical interview OR Narrative analysis OR Narrative medicine OR Narrative synthesis OR Needs assessment OR Nursing assessment OR Oral history OR Patient- physician OR Clinician communication OR Questionnaires OR Referral OR Routine assessment OR Scales OR Screening tools OR Standardised holistic assessment OR Symptom assessment OR Symptoms OR Systematic holistic approach OR Systems OR Toolkit OR Tools OR Unmet need OR Validated assessment. AND
Clinical outcomes OR Improved health OR Health care outcomes OR Improved patient management OR Improved patient well-being OR Patient centred care OR Patient experience OR Patient outcomes OR Psychological morbidity OR Anxiety OR Depression OR Distress OR Quality of life OR Relief of suffering OR Satisfaction with care OR Service utilisation OR Survival OR Survivorship OR Uptake OR Well-being.

The following sources were searched: electronic databases; key websites; grey literature sources; hand-searches of key journals; review of policy documents and reports; and I also made contact with experts in the field (**Figure 1**) (Ahmed, 2010; Ahmed et al., 2014).

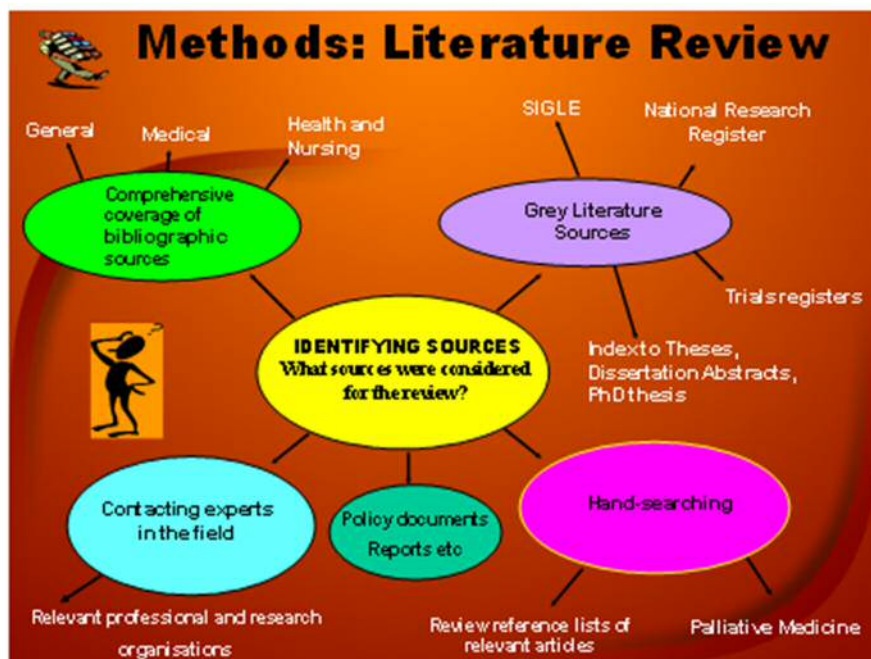


Figure 1: Literature review methods (overview)

Electronic databases searched

The following electronic databases were searched (no limits were applied to the years searched): Medline, In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), British Nursing Index and Archive, PsycInfo, Allied and Complementary Medicine Database (AMED), Cochrane Database of Systematic Reviews (CDSR), Cochrane Controlled Clinical Trials Register (CCTR), Centre for Reviews and Dissemination Databases: Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) Database, Cumulative Index to Nursing & Allied Health Literature (CINAHL), the British Library Database (ZETOC), System for Information on Grey Literature in Europe (OpenSIGLE), Scopus, Google Scholar, National Research Register, PubMed U.S. National Library of Medicine, National Institutes of Health, Web of Knowledge (includes Web of Science-Social Sciences Citation Index), Index to thesis, National Institute for Health and Care Excellence (NICE), Department of Health, The National Library for Health (www.library.nhs.uk), NHS Evidence - Supportive and Palliative care (formerly a Specialist Library of the National Library for Health), American Society of Clinical Oncology (ASCO), BIOSIS, NHS Evidence - National Library of Guidelines.

Hand-searching

The following 5 key journals were hand-searched in an attempt to identify articles that may not have been identified through electronic searches of databases. Hand-searches were limited to journals covering the last 18 years (1st Jan 1999- Dec 2016 inclusive). The reference lists of relevant articles were also reviewed.

1. *Palliative Medicine*
2. *Supportive Care in Cancer*
3. *Journal of Pain and Symptom Management*
4. *Quality of Life Research*
5. *Psychooncology*

Key websites searched

The following key websites were searched:

- Centre for Reviews and Dissemination (<http://www.york.ac.uk/inst/crd/>)
- Cochrane Collaboration (<http://cochrane.co.uk/en/index.html>)
- Health Information Resources formerly National Library for Health (<http://www.library.nhs.uk/>)
- Department of Health (<http://www.dh.gov.uk/en/index.htm>)
- National Institute for Health and Care Excellence (NICE) (<http://www.nice.org.uk/>)

Contacting experts in the field

Professor Alison Richardson (Clinical Professor of Cancer Nursing and End of Life Care, Kings College, London) and Mr Mathew Fry (Programme Manager Common Assessment Framework for Adults, London), both UK-based, were the two experts that were contacted in an attempt to identify additional papers and any other major developments in this field.

1.22 Inclusion/exclusion criteria

Primary/empirical studies with data, reports, guidelines, systematic reviews, and reviews concerning issues relating to holistic needs assessment in the fields of supportive and palliative care as well as the issues outlined in the search strategy and inclusion criteria of the review were considered.

No limits or restrictions were applied to the databases for the years searched. Papers were included if they met the inclusion criteria. Papers were not restricted to just cancer patients. I included papers that made reference to both cancer and non-cancer conditions e.g. Acquired Immune Deficiency Syndrome (AIDS); Motor Neurone Disease (MND); Chronic Obstructive Pulmonary Disease (COPD); Parkinson's Disease; Heart Failure; Dementia and Alzheimer's disease. A more detailed description of the inclusion and exclusion criteria is presented in **Table 3**.

Table 3: Literature review inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Philosophy of palliative care and supportive care (concepts and definitions, discussions of terminology)	Non-English
Development of supportive and palliative care services (historical context/accounts)	Evaluation of palliative care services (unless about access, exclusion, referral or holistic needs assessment)
Access and referral to palliative care (access to care, problems of access/barriers to timely referrals, referral criteria, eligibility for care)	Trials of surgical treatments
Prevalence of concerns, problems and issues in palliative care patients (e.g. physical symptoms; psychological problems; social issues including finance; ability to look after self/others; ADL; spiritual issues; religious and cultural issues; practical issues; medical or care issues; nursing; GP issues; aspects of social work etc.; communication and information issues)	Trials of medicines
Reporting of symptoms (and symptom enquiry)	Trials of equipment or technology
Working definitions of 'assessment' and 'needs'	Euthanasia

Holistic assessment of supportive and palliative care needs (main features of assessment and core content of assessment, ‘medical vs. holistic model of care’)	Economic factors in palliative care (e.g. cost-effectiveness papers)
Systematic holistic questioning in palliative care	Laboratory/animal studies
Assessment tools and instruments (questionnaires or outcomes currently used or developed for identifying supportive and palliative care needs)	
Studies examining the clinical utility of tools	

Abbreviations: ADL: Activities of Daily Living; GP: General Practitioner

1.23 Assessment of relevance and validity of studies

As mentioned earlier, whilst the search strategy was systematic, this is NOT a systematic review. The methodology adopted was comprehensive and focussed as possible, and systematic methods employed were designed to improve rigour. This literature review was undertaken to develop and inform the background to the thesis. This is distinct from a systematic review which traditionally asks specific research questions about the effectiveness of health care interventions, and synthesises evidence from the results of randomised controlled trials. For the purposes of this background review (which adopted a much more inclusive approach), it was more appropriate to undertake a literature review rather than a systematic review, because in an area where there is a limited number of RCTs and other forms of quantitative studies, as is the case in palliative care research, the evidence originates from a variety of different sources.

Since the studies/papers used different methods, outcome measures and samples, it was not appropriate to combine data across studies for meta-analysis. Furthermore, there have already been a number of substantial systematic reviews, reviews and guidelines published prior to this work (Ahmed et al., 2004; Cancer Plan, 2004; Cancer Action Team 2007; EOLC Strategy, 2008; NICE, 2004; Richardson et al., 2005; and Richardson et al., 2007), supporting the need for and highlighting the importance of undertaking patient holistic needs assessment.

In addition to identifying any research gaps, it was important to ensure the work that I was proposing as part of my doctoral study had not been previously undertaken.

Methodological quality of included papers

It was anticipated that the literature search would identify papers that used several different research methods (all-inclusive approach used), and it was therefore decided not to use conventional Cochrane study design criteria to weight or assess the quality of the studies, thus no formal assessment was undertaken as would be the case in a systematic review, where only high quality RCTs or other forms of quantitative investigation would be eligible.

While no formal assessment of the quality of the included papers was undertaken because of the reasons described above, in order to improve the rigour of the papers/studies included in the background literature review, I did review and assess each paper/study for inclusion using a previous method developed by Payne et al., 2002 and Hawker et al., 2002, this method is particularly suitable for palliative care studies.

Ten key areas that I considered to assess the methodological rigour of included papers, particularly when including papers describing empirical studies were as follows: title and abstract; introduction and aims; method and data; sampling; data analysis; ethics and bias; results; transferability or generalisability; implications and usefulness. Only studies as judged by me to be of moderate-high quality were included in the review, each area was assessed against a 4-point scale from 1 (very poor) to 4 (good) as a guide for making a judgement on which papers to include. All of the papers that were included in the background review were sorted into groups according to the topic reported.

1.24 Data extraction

All citations/abstracts were assessed to identify all relevant papers following a number of sifts. Full text copies were then requested. Papers which were identified and considered relevant after mutual agreement between myself and my supervisors were included in the background review, and data was then extracted.

1.25 Results of literature searches

The initial search for literature was undertaken in 2010 and again in 2014. The search strategy generated 35,000 hits, after several sifts of published and unpublished abstracts, I obtained 200 papers and on closer examination included and reviewed 63 papers of which 21 key papers are reported and published in an abridged version of the review (Ahmed et al., 2014). The search strategy employed to identify additional papers underwent an evolutionary process. With guidance from my supervisors and advice sought from advisory group members, I had a basic knowledge of most of the relevant papers in this field, and after undertaking the initial broad searches my knowledge increased further, I used a process of 'snowball sampling' and 'systematic funnelling' approach to focus and narrow the search to papers relating largely to the 'predetermined themes' and in keeping with the original aims of the review. Another more focussed search for literature was undertaken in 2016. After applying inclusion and exclusion criteria and eliminating duplicates, in total 175 papers were included in the background literature review section. Results of these searches are presented in **Figure 2**.

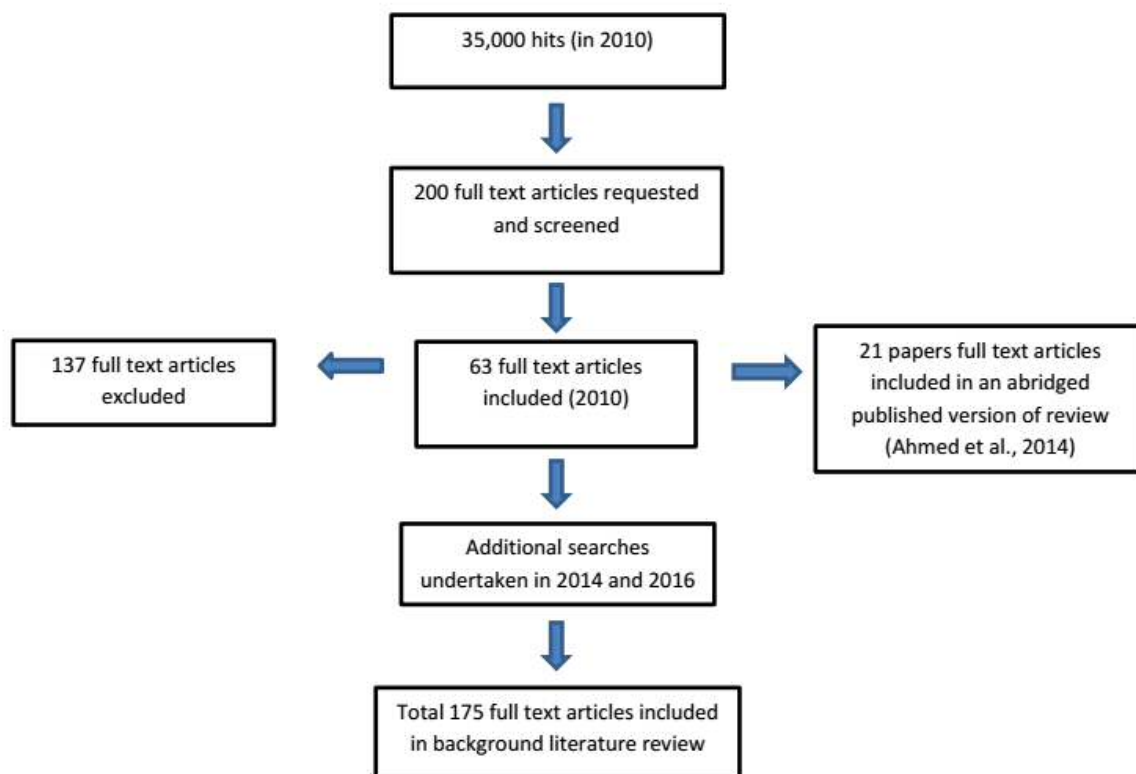


Figure 2: Results of literature searches

Of the 175 included papers, the authors/co-authors (number in brackets referring to number of papers) were based in the following countries: UK (n=90); USA (n=44); Australia (n=12); from multiple countries/from EU (n=11); Canada (n=5); Netherlands (n=4); Sweden (n=3); Switzerland (n=2); India (n=2); Denmark (n=1); Norway (n=1). Included papers were published between 1980-2016 inclusive. The majority of included papers were published between years 2000-2016 (n=146/174=83.4%).

It was clear that the studies were heterogeneous in all aspects of design including methods, results and the way in which key outcomes were assessed and reported. The studies employed a variety of research methods and participants. Most primary/empirical studies used qualitative methods predominantly interview, questionnaires and surveys to elicit data. There were also several interview studies, focus group papers, retrospective reviews of records, case note reviews, position papers, letters to editors and editorials, methodology papers, systematic reviews, reviews (including book chapter reviews), audits, national policy documents and guidelines, reports, short reports, commentaries and discussion papers. A total of six systematic reviews were included in the review covering different themes of interest. Only two RCTs were identified and included in this review, however there were no randomised controlled trials of holistic needs assessment tools assessing clinical utility. Some studies involved only cancer patients, some involved only patients with non-malignant disease, and some involved patients from both of these groups (cancer and non-cancer).

1.26 Data synthesis

Thematic analysis is one of the most widely used forms of analysis in qualitative research (Braun & Clarke, 2002; Ritchie & Spencer, 2004). The results of this review are presented in the form of themes in relation to the research aims. The thematic synthesis of evidence led to the emergence of 12 themes, themes were determined largely by the topics of ‘predetermined interest’ and guided by the inclusion criteria. Prominent themes were identified as:

1. Holistic assessment of supportive and palliative care needs: the evidence for routine systematic questioning;
2. Philosophy of palliative care and supportive care (concepts and definitions);
3. Basic/general palliative care versus specialised palliative care;
4. Access and referral to palliative care (barriers and timely referrals);
5. Prevalence of concerns, problems and issues in palliative care patients;
6. The need for systematic holistic questioning in palliative care;
7. Working definitions of ‘assessment’, ‘needs’ and ‘holistic needs assessment’;
8. Models of nursing that contain holistic assessment;
9. Concept of holistic assessment (‘medical vs. holistic model of care’);
10. Main features of assessment and core content of assessment;
11. Assessment tools and instruments;
12. Studies examining the clinical utility of tools (presented in **Chapter 8: Results in the context of other studies**).

(Ahmed, 2010; Ahmed et al., 2014).

Development of themes (how these related to the aims of literature review)

Key documents in the field

There have been a number of substantial systematic reviews, reviews, guidelines/national policy documents undertaken and published supporting the need for holistic assessment of patients’ needs (Ahmed et al., 2004; Ahmed et al., 2014; Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer-Assessment Guidance, 2007; NICE, 2004; Report to the National Cancer Action Team, 2007; Richardson et al., 2005; and Richardson et., 2007).

The following eighteen papers, key documents and national policy documents that emphasise the importance and priority of undertaking a comprehensive patient holistic needs assessment, that is tailored to meet patients’ needs, were used to guide the development of the themes, i.e. themes of pre-determined interest. These are presented in **Table 4**.

Table 4: Key papers, documents, and national policy documents used to guide the development of themes (i.e. themes of pre-determined interest)

1.	Ahmed, N., Bestall, J.C., Ahmedzai, S.H., Payne, S.A., Clark, D., & Noble, B. 2004. Systematic review of the problems and issues of accessing specialist palliative care by patients, carers and health and social care professionals. <i>Palliative Medicine</i> , 18, (6) 525-542.
2.	Ahmedzai SH, Payne SA, Bestall JC, et al. Developing a screening measure to assess the distress caused by advanced illness that may require referral to specialist palliative care. Academic Palliative Medicine Unit, Sheffield Palliative Care Studies Group, The University of Sheffield. Final Report to Elizabeth Clark Charitable Trust, London, UK, 2004.
3.	Bruera E. Routine symptom assessment: good for practice and good for business. <i>Supportive Care in Cancer</i> 2008; 16:537–8.
4.	Cancer Action Team. 2007. Holistic common assessment of supportive and palliative care needs for adults with cancer: Assessment Guidance. Kings College, University of London.
5.	Cancer Plan (2000)- The NHS Cancer Plan. A plan for investment. A plan for reform. Department of Health.
6.	Dunn, G.P. 2001. Patient assessment in palliative care: How to see the "big picture" and what to do when "there is no more we can do". <i>Journal of the American College of Surgeons</i> , 193, (5) 565-573.
7.	End of Life Care Strategy: promoting high quality care for adults at the end of their life. 2008. Department of Health.
8.	Maher, D., & Hemming, L. 2005. Understanding patient and family: holistic assessment in palliative care. <i>British Journal of Community Nursing</i> , 10, (7) 318-322.
9.	National Institute for Clinical Excellence. 2004. Guidance on cancer services: improving supportive and palliative care for adults with cancer. The manual. London. NICE.
10.	Radbruch, L., & Payne, S. 2009. White paper on standards and norms for hospice and palliative care in Europe: Part 1. <i>European Journal of Palliative Care</i> , 16, (6) 278-289.
11.	Radbruch, L., & Payne, S. 2010. White Paper on standards and norms for hospice and palliative care in Europe: Part 2. <i>European Journal of Palliative Care</i> , 17, (1) 22-33.
12.	Report to the National Cancer Action Team, 2007- Richardson, A., Tebbit., P., Brown, V., Sitzia, J., on behalf of the Cancer Action Team. The holistic common assessment of supportive and palliative care needs for adults with cancer- Assessment Guidance (Guidance, work commissioned by The Cancer Action Team).
13.	Richardson, A., Medina, J., Brown, V., & Sitzia, J. 2007. Patients' needs assessment in cancer care: A review of assessment tools. 2007b. <i>Supportive Care in Cancer</i> , 15, (10) 1125-1144.
14.	Richardson, A., Sitzia, J., Brown, V., Medina, J., Richardson, A. 2005. Patients' needs assessment tools in cancer care: Principles and Practice. London: King's College London (Report).
15.	Shah, M., Quill, T., Norton, S., Sada, Y., Buckley, M., & Fridd, C. 2008. "What bothers you the most?" initial responses from patients receiving palliative care consultation. <i>American Journal of Hospice and Palliative Medicine</i> , 25, (2) 88-92.
16.	White, C., McMullan, D., & Doyle, J. 2009. "Now that you mention it, doctor... ": Symptom reporting and the need for systematic questioning in a specialist palliative care unit. <i>Journal of Palliative Medicine</i> , 12, (5) 447-450.
17.	World Health Organization (WHO). 2002. National Cancer Control Programmes: Policies and Managerial Guidelines, 2nd ed. Geneva, Switzerland.
18.	WHO Definition of Palliative Care. http://www.who.int/cancer/palliative/definition/en/.2006

A summary of the key stages involved during the development of themes and thematic synthesis of evidence is summarised in **Table 5**.

Table 5: Summary of key stages involved during development of themes and thematic synthesis of evidence

Stage	Description of the process involved
Stage 1: Familiarising myself with the existing literature	<ul style="list-style-type: none"> ▪ Reading key documents and papers in the area to draw up initial ‘predetermined themes’ (key ideas and initial themes, any recurrent themes or emerging concepts were identified using 18 key papers).
Stage 2: Development of literature search strategy (inclusion and exclusion criteria)	<ul style="list-style-type: none"> ▪ The development of the literature review search strategy and inclusion and exclusion criteria was guided by my preliminary reading, and further advice was sought from the project advisory group, experts in the field, and an information specialist (The University of Sheffield) (Ahmed et al., 2004; Ahmed et al., 2014). ▪ Carried out some initial searches on Medline, reviewed the overall aims and objectives of the research and updated/revised search strategy accordingly.
Stage 3: Undertaking literature searches	<ul style="list-style-type: none"> ▪ An extensive and more comprehensive literature search was undertaken. ▪ All citations/abstracts were assessed to identify all relevant papers (following a number of sifts). ▪ Papers included or excluded based on the inclusion and exclusion criteria. ▪ Full text copies of all relevant papers requested. ▪ Papers which were identified and considered relevant after mutual agreement between myself and my supervisors were included in the review, and data was extracted. ▪ Familiarised myself with the range and diversity of the literature identified, noting down initial ideas.
Stage 4: Identifying a thematic framework	<ul style="list-style-type: none"> ▪ Developed ‘thematic conceptual framework’ or ‘index’, which was constructed using the recurrent themes identified during the familiarisation stage and after undertaking the searches. ▪ Themes/concepts identified were further sorted and grouped into a smaller number of broader categories (‘higher order categories’ or ‘main themes’), some were identical to ‘predetermined themes’ and some were newly developed from emerging themes and placed within an overall thematic framework. ▪ Reviewed original aims and objectives (research questions) of the review to ensure that they were being fully addressed.

Stage 5: Generating initial codes and searching for themes	<ul style="list-style-type: none"> ▪ Papers read and numerically coded by themes according to the thematic framework constructed in stage four.
Stage 6: Reviewing themes, defining and naming themes, and charting	<ul style="list-style-type: none"> ▪ Preliminary thematic framework (in stage 4), was reviewed and revised (i.e. addition or deletion/collapsing of themes and subthemes). ▪ Identifying key points/findings on a given theme/subtheme from the original paper and rearranging it and placing it in a chart according to the appropriate thematic reference, and making a note of the first author and year of the paper.
Stage 7: Mapping and interpretation, summarising and synthesising or interpreting the literature extracts to produce the literature review report	<ul style="list-style-type: none"> ▪ Final analysis of selected extracts. Comparing and contrasting information/extracts, highlighting key concepts and ideas, and searching for patterns, connections, motivations, associations and seeking explanations in order to draw the necessary conclusions in relation to the original aims of the review. ▪ Producing a scholarly report of the analysis (Ahmed et al., 2014 and background section to the thesis).

1.3 Holistic assessment of supportive and palliative care needs: the evidence for routine systematic questioning

There is evidence to suggest that patients with cancer (Ahmed et al., 2004; Ahmed et al., 2014; Grunfeld, 2005) and other non-malignant chronic progressive illnesses can experience distressing symptoms (such as pain, anxiety, and depression), concerns or issues (such as independence and activity issues or family and social issues) (Copp et al., 1998; Potter et al., 2003; Ryan et al., 2013), which can often remain unrecognised (Ahmed et al., 2004; Ahmed et al., 2014). Assessing patients' holistic needs using routine systematic questioning ('done or acting according to a fixed plan or system; methodical') is useful in identifying supportive or palliative care needs that would otherwise not be identified. There is at present no standardised systematic, evidence-based holistic approach to screening patients for supportive and palliative care needs (Ahmed et al., 2004; Ahmed et al., 2014). In this introductory chapter, I will provide an overview of the concepts and definitions of holistic needs assessment in the fields of supportive and palliative care, and present evidence of the value of routine systematic questioning. Systematic questioning allows patients' holistic needs (i.e. physical, psychological, religious, spiritual, and information needs etc.) to be identified and addressed (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

1.4 Philosophy of palliative care and supportive care (concepts and definitions)

The World Health Organisation (WHO) has defined palliative care as '*Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by*

means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual' (Ahmed, 2010; Ahmed et al., 2014; Doyle, 2005; Radbruch & Payne, 2009; Sepulveda et al., 2002; WHO Definition of Palliative Care, <http://www.who.int/cancer/palliative/definition/en/2006>). Palliative care is the active holistic care of patients with advanced, progressive illness, this new and modified WHO definition replaced an older 2002 definition that was restricted to patients' whose disease is not responsive to curative treatment and extended the scope of palliative care to patients and families facing problems associated with life limiting illness, with now a much greater emphasis on extending provision early on in the course of the illness (Ahmed, 2010; Ahmed et al., 2014; Association of Palliative Medicine Strategy, 2008; Bristowe et al., 2015; Gardiner et al., 2015; Hughes et al., 2015; Jarrett et al., 1999; Radbruch & Payne, 2009; Sepulveda et al., 2002; Skillbeck et al., 1999; Smyth, 2008).

There are calls for better integration of palliative care into disease management guidelines for all significant illnesses (Emanuel et al., 2004). Borgsteede et al., 2006, comment on this modified version of the definition, which recognises and promotes the early initiation of palliative care. Ahmedzai, 2005, argues that many of the earlier definitions of palliative care have mainly been associated with caring for dying patients with 'incurable and fatal cancer' (Sepulveda et al., 2002; Smyth, 2008), and questions the meanings of the terms 'active', 'progressive', 'far-advanced disease', and 'prognosis is limited', which are terms often used to describe palliative care (Ahmed, 2010; Ahmed et al., 2014).

The United Kingdom (UK) is widely regarded as the birthplace of modern palliative care (Clark et al., 2005). The modern hospice movement was introduced by Dame Cicely Saunders in 1960's. The first modern hospice St. Christopher's opened in 1967 to address the neglect of dying patients in general hospitals (Clark, 2002; Clark et al., 2005; Delamothe et al., 2010). Palliative medicine is considered to be part of the specialty of palliative care. In 1987, the UK became the first country in the world to recognise Palliative Medicine as a specialty (Ahmed et al., 2010; Doyle, 2005; Gilbert, 1996; Higginson, 2005; Smyth, 2008), and was ranked first in the European Union for development of supportive, palliative and end of life care services (Clark et al., 2010). Palliative care often comes into play when a patients' condition becomes incurable or terminal, and when the focus of care shifts from the curative phase to that of improving quality of life and provision of end of life care. Palliative care can be provided concurrently alongside other curative or disease modifying treatments as illustrated by **Figure 3**, which illustrates how the involvement of palliative care from the point of diagnosis onwards increases as the curative intent decreases. It also demonstrates that 'bereavement care' for patients' families or carers continues after the patients' death (WHO, 2002).

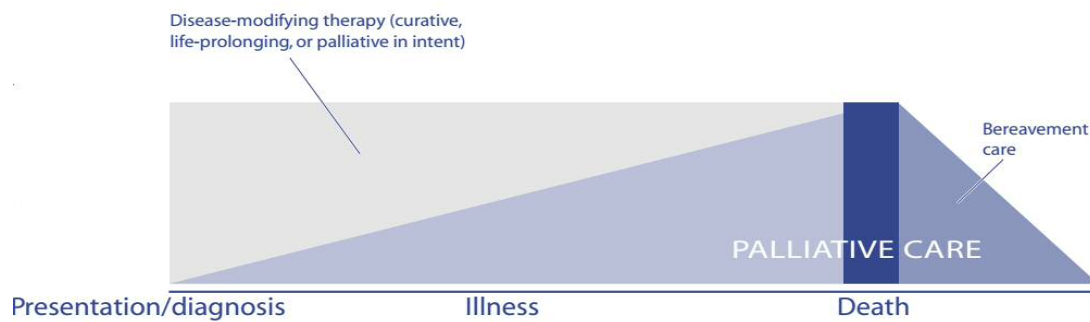


Figure 3: Palliative care integration model

(Adapted from World Health Organization; WHO, 2002)

1.5 Basic/general palliative care versus specialised palliative care

The European School of Oncology made an attempt to differentiate between the two different levels of palliative care and proposed the following definitions:

‘Basic/general palliative care is the level of palliative care which should be provided by all health care professionals, in primary or secondary care, within their duties to patients with life limiting disease’ (Ahmedzai et al., 2004a; Ahmedzai, 2005; Lee, 2005; Radbruch & Payne, 2009; WHO, 2002).

‘Specialised palliative care is the standard of palliative care provided at the expert level to patients with life threatening or debilitating chronic illness, and their families or carers, by a multi-professional and interdisciplinary team, who must continually update their skills and knowledge, in order to manage persisting and more complex problems and to provide specialised educational and practical resources to other non-specialist members of the primary or secondary care teams’ (Ahmedzai et al., 2004a; Ahmedzai, 2005; Radbruch & Payne, 2009).

In the past, the terms palliative care and specialist palliative care have been traditionally closely associated with care of the dying and linked almost entirely within cancer services (Mathew et al., 2003). Palliative care is considered to be part of supportive care, which has a much broader definition (Ahmed, 2010; Ahmed et al., 2014; Ahmedzai et al., 2004a; Ahmedzai, 2005).

Supportive care is the care of cancer and chronically ill patients and their families and carers from the early stages of illness i.e. from the time of diagnosis, or even pre-diagnosis, throughout and alongside both curative and palliative treatments, until the patients’ death, and the provision of aftercare (as with palliative care), for the bereaved family members or carers continues after the patients’ death. ‘Supportive care is the multi-professional attention to the individual’s overall physical, psychosocial, spiritual and cultural needs, and should be available at all stages of the illness. Information, communication and bereavement support are also part of supportive care’ (Ahmed et al., 2010; Ahmedzai et al., 2004a; Ahmedzai, 2005;

NICE, 2004), as illustrated by **Figure 4: The Sheffield Model of Comprehensive Supportive Care** (Ahmedzai, 2005).

Several authors have suggested that there appears to be considerable overlap and no clear distinction between the use of the terms ‘palliative care’ and ‘supportive care’, and there is an indication that the terms have been used synonymously in the past. Supportive care was originally part of oncological care (Harley et al., 2012), and like palliative care it is extending to all patients with life-threatening disease (Ahmedzai, 2005; Radbruch & Payne, 2009).

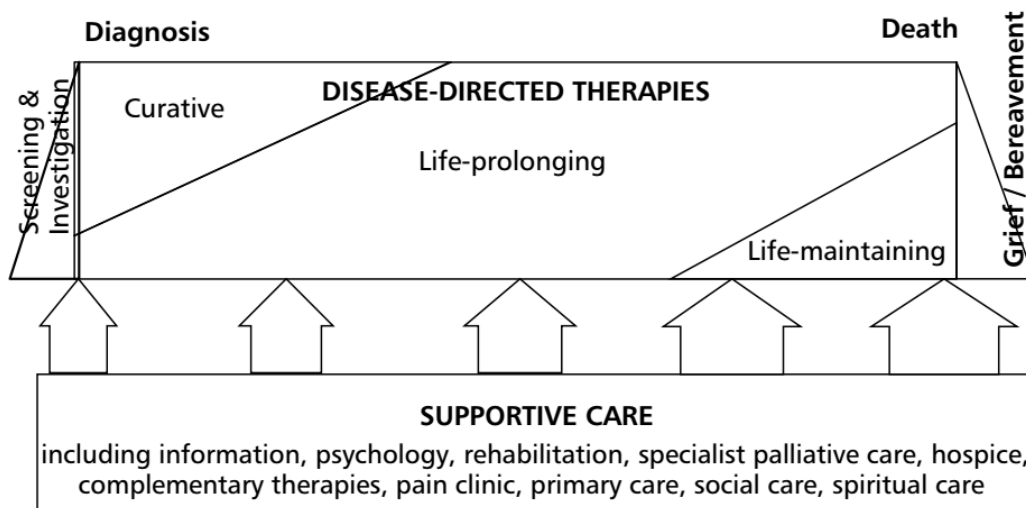


Figure 4: The Sheffield Model of Comprehensive Supportive Care

(Adapted from Ahmedzai, 2005)

Terminal care is an older term that has been used for comprehensive care of patients with advanced cancer and restricted life expectancy (Radbruch & Payne, 2009).

End of life care has also been used synonymously with palliative care or hospice care, and is the care provided to patients who are approaching the last months or years of their life (Radbruch & Payne, 2009).

The White Paper on standards and norms for hospice and palliative care in Europe, has put forward some suggestions for a ‘*Common European Terminology*’ for palliative care. This paper argues against using the terms ‘supportive care’ and ‘palliative care’ interchangeably, and considers supportive care as part of oncological care (Radbruch & Payne, 2009; Radbruch & Payne, 2010). Despite several attempts to define palliative care (Farquhar et al., 2002) and supportive care (Smyth, 2008), there remains a degree of uncertainty about what palliative care and supportive care is, what it offers, and who it’s meant for (Ahmed, 2010; Ahmed et al., 2014). Radbruch & Payne, 2009, state that much of the confusion is due to the considerable overlap and little or no differentiation between the two terms. The definitions

and role of both palliative care and supportive care have evolved and changed over time (Epstein & Morrison, 2012). Ahmedzai, 2005, proposed that WHO takes responsibility for a universal statement on palliative care which should be updated on a regular basis (Ahmed, 2010; Ahmed et al., 2014).

There is at present no widely used systematic, evidence-based holistic approach to screening patients for supportive and palliative care needs (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015). If such a system could be developed and shown to be workable in primary care or secondary care, this may be the first step towards reducing the distress associated with chronic progressive and life-limiting disease (Ahmed, 2010; Ahmed et al., 2014).

1.6 Access and referral to palliative care (barriers and timely referrals)

There are calls from the international community for the recognition of palliative care as an international human right (Ahmedzai et al., 2004a; Ahmedzai, 2005; Shrivastava et al., 2016), Gwyther et al., 2009, argue that some countries do not have palliative care services or policies in place, and even in countries that do, provision is considered to be variable across regions (Ahmed, 2010; Ahmed et al., 2010; Ahmed et al., 2014; Bruera & Sweeney, 2002; Higginson et al., 2000). In some countries palliative care is still not available to patients or considered a public health concern or problem, and therefore not even part of the health agenda (Sepulveda et al., 2002; Stjernsward et al., 2007a; Stjernsward et al., 2007b). Studies indicate limited access to services (Keegan et al., 2001) and high levels of patient distress particularly on general hospital wards in the UK (Ryan et al., 2013). The preference is usually to be cared for and to die at home (Aabom & Pfeiffer, 2009; Ahmed et al., 2010; Higginson & Sen-Gupta, 2000; Pollock, 2015), however just over half of deaths in the UK occur in an acute hospital setting (Ahmed et al., 2010; Barclay & Arthur, 2008; Barclay & Maher, 2010; Ellershaw et al., 2010; EOLC Strategy, 2008; Higginson et al., 1998; Higginson et al., 2010; Murray et al., 2004), and older people are particularly likely to die in this setting (Gardiner et al., 2011). That said preferences for 'place of care' and 'place of death' can change as illness progresses (Agar et al., 2008; Higginson et al., 2010). The future projections by Gomes and Higginson (2008) are that fewer than 1 in 10 people will die at home in 2030. There does however appear to be a large country variation in place of death. Cohen et al., 2015, cross sectional study using death certificate data for all deaths from cancer in 2008, showed a large between country differences and variation in home and hospital deaths which were partly attributed to differences in the availability of hospitals long-term beds and on the countries health care resources. Pollock, 2015, calls for further research, with an emphasis on the importance of recognising and accommodating the diversity and patient preferences for place of death (particularly in the context of e.g. cultural heterogeneity).

In 2004, I undertook an extensive systematic review of the literature on access and referral to palliative care. Several issues relating to access and referral to palliative care were identified, including: variable availability of services; lack of referral criteria to guide professionals

(Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014); health professional related factors (Bradley et al., 2000; Bradley et al., 2002; Daaleman & Frey, 1998; Kirchhoff & Beckstrand, 2000; Lamont & Christakis, 2002); and lack of guidance on the timing of this referral (Ahmed et al., 2004). The resistance and reluctance of healthcare professionals to refer to, and for patients and families to be referred for palliative care due to misconceptions about palliative care and hospice care, have also been cited as possible reasons for non-referral or may account for late referrals to palliative care (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Christakis, 1998; Friedman et al., 2002; Hayley et al., 2001; Johnson & Slaninka, 1999; Ronaldson & Devery, 2001). Various groups such as minority ethnic groups (Fountain, 1999; Koffman & Higginson, 2001), older people (Addington-Hall et al., 1998; Burge et al., 2002; Casarett, 2001; Davies & Higginson, 2004; Grande et al., 2002; Hunt & McCaul, 1998), those with non-malignant progressive conditions (Gadoud et al., 2013; Hanratty et al., 2002), and the socially disadvantaged groups, were also seen to be failing to receive timely referrals and sometimes not referred at all (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

Referral to palliative care and subsequent hospice admission are often governed by chance rather than need (Addington-Hall et al., 1998). To overcome these barriers, Lau and O'Connor, 2012, emphasise the need to take action on many fronts, because palliative care still remains underutilised by certain groups in the community (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

The systematic review that I undertook in 2004, concluded that the main barrier to receiving palliative care in the UK, was the failure to recognise need and also variable availability of services; it called for the development of more comprehensive standardised referral criteria to guide referrals, coupled with a need to improve education and knowledge about palliative care for health care professionals (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Bradley et al., 2000; Bradley et al., 2002; Dixon et al., 2002; Gott et al., 2001; Heedman & Starkhammar, 2002; Hodgson et al., 1997; Kite et al., 1999; Lagman et al., 2007; Miller et al., 1997; Schim et al., 2000; Wyatt et al., 2000), and for patients and their families or carers (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). Several other authors have also commented on similar issues which have an impact on access and referral to palliative care. Several lines of research show that most patients continue to be referred to palliative care late in the disease trajectory, often being referred in a 'far advanced' or 'terminal stages' of illness (Ahmed et al., 2004; Casarett, 2001; Costantini et al., 1999; Currow et al., 2008a; Fadul et al., 2009; Farnon & Hofmann, 1997; Le & Ashby, 2007; Melvin & Oldham, 2009; Myers, 2002; Osta et al., 2008; Radbruch & Payne, 2009; Radbruch & Payne, 2010; Raghavan et al., 2005; Rickerson et al., 2005).

Walshe et al., 2009, argue against conducting further studies on access and referral to palliative care, and instead focus attention on research which may shed light on reasons for the observed differences in access and utilisation patterns. Higginson, 2005, also supports this view. Currow et al., 2008b, argue that a lack of service uptake does not always represent unmet needs, and call for a prospective follow up study (Ahmed et al., 2004; Ahmed, 2010;

Ahmed et al., 2014). Karim et al., 2000, propose that further research should be undertaken to establish the levels of awareness, and attitudes towards palliative care and assess the demand and utilisation for specific palliative care services (inpatient and day care services) within various black and minority ethnic communities.

Several authors emphasise the importance of incorporating basic palliative care education in all medical, nursing, and allied health care professional courses (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Kenen, 2010; Radbruch & Payne, 2009; Radbruch & Payne, 2010). Palliative care education has become a priority in many European Union (EU) countries. It has been argued that palliative care specialists must do more to reach out to those patients in need. At the same time other health care professionals (e.g. generalists) must work with the specialists by adopting a 'shared care' and more integrated (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Hasselaar & Payne, 2016) care model approach (e.g. fuller integration of specialist palliative services) (Dharmasena & Forbes, 2001; Gadoud & Johnson, 2011; Gibbs et al., 1997; Hanratty et al., 2002; Kayashima & Braun, 2001; Kenen, 2010; Kite et al., 1999; Le & Ashby, 2007; Mitchell et al., 2008; Ogle et al., 2003; Skilbeck et al., 1999), which is often described in the literature as being 'patient-centred' and 'active' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Wijnia & Corstiaensen, 2008).

Several lines of research support the view that earlier referrals to palliative care are better (Temel et al., 2010), and may allow; 1) more time for professionals to undertake assessments and identify patients and their families or carers needs; and 2) more time for patients and their families or carers to benefit from the services they subsequently receive if needs are identified (Casarett et al., 2008; Currow et al., 2008a; Rickerson et al., 2005). However, Mitchell, 2005, argues against putting too many support systems in place at the wrong time, but this argument is based on one case study.

The transition from the curative or disease modifying to the palliative phase is often a very complex and difficult one to make (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Gardiner et al., 2011) for both healthcare professionals, patients and their families or carers (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Boyd & Murray, 2010; Fallowfield et al., 2002; Hayley et al., 2001; Higginson, 2005; Ronaldson & Devery, 2001; Schofield et al., 2006). Lofmark et al., 2005 and Lofmark et al., 2007, attribute this partly to the traditional 'medical model of care' which focuses primarily on curative or life prolonging measures (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Griffie et al., 1999).

The unpredictable course of some chronic progressive illnesses (e.g. cardiac/heart failure) with varying illness trajectories (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Barclay & Maher, 2010; Gadoud et al., 2013; Murray et al., 2002; Murray et al., 2007), and the difficulties in establishing a prognosis also add to these problems (Boyd & Murray, 2010; Hanratty et al., 2002; Murray et al., 2005; Quaglietti et al., 2000; Sigurdardottir & Haugen, 2008). Therefore, getting the 'timing right' is difficult without a comprehensive holistic assessment of the needs of patients and their families or carers (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Currow et al., 2008a; Melvin & Oldham, 2009; Osta et al., 2008;

Radbruch & Payne, 2009; Radbruch & Payne, 2010; Rickerson et al., 2005). Murray et al., 2007, identify a need to undertake more research in order to gain a better understanding and insight into the different illness trajectories and how best to cater for the needs of patients with varying illnesses. The implications of earlier referrals and expanding the provision of palliative care services to patients with non-malignant conditions are yet to be established (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

In the UK, many specialist palliative care teams have developed locally-based guidelines on referral; the Leeds Eligibility Criteria for specialist palliative care services, developed by Bennett and colleagues is one such example (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Bennett et al., 2000).

1.7 Prevalence of concerns, problems and issues in palliative care patients

There is evidence to suggest that patients with both cancer (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Lidstone et al., 2003; Potter et al., 2003), and other non-malignant chronic progressive illnesses (Ganzini et al., 2002; Higginson et al., 2000; Kite et al., 1999; Potter et al., 2003; Solano et al., 2006) can experience distressing symptoms and concerns such as physical, psychological, religious and spiritual needs etc., which can often remain unrecognised (Ahmed et al., 2004; Ryan et al., 2013; Salt et al., 1998). For this reason, the extension of supportive and palliative care, which are well established in cancer, to patients with other non-malignant progressive chronic illnesses is pressing (Bristowe et al., 2015; Murray et al., 2004), and there are calls for provision to be needs-based, irrespective of diagnosis or prognosis (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Ahmedzai, 2005).

Previous research has highlighted that distressing symptoms and concerns can be managed and treated, provided they are identified in a timely manner and systems are in place for a prompt referral to appropriate specialist teams (Ahmed et al., 2015; Fitzsimons et al., 2007; Homsy et al., 2006; Lagman et al., 2007; Shah et al., 2008; Sigurdardottir & Haugen, 2008; White et al., 2009). Ahmedzai et al., 2004a, argues that ‘many studies from different parts of the world have consistently shown that patients are referred for palliative care in an advanced and terminal stage of their illness’ (Ahmedzai et al., 2004a; Raghavan et al., 2005), often for symptom control. The timely identification of these symptoms and prompt referral to appropriate specialist teams for their management could potentially not only reduce the burden of individual patient suffering, but also lead to earlier discharge from expensive secondary and tertiary specialist care and thus save revenue for the National Health Service (NHS). Similarly, earlier detection of these problems in out-patients could prevent unnecessary admissions and their attendant costs. The potential gains to patients and the NHS are large, for a relatively small investment in screening. This may also have implications for the configuration and funding of services.

1.8 The need for systematic holistic questioning in palliative care

There is agreement amongst the research community that assessing patients' holistic needs using routine systematic questioning ('done or acting according to a fixed plan or system; methodical') is useful in identifying symptoms, problems and issues, which would otherwise not be identified by routine medical and nursing assessment, or by using open-ended questions (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Bruera, 2008; Homsy et al., 2006; Shah et al., 2008; White et al., 2009). For example, Shah et al., 2008, describe how a study using single open-ended questions that asked palliative care patients '*what bothers you most*' during the initial consultation, generated a variety of patient concerns. The authors propose the use of 'single open-ended' questions to identify 'most pressing needs'. However, this has the potential to exclude less urgent concerns that are nevertheless important for health professionals' understanding of a clinical case. This is illustrated by their finding that 'physical distress (44%) was reported more often than emotional, spiritual, existential or non-specific distress (16%)' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

For this reason, the 'total symptom experience' is best captured using a more systematic holistic assessment i.e. systematic questioning together with 'what bothers you most' questions so that health care professionals can gauge items to focus on which are most pressing to patients. A study that examined symptom evaluation in palliative medicine found that the frequency of symptoms identified during a systematic assessment (using 48-item symptom checklist) were ten-fold higher ($p < 0.001$) than those that were volunteered during open-ended questioning (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Homsy et al., 2006). Arguments against using systematic questioning are usually based on the time it takes to complete an assessment, which can be burdensome for this group of poorly and fatigued patients (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Homsy et al., 2006).

White et al., 2009, described a retrospective chart review study of 50 patients admitted to a specialist palliative care unit. They found that on average 8 further symptoms were detected per patient by systematic questioning than self-report (approximately 66% of symptoms were detected by systematic questioning). Pain was the most commonly self-reported symptom in this study. The authors propose a number of reasons which may account for this. Shorthose & Davies, 2003, also cite several reasons for under-reporting of symptoms. The main reasons as to why patients may under-report symptoms are presented below (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014):

Symptom 'is not considered severe, considered unimportant, and reporting or under-reporting is influenced by reason for referral, or referrer' (i.e. patient's perception of the reason for admission may have been influenced by the referrer) have been cited (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; White et al., 2009).

Symptom is 'inevitable, no treatment is available, perception that health care professional will see it as unimportant, and presence of other more important symptoms' have been cited (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Shorthose & Davies, 2003).

And the main reasons as to why health care professionals may not enquire about some symptoms are presented below:

Perception that 'symptom is uncommon, considered unimportant, no treatment is available and time constraints have been cited' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Shorthose & Davies, 2003).

The precise reasons why health care professionals do not enquire about some symptoms remains unclear and requires further investigation (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

Hoekstra et al., 2007, argue that the most 'severe' symptom is not necessarily the same as the 'most troublesome', and stress the importance of assessing both for an individual patient. Kirkova et al., 2010, report some complexities and challenges of symptom assessment in palliative medicine, and highlight the importance of supplementing the clinical interview with validated multi-symptom instruments and giving priority to 'total symptom experience' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

Bruera, 2008, stresses that early identification of and monitoring of symptoms is only useful if effective treatment programmes are in place. He argued that continued repeated assessments of patients' needs, when no systems or treatments are in place to meet those identified needs could be considered 'unethical' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

1.9 Working definitions of 'assessment', 'needs' and 'holistic needs assessment'

The following working definitions of 'assessment' and 'needs' were part of a Report to the National Cancer Action Team on Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Report to the National Cancer Action Team, 2007).

'Assessment is the overall process for identifying and recording the health and social care needs of an individual and for evaluating their impact on daily living and quality of life so that appropriate action can be agreed and planned with the individual' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

'Needs are what an individual requires to be met in order to maintain or improve current states of well-being or to anticipate and manage their deterioration. Areas of supportive and palliative care needs include physical, emotional, spiritual, environmental, social, sexual, financial and cultural needs' (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

1.10 Models of nursing that contain holistic assessment

The concept of holistic assessment is not a new concept, and several authors would argue that it has been around for many decades. Nurses have undertaken holistic assessments, often referred to as ‘nursing assessment’ as an established part of their practice. The ‘Roper, Logan and Tierney model of nursing’ (Roper’s activity of daily living, published 1980) (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Roper et al., 1980; Roper et al., 2000), and the ‘Orem model of nursing’ (Orem’s model of self-care, developed between 1959 and 2001) (Cavanagh, 1991; Orem, 1991; Orem, 1995; Orem, 2001), are examples of models of nursing that contain holistic assessments. The change with other health needs assessment tools is the systematic, standardised, evidence-based approach to questioning and terminology (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

1.11 Concept of holistic assessment (‘medical vs. holistic model of care’)

The holistic model of care is often described as ‘patient-centred’, ‘whole-person’ and ‘whole-situation’; mind, body and spirit approach to care where each domain assessed is given equal importance (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). The persons entire well-being is taken into account (i.e. physical, emotional, spiritual, mental, social and environmental) (Calman, 1984), and the assessment results are used to inform a care plan (NCSI, 2013). This ‘holistic’, ‘whole-person’ and ‘whole-situation’ approach to care challenges the traditional ‘medical model of care’ which is primarily ‘disease-focussed’ (National Cancer Survivorship Initiative: NCSI, 2013). The ‘holistic model of care’ recognises that any changes or disturbances to either the mind, body, or spirit, can have an effect on the overall health and quality of life of an individual and the family (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). These concepts are closely allied to Cicely Saunders’ concept of ‘total pain’ that underpins palliative care practice and comprises of the notions of physical, emotional, social and spiritual pain (Finlay, 2006; Locker, 2008). Therefore, multidisciplinary teams must assess patients holistically (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Locker, 2008; Maher & Hemming, 2005).

The National Institute for Clinical Excellence (now renamed as National Institute for Health and Care Excellence but with the same acronym NICE) issued guidance on improving supportive and palliative care for adults with cancer, setting out a series of recommendations based on research evidence, which became a major policy document in England and Wales. Service users, professionals and policy-makers were consulted during the development phase (NICE Guidance, 2004). The NICE guidance recognises the need for patients and their families to have their needs assessed on a regular basis and throughout the course of their illness by a multidisciplinary team (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

Maher & Hemming, 2005, present the ‘tangled web of cause and effect’ theory which proposes that without a comprehensive holistic assessment of an individual, the root cause of a problem is unlikely to be identified. In order to ‘unpack’ the complex nature of problems in patients, it is important to undertake a thorough holistic assessment. A poor or inadequate

assessment can result in unnecessary distress and suffering. A good assessment would inform others providing care from that moment forward thereby improving continuity of care (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Maher & Hemming, 2005).

In response to the NICE guidance recommendation 2, the Cancer Action Team commissioned the Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer- Assessment Guidance (2007). A report by Kings College London accompanied this guidance which called for a more unified approach to the assessment and recording of patients' needs (setting out the main features of holistic assessment and providing the core content of the assessment) (Report to the National Cancer Action Team, 2007).

1.12 Main features of assessment and core content of assessment

Dunn, 2001, describes assessment as a '*staging procedure*' for the dimensions of distress. This paper discusses nine dimensions of whole patient assessment for palliative care; these are: '1) illness/treatment summary; 2) physical; 3) psychological; 4) decision-making; 5) communication; 6) social; 7) spiritual; 8) practical; and 9) anticipatory planning for death'. This paper also addresses the duration of the assessment (20-30 minutes), who should be present at the assessment, and discusses the nine dimensions in considerable detail. Although this was developed by the authors of the American Medical Association's Education for Physicians on End-of-Life Care Curriculum, and is aimed primarily for surgeons to aid comprehensive assessment, this model could easily be applied to patients earlier on in the disease trajectory (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). It is debatable whether the full assessment as described by Dunn, 2001, could be successfully completed in 20-30 minutes, but this very much depends on the patient and the skills of the assessor. It could be argued that this form of assessment is best done over 20-30 minute slots per domain; otherwise trying to perform the entire assessment in 20-30 minutes, may be too overwhelming for the patient. Roberts et al., 2005, argued that there is no one single assessment that covers all domains that are necessary for a comprehensive holistic assessment. Ellis, 1999, have recommended the use of a patient-centred care model that is holistic/multi-professional/reflective, which essentially is a model of care that allows patients to determine their own needs, and is holistic in nature, multi-professional, and reflective (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer-Assessment Guidance (2007), (Cancer Action Team, 2007, Guidance, work commissioned by The Cancer Action Team) was developed by a team led by Professor Alison Richardson (Kings College, London, UK). The initial stages of development, involved a scoping exercise that comprised of: '1) a literature review to identify tools for holistic assessment; 2) a survey of current practice in cancer networks; and 3) an appraisal of the Single Assessment Process for older people'. This work led to the development of a specification for assessment and a report that set out the main features of an assessment and core content of the assessment. The recommendations are presented in **Table 6**. Although the

guidance was written for the assessment of cancer patients, the principles of assessment could easily be applied to other chronic progressive illnesses, such as heart failure (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Hanratty et al., 2002; Salt et al., 1998).

These recommendations carry implications for resources required to achieve adequate assessment. The recommendation that physical issues be addressed first should be acceptable to the majority of patients since it is in accordance with the finding that physical symptoms, notably pain and fatigue are the most frequently identified as the most important problems (Shah et al., 2008). Other recommendations include the proposal that the assessment can continue over many sessions and should supplement the routine clinical review.

Table 6: Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer- Assessment Guidance (2007)

Recommendations from The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer- Assessment Guidance (2007) (Cancer Action Team, 2007 Guidance, work commissioned by The Cancer Action Team).

- | |
|--|
| <ol style="list-style-type: none">1. 'Makes reference to five domains of assessment: background information and assessment preferences, physical well-being, social and occupational well-being, psychological well-being, and spiritual well-being. The guidance recommends that physical issues are addressed first, and spiritual and psychological issues towards the end'.2. 'Holistic assessment is a process that should ideally capture full range of needs, the use of more than one tool is recommended for this purpose, since research suggests that no one tool is capable of capturing full range of needs'.3. 'Holistic assessment should take place throughout the course of the illness (from time of diagnosis, before and after treatments, and during follow-up)'.4. 'Unnecessary repeated assessments should be avoided'.5. 'Assessment should be done over several sessions'.6. 'Appropriately trained professionals, who have knowledge about the illness, and local services available, should undertake the assessment/s'.7. 'Assessment of needs should be seen as patient-led, patient-centred, continuous, and supplement but not replace day-day assessment'.8. 'The guidance recommends that summary records of assessments should be first agreed with patients. This process must take place prior to any further actions being undertaken'.9. 'The guidance recommends that records of assessment should be well documented, and easily accessible to other professionals within and across settings (though patient consent may be required)'. |
|--|

(Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014)

1.13 Assessment tools and instruments

Richardson et al., 2005, and Richardson et al., 2007, undertook a review of the tools for patient assessment in cancer care; they found and critiqued 15 tools. **Table 1 of Appendix 3**, provides a summary of some of these assessment tools used in supportive and palliative care (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). Their findings indicate that of the 15 tools identified, only 6 tools were considered to be comprehensive with respect to health status. These included: 1) Problems and Needs in Palliative Care Instrument (PNPC), designed for advanced cancer patients, and developed in The Netherlands (Osse et al., 2004;

Richardson et al., 2007); 2) Oncology Clinic Patient Checklist (OCPC), designed for cancer patients, and developed in the USA (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Richardson et al., 2007; Romsaas et al., 1983); 3) Symptoms and Concerns Checklist designed for advanced cancer patients, and developed in the UK (Lidstone et al., 2003; Richardson et al., 2007); 4) Supportive Care Needs Survey (SCNS), designed for cancer patients, and developed in Australia (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Bonevski et al., 2000; Richardson et al., 2007); 5) Sheffield Profile for Assessment and Referral for Care (SPARC), a generic tool designed for patients with an advanced illness, and developed in the UK (Ahmed et al., 2015; Ahmedzai et al., 2004b; Hughes et al., 2015); and 6) the Distress Management Tool designed for cancer patients and developed in the USA (Richardson et al., 2007). SPARC and the Distress Management Tool were considered to be the most comprehensive tools identified, according to the author's classification, covering all dimensions of need and in relation to health status (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Richardson et al., 2007).

1.14 Sheffield Profile for Assessment and Referral for Care (SPARC)

The Sheffield Profile for Assessment and Referral for Care (SPARC) is a holistic screening tool for identifying supportive and palliative care needs. As part of a team of researchers based at the Academic Unit of Supportive Care, The University of Sheffield, I assisted in the development of the SPARC tool (**Figure 5**), and SPARC guidance over a period of 5 years. The work was initially commissioned by the Elizabeth Clark Charitable Trust. A final report was submitted to the funders in December 2004. SPARC has been subjected to rigorous psychometric development, preliminary field-testing, and validation (Ahmed et al., 2004; Ahmed et al., 2009; Ahmed, 2010; Ahmed et al., 2014; Ahmedzai et al., 2004b; Bestall et al., 2004). The acceptability of SPARC to patients in a variety of settings as well as support groups (Hughes et al., 2015), and at diagnosis (Wilcock et al., 2010), have also been successfully demonstrated (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

SPARC is a multidimensional screening tool which gives a profile of needs to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of disease. SPARC is intended for use by primary care, hospital teams or other services to improve patient management, either by current professional carers or by referral to a specialist team.

Figure 5: SPARC Tool

SPARC

We would like to know a bit more about you and your concerns. Please fill in the questionnaire overleaf (with help from a relative or carer if needed) and return it with the study questionnaire booklet. There are no “right” or “wrong” answers. If you are unsure of a question, please leave it blank.

THANK YOU.

SPARC*

COMMUNICATION AND INFORMATION ISSUES			
1.	Have you been able to talk to any of the following people about your condition?	Yes	No
a.	Your doctor	<input type="checkbox"/>	<input type="checkbox"/>
b.	Community nurse	<input type="checkbox"/>	<input type="checkbox"/>
c.	Hospital nurse	<input type="checkbox"/>	<input type="checkbox"/>
d.	Religious advisor	<input type="checkbox"/>	<input type="checkbox"/>
e.	Social worker	<input type="checkbox"/>	<input type="checkbox"/>
f.	Family	<input type="checkbox"/>	<input type="checkbox"/>
g.	Other people (please state) <input style="width: 100%;" type="text"/>		

PHYSICAL SYMPTOMS					
Please circle <u>one</u> answer per line					
		Not at all	A little bit	Quite a bit	Very much
2.	<i>In the past month have you been distressed or bothered by</i> Pain?	0	1	2	3
3.	Loss of memory?	0	1	2	3
4.	Headache?	0	1	2	3
5.	Dry mouth?	0	1	2	3
6.	Sore mouth?	0	1	2	3
7.	Shortness of breath?	0	1	2	3
8.	Cough?	0	1	2	3
9.	Feeling sick (nausea)?	0	1	2	3
10.	Being sick (vomiting)?	0	1	2	3
11.	Bowel problems (eg constipation, diarrhoea or incontinence)?	0	1	2	3
12.	Bladder problems (urinary incontinence)?	0	1	2	3
13.	Feeling weak?	0	1	2	3
14.	Feeling tired?	0	1	2	3
15.	Problems sleeping at night?	0	1	2	3
16.	Feeling sleepy during the day?	0	1	2	3
17.	Loss of appetite?	0	1	2	3
18.	Changes in your weight?	0	1	2	3
19.	Problems with swallowing?	0	1	2	3
20.	Being concerned about changes in your appearance?	0	1	2	3
21.	Feeling restless and agitated?	0	1	2	3
22.	Feeling that your symptoms are not controlled?	0	1	2	3

PSYCHOLOGICAL ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
23.	Feeling anxious?	0	1	2	3
24.	Feeling as if you are in a low mood?	0	1	2	3
25.	Feeling confused?	0	1	2	3
26.	Feeling unable to concentrate?	0	1	2	3
27.	Feeling lonely?	0	1	2	3
28.	Feeling that everything is an effort?	0	1	2	3
29.	Feeling that life is not worth living?	0	1	2	3
30.	Thoughts about ending it all?	0	1	2	3
31.	The effect of your condition on your sexual life?	0	1	2	3

*Sheffield Profile for Assessment and Referral to Care
SPARC-45(clinical) v1 July 2005 © The University of Sheffield - Academic Unit of Supportive Care

		Please circle <u>one</u> answer per line			
		Not at all	A little bit	Quite a bit	Very much
RELIGIOUS AND SPIRITUAL ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
32.	Worrying thoughts about death or dying?	0	1	2	3
33.	Religious or spiritual needs not being met?	0	1	2	3

INDEPENDENCE AND ACTIVITY					
<i>In the past month have you been distressed or bothered by</i>					
34.	Losing your independence?	0	1	2	3
35.	Changes in your ability to carry out your usual daily activities such as washing, bathing, or going to the toilet?	0	1	2	3
36.	Changes in your ability to carry out your usual household tasks such as cooking for yourself or cleaning the house?	0	1	2	3

FAMILY AND SOCIAL ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
37.	Feeling that people do not understand what you want?	0	1	2	3
38.	Worrying about the effect that your illness is having on your family or other people?	0	1	2	3
39.	Lack of support from your family or other people?	0	1	2	3
40.	Needing more help than your family or other people could give?	0	1	2	3

TREATMENT ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
41.	Side effects from your treatment?	0	1	2	3
42.	Worrying about long term effects of your treatment?	0	1	2	3

PERSONAL ISSUES					
				Yes	No
43.	Do you need any help with your personal affairs?			<input type="checkbox"/>	<input type="checkbox"/>
44.	Would you like to talk to another professional about your condition or treatment?			<input type="checkbox"/>	<input type="checkbox"/>
45.	Would you like any more information about the following?				
a.	Your condition			<input type="checkbox"/>	<input type="checkbox"/>
b.	Your care			<input type="checkbox"/>	<input type="checkbox"/>
c.	Your treatment			<input type="checkbox"/>	<input type="checkbox"/>
d.	Other types of support			<input type="checkbox"/>	<input type="checkbox"/>
e.	Financial issues			<input type="checkbox"/>	<input type="checkbox"/>
f.	Other (please state) <input type="text"/>				

Are there any other concerns you would like us to know about?

This form was completed by:
 Name [Please print]
 Patient / Carer / Professional*
 *circle as appropriate
 Date

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*Sheffield Profile for Assessment and Referral to Care
 SPARC-45(clinical) v1

The patient-rated (self-complete) 45-item tool reflects nine dimensions of need and as such represents a comprehensive early needs assessment or holistic tool (**Table 7**) (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

Table 7: SPARC domains, number of items and response types

SPARC

What does SPARC screen for? 45 item tool, patient self-complete.

Domain	Number of items	Response type
Physical symptoms	21	Distress or bother
Psychological	9	Distress or bother
Religious / spiritual	2	Distress or bother
Independence / activity	3	Distress or bother
Family / social	4	Distress or bother
Treatment issues	2	Distress or bother
Information / communication	3	Yes / No
Personal affairs	1	Yes / No

SPARC Guidance, 2004 recommends that ‘SPARC is capable of being completed by patients with or without the help of their informal carers or professional carers. It does not point to a diagnosis or define a sum total of distress, but rather it describes a profile of the patient’s situation, in the way that clinicians and other health and social care professionals can relate to and act on. It may be a useful indicator to professionals that a patient could benefit from additional care in previously unrecognised areas’ (Ahmed, 2010; Ahmed et al., 2014; SPARC Guidance, 2004).

Domains in SPARC include –

- Communication and information issues
- Physical symptoms
- Psychological issues
- Religious and spiritual issues
- Independence and activity
- Family and social issues
- Treatment issues
- Personal issues

(Ahmed, 2010; Ahmed et al., 2014; Hughes et al., 2015)

SPARC Guidance, 2004

SPARC Guidance, 2004, provides guidance about how SPARC should be used, this is summarised below.

SPARC is designed for use as a comprehensive and holistic self-assessment tool and gives a profile of needs to identify patients who could benefit from additional supportive or palliative care. It is designed to complement and not to replace the face-to-face clinical assessment by healthcare professionals (Hughes et al., 2015).

SPARC is intended to highlight need, in order to improve patient management, either by the current professional carers or by referral to specialist supportive and palliative care services, and is found to be acceptable and relevant to patients with a wide range of diagnoses (Hughes et al., 2015; Richardson et al., 2005).

SPARC is designed to give a clinical profile and NOT a single index score. Each item should be regarded on its own merit. Currently we do not recommend attaching any clinical significance to the total score or sum of scores in any category.

SPARC does not generate a clinical diagnosis. For example, it cannot indicate if a patient has clinical depression or a specific pain syndrome. It should not be used as the structure for a clinical interview unless 60 to 90 minutes are available for the task.

It may be helpful to direct the clinician to another screening tool. For example, a high pain score could trigger the use of the Brief Pain Inventory (BPI) and/or Leeds Assessment of Neuropathic Symptoms and Signs (LANSS). A high score within the psychological section could trigger the use of Hospital Anxiety and Depression Scale (HADS).

SPARC may be used at any time for patients with any diagnosis or combination of medical problems that indicate need for supportive or palliative care. Clinicians whose patients use the scale should be made aware of any individual score of **1** or above. Items scoring **2** on the scale require early attention. An appropriate course of action may be discussing the issue at a meeting of the multidisciplinary team or at the next consultation with the patient. Items scoring **3** would usually merit immediate attention by the attending clinician. The speed of response and the specific actions taken will depend on the clinical context, how long the issue has been a problem and the level of supportive care or palliative care already in place.

1.15 Summary

The gap in knowledge: Implications for future research and practice

Many of the symptoms and problems associated with cancer or advanced progressive illnesses are potentially treatable, but often remain unrecognised and may cause significant impairment of quality of life or loss of independent functioning (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

This review has presented a strong argument in favour of the need for a comprehensive holistic assessment of supportive and palliative care needs, and recommendations for conducting a HNA have also been presented (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). There is evidence to indicate a lack of studies on the clinical utility of tools (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Richardson et al., 2007).

There is at present no standardised systematic, evidence-based holistic approach to screening patients for supportive and palliative care needs (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). Systems and services must be in place in order to address any identified needs in a timely manner, and we must consider and evaluate new methods to achieve practice change. Further research is also needed on the effective integration of these tools into routine clinical care. Future work must therefore address these issues (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

SPARC has been developed by the Academic Unit of Supportive Care, The University of Sheffield over a period of 5 years. SPARC has undergone rigorous psychometric development, preliminary field-testing, and extensive validation. SPARC has been shown to be acceptable to patients in various settings (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). Despite rigorous psychometric development, preliminary field-testing, and validation, the clinical utility of SPARC has yet to be established (Ahmed et al., 2015).

This review provides the evidence base and the justification for a prospective randomised controlled trial of the clinical utility of SPARC as an early holistic needs assessment (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). Palliative care trials are complex, and in light of this, the SPARC intervention study was developed, piloted, evaluated, reported and implemented in accordance with the MRC framework for developing and evaluating complex interventions (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014; Craig et al., 2008a; Craig et al., 2008b). Data generated from this pilot study will guide the development of a further, larger definitive multicentre study (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014). This trial is the first step in a process that would define the clinical utility of SPARC (Ahmed et al., 2004; Ahmed, 2010; Ahmed et al., 2014).

Chapter 2

2 Hypothesis, aims and objectives

2.1 Hypothesis

The hypothesis was that the use of a validated multidimensional holistic screening tool for supportive and palliative care needs; the Sheffield Profile for Assessment and Referral for Care (SPARC) would lead to improved recognition of supportive and palliative care needs, and improved health care outcomes for patients (Ahmed, 2010).

2.2 Aims

- To determine whether the use of a validated multidimensional holistic screening tool for supportive and palliative care needs; SPARC, will lead to improved recognition of supportive and palliative care needs and improved health care outcomes for patients (Ahmed, 2010).

2.3 Objectives

- To design and undertake a pilot study to evaluate clinical outcomes associated with the use of SPARC in a supportive and palliative care service using a randomised, waiting-list controlled trial in order to test its clinical utility.
- To undertake a detailed process evaluation of the SPARC pilot trial, in order to gain a better understanding of ‘whether and how the SPARC intervention works (or does not work) and inform the design of subsequent studies’ (Farquhar et al., 2011).
- To elicit the views of supportive and palliative care professionals concerning the use of SPARC in Sheffield (UK), particularly with regards to ‘the effective integration’ of SPARC into routine care and standard operating systems (Ahmed, 2010).

2.4 Potential impact of this work

This study provides an opportunity to ‘test-drive’ SPARC with patients that have supportive and palliative care needs. It will contribute to recognising the best methods for identifying patients’ needs, and determine the extent to which these needs are addressed by following patients prospectively. This study represents a development of the SPARC tool for use as an early holistic needs assessment tool, within the MRC framework for evaluation of complex interventions (Ahmed, 2010; Craig et al., 2008a; Craig et al., 2008b).

Chapter 3

3 Methodological approach

3.1 Methodological and theoretical underpinnings of the study

This study was conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for evaluating complex interventions (Boon et al., 2007; Craig et al., 2008a; Craig et al., 2008b; Craig et al., 2013a; Craig et al., 2013b). This chapter focuses on the methodological and theoretical framework that was used to inform the methods and the design of this study. Palliative care researchers employ a variety of methods, the choice and selection of an appropriate design is an important aspect of the research process (Noble, 2014). An embedded (or nested) concurrent mixed methods design was considered the most appropriate design for this study. The rationale for this design being discussed further within this chapter.

3.2 Philosophy in mixed methods research

Creswell, 2009, defines a worldview as a basic set of beliefs that guide action. Mixed methods researchers may hold different philosophical positions (dialectical stances), this can be particularly challenging when undertaking mixed methods research, due to tensions created by the different beliefs; leading to so called ‘paradigm wars’ (Albright et al., 2013; Alise & Teddlie, 2010; Bazeley, 2009; Creswell, 2009; Creswell & Clark, 2010; Creswell & Tasshakkorri, 2008; Kelle, 2006). The mixed methods literature makes reference to 4 major worldviews, namely: 1) postpositivism; 2) constructivism; 3) advocacy/participatory; and 4) pragmatism (Creswell, 2009; Creswell & Clark, 2010). Creswell, 2009, provides a summary (breakdown) of the four worldviews of research (**Table 8**); and summarises the interconnection of worldviews, strategies of inquiry, and research methods and designs commonly used in mixed methods research (**Figure 6**).

This doctoral study adopted pragmatism as the underpinning philosophical framework to inform the choice of methodology and methods.

Table 8: Summary (breakdown) of four world views of research (adopted from Creswell, 2009; and Creswell & Clark, 2010)

Postpositivism	Constructivism
<ul style="list-style-type: none"> ▪ Determination ▪ Reductionism ▪ Empirical observation and measurement ▪ Theory verification 	<ul style="list-style-type: none"> ▪ Understanding ▪ Multiple participant meaning ▪ Social and historical construction ▪ Theory generation
Advocacy/Participatory	Pragmatism
<ul style="list-style-type: none"> ▪ Political ▪ Empowerment issue-oriented ▪ Collaborative ▪ Change-orientated 	<ul style="list-style-type: none"> ▪ Consequences of actions ▪ Problem-centered ▪ Pluralistic ▪ Real world practice oriented

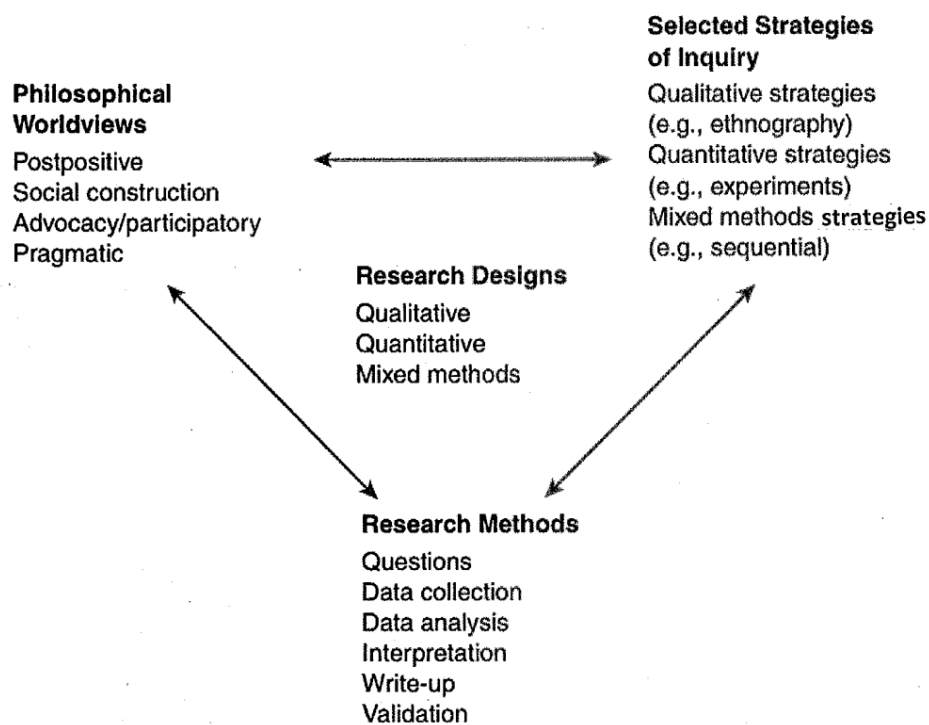


Figure 6: The Interconnection of worldviews, strategies of inquiry, and research methods: A Framework for Design (adopted from Creswell, 2009; Creswell & Clark, 2010)

The pragmatic approach is a philosophical movement that has its origins in the United States around 1870 (late 19th and early 20th century) (Hookway, 2016), and originated as a result of

the ongoing debates between qualitative and quantitative researchers (Creswell, 2009; Creswell & Clark, 2010).

Mixed methods researchers advocate the use of this approach, which is widely regarded as the best paradigm in mixed methods research (Patton, 1999; Protheroe et al., 2007; Tashakkori & Teddlie, 2010), where the focus is primarily on the importance on answering the research questions i.e. drawing on the principles of what works as an ideology, and using diverse or multiple approaches (i.e. quantitative and qualitative) to reach a practical solution (Feilzer, 2010; Miller et al., 2013; Onwuegbuzie & Leech, 2005). This approach does not align itself to any one particular approach, or philosophical assumption. Creswell, 2009, state that ‘multiple methods and procedures, different worldviews or paradigms, different assumptions as well as different forms of data collection and analysis that best fit the research question/s’ can be used in a mixed methods research study to address research problems (Creswell, 2009; Creswell & Clark, 2010; Feilzer, 2010).

3.3 Methodological and ethical issues of conducting research in palliative care

Methodological and ethical considerations are important aspects for all types of research involving patients and are a fundamental part of palliative care research. Keeley, (2008), cites the need to improve the evidence base in palliative medicine, however the difficulties of conducting research in patients with chronic and advanced progressive diseases, cancer, serious illnesses and those at the end of life, who are often regarded as a ‘vulnerable group of patients’ are well documented, and much of the ethical debate is based on the issue of ‘vulnerability’, treatment allocation, respect, confidentiality, burden and gaining informed consent (Ahmed, 2010; Addington-Hall, 2002; Ross & Cornbleet, 2003).

A number of authors have commented on the methodological and ethical difficulties of conducting research in palliative care, particularly when self-report methods are used to investigate experiences of patients (Entwistle et al., 2002). Challenges include: recruitment difficulties; defining the patient population; retention; follow up difficulties; gate keeping; high patient attrition rates; patients often regarded as vulnerable; frail; weak; and with cognitive impairments; small sample sizes; compliance; dropouts and withdrawals; missing data; as well as difficulties with obtaining informed consent have all been cited (Ahmed, 2010; Addington-Hall., 2002; Borgsteede et al., 2006; Diehr & Johnson, 2005; Dobratz, 2003; Entwistle et al., 2002; Ewing et al., 2004; Flemming et al., 2008; Grande & Todd, 2000; Jordhoy et al., 1999; Ly et al., 2002; Mazzocato et al., 2001; McGrath & Phillips, 2007; O’Mara et al., 2009; Palmer, 2004; Plu et al., 2007; Ross & Cornbleet, 2003; Seymour et al., 2005; Steinhauer et al., 2006; Stevens et al., 2003; van der Krieke et al., 2013).

In light of such challenges within palliative care research, Flemming et al., 2008, present a strong case for using a multi-method research design, and supplementing the RCT with additional mixed methods research (i.e. with qualitative research), as a way forward.

Flemming et al., 2008, cite ‘lack of experience in a research team of using mixed method research’ as one factor which could account for few studies employing this approach. Some strategies to improve recruitment for palliative care studies, include reducing healthcare professional workload, recruiting patients from a variety of settings including inpatient, outpatient and from hospital admissions (Jordhoy et al., 1999), and employing research nurses (Ross & Cornbleet, 2003). Stevens et al., 2003, argue against using restrictive inclusion and exclusion criteria, which often restricts opportunities for some patients to participate. Borgsteede et al., 2006, propose using the ‘broadest possible inclusion criteria’ (Ahmed, 2010). All of these approaches were incorporated into the design of this study, and I ensured that health care professional input and workload was kept to minimal. However, research nurses were not employed, as I was the main researcher working on this project.

Despite these challenges, there appears to be a general consensus that palliative care research is acceptable and possible in this group of patients (Steinhauser et al., 2006), provided patients are treated with ‘empathy’, regularly assessed and monitored, offered support and given choice (Ahmed, 2010; Dobratz., 2003; Ross & Cornbleet, 2003).

How methodological and ethical considerations informed the actual design of the PhD study components?

Randomised controlled trials, particularly in the fields of supportive and palliative care can place additional methodological and ethical demands on research design, and there are special considerations in this patient population that one must consider. I will discuss how methodological and ethical issues (e.g. patient vulnerability, respect, informed consent, confidentiality, burden etc.) informed the actual design of the PhD study components.

Intervention (SPARC) allocation

The idea of allocating ‘vulnerable patients’ to less than optimal care is contentious. The waiting-list control design was appropriate here for ethical and practical reasons. Recruitment is facilitated in studies where an intervention (e.g. SPARC) perceived as potentially beneficial is made available at some point to all who agree to participate in a study. The two-week waiting period was chosen to allow for maximum data to be obtained at the follow-up stage, while not unduly delaying offering the SPARC to the waiting-list controls (described in more detail in **Chapter 4** outcome evaluation). The 2-week point was selected as the crucial follow up measure following baseline in order to minimise attrition in a service where we know that the median survival is 13 days. Instead of an estimated 75% attrition rate limiting the data returned at two weeks, a 32.4% attrition rate was observed from consent to two-week follow up in a population largely made up of home care and out-patient clinic patients.

3.31 Participant vulnerability

The vulnerability of patients taking part in this study was protected at all times. This study only included adult patients (18 years old or above) who had the capacity to give informed consent. Patients incapable of giving informed consent or incapable of completing SPARC even with the help of a relative or informal carer were excluded. All members of the research team applied for an honorary contract and Criminal Records Bureau (CRB) checks were undertaken. A Criminal Record check at an Enhanced Disclosure level was undertaken, this is the highest level required for undertaking research with ‘vulnerable adults’. Patients were recruited from a variety of settings (including inpatients, outpatients, day care and community settings), and the study used the broadest possible inclusion and exclusion criteria, this enabled the study team to include a representative sample of patients that are seen by the supportive and palliative care service (i.e. not restricted to only inpatients on general hospital wards who are acutely unwell). Study invitation packs were initially sent out to all patients referred to the supportive and palliative care service. However some health care professionals caring for the patients expressed concerns and had reservations about sending study invitations out to all patients, because they felt that some of their patients were too ill to participate (especially inpatients), and some preferred seeing the patients first and getting to know them better before inviting them to take part in the study. In some instances, patients received the study invitation packs before they had seen anyone from the palliative care team. For this reason, the study methodology was changed to allow the clinical team to screen all eligible patients from their lists of patients they were seeing prior to sending out the study invitation packs. A recruitment guidance sheet was developed for the medical and nursing staff (**Appendix 9**) to help identify potentially suitable patients. This change in methodology worked well in identifying suitable patients, and at the same time protected patient vulnerability.

3.32 Participant respect

Patients were given the option to withdraw from the study at any time without giving a reason, the patient information sheet stated that a decision to not to take part or withdraw from the study will not affect their future medical care. The patient information sheet also stated that there were no specific risks associated with this study, and it was highly unlikely that patients will be harmed, however if patients did have any concerns/complaints or were unhappy about any aspect of the study, they were advised to contact in the first instance, the principal investigator (Professor Bill Noble), and if they remained unhappy, or wanted to complain formally, they had the option go through the NHS complaints procedure by contacting the Medical Director at STH NHS FT (study sponsor; address and telephone details were provided in the patient information sheet). If patients wanted any further information about the study, they could contact the research team, principal investigator, myself (Project Manager), or my colleague MW (telephone and address provided in the patient information sheet). No formal complaints were registered.

3.33 Participant confidentiality

The patient information sheet made it clear that taking part in the trial would be kept strictly confidential, and that completed SPARC questionnaires and information (e.g. thoughts about death and dying or having suicidal thoughts) would be given to doctors and nurses or other health care professionals caring for the patients. Patients were also advised that information from research questionnaires (MYCAW, EQ-5D, and PEI), their clinical records and from the interviews would be kept strictly confidential and it will be securely stored. All research data collected in this study was treated in accordance with the 'EU Directive on the protection of individuals with regard to the processing of personal data' and UK regulations.

In order to preserve anonymity, I took out details of characteristics of individuals (patients and HCPs), the analysis was described as a group rather than at an individual level. Furthermore clinical and research data collected was kept separate from personal data e.g. postcodes/address/date of birth or other directly related personal identifiers were not present in datasets containing clinical data or research data. Identification numbers (ID) were assigned to each participant, thus allowing the research team to link the different datasets.

3.34 Participant burden

The outcome measures (research questionnaires) selected were all short and easy to complete, and as per recommended guidance (Finlay & Dunlop, 1994), responses are more likely when short questionnaires are used (Boynton, 2004; Edwards et al., 2002; Nakash et al., 2006) on quality of life instruments/outcome measures for palliative care (Hearn & Higginson, 1999), and place minimal burden on the patient and capture items of most importance (Brasel, 2007). The three measures were compiled into a booklet (**Appendix 10**). Out of 225 patients that consented, only 7 withdrew for reasons of burden of research assessments.

Pre-paid envelopes (freepost) were provided to all participants for returning completed consent forms, research questionnaires, SPARC and opt-in forms for semi-structured interviews. Patients were given the option to complete the SPARC questionnaire and the research questionnaires with or without the help of their informal carers/professional carers or family members. Semi-structured interviews with patients were undertaken, which are potentially less demanding and less-time consuming than in-depth interviews which can place extra burden on participants with an advanced or progressive illness, who may be too ill and emotionally upset to participate. Strengths/advantages and limitations of semi-structured interviews are presented in more detail in **Chapter 5**; process evaluation.

Formal and informal discussions with staff at various sites ensured that they were familiar with and comfortable with the study taking place. The patient information sheet outlined the benefits, risks and disadvantages of taking part. All potential participants were advised that occasionally people (in this field) may feel upset by being reminded of illness or difficulties, and that specialist help and support was available should any part of the study upset or affect them in anyway, and that the research would be undertaken by experienced researchers. If

they wanted to obtain general advice in participating in research studies, participants could contact INVOLVE: a national advisory group that supports greater public involvement in the NHS, public health and social care research (funded by National Institute for Health Research), a link to the website and a telephone contact were provided in the patient information sheet.

Prior to sending out follow-up questionnaires, it was important to ensure that the patient was still alive and not deceased, appropriate checks were made with administration teams at the different settings at the time of sending out additional questionnaires. This was very important for continuity purposes as patients may be referred to a number of different settings. As patients may move from one setting to another, careful monitoring was necessary to establish whether patients had been admitted to, or discharged from, hospital, and also to ensure that continuing contact was appropriate.

With the methodological and ethical considerations of undertaking palliative care research in mind, this study adopted an embedded (or nested) concurrent mixed methods design. 'A concurrent design is where quantitative data and qualitative data are collected concurrently or roughly at the same time, thus allowing researchers to maximise the amount of data collected in a given time' (Creswell & Clark, 2010; Tashakkori & Teddlie, 2010). The strategy of stratification for baseline quality of life was added to the design to ensure equivalence between trial arms.

There was close cooperation between the research team and the staff at the different study sites.

3.35 Ethics and research governance approvals and considerations

Ethical approval was required for the main trial, and an ethics application was submitted to the appropriate committee. A Research Governance application was made to the Sheffield Teaching Hospitals NHS Foundation Trust (STH NHS FT) body which deals with access to the study sites. I had the overall responsibility for completing the protocol, ethics submission, logistics of the study and analysis. Along with other members of the research team, I applied for an Honorary Contract (**Appendix 11**) and obtained necessary permissions to undertake the study at the different study sites. A *Criminal Records Bureau* (CRB) check was undertaken as part of this procedure.

Informed consent

Ethics committee requirements for patients losing capacity to consent during the study

Only patients who are mentally competent to make a decision, as judged by the health care professionals caring for them can give informed consent. This is particularly challenging in palliative care research due to issues around 'cognitive failure, fatigue and depression'. Thus, the study excluded participants that were unable to consent for themselves at the point of

recruitment. In this area of care (i.e. palliative care), many patients initially able to provide informed consent lose the capacity to do so as the disease progresses. Information about patients from family members, carers, their health care professionals, case notes and records was an important part of this study. Any participant that lost the capacity to consent during the study was not approached again for further questionnaire data, but information from their case notes was gathered as part of the study. However, one of the requirements of the ethics committee was that under these circumstances an appropriate personal consultee (a named next of kin or person to consult) should be identified and supplied with written information about the study, and then be required to complete a consent form to agree to patients' notes and records continuing to be used in this study.

Another requirement of the ethics committee was that if the capacity to consent had been lost, but subsequently regained (as established by the clinicians) at some point during the study, continuing consent to the study would have to be explored and if necessary formally re-confirmed. This required careful consideration on how to re-introduce questionnaires for patients, and the opportunity to participate in the semi-structured interviews that followed.

Substantial period for set up required

The study took place over 35 months (the recruitment period was 22 months). A substantial period for setup was necessary for the study. Some factors contributing to the complexity in this case were as follows: the use of several different settings; hospital; community; out-patient and hospice; the need to fulfil procedures for governance in non-NHS settings; and addressing procedures for a study in which we might expect that many participants who initially had capacity to consent would lose this capacity during the course of the study.

Obtaining research ethics committee approval and research governance approval proved challenging due to the complexity of the trial. The recruitment start date was delayed by around 6 weeks. The Bradford Research Ethics Committee received our application on 3rd November 2010, and subsequently reviewed it at the ethics committee meeting on 16th November 2010. The committee raised several points of discussion about the study. Plans were also agreed for using data given by patients who initially had capacity to consent to the study, but then lost capacity.

The committee required further clarification on minor issues and following review of our amendments, approval was given on 9th December 2010 (**Appendix 12**). Given that I was undertaking a PhD, we were also asked to notify and make changes to some study documentation to reflect this in a substantial amendment which was submitted on 16th December 2010. The committee reviewed the documents and a final favourable ethical opinion was granted on 14th January 2011 (**Appendix 13**).

Applications to NHS and non-NHS sites

The favourable ethical opinion applied only to conducting the study in NHS sites, therefore a similar application to undertake the study at St Luke's Hospice (non NHS site) was submitted to Sheffield REC (based in Leeds) on 13th January 2011, and approved (**Appendix 14**). Non-NHS sites have separate research governance arrangements and I submitted all the study documents to St. Luke's Hospice, Sheffield, for review by their committee. All Research Passport applications were approved for researchers undertaking the study.

Reminder/follow-up letters

Another amendment involved developing a reminder letter/follow up contact to patients who had not returned the baseline or 2 week questionnaires, as per recommended guidance, reminders have the potential to improve response rates (Edwards et al., 2002; Nakash et al., 2006). Burns et al., 2008, suggest that 'for postal surveys, each additional mailed reminder yields about 30-50% of the initial responses'. The ethics Committee approved this reminder letter. We decided to use a reminder letter that did not include another copy of a questionnaire that had already been sent. Some patients completed and returned the original questionnaire and also completed the one sent with the reminder letter, thus causing confusion for some patients. Furthermore, one patient wrote a letter of complaint saying that she had received too many questionnaires and reminders in the post, and declined further participation. This prompted us to change the procedure, so that the reminder letter (edited) (**Appendix 15**), was only sent one week after baseline and one week after the two-week questionnaires were sent. For the analysis it was critical that we received the completed two-week questionnaires. Reminder letters were not sent after sending out the four or six week questionnaires.

Research Governance applications were made to the relevant organisations (Trust R&D approval letter presented in **Appendix 16**). It was necessary to wait until the ethical submission was underway before proceeding with parts of this process. Negotiation for use of facilities and staff time was also delayed somewhat. Liaison with clinical colleagues and detailed preparation of materials was crucial to the success of this study as it involved working in clinical areas. The process of setting up the study had taken the project team longer than anticipated, and as a result the project was slightly behind schedule.

The original intention was to have started data collection in January 2011; this was amended to start data collection in February/March 2011. Furthermore, recruitment slowed down towards the end of the recruitment period and for this reason the team applied for a no-cost extension to extend the recruitment period in order to recruit the required number of patients to power the study. This was approved by Macmillan Cancer Support in June 2012, and a no-cost extension to 30th November 2012 was officially granted. There were no significant changes to the project in its aims or methodology (Macmillan Cancer Report Final Report, January 2013).

General ethical and research governance issues

If a hospital patient was identified through the survey as having a significant problem, i.e. a score of 2 or 3 on SPARC for any of the symptoms or psychological distress scores, then they were offered a referral to the appropriate specialist care nurse/team for their disease site. This information was relayed back to their own team, with the patient's permission. For patients who may become distressed when answering the questionnaires, specialist help and support was initially available from the study team. If the situation was outside of the team members' experience then the principal investigator was advised of the situation and the patient offered appropriate help and support. Patients who were resident or attending the Macmillan Palliative Care Unit (MPCU) (Sheffield) or St. Luke's Hospice (Sheffield) were offered to have their problems communicated to the senior nurse in charge on the day, with the patient's permission.

3.36 Timescale

Phase 1: Outcome evaluation

The first year of the research project was devoted to setting up the project: which involved undertaking a literature review; study design and protocol writing; making necessary research governance and ethics applications; service user consultation; familiarisation with the service and liaison with clinical personnel (Ahmed, 2010; Ahmed et al., 2014). A long set-up period was allowed. This was based on our previous experience of the time needed to gain the relevant permissions for a study to go ahead. In particular, new procedures for approving research field-workers to carry out the research with patients were proving lengthy at our institution and at others in the country. Applications for approval in the Sheffield Teaching Hospitals, was at that time taking in excess of six months to process. The set-up part of the study was also important for informing and liaising with clinical staff, and the time given to this area was crucial in ensuring the proper functioning and successful carrying out of the study. This was followed by a data collection period of 15 months. A no-cost extension was approved by the funding body to allow data collection to continue. In the end the recruitment period was 22 months in duration. The final 12 months of the project were allocated to analysis, report writing and dissemination (SPARC study timescale is presented in **Appendix 17**).

Phase 2: Process evaluation

A process evaluation of the trial was undertaken from 1st February 2013-14th July 2014.

Regular monitoring of recruitment was necessary to identify any accrual problems, and to identify the amount of missing data. Early identification of these problems enabled the research team to make any necessary changes to the protocol and design of the study early on, as missing data can present significant challenges to researchers at the data analysis stage (Diehr & Johnson, 2005; Palmer, 2004). Considerable groundwork was undertaken to ensure that clinicians/health care professionals and patients perceived the pilot RCT to be fair,

justified and useful, and it was essential to gain their full support for the successful completion of the study.

3.4 Randomised controlled trials

In this section, I will explain why RCTs are considered the Gold Standard, and discuss the underlying principles and rationale behind choosing an RCT design for this study in order to establish the effectiveness of the SPARC intervention.

Clinical trials are essentially scientific experiments that are undertaken to establish the benefits and harms of a particular treatment or intervention (e.g. professional assessment and advice, medicines, medical/surgical procedures or devices). In palliative care the primary focus is often on improving quality of life of patients with an advanced progressive or incurable disease (Addington-Hall., 2007a; Addington-Hall., 2007b; Bausewein et al., 2016).

Sir Austin Brad-Hill, is widely regarded as one of the pioneers of the Randomised Controlled Trial (RCT). With growing emphasis on evidence based medicine, the RCT is traditionally regarded as the ‘gold standard’ and most scientifically robust method for evaluating new treatments, interventions, or services. This is largely attributed to features such as random allocation of participants to treatment/interventions, the use of control groups and blinding of participants and researchers, thus minimising bias and improving rigour and the strength of evidence that is generated (Bennett, 2007). RCTs are undertaken to establish a causal connection between an intervention or treatment and an outcome. In other words, to determine whether a ‘cause-effect’ relation exists between the intervention/treatment and outcome of interest (Bennett, 2007; Hanley et al., 2016; Midgley et al., 2014; O’Cathain et al., 2009b). The prospective RCT allows comparisons to be made between interventions and standard (control) groups (Flemming et al., 2008; Grande & Todd, 2000; Hudson et al., 2001; Mazzocato et al., 2001).

However, designing and conducting prospective RCTs with potentially ‘vulnerable patients’ with an advanced progressive illness who often have many symptoms and limited survival times is challenging (Bennett, 2007). Furthermore, patients may have a preference of one treatment to another, and the concept of allocating vulnerable patients ‘less than optimal care’ (control group) is contentious (Bennett, 2007; Relton et al., 2010; Reyna et al., 2007). For these reasons a very limited number of RCTs have been undertaken and reported in this field (Addington-Hall, 2007a; Addington-Hall, 2007b; Bennett, 2007). In the previous section, I have addressed some of the ethical and practical challenges involved in designing and conducting clinical trials in palliative care.

Evidence based medicine is the systematic approach to clinical problem solving and involves making use of best available research evidence (i.e. research that is well designed and conducted to the highest standards), to optimise the decision-making process, particularly when it comes to making important decisions about the care of individual patients. Some research designs such as RCTs, are considered to be more ‘superior’ and more ‘powerful’

compared to other research designs (e.g. surveys or service evaluations) in answering research questions, such as determining the effectiveness of interventions, hence giving rise to the concept of ‘hierarchy of evidence’. For these reasons RCTs (along with systematic reviews of these trials) are well positioned in the hierarchy of evidence (**Figure 7**) compared to other methods employed by researchers (Sackett et al., 2000).

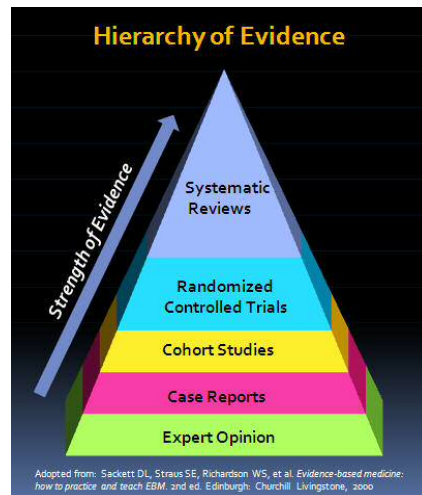


Figure 7: Hierarchy of evidence diagram (position of RCTs in the hierarchy of evidence in relation to other methods used) (adapted from Sackett et al., 2000)

The characteristic pyramid shape is used to represent the inherent risk of bias in study design, which increases as one goes down the pyramid, with more ‘scientifically rigorous’ methodologies, such as RCTs and systematic reviews situated at the top of the pyramid and methodologically ‘simpler/weaker’ methods placed towards the bottom of the pyramid (e.g. case reports, expert opinion etc.). The rigorous processes undertaken during the design and conduct of a properly conducted and executed RCT are considered to be of paramount importance in minimising the risk of confounding factors that could potentially influence the results and damage the internal validity of the study. It is widely acknowledged that the findings generated by well-designed and well-conducted RCTs, are closer to the true effect than findings generated by other forms of research methods used lower down the pyramid, hence providing a more powerful and reliable form of evidence (Bennett, 2007).

RCTs as the name suggests, involves the random allocation of patients (population of interest) to one or another intervention/treatment (in this case SPARC). The waiting-list control design used in this study is discussed further in **Chapter 4** (outcome evaluation). This approach ensures that each participant has an equal probability of being assigned to any given group (intervention or control), and they are followed up for a specified period of time.

However, it must be stressed that this strict process of randomisation does not eliminate confounding variables (i.e. both known and unknown); such as age, sex, disease activity, and duration of disease etc., but rather it distributes them equally between the two groups. Thus, the characteristics of patients or any other confounding variables that could potentially

influence the outcome of the trial result are randomly distributed equally between the two groups, so that any effects cancel out and any difference in outcome can only be attributed to the intervention or treatment administered (i.e. randomisation cancels out the impact of everything but the intervention), thereby, reducing the overall bias in the trial.

Random allocation or assignment of an intervention or treatment is typically undertaken after potential participants have been assessed for eligibility against study inclusion and exclusion criteria and recruited to the trial, but prior to administering the intervention or treatment.

The presumption of causality cannot be achieved in other research designs e.g. retrospective designs where confounding variables may create associations with causal relationships which do not arise out of intervention.

Apart from receiving the intervention (or timing of receiving the SPARC intervention, as was the case in this study), the intervention and control groups were treated and observed in an identical manner, and at the end of the study, the two groups were analysed in terms of outcomes defined at the outset/start of the study. This approach ensured that any differences in outcomes are attributed to the trial intervention (SPARC in this case).

Methods employed to randomly assign participants to either the intervention or control group, include the use of a table of random numbers and a computer program that generates random numbers. This study used a computer to generate random numbers. There is no other robust and reliable method of controlling a trial which will allow presumption of absence of systematic bias.

Block randomisation and stratification are strategies that can add to the credibility of a trial and are often used to help ensure balance between groups in size and patient characteristics. In this study stratification for baseline quality of life ensured comparability between study arms in terms of severity of symptoms and level of quality of life. In terms of implementation, the trial statistician (Professor Peter Bath and others involved with the trial) generated the randomisation sequence.

It was important to document that random allocation of intervention or treatment was successfully achieved. The CONSORT statement suggests that sequence generation, allocation concealment and implementation should be reported. These are reported further in **Chapter 4** (outcome evaluation).

Allocation concealment underpins successful randomisation strategies, and is the term used to describe the process by which those running the trial and responsible for recruiting patients who have agreed to take part in the trial, remain unaware of the group to which group participants will be allocated, thus avoiding both conscious and unconscious selection of patients into the study. Concealment of allocation, clarification of who generated the sequence, the method used, and how concealment was achieved and monitored is discussed further in **Chapter 4** (outcome evaluation).

Blinding is used to reduce bias and usually refers to keeping patients, investigators and those collecting and analysing clinical data unaware of assigned treatment (single blind, double blind, or open blind), so that they are not influenced by that knowledge and any expectations do not bias the results of the trial. Blinding can be difficult to achieve or sometimes impossible. The rationale behind using an open blind approach in this study is discussed further in **Chapter 4** (outcome evaluation).

3.5 Feasibility vs. pilot studies

The UK MRC guidance for designing and evaluating complex interventions to improve health was updated in 2008 (Craig et al., 2008a; Craig et al., 2008b), making specific reference for the need to undertake feasibility and pilot studies prior to embarking on costly and large scale definitive trials of complex interventions (De-Silva et al., 2014; Sampson et al., 2008; Simmons et al., 2013). However, there appears to be still a lack of agreement and clarity in the research community about the use of the terms ‘feasibility’ and ‘pilot’ study. The literature suggests differences of opinion, and inconsistent use of these terms, with some researchers using the two terms interchangeably and consider them to be synonymous, others argue that they are different, thus leading to conflicting approaches to interpretation of the two terms (Eldridge et al., 2016). Whitehead et al., 2014, state that the different terms are often used to define stages of development of a study. However, while there appears to be no formal guidance as to what constitutes a pilot study and what constitutes a feasibility study, some authors have called for a more consistent usage of these terms and attempted to reach a consensus over the conceptual framework for definitions, but this still remains a grey area (O’Cathain et al., 2015). There is a difference between feasibility and pilot studies, and I will outline the main distinguishing features of a pilot study (i.e. descriptions not usually applied to feasibility studies) from a feasibility study (**Table 9**).

Eldridge et al., 2016, and the National Institute for Health Research (Close et al., 2015; NIHR); define ‘feasibility as an overarching concept for studies assessing whether a future study or project development can be done’, ‘whereas pilot studies, are viewed as the miniature version of the RCT that resembles the main study in many respects, and are a subset of feasibility studies with a specific design’ (O’Cathain et al., 2015). Most researchers agree that feasibility/pilot studies should not test treatment comparisons nor estimate feasible effect sizes (Eldridge et al., 2016; Whitehead et al., 2014). The primary focus of these studies is to ensure that there is an accurate assessment of processes such as: recruitment; randomisation; treatment and follow-up assessments; that all ‘run smoothly to plan’; prior to commencing much larger definitive trials (Arain et al., 2010; Eldridge et al., 2016; Olstad et al 2016).

In 2015, and following on from the work undertaken as part of my doctoral study, I published an article in *Journal of Pain and Symptom Management* entitled ‘A Pilot Randomised Controlled Trial of a Holistic Needs Assessment Questionnaire in a Supportive and Palliative Care Service’, this is an example of a pragmatic pilot RCT (Ahmed et al., 2015, **Appendix 1**). The aim of this pragmatic pilot RCT was to determine whether the use of SPARC leads to

improved health care outcomes (health-related quality of life and self-identified concerns) for patients referred to a palliative care service. This was an effectiveness trial that would guide the development of a definitive multicentre study designed as a definitive assessment of clinical effectiveness of SPARC in triggering clinical interventions, a description usually applied to a pilot and none of the outcomes usually related to feasibility (e.g. time to completion, missing items) were assessed. The term ‘pragmatic’ was used in this context as the study was focussing on what works in a clinical service. SPARC could either be used as an aid to specialist clinical assessment or as a screening tool. In this study, SPARC was used primarily to assess need. Thus, this pilot trial is the first step in a process to define the clinical utility of SPARC in a specialist service (not as a screening tool for referral to specialist palliative care services).

A feasibility study on the other hand might typically involve undertaking interviews with patients and health care professionals and other users of services; to ascertain the acceptability and implementation of an intervention; or questionnaires; to assess the types of outcomes participants might think are important; the willingness of patients to be randomised; or the willingness of clinicians to recruit participants; and the number of people eligible to take part etc. Elbridge et al., 2016, provide an example of a feasibility study that is not a pilot study. They describe a study undertaken by Palmer et al., 2013. In this study, questionnaires were sent to surgeons to determine their opinion about whether it would be feasible to conduct an RCT that compared operative with non-operative treatment for femoroacetabular impingement surgery. The aims of this feasibility study are consistent with the consensus view of what constitutes a feasibility study.

The randomised pilot study undertaken during this doctoral study can be considered as a miniature version of the main RCT (i.e. regarded as the first phase of a substantive study), that mimics the definitive trial design, and was conducted on a smaller scale with a specific design feature. It resembled the main proposed trial in many ways, e.g. having an intervention and a control group as well as randomisation (Whitehead et al., 2014). The use of the term ‘pilot’ in this context implies an intention for further definitive work in the future. In other words, it was conducted in preparation for a future definitive RCT to assess the effect of an intervention; namely SPARC (Eldridge et al., 2016). Furthermore there was an assessment of processes e.g. recruitment, randomisation, treatment and follow-up assessments, retention, assessment procedures, to determine whether they all run smoothly and to plan and to determine if the intervention SPARC can be delivered as intended to highlight any problems so that they may be corrected prior to proceeding to the main trial and prior to any scaling up projects (Eldridge et al., 2016). The main distinguishing features of a pilot study (i.e. descriptions not usually applied to feasibility studies) from a feasibility study are presented in **Table 9**.

Table 9: The main distinguishing features of a pilot study (i.e. descriptions not usually applied to feasibility studies) from a feasibility study

Pilot studies	Feasibility studies
<ul style="list-style-type: none"> ▪ ‘Subset of feasibility studies’ ▪ ‘All pilot studies are feasibility studies but not all feasibility studies are pilot studies’ ▪ ‘Studies labelled ‘pilot’ should have different aims and objectives to main trials’ ▪ ‘More likely to mimic design of main study’ ▪ ‘Smaller version of the main study (e.g. use of a control group and randomisation)-and results should be interpreted with caution’ ▪ ‘Stricter study methodology-with more rigorous methodological components (e.g. a justification of the sample size in a subsequent main study, which should be adequate to estimate critical parameters, such as recruitment rate)’ ▪ ‘Focus on trial processes (1. testing procedures, 2. estimating recruitment/retention, 3. determining sample size) to identify problems prior to undertaking main trial’ ▪ ‘An intention for further work’ 	<ul style="list-style-type: none"> ▪ ‘A catch-all/ all-encompassing term for preliminary work- overarching concept/term for preliminary studies to assess whether a future study/project/development can be done, and if so how to proceed with a full-scale study’ ▪ ‘May or may not include a pilot RCT/randomised design/an evaluation of outcome of interest and power calculations are not normally undertaken’ ▪ ‘Umbrella term for three distinct types of study 1) randomised pilot studies, 2) non-randomised pilot studies, or 3) feasibility studies that are not pilot studies’ ▪ ‘Occur slightly earlier in the research process’ ▪ ‘Studies labelled feasibility are often conducted with more flexible methodology compared to those labelled pilot’ ▪ ‘May have no plan for further work and no part of the future RCT is being conducted on a smaller scale’
<p>Key references</p> <ul style="list-style-type: none"> ▪ Arain et al., 2010; Eldridge et al., 2016; O’Cathain et al., 2015; Olstad et al., 2016; Whitehead et al., 2014 	

Strengths of pilot study

The strengths and weaknesses of this pilot study are discussed further in the discussion section (**Chapter 8**). This pilot study defined clear circumstances in which the intervention, namely; SPARC, could be potentially harmful i.e. in which the outcomes were adversely affected. The trial was sufficiently powered to detect the adverse effect, and provided a framework within which a process evaluation was possible. Furthermore, the design and methods used for the pilot study were appropriate to the study population. A recruitment rate of 26.5% (225/850), and with only a few consenting patients (7/225) withdrawing for reasons of burden due to completion of research assessments, as well as the lack of differences between the study arms for either demographic factors or baseline research assessment values are all indicators of good data quality and a successful randomisation. The strategy of stratification for baseline quality of life which was added to the design to ensure equivalence between trial arms, also proved successful. Instead of an estimated 75% attrition rate limiting the data returned at two-weeks, a 32.4% attrition rate was observed from consent to two-week follow up in a population that was largely made up of home care and out-patient clinic patients.

Weaknesses/limitations of pilot study

This pilot did not take account of unforeseen factors that would damage feasibility. The study failed to recruit patients from the inpatient units and the hospital support service. This meant that the study sample had fewer patients with conditions other than cancer and a smaller

proportion of patients acutely ill than the whole population of patients referred to the palliative care service, and because of this attrition was rather less than expected. Thus, the findings from this pilot study are particularly relevant to cancer patients in the community.

This was not designed as a feasibility study (which is seen as more of an earlier stage), because of clinicians previous experience of using SPARC during earlier development work. The weaknesses of the pilot study would have been accounted for in a formal feasibility examination of how SPARC would have been integrated into clinical practice, however this was not undertaken. The design of the study erroneously thought that this was not necessary because clinicians and other health care professionals taking part in the study had previously used SPARC in a clinical context and this was another reason why a pilot design was chosen. An earlier feasibility study could have helped to ‘iron-out’ some of the weaknesses of the pilot study. O’Cathain et al., 2015, outline the possible questions that qualitative research can address in a feasibility study (**Table 10**).

Table 10: Range of issues and questions including category of question, sub-category, and examples of possible questions that qualitative research can address in a feasibility study (Reproduced from O’Cathain et al., 2015)

Category of question	Sub-category	Examples of possible questions
Intervention content and delivery	Intervention development	To what extent does the planned intervention need to be refined or adapted to make it more acceptable to users or more relevant or useful to the specific context in which it is delivered?
	Intervention components	Consider the different aspects of the intervention and which are fixed and flexible. The intervention may be different in practice from the planned intervention and may need to be documented so it can be delivered consistently in the full trial.
	Mechanisms of action	How might the intervention be working? How might it produce the outcomes important to the trial? Data collected to address these questions may be interpreted in relation to the theory upon which the intervention is based or may help to develop new theory.
	Perceived value, benefits, harms or unintended consequences of the intervention	What value do service providers and intervention users place on the intervention and the outcomes it plans to deliver? What benefits and harms do they feel they have experienced from the intervention so that these can be measured in the full trial?
	Acceptability of intervention in principle	Are service users or health care providers unhappy with any aspect of the content or delivery of the intervention?
	Feasibility and acceptability of intervention in practice	What are service users or health care providers’ views of the implementation of the intervention? Has implementation varied by setting? Are there any important intervention-context interactions? Should implementation be tailored by setting?
	Fidelity, reach and dose of intervention	Is the right amount of the intervention getting to the right recipients in the right way? Do those delivering the intervention and/or receiving it adhere to the planned intervention? If not, what are the reasons for this? What are the limits of acceptable tailoring of the intervention?
Trial design, conduct and processes	Recruitment and retention	How do the planned recruitment practices work in the field? Do recruitment practices need to be improved to increase recruitment rates and levels of informed consent? If so, how? Are the trial participants willing to be randomised? Are clinicians willing to recruit patients, or are they uncomfortable? Are there ways in which trial procedures could be improved to increase retention rates?
	Diversity of participants	Are the planned recruitment practices likely to result in recruitment of the desired range of participants for the trial? If not, how might recruitment practices be improved?
	Trial participation	How is the planned trial communication implemented by recruiters and received by participants? How can trial communication be improved to ensure recruiters understand patients’ views about participating in the trial?
	Acceptability of the trial in principle	Is the trial design acceptable to patients, recruiters and service providers in principle?

Category of question	Sub-category	Examples of possible questions
	Acceptability of the trial in practice	Is the trial design acceptable to patients, recruiters and service providers in practice, or are there ways in which participants try to alter the procedures?
	Ethical conduct	Are the informed consent procedures appropriate and acceptable to likely trial participants?
	Adaptation of trial conduct to local context	Will the planned trial procedures allow the trial to operate effectively in the proposed context? Do any changes need to be made to these procedures?
	Impact of trial on staff, researchers, participants and the health system	Does this trial have any unanticipated negative impacts on recruiters, participants, other stakeholders and the health system? How can these impacts be minimised (e.g. workload involved in recruitment, numbers of measures undertaken)?
	Patient and public involvement	How is patient and public involvement best achieved in the trial?
Outcomes	Breadth and selection of outcomes	Are outcomes important to service users selected for measurement in the full trial—both primary and secondary? Do some trial participants feel that they have experienced or noticed improvements in some outcomes that need to be included in the full trial?
Measures	Accuracy of measures	Are the process and outcome measures valid for this participant group?
	Completion of measures	Can completion rates of measures be improved?
	Development of measures	If validated measures do not exist for all the outcomes to be measured in the full trial, can they be developed in preparation for the trial?

The weaknesses identified during the pilot study have important consequences on the study design, the intervention, the timing of assessments, and on outcomes and these are discussed further in the discussion section (**Chapter 8**).

3.6 MRC complex interventions framework

The MRC complex interventions framework, provides a framework for conducting and reporting complex interventions and process evaluations. A complex intervention is described as having ‘several interacting components’ any of which could have an impact on the outcome (MRC framework for developing and evaluating complex interventions, new guidance, 2008 www.mrc.ac.uk/complexinterventionsguidance), (Ahmed, 2010; Boon et al., 2007; Campbell et al., 2000; Craig et al., 2008a; Craig et al., 2008b; Craig et al., 2013a; Craig et al., 2013b; Higginson, 2005; Paterson et al., 2009; Redfern et al., 2006; Richards & Hamers, 2009; Webb et al., 2016).

The development and evaluation of complex interventions of RCTs, particularly in palliative care remains a challenging area in health services research (Bradley et al., 1999; Brady et al., 2011; Burr et al., 2011).

Palliative care patients’ needs and interventions required to address them, as well as the trials themselves are complex (Farquhar et al., 2011; Farquhar et al., 2013; Higginson et al., 2013), complexity can be at an individual level, system level or at an organisational level (complex interventions versus complex systems) (Hawe et al., 2004; Shiell et al., 2008), and in light of this, the SPARC intervention study was developed, piloted, evaluated, reported and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions to improve health (Ahmed, 2010; Craig et al., 2008a; Craig et al., 2008b) (**Figure 8**). The framework is regarded as one of the most widely used guidelines reported for developing complex interventions (Ahmed, 2010; Boon et al., 2007; Campbell et al., 2007; Corry et al., 2013; Curry et al., 2013; Craig et al., 2008a; Craig et al.,

2008b; Craig et al., 2013a; Craig et al., 2013b; Paul et al., 2007). The mixed methods inquiry is advocated by MRC (Craig et al., 2008a; Craig et al., 2008b; Moore et al., 2015; NICE Guidance, 2004). A multi-method research methodology was therefore employed using both qualitative and quantitative techniques.

This study represents a development of the SPARC tool for use as an early holistic needs assessment tool, within the MRC framework for evaluation of complex interventions (Ahmed, 2010; Craig et al., 2008a; Craig et al., 2008b).

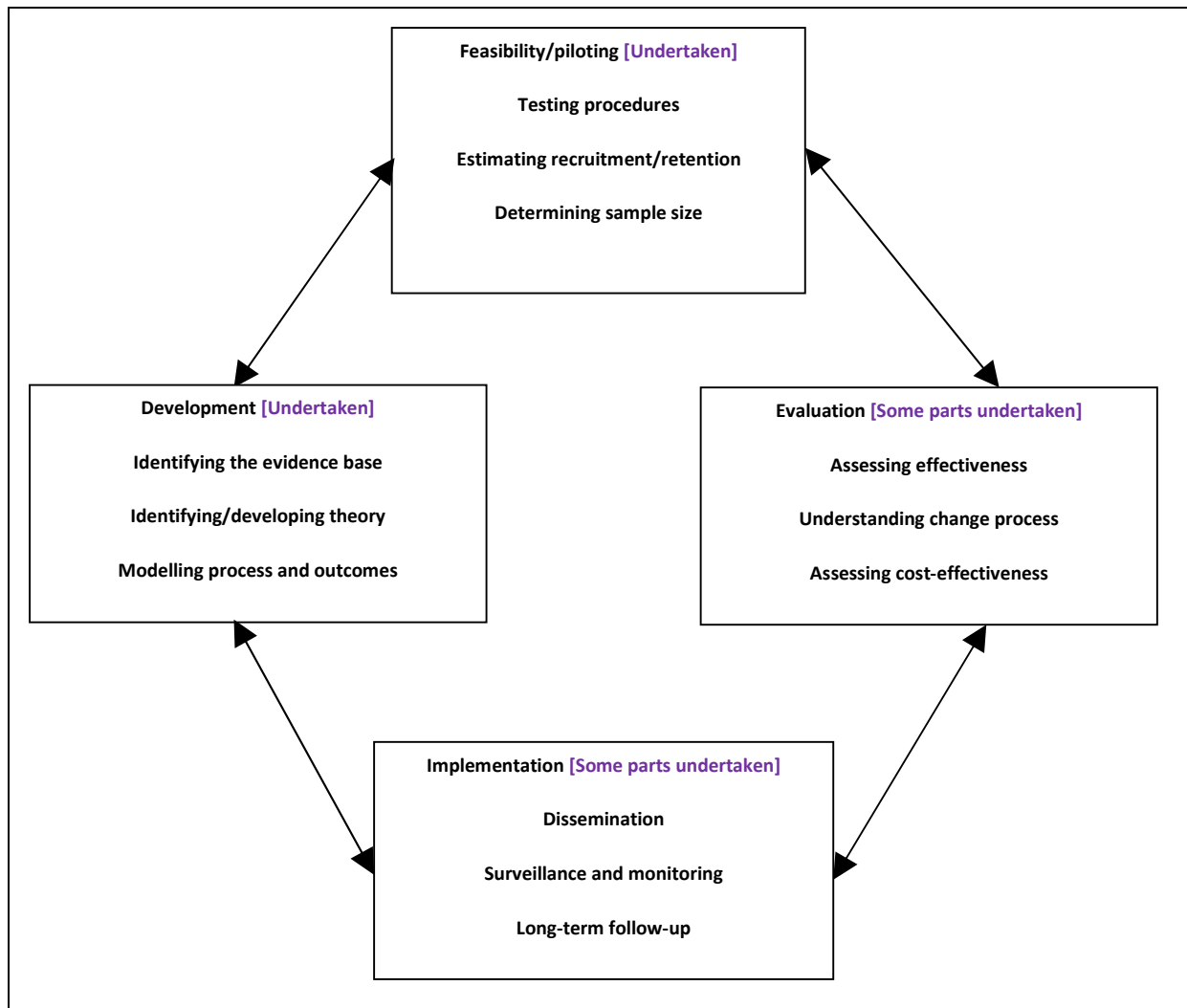


Figure 8: MRC framework for developing and evaluating complex interventions

Key elements of the development and evaluation process. ‘Different stages do not necessarily follow a linear or a cyclical sequence’ Palliative care trials are complex, and in light of this, the SPARC intervention study was developed, piloted, evaluated, reported and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions (Ahmed, 2010; Craig et al., 2008a; Craig et al., 2008b; Craig et al., 2013a; Craig et al., 2013b; Higginson, 2005; new MRC Guidance, 2008; www.mrc.ac.uk/complexinterventionsguidance).

3.7 Phases of MRC framework completed

SPARC has already been developed and undergone rigorous psychometric development, preliminary field-testing and validation (Ahmed et al., 2004; Ahmed et al., 2009; Ahmed, 2010; Ahmed et al., 2014; Ahmedzai et al., 2004b; Ahmedzai et al., 2010; Bestall et al., 2004; Burton et al., 2010; Leppert et al., 2012). I was involved in all stages of SPARC development including the study design, ethics application submissions, recruitment of participants, writing up the report and publications, and presenting the work at local, national and international conferences.

I identified the evidence-base by undertaking a review of the literature (Ahmed et al., 2014). I also identified the hypothesis, and undertook the modelling process with outcomes being identified for the doctoral study. The prospective randomised controlled pilot study tested procedures, estimated recruitment/retention, and outcomes. Patients with selected chronic progressive diseases were recruited from a range of settings including the community, day care, in-patient and outpatient settings. The implementation of SPARC (stages which come later) are outside the scope of this doctoral study. However, the evaluation (process evaluation) of the SPARC tool was undertaken as part of this doctoral study and is reported in Phase II (process evaluation; **Chapters 5-7**).

3.8 Quantitative, qualitative and mixed methods research approaches

At a very simple level, a quantitative study such as an RCT, involves gathering and analysing numbers (expressed in terms of ‘quantity’ or measured in numbers rather than its quality), in an attempt to answer ‘how many/how much/how often’ questions, focussing primarily on prevalence, trends and relationships amongst two or more variables.

A qualitative study deals with the ‘what, who, when, why, and how’ questions in an attempt to capture participants’ experiences and views (Elliott et al., 1999; Jansen et al., 2010; Payne, 2007; Stapleton et al., 2002; Yardley, 2000). Qualitative research has its origins in Sociology and Anthropology, and the approach has been widely adopted by researchers from other disciplines (Daly & Lumley, 2007).

A mixed methods approach combines both quantitative and qualitative approaches into a single study, providing multiple perspectives and comprehensiveness to addressing research questions and is particularly useful in dealing with complex and multifaceted research questions (Craig et al., 2008a; Craig et al., 2008b; Creswell, 2003; Creswell & Clark, 2010; Creswell & Tashakkori, 2008; Curry et al., 2013; Farquhar et al., 2011; Freshwater, 2013; Ingleton & Davies, 2007; NICE, 2004; O’Cathain et al., 2004; O’Cathain et al., 2007a; O’Cathain et al., 2007b; O’Cathain et al., 2008a; Pope & Mays, 1993; Seymour, 2012; Small, 2011; Tariq & Woodman, 2013; Tashakkori & Teddlie, 1998; Teddlie & Tashakkori, 2009). Tashakkori & Teddlie, 2010, describe mixed methods as the ‘third methodological movement’ (Collins et al., 2012; Denzin, 2010; Tashakkori, 2009).

A mixed methods study draws on the strengths of each method to counterbalance their weaknesses (Creswell & Clark, 2010; Tashakkori & Teddlie, 2010).

3.9 Mixed methods definition

Tashakkori & Creswell, 2007a, 2007b, definition of mixed methods is as follows: ‘mixed methods is a procedure for collecting, analysing, and ‘mixing’ or integrating both quantitative and qualitative data at some stage of the research process within a single study for the purpose of gaining a better understanding of the research problem’ (Collins & O’Cathian, 2009; Creswell, 2009; Creswell & Clark, 2010; Tashakkori & Creswell, 2007a; Tashakkori & Creswell, 2007b; Tashakkori & Teddlie, 2003). All approaches (quantitative, qualitative and mixed methods) have advantages/strengths and weaknesses/limitations (Creswell & Clark, 2010), these are summarised in **Table 11**.

When undertaking a mixed methods study it is important to consider whether a mixed methods study is feasible and that there is sufficient time and resources available to collect and analyse both quantitative and qualitative data. The research team must have the appropriate levels of skills and experience for the successful completion of the study (Creswell & Clark, 2010).

Creswell & Clark, 2010, argue that ‘the use of quantitative and qualitative approaches, provides a much more comprehensive and complete account of both intended and unintended outcomes of the intervention than either approach used alone’. The qualitative data that is derived from this study, serves to enhance the inferences and interpretations from the RCT.

Table 11: Quantitative, qualitative and MMR approaches (strengths/advantages and limitations). Summary of strengths/advantages and limitations/weaknesses of quantitative, qualitative and MMR approaches

	Strengths/advantages	Weaknesses/challenges/disadvantages/limitations
Quantitative	<ul style="list-style-type: none"> ▪ ‘Often involve large sample sizes (vs. qualitative research): conclusions generalisable to target population’ ▪ ‘Statistical validation’ ▪ ‘More efficient data analysis’ ▪ ‘Bias control/limitation (minimisation)’ ▪ ‘Gathers and analyses numbers: examine and explore prevalence, trends and relationships- (cause and effect/confirmatory)’ 	<ul style="list-style-type: none"> ▪ ‘Limited/weak understanding of context/setting of participants’ ▪ ‘Limitations of statistical analysis (does not reveal participants complex lives and subjective experiences)’ ▪ ‘Words/voices/experiences of participants not directly heard (limited understanding of participants’ thoughts and feelings)’ ▪ ‘Researcher personal biases in interpretations of results seldom discussed or reported- qualitative research makes up for those weaknesses’ ▪ ‘Mainly researcher driven’
Qualitative	<ul style="list-style-type: none"> ▪ ‘Examining perspectives and views of a smaller sample of participants in more detail’ ▪ ‘Voices of participants heard (stories/narratives) in an attempt to capture/understand participants’ views, behaviours and experiences within a certain context’ ▪ ‘Not researcher driven’ ▪ ‘Increased recognition that qualitative 	<ul style="list-style-type: none"> ▪ ‘Most studies use small sample sizes, too small to detect statistically significant differences’ ▪ ‘Generates a large amount of detailed information about a small number of participants/settings’ ▪ ‘Lacking scientific rigour, generalisability, reproducibility, and labelled unscientific’ (compared to quantitative research, which does not have those weaknesses)

	methods have potential to reach parts that other methods cannot reach’	<ul style="list-style-type: none"> ▪ ‘Assembly of anecdote and personal impressions’ (most common) ▪ ‘Highly interpretative: strongly subject to researcher bias’ ▪ ‘Often resource-intensive, requiring more time and resources than quantitative research procedures for data collection and analysis’
Mixed methods	<ul style="list-style-type: none"> ▪ ‘Evidence-derived from a variety of sources to study a research problem, to provide a comprehensive picture (multiple views and perspectives) than either approach alone’ ▪ ‘Utilisation of a variety of tools and methods for data collection: not restricted to using those tools typically associated with quantitative or qualitative research’ ▪ ‘Useful in answering research questions that cannot be answered by either approach alone (e.g. the use of qualitative research to explain quantitative findings)’ ▪ ‘Provides a bridge across the divide/divisions/disciplines between quantitative and qualitative researchers’ ▪ ‘Encourages use of multiple worldviews/paradigms (i.e. beliefs and values)- not restricted to any one particular paradigm associated with quantitative or qualitative research’ ▪ ‘Strengths of one method may offset weaknesses of the other’ ▪ ‘Encourages pragmatism’ ▪ ‘Considered practical and intuitive’ ▪ ‘Use of both numbers and words, combines inductive and deductive thinking’ ▪ ‘Well suited for ‘interdisciplinary and multidisciplinary’ research- brings together scholars from different fields’ 	<ul style="list-style-type: none"> ▪ ‘Complex, difficult and challenging’ ▪ ‘Extensive time, resources and effort required for data collection and analysis’- gathering both quantitative and qualitative data (sometimes over a much longer period of time)’ ▪ ‘May not be appropriate for all research questions/problems’ ▪ ‘A need to educate and convince others of the value of using MMR’ ▪ ‘Minimum skills set: basic quantitative and qualitative skills required-need a solid grounding in MMR’ ▪ ‘Variety of terms used to describe MMR, so difficult to locate in literature’ ▪ ‘Practical challenges- team members from diverse professional backgrounds, managing power differentials and roles within team challenging, and lack of shared language, different values and beliefs, sometimes conflicting views, leading to philosophical discordance’ (O’Cathain et al., 2008b) ▪ ‘Dissemination: difficulty in publication of MMR findings- due to strict word count restrictions in many journals’ ▪ ‘MMR challenges in relation to data collection, representation, integration, analysis, dissemination, legitimation and politics- quantitative and qualitative components bring to the study their own unique challenges’ (Farquhar et al., 2011)
<p>Adapted from</p> <p>(Creswell & Clark, 2010)</p> <p>&</p> <p>(Bowers et al., 2013; Bradley et al., 1999; Clark, 1997; Curry et al., 2012; Daly & Lumley, 2007; Elliott et al., 1999; Farquhar et al., 2011; Kelle, 2006; Mays & Pope, 1995; Schwartz & Revicki, 2012; Small, 2011; Steckler et al., 1992)</p>		

3.10 Rigour of mixed methods, quantitative and qualitative research

The strategies available for quantitative, qualitative and mixed methods researchers to protect against bias, and enhance the rigour, reliability and trustworthiness of findings are described in methodological checklists that assess the quality of the research. In this Chapter, I will

discuss why the principles of rigour and trustworthiness were relevant to my study, the strategies that I used to ensure rigour and trustworthiness and the implications of these on the design of my study.

Creswell & Colleagues (2004), outline five criteria to consider when evaluating the rigour of mixed methods research, these are as follows: 1) the reasons for mixing; 2) types of data that will be collected and analysed; 3) the priority assigned to quantitative and qualitative components (emphasis on either quantitative or the qualitative component, or assigned equal priority); 4) implementation sequence (e.g. concurrent or sequential); and 5) the point of interface, or the point where mixing occurs (Creswell et al., 2004).

The main purpose of combining methods within this doctoral study was to bring complementary datasets using methods to address different aspects of the intervention; and also for comprehensiveness, to ensure that views of both patients and health care professionals are taken into account, thus increasing confidence in interpretation of findings of the RCT (Moffatt et al., 2006; O’Cathain et al., 2007a; O’Cathain et al., 2007b). The mixed methodology design adopted was practical, and strengthened the credibility and trustworthiness of findings (advantages/disadvantages of this approach have been presented). The process evaluation required a mixed methods design in order to consider all the data that might point to causes of the result of the trial. Consideration of both quantitative and qualitative data enabled a coherent explanation of the effects of clinical intervention.

The principles of rigour and trustworthiness were the principle reasons for using a pilot RCT to assess the clinical utility of SPARC. The RCT is considered to provide the most reliable evidence on the effectiveness of interventions and the processes undertaken during the conduct of this trial minimised the risk of confounding factors influencing the results. Palliative care trials are complex, and in light of this, the SPARC intervention study was developed, piloted, evaluated, reported and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions (Ahmed, 2010; Craig et al., 2008a; Craig et al., 2008b; Craig et al., 2013a; Craig et al., 2013b; Higginson, 2005; new guidance, MRC Guidance, 2008; www.mrc.ac.uk/complexinterventionsguidance).

The quantitative component (pilot RCT) is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement, which is a checklist of information to include when reporting a randomised trial (Altman et al., 2012; CONSORT, 2010; Hopewell et al., 2008a; Hopewell et al., 2008b; Turner et al., 2012; Zwarenstein et al., 2008).

The reliability and validity (or trustworthiness) of qualitative research cannot be assessed using the same criteria used to assess quantitative research, due to the different philosophical, methodological, and theoretical positions and origins of the two components. Various strategies and checklists are available to assess the quality and rigour of qualitative research (Barbour, 2001; Campbell & Machado, 2013; Noble & Smith, 2015; Pope & Mays, 1995;

Pope & Mays, 2000; Tracy, 2010). Barbour, 2001, argues that checklists should be viewed as being 'reflective', of good research, there is evidence to suggest that sometimes they are used 'prescriptively' which can be counter-productive. The qualitative interviews (with patients and health care professionals) components of this study followed the generic criteria included in COREQ, a 32-item checklist developed for the 'explicit and comprehensive reporting of qualitative studies' (Tong et al., 2007).

Analysis of qualitative data was designed in accordance with framework analysis approach (Ritchie & Spencer, 2004; **Chapter 6**), considered to be sufficiently rigorous for purposes of this study. The rigour of the analysis and the validity of the categories that I developed could be questioned if only a small part of the dataset that I coded was covered by the coding categories, however this was not the case because only a relatively small part of the coded text from the transcriptions of the semi-structured interviews had to be assigned to the 'miscellaneous' category, and my comprehensive classifications and coding of the data were able to account for most of the dataset. In order to ensure the retest reliability of my analyses, I kept and maintained meticulous records of interviews and observations/field notes and documented the process of analysis in considerable detail. Transcriptions were undertaken by an experienced research administrator (PH), and I checked each transcript against each of the interview audio-recordings to ensure accuracy and identify any ambiguities. I then made changes to the electronic versions. In order to minimise any bias, and improve the reliability of the analysis, 20% (7 out of 33) of the patient interview transcripts, and 20% (4 out of 20) of the health care professional interview transcripts were independently coded and charted by two experienced qualitative researchers (NA and KC). Subsequent detailed discussions of the analysis optimised consistency and agreement within interpretation and the development of themes, as an on-going process throughout the data analysis. Thus, the integrity of the qualitative component was protected throughout the research process, by using this systematic approach to research design, data collection, analysis, reporting and the communication of results.

The audio-recording of all the semi-structured interviews undertaken provides an opportunity for independent observers to analyse, scrutinise and check the study findings against the original audio-recordings at a later date if the need arises, and for comparing oral testimony with written records and case notes.

In the interest of safeguarding validity and trustworthiness of findings, the approach that I adopted was called 'triangulation', which involves using at least two different data collection methods and techniques and information sources to obtain the information about the same phenomenon with the aim of reducing inherent bias associated with a single source, or method. This approach was used to good effect, the qualitative study running alongside the pilot RCT concerning the views of patients about their experiences of completing SPARC and the views of health care professionals, conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for developing and evaluating complex interventions, helped in the interpretation of the trial outcome results (quantitative component). Eliciting the views of patients and health care professionals

represented an important phase in the development of SPARC. The accounts of patients and health care professionals, were compared with field notes and case notes in order to undertake a comparative analysis of views (i.e. for similarities and differences and for comparing oral testimony with written records and case notes).

In order to describe the rigour, reliability, validity and the quality of the research undertaken during this doctoral study, I have explicitly outlined the theoretical framework and methods, and data collection techniques used at every stage of the research process. Both quantitative and qualitative approaches describe the context (settings), as well as the sampling strategy used. I have provided a detailed description of how the trial and qualitative fieldwork was undertaken (fieldwork notes, interview transcripts, recordings, case note reviews), and how these were inspected independently by others to ensure reliability. I have also outlined the procedures for data analysis and the methodological checklists used to assess the quality of the research and how this related to the original research questions e.g. how the themes and concepts were identified from the data. This was presented systematically in the written account to improve rigour, transparency, justification of data collection and analysis methods being used, and hence the integrity of findings.

3.11 Embedded (or nested) designs

For the purposes of this study the embedded (or nested) design was considered most appropriate. The embedded or nested design is increasingly used in health services research, and is particularly useful when collecting supplemental qualitative data that informs how participants (patients and HCP's) are experiencing an intervention. In this form of integration, it is common to have a dataset of secondary priority (i.e. participants' experience of using SPARC), that is embedded within a larger primary design (i.e. pilot RCT) (Fairbrother et al., 2013).

Quantitative and qualitative approaches in this study were used in tandem (i.e. one dataset was embedded in the other). In the case of this study, the SPARC intervention study was undertaken (pilot RCT), and the qualitative data (patient and health care professional interviews) was embedded within the intervention procedures in order to better understand the quantitative outcomes. The intervention was followed by individual semi-structured qualitative interviews with the trial participants in order to get a better understanding of why the intervention worked or did not work. The results provide evaluation of both outcomes and process of intervention (Creswell & Clark, 2010; Tashakkori & Teddlie, 2010).

3.12 Concurrent or sequential data collection

Embedded (or nested) designs may be either convergent or sequential designs. 'A concurrent design is where quantitative data and qualitative data are collected concurrently or roughly at the same time, thus allowing researchers to maximise the amount of data collected in a given time' (Creswell & Clark, 2010; Tashakkori & Teddlie, 2010).

‘The sequential design is where the researcher collects quantitative and qualitative data in a sequence, with one phase of data collection followed by another’. However, this approach requires data to be collected over a longer time period, and is particularly useful when the results of one phase of the study are required to inform a subsequent phase (Creswell & Clark, 2010; Curry et al., 2013; Tashakkori & Teddlie, 2010). This study adopted an embedded (or nested) concurrent mixed methods design.

3.13 Priority

In some mixed methods studies equal priority is assigned to the quantitative and qualitative components. An unequal priority occurs for example when a secondary dataset (e.g. from a qualitative study) as is the case in this study, is embedded within a larger primary design (quantitative study) (Creswell et al., 2004; Creswell & Clark, 2010; Tashakkori & Teddlie, 2010).

3.14 Point of interface (integration phase)

The ‘point of interface’ also known as triangulation or the point at which the mixing occurs is dependent upon the design of the mixed methods study (Bazeley, 2009; Farmer et al, 2006; Fetters et al., 2016; Moran-Ellis et al., 2006; O’Cathain et al., 2010; Ostlund et al., 2011; Tashakkori & Creswell, 2007a; Tashakkori & Creswell, 2007b; Tashakkori & Creswell, 2008; Thurmond, 2001). Teddlie & Tashakkori, 2009, outline the different time points when mixing can take place. Quantitative and qualitative data can be integrated during the data collection stage (e.g. collecting both quantitative items and qualitative open-ended questions on the same survey/questionnaire), at the analysis stage (e.g. converting qualitative data into quantitative scores to then compare with the quantitative dataset), or alternatively findings may be integrated at the stage of interpretation and conclusion (e.g. comparing results of quantitative data analysis with the emergent themes from the qualitative data analysis) (Bazeley, 2009; Creswell et al., 2004; Creswell & Tashakkori, 2007; Curry et al., 2013; Fetters et al., 2013; Johnson et al., 2007; O’Cathain et al., 2010; Teddlie & Tashakkori, 2009; Zhang & Creswell, 2013). In this study, findings were integrated at the stage of interpretation and conclusion.

3.15 Reporting of data- approach used in this thesis

This is an embedded concurrent mixed methods study. This thesis will report the outcome evaluation in the following steps: data collection and analysis (pilot RCT) first followed by a process evaluation: data collection and analysis (supplemental qualitative data from interviews) separately, and will then discuss the results of both analysis, from both phases of the study in the discussion and conclusions section (**Chapter 8**; thesis summary and discussion) (Creswell et al., 2004).

3.16 Instruments and data collection

A variety of different types of instruments are available for data collection, with different methods employing different types of instruments. This study makes use of quantitative questionnaires for data collection during the trial, data extraction templates for case note reviews (**Appendix 18**), and qualitative semi-structured interviews with patients and health care professionals to gain further insights into why the intervention namely; SPARC, did or did not work (Yin, 2006).

Chapter 4

RESEARCH PHASE I: Outcome evaluation

4 A pilot randomised controlled trial of a holistic needs assessment questionnaire in a supportive and palliative care service

Professor Peter Bath is a health informatics specialist/statistician (Information School, The University of Sheffield) working on the project. He undertook the quantitative statistical analysis component of this study, which is reported in this section.

4.1 Abstract

Context: At present, there is no widely used systematic evidence-based holistic approach to assessment of patients' supportive and palliative care needs.

Objectives: To determine whether the use of a holistic needs assessment questionnaire; Sheffield Profile for Assessment and Referral for Care (SPARC), will lead to improved health care outcomes for patients referred to a palliative care service.

Methods: This was an open, pragmatic, randomised controlled trial. Patients (n=182) referred to the palliative care service were randomised to receive SPARC at baseline (n=87) or after a period of two weeks (waiting-list control n=95). Primary outcome measure is the difference in score between Measure Yourself Concerns and Wellbeing (MYCAW) patient-nominated Concern 1 on the patient self-scoring visual analogue scale at baseline and the two-week follow-up. Secondary outcomes include difference in scores in the MYCAW, EuroQoL (EQ-5D), and Patient Enablement Instrument (PEI) scores at Weeks 2, 4, and 6.

Results: There was a significant association between change in MYCAW score and whether the patients were in the intervention or control group (χ^2 trend = 5.51; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in the control group had an improvement in MYCAW score from baseline to Week 2: control (34 of 70 [48.6%]) vs. intervention (19 of 66 [28.8%]). There were no significant differences (no detectable effect) between the control and intervention groups in the scores for EQ-5D and Patient Enablement Instrument at 2-, 4-, or 6-week follow-up.

Conclusion: This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan (Ahmed et al., 2015).

Key Words: Palliative care, holistic needs assessment questionnaire, SPARC, MYCAW, EQ-5D, PEI

Trial registration: ISRCTN 25758268

4.2 Introduction

A pilot study of a pragmatic randomised controlled trial was undertaken to determine whether the use of SPARC leads to improved health care outcomes (health-related quality of life and self-identified concerns) for patients (Ahmed et al., 2015), and to guide the development of a further, and larger definitive multicentre study. This trial was the first step in a process that would define the clinical utility of SPARC (Ahmed, 2010; Ahmed et al., 2015).

This study represents a development of SPARC for use as an early holistic needs assessment questionnaire within a specialist palliative care service in accordance with the MRC framework for developing and evaluating complex interventions (Craig et al., 2008a; Craig et al., 2008b). This study does not test the utility of SPARC as a screening questionnaire for specialist palliative care (Ahmed, 2010; Ahmed et al., 2015).

4.3 Methods

4.3.1 Trial design and recruitment

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement, which is checklist of information to include when reporting a randomised trial (Ahmed et al., 2015; Altman et al., 2012; CONSORT 2010; Hopewell et al., 2008a; Hopewell et al., 2008b; Turner et al., 2012; Zwarenstein et al., 2008), and was registered with the International Standard Randomised Controlled Trials Register (ISRCTN Number: 25758268) (**Appendix 5**). ‘The ISRCTN is a simple numeric system for the identification of randomised controlled clinical trials worldwide’. This open randomised controlled trial used a waiting-list control design. All patients referred to the supportive and palliative care service who met the study inclusion criteria were invited to take part in the study. Invitations to participate were sent by post (outpatients and those in the community) or given face to face (inpatients and day care patients). Patients who consented to taking part in the study were randomised to receive the SPARC questionnaire at baseline (intervention group) or after a two-week period (control group). The study received approval from the Bradford Research Ethics Committee, UK Multicentre Research Ethics Committee (MREC) reference number: 10/ H1302/88 on 14th January 2011, and received Research and Development (R&D) permission from local trusts (Ahmed et al., 2015).

As part of a process evaluation, case notes were reviewed at week 8 (findings reported in this Chapter), and semi-structured interviews were undertaken with a sub-group of patients (**Chapter 6**) and health care professionals (**Chapter 7**). The waiting-list control design was appropriate here for ethical and practical reasons. Recruitment is facilitated in studies where

an intervention perceived as potentially beneficial is made available at some point to all who agree to participate in a study. The two-week waiting period was chosen to allow for maximum data to be obtained at the follow-up stage, while not unduly delaying offering the SPARC to the waiting-list controls. In this group of patients, usual care is different in the different settings, and has not therefore been closely defined here (in the context of the trial, 'usual care' concerns clinical encounters in the first 2 weeks of the trial, these are in the nature of ongoing assessment by clinical staff, specialist palliative care, clinical nurse specialists and physicians working in outpatients who routinely assess physical, social, spiritual, and psychological features of a patients' condition and progress. This is routinely done in a structured clinical interview such as medical clerking or nursing assessment or as a cue-based intervention where patient concerns are elicited). The key feature of the study was to introduce the SPARC structured questionnaire in addition to the clinical interview (which takes place in all settings), either at baseline (Intervention Group), or at 2 weeks (Control Group). Data relating to demographic variables were collected at baseline.

4.3.2 Participants

4.3.3 Inclusion criteria

1. Any diagnosis (cancer and non-cancer).
2. Any referral to the palliative care service in any care setting.
3. Patients 18 years old or above.
4. Patients able to give informed consent.

4.3.4 Exclusion criteria

1. Patients incapable of giving informed consent.
2. Patients incapable of completing SPARC even with the help of a relative or informal carer.
3. Patients under 18 years old.

4.3.5 Stratification

Baseline quality of life may confound response to an intervention by reversion to the mean, so patients were stratified for baseline EQ-5D (standardised outcome measure of health-related quality of life) thermometer score. Thus, patients completing the consent form were also asked to complete the EQ-5D thermometer score before randomisation. Based on previous work (Brooks, 1996), the research team set the EQ-5D thermometer score at 40. Patients scoring 40 or above at baseline were placed in the median and above group (MA), and those scoring less than 40 were placed in the below median group (BM) (Ahmed et al., 2015).

4.3.6 Collection of baseline data relating to demographic variables

At baseline, I collected data relating to demographic variables, and whether the diagnosis was cancer or non-cancer, and whether the patient was a cancer survivor or a cancer patient

needing end of life care. Descriptive analyses of these data helped to characterise the samples across the care settings, and for control purposes in the analyses (Burgess et al., 2003).

4.3.7 Sheffield palliative care service context and settings

Study population, settings and locations where the data were collected

Patients were recruited from the whole range of settings (in-patients, outpatients, day care and from the community), and were recruited from the following sites in Sheffield: Central site: Royal Hallamshire Hospital (RHH); Northern site: Northern General Hospital (NGH); Sheffield Macmillan Unit for Palliative Care (SMUPC, NGH); and from the Community via a team of community specialist nurses based at St. Luke's Hospice (Sheffield) (Ahmed et al., 2015).

Over 2000 patients a year are referred to these services, which deal with a much wider range of patients than might be assumed from the name of the service. They include those with long-term conditions and cancer survivors as well as those needing end of life care. There is a wide range of survival within the population referred to the palliative care service (Ahmed et al., 2015). In Sheffield, about one third of patients die within a week of referral, two thirds within a month, while a sixth survive beyond three months. Patients seen by the service are a very varied group. In the year 2008-9, 342 patients were admitted to the Macmillan Palliative Care Unit. Of these, 40% went home, while 10% were transferred to other care. 2,150 patients were seen as in the hospital support part of the service at the two sites. The 65 and over age group were in a majority, but at the Central site over 40% were younger than this, while at the Northern site over a third had diagnoses other than cancer.

At the Central site; 44% of patients were discharged home vs. 30% at the Northern site, and 32% were discharged to other care at the Central site vs. 35% at the Northern site. A further 921 patients were seen in out-patient clinics. The out-patient group seen is very varied, and includes a greater proportion of patients with long-term conditions, and cancer survivors who are reviewed regularly.

Sheffield Teaching Hospitals

The Palliative Care Team at Sheffield Teaching Hospitals NHS Foundation Trust (STH NHS FT) provides a specialist palliative care service, including symptom control and support, to patients admitted to the Royal Hallamshire Hospital (RHH), Weston Park Hospital (WPH) & Northern General Hospital (NGH) with supportive or palliative care needs, irrespective of diagnosis, in order to help them achieve the best possible quality of life. Working alongside colleagues in other services, the team aims to extend this support to families, carers and professionals involved with the patient, and to provide an educational resource to professionals involved in palliative care. The STH Team provides a hospital support service, an outpatient service and the Sheffield Macmillan Unit for Palliative Care (MPCU) with 18 specialist palliative care beds at the NGH site. Some medical staff undertake home visits and

the Macmillan Unit Therapy Team also provide an outreach service to selected patients as part of their treatment plan. A more detailed description of the STH Sheffield Palliative Care Service (Context and Settings) is presented in **Appendix 19** (Adapted from Palliative Care Annual Report Summary, Sheffield Teaching Hospitals; STH) (Ahmed et al., 2015).

St. Luke's - The Sheffield Hospice

St. Luke's Sheffield Hospice, offers specialist palliative care in 3 settings, the in-patient unit with its 20 beds, the Therapies and Rehabilitation Centre, which looks after the needs of day patients, and has a team of 10 St. Luke's Community Palliative Care Nurses, caring for people in their own homes covering the whole of Sheffield. Patients in the community seen by the St. Luke's Community Palliative Care Nurses were invited to participate. Recruitment was extended to patients attending the Therapies and Rehabilitation Centre (day care). A more detailed description of the St. Luke's Hospice Palliative Care Service (Context and Settings) is presented in **Appendix 20** (Adapted from St Luke's Sheffield Hospice Corporate Brochure, 2011/2012) (Ahmed et al., 2015).

ENROLMENT, RANDOMISATION AND INTERVENTION ALLOCATION, FOLLOW-UP PROCEDURE AND DATA ANALYSIS

4.38 Enrolment/recruitment

Patients who met the study inclusion criteria were recruited to the trial using purposive sampling (i.e. patients who had already been referred to the palliative care service in any care setting irrespective of diagnosis were recruited). As part of the recruitment procedure for the main trial, all patients received a study invitation pack (full study pack), which consisted of a patient invitation letter (**Appendix 21**), patient information sheet (**Appendix 22**), patient consent form and EQ5D (thermometer) (**Appendix 23**), and a freepost envelope. A recruitment guidance sheet was developed for the medical and nursing staff (**Appendix 9**) (Ahmed et al., 2015).

For inpatients and day care patients, I had prepared study invitation packs for health care professionals to give to patients. A health care professional, who was caring for the patient informed suitable and eligible patients about the study and asked whether they were willing to participate. Health care professionals, then hand-delivered invitation study packs to those patients expressing an interest in the study. Patients were given an opportunity to ask any questions that they may have prior to taking part. Those patients wishing to participate were asked to sign and complete the consent form and the EQ-5D thermometer which could either be handed to the health care professional or sent back to the research team via post in the pre-paid envelope. Patients were informed that their participation was completely voluntary and that they would receive the same care whether or not they chose to participate.

Community patients and outpatients were sent study invitation packs via medical secretaries. The list of patients was first agreed with the health care professional with responsibility for

the care of these patients, who first screened suitable patients who would be suitable and eligible (Ahmed et al., 2015).

When patients (inpatients and day care patients) were provided with or sent study invitation packs via post (community patients and outpatients), the administration staff at the different settings (in-patients, outpatients, day care and community), were asked to make a note of this on infoflex (electronic clinical record), to avoid any duplication and any patient being sent an invitation more than once. They also ensured that patients were alive, and deemed suitable by the health care professional caring for the patient, and that the patient was not an in-patient prior to sending invitations out by post.

Semi-structured interviews were then conducted with a sub-group of trial participants as well as with health care professionals caring for these participants. All participants were interviewed after they had completed the study (i.e. 8 weeks from the date baseline questionnaires were received) (Ahmed et al., 2015; EAPC abstract, 2015). The method that I used to recruit patients and health care professionals for the follow-up semi-structured interviews (i.e. how participants were identified and who was invited to participate) is described in more detail in **Chapter 6** (patient interviews) and in **Chapter 7** (health care professional interviews). All patients had the option of withdrawing from the study at any time without giving any reason, and without their medical care or legal rights being affected.

4.39 Randomisation and intervention allocation

Randomisation

A set of sequentially numbered, opaque, sealed, A4 envelopes containing all study documents were set up (henceforth called the study pack). The randomisation process was undertaken by a member of the study team (M.W.), who then identified which study packs were for the intervention arm and which were for the control arm. MW and PM were the only members of the research team who knew which envelopes were for which arms of the study. A copy of the SPARC tool (**Figure 5**) was added to the study packs for the intervention arm, and an equivalent number of blank sheets were added to the study packs for the control arm of the study. All of the study packs were placed into separate boxes in the numbered sequence, and 182 patients were randomised with computer-generated random numbers in prepaid sealed envelopes to receive SPARC at baseline (n=87) or after a period of two weeks (waiting-list control n=95) (Ahmed et al., 2015).

Upon receiving consent, I was blinded to the study and so did not know to which arm of the study patients belonged, and I collected the next sequentially-numbered, opaque, sealed envelope (SNOSE, containing the questionnaires) from the appropriate box (labelled MA: median and above group; or BM: below median group), and hand-delivered it to the patient (for inpatients/day care patients), or sent it via post (for community care patients/those seen in

outpatients) for recruitment purposes (Ahmed et al., 2015). The number of patients recruited during follow up is described in the results section.

Intervention (SPARC) allocation (details of how the intervention actually worked)

Patients returned the completed forms (i.e. signed and completed consent form and the EQ-5D thermometer questionnaire; **Appendix 23**) to the research team (University of Sheffield postal address) in freepost envelopes. Patients were stratified according to baseline quality of life (details of stratification presented earlier).

Those patients who consented were randomised to receive the SPARC questionnaire at baseline (intervention group) or after a two-week waiting-list period (control group) (**Table 12**). All patients received ongoing care as usual.

Upon receiving the completed SPARC questionnaire, I immediately hand-delivered it to the administration team at each site and asked that it be immediately given to the health care professional caring for the patient. The administration staff at each site were also asked to keep a completed SPARC questionnaire (paper copy) and file it in the patients' notes, and to scan a copy of it and upload it onto the electronic clinical record (Infoflex). The original copy of SPARC was filed with other completed research questionnaires and retained by the research team. Constant and careful monitoring and supervision of administration staff ensured that this procedure was strictly adhered to in all care settings.

Prior to sending out follow-up questionnaires it was important to ensure that the patient was still alive and not deceased, appropriate checks were made with administration teams at the different sites and settings at the time of sending out additional questionnaires. This was very important for continuity purposes as patients may be referred to a number of different settings.

Patients were made aware that information from SPARC would be sent to the health care professional/s caring for them. If participants returned a completed SPARC form (or raised concerns in a follow up interview) which indicated that they were very much distressed by thoughts of death or dying or if they were having suicidal thoughts, then I would immediately convey this concern to the health care professional caring for the patient. Only on one occasion did this occur. As a health services researcher, I could not provide any medical advice, but when concerns were raised, I did suggest to the patient that they could contact their GP or a health care professional caring for them for help or further advice.

4.3.10 Follow-up procedure

Follow up questionnaires were administered either face to face (inpatients, and day care patients), or by post (community and home care patients), according to the following table (**Table 12**). The 2-week point was selected as the crucial follow up measure following

baseline in order to minimise attrition in a service where we know that the median survival is 13 days (Ahmed et al., 2015).

Table 12: Study follow up procedure (questionnaire completion at 2-week intervals) (Ahmed et al., 2015)

Baseline	Randomisation	
	Group A intervention group	Group B waiting-list control
	MYCAW; EQ-5D; PEI SPARC	MYCAW; EQ-5D; PEI
Two weeks	MYCAW; EQ-5D; PEI [Invitation for patient interview]	MYCAW; EQ-5D; PEI SPARC
Four weeks	MYCAW; EQ-5D; PEI plus supplementary question on experience of completing SPARC	MYCAW; EQ-5D; PEI [Invitation for patient interview]
Six weeks	MYCAW; EQ-5D; PEI	MYCAW; EQ-5D; PEI plus supplementary question on experience of completing SPARC
Eight weeks	Case Note Reviews Semi-Structured Interviews with Patients Semi-Structured Interviews with Health Care Professionals	

SPARC: *Sheffield Profile for Assessment and Referral for Care*

MYCAW: *Measure Yourself Concerns and Wellbeing*

EuroQoL (EQ-5D): *Standardised outcome measure of Health Related Quality of Life*

PEI: *Patient Enablement Instrument*

(Ahmed et al., 2015)

Those patients who consented were randomised to receive the SPARC questionnaire at baseline (intervention group) or after a two-week waiting-list period (control group). Follow-up for patients was conducted by post as far as this was possible (Ahmed et al., 2015). As patients may move from one setting to another, careful monitoring was necessary to establish whether patients had been admitted to, or discharged from, hospital, and also to ensure that continuing contact was appropriate.

4.3.11 Research questionnaires (outcome measures)

An outcome has been defined by the Working Party on Clinical Guidelines in Palliative Care as ‘any end result that is attributable to health services intervention’, and chosen outcome

measures must measure the effects of a service or intervention, that is a change in a patient's health status (Higginson, 1995; O Boyle & Waldron, 1997).

Study participants were required to complete three validated brief self-complete research outcome measures: the Measure Yourself Concerns and Wellbeing (MYCAW), the EuroQoL (EQ-5D) (measure of health-related quality of life), and the Patient Enablement Instrument (PEI), at Baseline, Week 2, Week 4, and Week 6 (Ahmed et al., 2015). The measures selected were all short and easy to complete, and as per recommended guidance (Finlay & Dunlop, 1994), responses are more likely when short questionnaires are used (Boynton, 2004; Edwards et al., 2002; Nakash et al., 2006) on quality of life instruments/outcome measures for palliative care (Hearn & Higginson, 1999), that place minimal burden on the patient and capture items of most importance (Brasel, 2007). The three measures were compiled into a booklet (**Appendix 10**). The rationale for the choice of outcome measures is presented in **Table 13** (Ahmed et al., 2015; EuroQoL Group, 1990; Guyatt et al., 1998; Howie et al., 1999; Paterson, 1996; Paterson et al., 2007; Peace & Manasse, 2002; Thompson et al., 2008).

Table 13: Research questionnaires: Rationale for choice of outcome measures (Ahmed et al., 2015)

MYMOP (Measure Yourself Medical Outcomes Profile)	MYCAW (Measure Yourself Concerns and Wellbeing)	EuroQoL (EQ-5D) (Health-related quality of life outcome measure)	PEI (Patient Enablement Instrument)
<ul style="list-style-type: none"> ▪ A precursor of MYCAW. ▪ Demonstrated sensitivity to change. ▪ Used in a range of contexts. ▪ Patient self-complete, outcome questionnaire, problem-specific (includes general wellbeing). ▪ Applicable to all symptomatic patients. ▪ Brief and simple questionnaire to administer. ▪ MYCAW used in preference to MYMOP because concerns raised could be of any kind, and not restricted to symptoms or activity (may be of significance when comparing the information from the three groups: cancer survivors, people with long term conditions and people needing end-of-life care). ▪ For the purposes of this study it was important to use an outcome measure which covered the diversity in the patient group. ▪ A slightly modified version of MYCAW was used (the sentence “Please write down one or two concerns or problems which you would most like us to help you with” was replaced with “Please write down one or two concerns or problems that bother you most”). <p>(Adapted from Paterson, 1996; Paterson et al., 2007; Peace & Manasse, 2002)</p>	<ul style="list-style-type: none"> ▪ Developed from a validated tool MYMOP, simple to use and sensitive enough to show any changes with time. ▪ Patients nominate concerns, which may or may not be medical (MYCAW) or symptoms (MYMOP) of importance to them (two concerns/symptoms can be identified). ▪ They then score these on a scale of 0 (not bothering me at all) - 6 (bothers me greatly). ▪ Patients are also asked to rate their general feeling of wellbeing on a scale of 0 (as good as it could be) - 6 (as bad as it could be). ▪ The follow-up form asks patients to re-score the concerns/symptoms, and rate their general feeling of wellbeing they previously nominated, thus capturing any changes over time that are important to the patient. ▪ However, HRQoL may not be sensitive enough to changes in the short term, possibly because people adjust their expectations. ▪ Work by Guyatt et al., 1998, indicates that in seven-point scales of this kind, a shift of one point corresponds to a moderately important change for a patient. ▪ Is an additional element of needs assessment, stated concerns, are truly patient generated, reflecting an accurate expression of need at that time. <p>(Adapted from Guyatt et al., 1998; Paterson et al., 2007; Peace & Manasse, 2002)</p>	<ul style="list-style-type: none"> ▪ Outcome measure of health-related quality of life. ▪ Patient self-complete. ▪ Five questions (3 varying response categories): on mobility, self-care, usual activities (e.g. work, study, housework, family, or leisure activities), pain/discomfort and anxiety/depression. ▪ A further question (EQ-5D thermometer scale) asks people to mark their current health status on a scale of 0 (worst imaginable health state)-100 (best imaginable health state). ▪ Used extensively in studies where quality of life is compared between patient groups. <p>(Adapted from Brooks, 1996; EuroQoL Group, 1990)</p>	<ul style="list-style-type: none"> ▪ Outcome measure of a patient’s ability to cope with life and their illness and the confidence and ability to help themselves (as a result of visiting a doctor or health care professional). ▪ Patient self-complete. ▪ One main question “thinking about the last time you saw a doctor or nurse from palliative care, do you feel you are...?” (6 sub-questions with 4 varying response categories). ▪ Studies in general practice to assess quality of consultations using PEI, have shown it to be a crucial outcome measure, with enablement correlating best with the length of consultation and how well the patient knew the doctor. ▪ PEI scores consultations in cancer clinics, independently of quality of life and scores higher when sufficient time is allocated or when staff have communication skills training (our own unpublished work). ▪ PEI may detect an effect of SPARC (if any) on the quality of subsequent consultations with the clinical team. ▪ A measure of consultation quality was included in order to detect an effect on communication between patients and professionals. However, we overestimated the intensity of contact between patients and professionals and palliative care services in the duration of this trial. <p>(Adapted from Howie et al., 1999; Thompson et al., 2008)</p>

Abbreviations

MYMOP: Measure Yourself Medical Outcomes Profile; MYCAW: Measure Yourself Concerns and Wellbeing; EuroQoL (EQ-5D): Standardised outcome measure of health-related quality of life; PEI: Patient Enablement Instrument; HRQoL: Health-related quality of life (Ahmed et al., 2015).

4.3.12 Outcomes

Primary outcome

- The change in MYCAW score between the first MYCAW patient nominated concern (MYCAW Concern 1) at baseline and the two-week follow up. This is the nominated first concern (Ahmed et al., 2015).

Secondary outcomes

- The change in scores in the EQ-5D at the two time points.
- Changes in the enablement scores (PEI) at the two time points.
- Comparisons of MYCAW patient nominated concerns, EQ-5D, and the PEI at baseline, 2 weeks, 4 weeks and 6 weeks between patient groups.
- The pattern of actions taken and referrals made as a result of administering the SPARC screening tool were examined, by analysis of the clinical record (reported in **Chapter 4**) (Ahmed et al., 2015).

DATA ANALYSIS

4.3.13 Statistical methods and analysis

Sample size calculation

Calculation of the number of patients needed to recruit was based on the sample size required to power the study, which had taken into account the likely attrition, also considering that a proportion of patients that will be too ill to be approached to participate. Patients attending as outpatients for review were included as well as new referrals, and this group included cancer survivors and those with long-term conditions (Ahmed et al., 2015).

Primary endpoint analysis

The primary outcome measure was the difference in score between the patient-nominated concern (MYCAW; Concern 1) on the self-scored visual analogue scale at baseline and at the two-week follow-up. Assuming the changes in the score (baseline to Week 2) would be normally distributed, we had planned to carry out a *t*-test to test the null hypothesis that the difference between the intervention and control groups in the mean score on the first symptom nominated on the scale at baseline and two weeks is 0. However, because the data were not normally distributed, the Mann-Whitney test was used to test for difference in the two groups in the rankings of Weeks 2, 4, and 6 scores and the rankings of the change in scores from baseline to Weeks 2, 4, and 6 (Ahmed et al., 2015).

Statistical power

To detect a medium-sized difference between two independent sample means at $\alpha=0.05$ and $\beta=0.80$, required a minimum of 64 individuals in each group with scores at baseline and two weeks (Cohen, 1992). Therefore, a total of 128 patients would need to be recruited. The power of the study was based on the randomised controlled trial with the group of patients from whom it would be possible to obtain follow-up data. Differences between the control and intervention groups were tested using *t*-tests to compare the mean scores at Weeks 2, 4, 6, and the mean change in scores from baseline to Weeks 2, 4, and 6 (Ahmed et al., 2015).

4.3.14 Secondary and exploratory analyses

Statistical analysis of the comparisons between patient groups for the secondary outcomes involved both descriptive analyses and statistical tests. A qualitative content analysis (Ahmed et al., 2015; Graneheim & Lundman, 2004; Hsieh & Shannon, 2005) of the nominated first concern and the nominated second concern was undertaken at baseline. Stated concerns were examined for key words and themes, with the context taken into account for the final interpretation. Analysis of the data from patient semi-structured interviews, health care professional semi-structured interviews (Ritchie & Spencer, 1994), and from the supplementary question about patients' experience of completing the SPARC (Ahmed et al., 2015) are presented in **Chapters 6 and 7** respectively.

4.4 Results

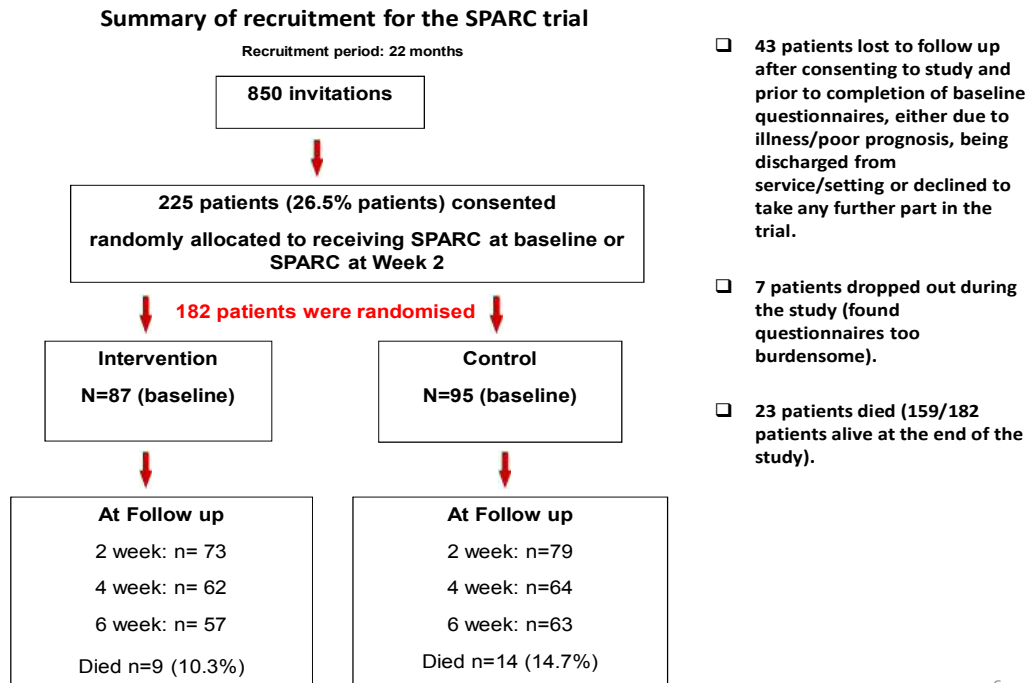
4.4.1 Recruitment and attrition rates

A total of 850 patients were invited to take part in the study, of which: 225 consented to take part ($225/850=26.5\%$ response rate); 182 patients completed baseline questionnaires; 152 completed the 2 week questionnaires; 126 completed the 4 week questionnaires; and 120 completed the 6 week questionnaires. The critical point in the analysis was the 2-week point, the point at which patients in Group A (intervention arm) had already received the SPARC intervention, and patients in Group B (control arm) had not yet received the SPARC intervention. A few patients ($n=7$) dropped out and did not complete the trial, citing questionnaire completion and taking part in the trial as being too burdensome as reasons for not continuing to take part. Two patients expressed concern around issues of data collection, and had anticipated more face to face contact visits as opposed to receiving postal questionnaires (Ahmed et al., 2015).

At the end of the trial (eight weeks after completion of baseline questionnaires), 23 patients had died, and 159 patients were alive. There was no significant difference in the number of deaths between the intervention and control groups. In Group A (Intervention), nine people (10.3%) died within the 8-week study period and in Group B (Control), 14 people (14.7%)

died within the 8-week study period ($\chi^2 = 0.445; df = 1; p = 0.504$). A summary of the recruitment for the SPARC intervention trial is presented in **Figure 9** (Ahmed et al., 2015).

Figure 9: Summary of recruitment for the SPARC trial (Ahmed et al., 2015)



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4.4.2 Summary of recruitment for the SPARC trial

There was fluctuation in the recruitment rate, with recruitment rate increasing steadily, and then tailing off and reaching a plateau towards the end of the study (**Figure 10**).

The medical secretaries and staff at the recruitment centres were updated on the study progress on a regular basis, and methods to achieve a better response rate were discussed. Careful monitoring of recruitment and several requests for medical secretaries to increase the number of invitations sent out, enabled the successful completion of the study (Ahmed et al., 2015).

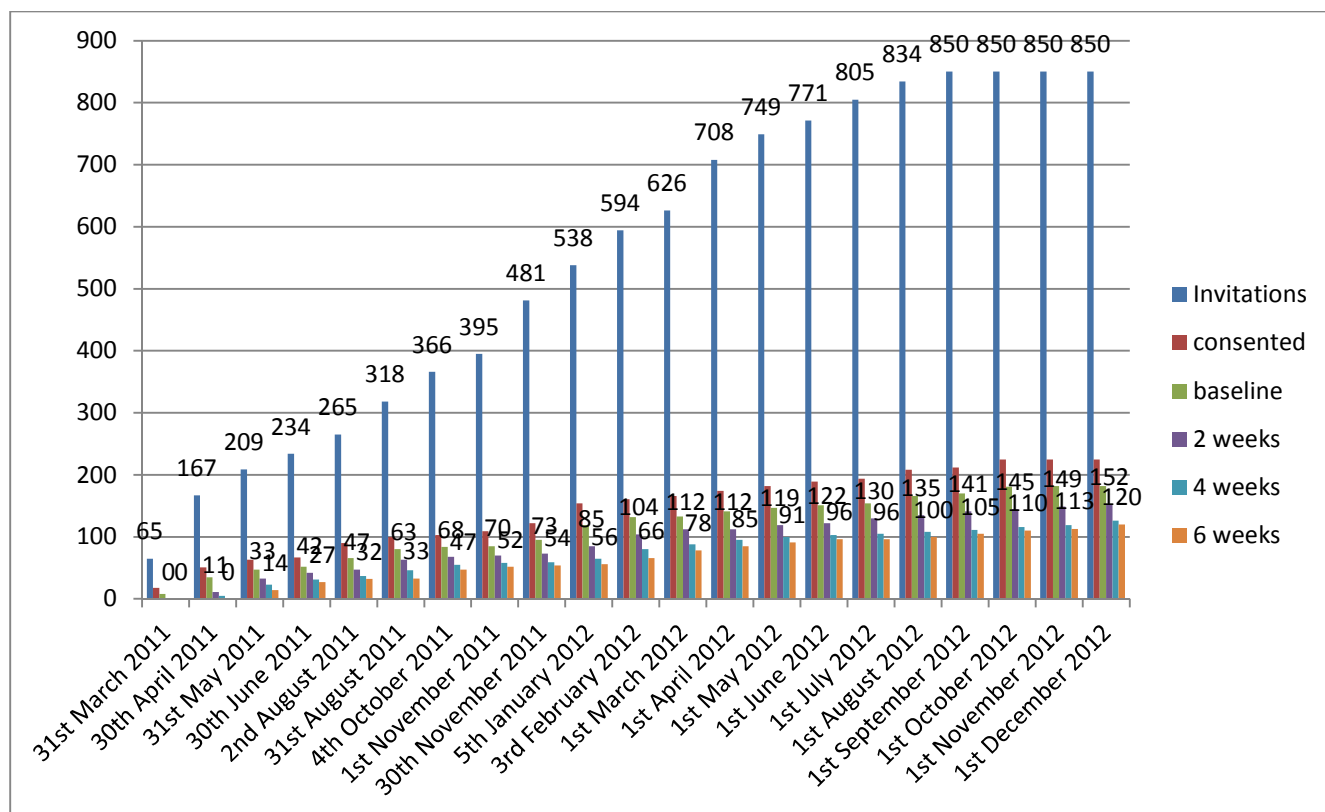


Figure 10: SPARC study recruitment

Update 31st March 2011 to 1st December 2012

Shows the fluctuation in the recruitment rate. Recruitment rate increases steadily, tailing off and reaching a plateau towards the end of the study (Ahmed et al., 2015).

4.4.3 Baseline data

Of the 182 study participants, 84 were males (46.2%) and 98 were females (53.8%). The mean age of the participants on trial registration was 64.47 years (median 66.00 years; SD 12.57; minimum age 27 years; and maximum age 90 years). There were 87 (47.8%) participants in the intervention arm (Group A) and 95 (52.2%) participants in the control arm (Group B); there was no significant difference in the partnership status of patients in Group A vs. Group B. Most patients were married (n = 118; 64.8%) and of White-British ethnicity (n = 173; 95.1%). No significant differences were observed between the intervention and control groups with respect to age distribution, gender distribution, in the baseline scores for MYCAW, EQ-5D, and PEI, or in any other study parameters (Ahmed et al., 2015).

Study participants were categorised on the basis of care received, the four categories of care participants received were as follows: end of life cancer (93); end of life care for non-cancer conditions (4); care as cancer survivors (71); or care as people with a long-term condition

(14). Demographic characteristics of participants are summarised in **Table 14**. No significant differences were observed between the intervention and control groups with respect to age distribution, gender distribution, partnership status/marital status, ethnicity, living arrangements, religion or in any other study parameters (Ahmed et al., 2015).

Table 14: Baseline demographic characteristics of participants (Ahmed et al., 2015)

Baseline Demographic Characteristics of Participants in Group A (Intervention), Group B (Control), and Total Sample (A + B)				
Characteristic	Intervention Group A (87)	Control Group B (95)	All Patients (182)	Notes A vs. B
	n (%)			
Age (mean age in yrs) on registration	63.90 years (median = 65.00 years; SD = 11.68; minimum age = 28 years; maximum age = 87 years)	64.99 years (median = 67.00 years; SD = 13.34; minimum age = 27 years; maximum age = 90 years)	64.47 years (median = 66.00 years; SD = 12.57; minimum age = 27 years; maximum age = 90 years)	No significant difference (Mann-Whitney $Z = -0.865$; $P = 0.387$)
Gender				No significant difference ($\chi^2 = 1.183$; degrees of freedom = 1; $P = 0.277$)
Male	36 (41.4)	48 (50.5)	84 (46.2)	
Female	51 (58.6)	47 (49.5)	98 (53.8)	
Partnership/marital status				No significant difference ($\chi^2 = 1.706$; degrees of freedom = 3; $P = 0.636$). Most patients were married ($n = 118$; 64.8%)
Married	56 (64.4)	62 (65.3)	118 (64.8)	
Single	10 (11.5)	7 (7.4)	17 (9.3)	
Divorced/parted/separated	5 (5.7)	9 (9.5)	14 (7.7)	
Widowed	15 (17.2)	15 (15.8)	30 (16.5)	
Ethnicity				The low numbers in many of the groups meant that it was not possible to test for differences
White—British	83 (95.4)	90 (94.7)	173 (95.1)	
White—other background	2 (2.3)	0 (0)	2 (1.1)	
Black or Black British	1 (1.1)	0 (0)	1 (0.5)	
Caribbean				
Asian or Asian British-Indian	0 (0)	1 (1.1)	1 (0.5)	
Information withheld/not documented	1 (1.1)	4 (4.2)	5 (2.7)	
Living arrangements				Most patients were living at home ($n = 177$; 97.3%), three patients were living in a care or nursing home (1.6%), and for two patients (1.1%) it was not known where they were living
Home	83 (95.4)	94 (98.9)	177 (97.3)	
Care home/nursing home	3 (3.4)	0 (0)	3 (1.6)	
Patient lives alone				No significant difference in the proportions of patients living alone ($\chi^2 = 0.020$; degrees of freedom = 1; $P = 0.887$)
Living alone	15/73 (20.5)	20/88 (22.7)	35 (19.2)	Most patients ($n = 115$; 63.2%) gave their religious denomination as Church of England
Religion				
Church of England	56 (64.4)	59 (62.1)	115 (63.2)	
Roman Catholic	6 (6.9)	5 (5.3)	11 (6.0)	
Christian	5 (5.7)	7 (7.4)	12 (6.6)	
Jewish	2 (2.3)	2 (2.1)	4 (2.2)	
Methodist	3 (3.4)	4 (4.2)	7 (3.8)	
Protestant	1 (1.1)	1 (1.1)	2 (1.1)	
Humanist	1 (1.1)	0 (0)	1 (0.5)	
Anglican	1 (1.1)	0 (0)	1 (0.5)	
Agnostic	0 (0)	2 (2.1)	2 (1.1)	
Quaker	1 (1.1)	2 (2.1)	3 (1.6)	
Church of Scotland	1 (1.1)	0 (0)	1 (0.5)	
None	10 (11.5)	13 (13.7)	23 (12.6)	

The most frequently occurring primary diagnosis in Group A (Intervention) was malignant neoplasm of the breast (unspecified) ($n=11$; 12.5%) and in Group B (Control) was malignant neoplasm of the bronchus or lung (unspecified) ($n=10$; 10.5%). The most common National Diagnosis Code was Cancer/Malignant Disease ($n=77$; 88.5%) in Group A (Intervention) and 10 patients had a ‘Other Non-Cancer Diagnosis’ (11.5%). In Group B (Control), 87 patients (92.6%) had a National Diagnosis Code of Cancer/Malignant Disease and 7 patients had a ‘Other Non-Cancer Diagnosis’ (7.4%) ($\chi^2 = 0.459$; $df = 1$; $p = 0.498$). There was no significant difference in the National Diagnosis Code between the intervention and control groups. The majority of patients ($n=153$; 84.1%) were referred for pain/ symptom control. The most common additional reason for referral was emotional/psychological support ($n = 46$; 57.5%) (Ahmed et al., 2015). There was no significant difference in the urgency of referral between the intervention and control groups ($\chi^2 = 0.018$; $df = 1$; $p = 0.894$). There was no significant difference in care received upon referral across the two groups ($\chi^2 = 6.498$; $df = 3$; $p = 0.090$). There was no difference between Groups A (Intervention) and B (Control) as to where patients were recruited from ($\chi^2 = 0.160$; $df =$

2; $p = 0.923$). In Group A (Intervention), 60 patients were recruited from SLH Community (69.0%), 26 patients were recruited from STH outpatients (29.9%) and one patient was recruited from STH inpatients (1.1%). In Group B (Control), 63 patients were recruited from SLH Community (66.3%), 31 patients were recruited from STH outpatients (32.6%) and one patient was recruited from STH inpatients (1.1%) (Ahmed et al., 2015).

Information relating to referral of patients and care received upon referral in the intervention and control groups is presented in **Table 15**.

Table 15: Referral of patients and care received upon referral in the intervention and control groups (Ahmed et al., 2015)

Characteristic	Intervention Group A n (%)	Control Group B n (%)	All patients n (%)	Notes p
Location before service				No significant difference ($\chi^2 = 4.561$; $df = 2$; $p = 0.102$). Most patients (n=141; 77.9%) were at home before service, followed by those in hospital (acute) (n=38; 21.0).
Home	62 (72.1)	79 (83.2)	141 (77.9)	
Hospital (acute)	22 (25.6)	16 (16.8)	38 (21.0)	
Care Home/Nursing Home	2 (2.3)	0 (-)	2 (1.1)	
Total	86 (100)	95 (100)	Unknown: 1 181 (100)	
Location referred to (before trial entry)				No significant difference ($\chi^2 = 2.012$; $df = 3$; $p = 0.570$). The majority of patients were referred to St. Luke's Hospice (n= 108; 59.3%).
Northern General Hospital	9 (10.3)	13 (13.7)	22 (12.1)	
Royal Hallamshire Hospital	21 (24.1)	17 (17.9)	38 (20.9)	
St. Luke's Hospice	49 (56.3)	59 (62.1)	108 (59.3)	
Weston Park Hospital	8 (9.2)	6 (6.3)	14 (7.7)	
Total	87 (100)	95 (100)	182 (100)	
Services requested (before trial entry)				The majority of patients (n=98; 53.8%) had the St. Luke's Hospice Community team requested.
Northern General Hospital HST	6 (6.9)	6 (6.3)	12 (6.6)	
Royal Hallamshire Hospital HST	9 (10.3)	7 (7.4)	16 (8.8)	
SLH Community Team	45 (51.7)	53 (55.8)	98 (53.8)	
WPH HST	8 (9.2)	6 (6.3)	14 (7.7)	
NGH Outpatients	2 (2.3)	6 (6.3)	8 (4.4)	
RHH Outpatients	12 (13.8)	10 (10.5)	22 (12.1)	
SLH Therapies and Rehab	4 (4.6)	5 (5.3)	9 (4.9)	
St. Luke's Hospice Inpatients	0 (-)	1 (1.1)	1 (0.5)	
NGH Inpatients	0 (-)	1 (1.1)	1 (0.5)	
Other	1 (1.1)	0 (-)	1 (0.5)	
Total	87 (100)	95 (100)	182 (100)	
Referral sources				The largest source of referrals in both groups was the Ward Nurse/Other (n=57; 31.3%).
Hospital doctor/Consultant	21 (24.1)	18 (18.9)	39 (21.4)	
GP	11 (12.6)	14 (14.7)	25 (13.7)	
Ward nurse/Other	31 (35.6)	26 (27.4)	57 (31.3)	
District Nurse	6 (6.9)	9 (9.5)	15 (8.2)	

CNS/Other	15 (17.2)	24 (25.3)	39 (21.4)	
Care/Nursing Home	0 (-)	1 (1.1)	1 (0.5)	
Community Liaison Nurse	0 (-)	1 (1.1)	1 (0.5)	
Self-referral	0 (-)	1 (1.1)	1 (0.5)	
Day Unit	1 (1.1)	0 (-)	1 (0.5)	
Other	1 (1.1)	1 (1.1)	2 (1.1)	
Unknown	1 (1.1)	0 (-)	1 (0.5)	
Total	87 (100)	95 (100)	182 (100)	
Primary reason for referral				
Pain/symptom control	70 (80.5)	83 (87.4)	153 (84.1)	
Social/financial support	2 (2.3)	1 (1.1)	3 (1.6)	
Emotional/psychological support	15 (17.2)	9 (9.5)	24 (13.2)	
Other	0 (-)	2 (2.1)	2 (1.1)	
Total	87 (100)	95 (100)	182 (100)	
Additional reasons for referral				The most common additional reason for referral was emotional/psychological support (n = 46; 57.5%).
Pain/symptom control	1 (2.4)	0 (-)	1 (1.3)	
Social/financial support	7 (16.7)	3 (7.9)	10 (12.5)	
Emotional/psychological support	23 (54.8)	23 (60.5)	46 (57.5)	
Other	Other: 4 (9.5)	Other: 5 (13.2)	Other: 9 (11.3)	
Emotional/psychological support and Social/financial support	7 (16.7)	7 (18.4)	14 (17.5)	
Total	42 (100)	38 (100)	80 (100)	
Urgency of referral				No significant difference ($\chi^2 = 0.018$; $df = 1$; $p = 0.894$).
Urgent	32 (38.1)	37 (40.2)	69 (39.2)	
Routine	52 (61.9)	55 (59.8)	107 (60.8)	
Total	84 (100)	92 (100)	176 (100)	
Care received upon referral				No significant difference ($\chi^2 = 6.498$; $df = 3$; $p = 0.090$). The condition of the people in the study sample was categorised under four categories, according to whether they were considered to require care for end of life cancer (93); end of life care for non-cancer conditions (4); care as cancer survivors (71); or care as people with a long-term condition (14).
EOLC cancer	48 (55.2)	45 (47.4)	93 (51.1)	
EOLC non-cancer	1 (1.1)	3 (3.2)	4 (2.2)	
Cancer survivor	28 (32.2)	43 (45.3)	71 (39.0)	
Long-term condition	10 (11.5)	4 (4.2)	14 (7.7)	
Total	87 (100)	95 (100)	182 (100)	

Comparisons at baseline between people receiving EOLC for cancer and cancer survivors

There were no significant differences in baseline data between participants receiving EOLC for cancer and cancer survivors for any of the following parameters; MYCAW concern 1 score, the total EQ5D score, the EQ5D responses or in the PEI responses. However, it is worth noting that there was a significant difference between the two groups in baseline EQ5D thermometer score, with the mean EQ5D thermometer score at baseline for people receiving end of life care for cancer being lower than that for cancer survivors (Ahmed et al., 2015).

4.4.4 MYCAW data analysis: Comparison of Groups from Baseline to Weeks 2, 4, and 6

The mean MYCAW Concern 1 score for both groups improved over six weeks (**Table 16**). The overall mean change in score from baseline to Week 2 was 0.368 (median 0; SD 1.39); from baseline to Week 4 was 0.430 (median 0; SD 1.66); and from baseline to Week 6 was 0.462 (median 0; SD 1.59). There were no significant differences (no detectable effect) between the control and intervention groups in the change in mean MYCAW Concern 1 scores at two-, four-, or six-week follow-up (Ahmed et al., 2015).

Table 16: Distribution of scores for MYCAW Concern 1 at baseline, 2, 4, and 6 week follow up in the intervention and control groups (Ahmed et al., 2015)

MYCAW Concern 1 Score	n (%)											
	Baseline			Week 2			Week 4			Week 6		
	A	B	Total	A	B	Total	A	B	Total	A	B	Total
0	2 (2.5)	3 (3.2)	5 (2.9)	2 (2.9)	2 (2.9)	4 (2.9)	3 (5.1)	6 (10.0)	9 (7.6)	2 (3.6)	3 (5.6)	5 (4.6)
1	1 (1.2)	4 (4.3)	5 (2.9)	1 (1.4)	8 (11.4)	9 (6.5)	2 (3.4)	3 (5.0)	5 (4.2)	3 (5.5)	4 (7.4)	7 (6.4)
2	6 (7.4)	6 (6.5)	12 (6.9)	6 (8.7)	11 (15.7)	17 (12.2)	4 (6.8)	4 (6.7)	8 (6.7)	4 (7.3)	4 (7.4)	8 (7.3)
3	7 (8.6)	9 (9.7)	16 (9.2)	14 (20.3)	11 (15.7)	25 (18.0)	9 (15.3)	10 (16.7)	19 (16.0)	11 (20.0)	11 (20.4)	22 (20.2)
4	20 (24.7)	20 (21.5)	40 (23.0)	13 (18.8)	11 (15.7)	24 (17.3)	14 (23.7)	14 (23.3)	28 (23.5)	9 (16.4)	15 (27.8)	24 (22.0)
5	19 (23.5)	21 (22.6)	40 (23.0)	16 (23.2)	11 (15.7)	27 (19.4)	11 (18.6)	13 (21.7)	24 (20.2)	10 (18.2)	7 (13.0)	17 (15.6)
6	26 (32.1)	30 (32.3)	56 (32.2)	17 (24.6)	16 (22.9)	33 (23.7)	16 (27.1)	10 (16.7)	26 (21.8)	16 (29.1)	10 (18.5)	26 (23.9)
Total	81 (100)	93 (100)	174 (100)	69 (100)	70 (100)	139 (100)	59 (100)	60 (100)	119 (100)	55 (100)	54 (100)	109 (100)

MYCAW = Measure Yourself Concerns and Wellbeing.

4.4.5 MYCAW: Comparison of Groups from Baseline to Week 2

There was a significant difference in the rankings for the change in MYCAW Concern 1 score [Baseline to Week 2] of patients in Groups A (Intervention: mean rank of patients: 61.21) and B (Control: mean rank of patients: 75.37) (Mann Whitney $Z = -2.192$; $p = 0.028$; $n = 136$). Overall patients in Group B (Control) showed greater improvement or less deterioration in the MYCAW score than patients in Group A (Intervention). The mean change in MYCAW Concern 1 score [baseline to Week 2] in Group A (Intervention) was 0.15 (SD = 1.32; median = 0) [a small improvement] vs. Group B (Control) was 0.57 (SD = 1.44; median = 0). When the scores for changes in MYCAW Concern 1 score for the patients were re-coded [baseline to week 2] into groups for deterioration/ no change / improvement, there was a statistically significant association between the change in MYCAW Concern 1 score and study arm ($\chi^2_{\text{trend}} = 5.51$; $df = 1$; $p = 0.019$). A higher proportion of patients in Group B (Control: 34/70 [48.6%]) had an improvement in the MYCAW Concern 1 score [baseline to Week 2] compared with patients in Group A (Intervention: 19/66 [28.8%]). A higher proportion of patients in Group A (Intervention: 16/66; [24.2%]) showed a deterioration in the MYCAW Concern 1 score [baseline to Week 2], compared with patients in Group B (Control: 10/70 [14.3%]) (**Table 17**) (Ahmed et al., 2015).

From Baseline to Week 2

Table 17: Distribution of level of change in MYCAW scores from Baseline to Week 2 in the intervention and control groups (Ahmed et al., 2015)

Change in MYCAW score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Total Sample (A plus B)
Deterioration	16 (24.2)	10 (14.3)	26 (19.1)
No change	31 (47.0)	26 (37.1)	57 (41.9)
Improvement	19 (28.8)	34 (48.6)	53 (39.0)
Total	66 (100)	70 (100)	136 (100)

4.4.6 MYCAW: Comparison of Groups from Baseline to Week 4

There was no significant difference in the rankings for the change in MYCAW Concern 1 score [Baseline to Week 4] of patients in Groups A (Intervention: mean rank of patients: 55.41) and B (Control: mean rank of patients: 59.45) (Mann Whitney $Z = -0.679$; $p = 0.497$; $n = 114$). The mean change in MYCAW Concern 1 score [baseline to Week 4] in Group A (Intervention) was 0.31 (SD = 1.44; median = 0) [a small improvement] vs. Group B (Control) was 0.54 (SD = 1.85; median = 0). When the scores for changes in MYCAW Concern 1 score [baseline to Week 4] for the patients were re-coded into groups for deterioration/ no change / improvement, a higher proportion of patients in Group B (Control: 25/59 [42.4%]) had an improvement in the MYCAW Concern 1 score [baseline to Week 4] vs. patients in Group A (Intervention: (19/55; [34.5%])); however, this association was not statistically significant ($\chi^2_{\text{trend}} = 0.026$; $df = 1$; $p = 0.872$). A higher proportion of patients in Group B (Intervention: 14/59; [23.7%]) showed a deterioration in the MYCAW Concern 1 score [baseline to Week 4], vs. patients in Group A (Control: 10/55 [18.2%]) (**Table 18**) (Ahmed et al., 2015).

From Baseline to Week 4

Table 18: Distribution of level of change in MYCAW scores from Baseline to Week 4 in the intervention and control groups (Ahmed et al., 2015)

Change in MYCAW score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Total Sample (A plus B)
Deterioration	10 (18.2)	14 (23.7)	24 (21.1)
No change	26 (47.3)	20 (33.9)	46 (40.4)
Improvement	19 (34.5)	25 (42.4)	44 (38.6)
Total	55 (100)	59 (100)	114 (100)

4.4.7 MYCAW: Comparison of Groups from Baseline to Week 6

There was no significant difference in the rankings for the change in MYCAW Concern 1 score [Baseline to Week 6] of patients in Groups A (Intervention: mean rank of patients: 48.28) and B (Control: mean rank of patients: 56.56) (Mann Whitney $Z = -1.439$; $p = 0.150$; $n = 104$). The mean change in MYCAW score [baseline to Week 6] in Group A (Intervention) was 0.27 (SD = 1.34; median = 0; $n=51$) vs. mean change in Group B (Control) was 0.64 (SD = 1.78; median = 0; $n=53$). When the scores for changes in MYCAW Concern 1 score [baseline to Week 6] for the patients were re-coded into groups for deterioration/ no change / improvement, a higher proportion of patients in Group B (Control: 26/53 [49.1%]) had an improvement in the MYCAW Concern 1 score [baseline to Week 6] compared with patients in Group A (Intervention: (18/51; [35.3%]); however, this association was not statistically significant ($\chi^2_{trend} = 1.428$; $df = 1$; $p = 0.232$). A slightly higher proportion of patients in Group A (Intervention: 13/51; [25.5%]) showed a deterioration in the MYCAW Concern 1 score [baseline to Week 6], vs. patients in Group B (Control: 11/53 [20.8%]) (**Table 19**) (Ahmed et al., 2015).

From Baseline to Week 6

Table 19: Distribution of level of change in MYCAW scores from Baseline to Week 6 in the intervention and control groups (Ahmed et al., 2015)

Change in MYCAW score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Total Sample (A plus B)
Deterioration	13 (25.5)	11 (20.8)	24 (23.1)
No change	20 (39.2)	16 (30.2)	36 (34.6)
Improvement	18 (35.3)	26 (49.1)	44 (42.3)
Total	51 (100)	53 (100)	104 (100)

4.4.8 MYCAW: Qualitative analysis of patients/respondents stated concerns

The MYCAW questionnaire invites patients to nominate concerns, which may or may not be medical (MYCAW) or symptoms (MYMOP) of importance to them (two concerns/symptoms can be identified). They then score these on a scale of 0 (not bothering me at all) – to 6 (bothers me greatly). Patients are also asked to rate their general feeling of wellbeing on a scale of 0 (as good as it could be) – to 6 (as bad as it could be). The follow-up form asks patients to re-score the concerns/symptoms, and rate their general feeling of wellbeing they previously nominated, thus capturing any changes over time that are important to the patient. The primary outcome measure was the change in score between the first MYCAW patient nominated concern at baseline and the two-week follow up. This is the nominated first concern (Ahmed et al., 2015; Guyatt et al., 1998; Paterson et al., 2007; Peace & Manasse, 2002). Three respondents gave scores on concern one, but without stating the concern; one respondent did this for concern two.

MYCAW concerns at Baseline

Of the 182 patients completing baseline questionnaires, 173 (95.1%) respondents nominated and scored a primary concern (MYCAW Concern 1) and 125 (68.7%) nominated and scored a secondary concern (MYCAW Concern 2) (Ahmed et al., 2015).

First concerns nominated

A thematic analysis revealed that several areas of concern were nominated as a first concern. These are summarised below.

Nominated concerns relating to (number of patients in brackets):

1. Physical symptoms (66);
2. Apprehension for themselves (24) or for others (10);
3. Disease progression (18);
4. Current condition or state of health (16);
5. Disability, either from their symptoms or from other causes (14);
6. Loss of faculties, function or role (12);
7. Needing help from family/services (11);
8. Effects of treatment (9);
9. Worrying thoughts about death and dying (6);
10. Loneliness, loss of meaning of their place in the world, existential concerns (6);
11. Psychological concerns e.g. depression (4);
12. Effects on social life (3);
13. Information on their disease (2);
14. Hope of improvement (2);
15. Work and finance (1);
16. No concerns voiced (6), suggesting that things were fine at present.

Some respondent's nominated more than one concern. One respondent made a specific comment about the forms themselves.

Second concerns nominated

A thematic analysis revealed that several areas of concern were nominated as a second concern. These are summarised below.

Nominated concerns relating to (number of patients in brackets):

1. Physical symptoms (51);
2. Apprehension for themselves (10) or for others (10);
3. Loss of faculties, function or role and existential concerns (15);
4. Current condition or state of health (13);
5. Disease progression (12);
6. Effects of treatment and treatment plans (12);
7. Disability, either from their symptoms or from other causes (11);
8. Needing help from family/services (7);
9. Effects on social life (6);
10. Worrying thoughts about death and dying (3);

11. Psychological concerns (3);
12. Work (2) and finance (2);
13. Loneliness, loss of meaning of their place in the world, existential concerns (1);
14. No concerns voiced (4), suggesting that things were fine at present.

Some respondents named concerns in more than one area.

Summary of MYCAW Concern 1

For MYCAW concern 1, physical symptoms, condition and disability predominate in the first stated concern, but other concerns such as apprehension for themselves or others, concerns about disease progression and dying, feelings of loss of function or purpose, and on help needed are also prominent. There were a minority of respondents that appear to be without any problems, issues or concerns (Ahmed et al., 2015).

Summary of MYCAW Concern 2

The pattern of concerns closely follows that stated in the first concerns, although a smaller number named a second concern. Individuals' second concerns may not be of the same nature as their first ones. Physical symptoms predominate, but other concerns such as apprehension for themselves or others, concerns about disease progression and dying, and on feelings of loss of function or purpose, are also prominent. There were a minority without issues that are currently causing them concern (Ahmed et al., 2015).

Summary of MYCAW Concerns 1 and 2 according to clinical groups

The condition of the people in the study sample was categorised under four categories, according to whether they were considered to require care for end of life cancer; end of life care for non-cancer conditions; care as cancer survivors; or care as people with a long-term condition. Several points are raised by viewing the data for the analysis of MYCAW concerns 1 and 2 according to the clinical groups. Similarities are marked, in that for all groups, symptoms, condition and disability feature most strongly. For cancer survivors, and those receiving end of life cancer care, all concerns are named: apprehension for themselves or others; concerns related to the progression of disease; psychological concerns; concerns related to loss or existential issues; concerns about needing help; the effect on their social life; work or financial issues; and treatment effects (**Table 20**) (Ahmed et al., 2015). Any possible differences in emphasis in concerns between these two groups could be explored by further analysis of SPARC and other data.

Table 20: Summary of MYCAW Concerns 1 and 2 according to clinical groups

ANALYSIS ACCORDING TO CLINICAL GROUP	
Clinical group (number of patients)	Summary
<p>End of life care in cancer conditions (93)</p> <ul style="list-style-type: none"> ▪ 87 named a first concern ▪ 66 named a second concern ▪ Some respondents named concerns in more than one area 	<p>Physical symptoms predominate in the first stated concern, closely followed by feelings of apprehension, and concerns about disease progression. Other concerns, such as feelings of loss; concerns about needing help and the effects of treatment are also present. There are a minority without issues that are currently causing them concern. The pattern of second concerns closely follows that stated in the first concerns, although individuals' second concerns are not necessarily of the same nature as their first ones.</p>
<p>End of life care in non-cancer conditions (4)</p>	<p>In this small group, respondents' concerns were about dying; their illness; the effect on their families; wanting to do more; the restrictions caused by pain; adjusting to a new house; and fear of falls.</p>
<p>Cancer survivors Care for people who are cancer survivors (71)</p> <ul style="list-style-type: none"> ▪ 69 named a first concern ▪ 56 named a second concern ▪ Some respondents named concerns in more than one area 	<p>Physical symptoms predominate in the first stated concern, closely followed by feelings of apprehension and concerns about disease progression. Other concerns, such as feelings of loss, are present; with concerns about needing help, wanting to be independent, and the effects of treatment are also present. There are a minority without issues that are currently causing them concern. The pattern of concerns closely follows that stated in the first concerns in the sample overall, although individuals' second concerns may not be of the same nature as their first ones.</p>
<p>Long-term conditions Care for people with long-term conditions (14)</p> <ul style="list-style-type: none"> ▪ All 14 named a first concern ▪ 8 named a second concern ▪ Some respondents named concerns in more than one area 	<p>Physical symptoms, condition and disability predominate in the first stated concern, with apprehension, help needed, and loss being other stated concerns. The second concern reflects the predominance of concerns related to physical symptoms, with emotional concerns also present.</p>

4.4.9 EQ5D: Comparison of Groups from Baseline to Weeks 2, 4, and 6

There were no meaningful or significant associations between any of the EQ-5D domains for Groups A (intervention) and B (control) at baseline, Weeks 2, 4, or 6. **Table 21** shows the frequency of responses for the EQ-5D domains at all of the time points. It is also worth noting that, in this analysis, the mean EQ-5D scores did not change in any significant or meaningful way (Ahmed et al., 2015).

Table 21: Frequency of EQ5D responses at Baseline, Weeks 2, 4 and 6 in the intervention and control groups (Ahmed et al., 2015)

Frequency of EQ-5D Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline and Weeks 2, 4, and 6													
Domain	Statement	Baseline Response, n (%)			Week 2 Response, n (%)			Week 4 Response, n (%)			Week 6 Response, n (%)		
		A	B	Total	A	B	Total	A	B	Total	A	B	Total
Group Mobility	I have no problems in walking about	13 (15.7)	9 (9.5)	22 (12.4)	11 (15.1)	10 (13.0)	21 (14.0)	10 (16.9)	8 (12.5)	18 (14.6)	8 (14.3)	5 (7.9)	13 (10.9)
	I have some problems in walking about	66 (79.5)	85 (89.5)	151 (84.8)	60 (82.2)	64 (83.1)	124 (82.7)	48 (81.4)	53 (82.8)	101 (82.1)	45 (80.4)	56 (88.9)	101 (55.5)
	I am confined to bed	4 (4.8)	1 (1.1)	5 (2.8)	2 (2.7)	3 (3.9)	5 (3.3)	1 (1.7)	3 (4.7)	4 (3.3)	3 (5.4)	2 (3.2)	5 (2.7)
Self-care	Total	83 (100)	95 (100)	178 (100)	73 (100)	77 (100)	150 (100)	59 (100)	64 (100)	123 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with self-care	43 (53.1)	43 (45.3)	86 (48.9)	37 (51.4)	36 (46.8)	73 (49.0)	34 (57.6)	28 (44.4)	62 (50.8)	31 (55.4)	27 (42.9)	58 (48.7)
	I have some problems washing or dressing myself	33 (40.7)	48 (50.5)	81 (46.0)	31 (43.1)	36 (46.8)	67 (45.0)	22 (37.3)	33 (52.4)	55 (45.1)	20 (35.7)	33 (52.4)	53 (44.5)
Usual activities	I am unable to wash or dress myself	5 (6.2)	4 (4.2)	9 (5.1)	4 (95.6)	5 (6.5)	9 (6.0)	3 (5.1)	2 (3.2)	5 (4.1)	5 (8.9)	3 (4.8)	8 (6.7)
	Total	81 (100)	95 (100)	176 (100)	72 (100)	77 (100)	149 (100)	59 (100)	63 (100)	122 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with performing my usual activities	7 (8.4)	6 (6.5)	13 (7.4)	7 (9.7)	8 (10.3)	15 (10.0)	3 (5.1)	8 (12.5)	11 (8.9)	4 (7.4)	7 (11.1)	11 (9.4)
Pain/discomfort	I have some problems with performing my usual activities	54 (65.1)	59 (63.4)	113 (64.2)	46 (63.9)	49 (62.8)	95 (63.3)	40 (67.8)	38 (59.4)	78 (63.4)	31 (57.4)	40 (63.5)	71 (60.7)
	I am unable to perform my usual activities	22 (26.5)	28 (30.1)	20 (28.4)	19 (26.4)	21 (26.9)	40 (26.7)	16 (27.1)	18 (28.1)	34 (27.6)	19 (35.2)	16 (25.4)	35 (29.9)
	Total	83 (100)	93 (100)	176 (100)	72 (100)	78 (100)	150 (100)	59 (100)	64 (100)	123 (100)	54 (100)	63 (100)	117 (100)
Anxiety/depression	I have no pain or discomfort	11 (13.3)	9 (9.8)	20 (11.4)	9 (12.5)	10 (13.2)	19 (12.8)	6 (10.3)	3 (4.8)	9 (7.5)	8 (14.8)	4 (6.6)	12 (10.4)
	I have moderate pain or discomfort	59 (71.1)	72 (78.3)	131 (74.9)	55 (76.4)	55 (72.4)	110 (74.3)	44 (75.9)	54 (87.1)	98 (81.7)	34 (63.0)	53 (86.9)	87 (75.7)
	I have extreme pain or discomfort	13 (15.7)	11 (12.0)	24 (13.7)	8 (11.1)	11 (14.5)	19 (12.8)	8 (13.8)	5 (8.1)	13 (10.8)	12 (22.2)	4 (6.6)	16 (13.9)
Anxiety/depression	Total	83 (100)	92 (100)	175 (100)	72 (100)	76 (100)	148 (100)	58 (100)	62 (100)	120 (100)	54 (100)	61 (100)	35 (29.9)
	I am not anxious or depressed	34 (42.0)	29 (31.9)	63 (36.6)	31 (43.1)	23 (29.9)	54 (36.2)	23 (40.4)	18 (29.0)	41 (34.5)	19 (34.5)	23 (37.7)	42 (36.2)
	I am moderately anxious or depressed	42 (51.9)	55 (60.4)	97 (56.4)	37 (51.4)	52 (67.5)	89 (59.7)	31 (54.4)	41 (66.1)	72 (60.5)	29 (52.7)	34 (55.7)	69 (54.3)
Anxiety/depression	I am extremely anxious or depressed	5 (6.2)	7 (7.7)	12 (7.0)	4 (5.6)	2 (2.6)	6 (4.0)	3 (5.3)	3 (4.8)	6 (5.0)	7 (12.7)	4 (6.6)	11 (9.5)
	Total	81 (100)	91 (100)	172 (100)	72 (100)	77 (100)	149 (100)	57 (100)	62 (100)	119 (100)	55 (100)	61 (100)	116 (100)

EuroQol. (EQ-5D) = standardized outcome measure of health-related quality of life.

4.4.10 EQ5D thermometer scores

There was no significant difference in the rankings of the EQ5D thermometer scores for Groups A (Intervention) and B (Control) at baseline (Mann Whitney $Z = -0.311$; $p = 0.756$), Week 2 (Mann Whitney $Z = -0.125$; $p = 0.900$), Week 4 (Mann Whitney $Z = -0.694$; $p = 0.487$) or Week 6 (Mann Whitney $Z = -1.260$; $p = 0.208$). There was no significant difference in the rankings of the changes in EQ5D thermometer scores for Groups A (Intervention) and B (Control) from baseline to Week 2 (Mann Whitney $Z = -1.227$; $p = 0.220$), baseline to Week 4 (Mann Whitney $Z = -1.425$; $p = 0.154$) or baseline to Week 6 (Mann Whitney $Z = -1.199$; $p = 0.231$) (Ahmed et al., 2015).

4.4.11 Total EQ5D scores

There was no significant difference in the rankings of the total EQ5D scores for Groups A (Intervention) and B (Control) at baseline (Mann Whitney $Z = -1.043$; $p = 0.297$), Week 2 (Mann Whitney $Z = -0.930$; $p = 0.353$), Week 4 (Mann Whitney $Z = -0.559$; $p = 0.576$) or Week 6 (Mann Whitney $Z = -0.324$; $p = 0.746$). There was no significant difference in the rankings of the changes in total EQ5D scores for Groups A (Intervention) and B (Control) from baseline to Week 2 (Mann Whitney $Z = -0.838$; $p = 0.402$), baseline to Week 4 (Mann Whitney $Z = -0.125$; $p = 0.900$) or baseline to Week 6 (Mann Whitney $Z = -1.035$; $p = 0.301$) (Ahmed et al., 2015).

4.4.12 EQ5D: Comparison of Groups from Baseline to Week 2

When the scores for changes in the total EQ5D score for the patients were re-coded into groups for deterioration/ no change / improvement, the association between change in total EQ5D score from Baseline to Week 2 and study arm was not statistically significant ($\chi^2_{\text{trend}} = 0.43$; $df = 1$; $p = 0.511$). The distribution across the two groups is shown in **Table 22** (Ahmed et al., 2015).

From Baseline to Week 2

Table 22: Distribution of level of change in total EQ5D scores from Baseline to Week 2 in the intervention and control groups (Ahmed et al., 2015)

Change in total EQ5D score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Group A plus Group B
Deterioration	17 (6.2)	24 (33.8)	41 (30.1)
No change	32 (49.2)	30 (42.3)	62 (45.6)
Improvement	16 (24.6)	17 (23.9)	33 (24.3)
Total	65 (100)	71 (100)	136 (100)

4.4.13 EQ5D: Comparison of Groups from Baseline to Week 4

When the scores for changes in the total EQ5D score for the patients were re-coded into groups for deterioration/ no change / improvement, the association between change in total EQ5D score from Baseline to Week 4 and study arm was not statistically significant ($\chi^2_{\text{trend}} = 0.025$; $df = 1$; $p = 0.876$). The distribution across the two groups is shown in **Table 23** (Ahmed et al., 2015).

From Baseline to Week 4

Table 23: Distribution of level of change in total EQ5D scores from Baseline to Week 4 in the intervention and control groups (Ahmed et al., 2015)

Change in total EQ5D score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Group A plus Group B
Deterioration	18 (36.7)	19 (33.3)	37 (34.9)
No change	17 (34.7)	25 (43.9)	42 (39.6)
Improvement	14 (28.6)	13 (22.8)	27 (25.5)
Total	49 (100)	57 (100)	106 (100)

4.4.14 EQ5D: Comparison of Groups from Baseline to Week 6

When the scores for changes in the total EQ5D score for the patients were re-coded into groups for deterioration/ no change / improvement, the association between change in total EQ5D score from Baseline to Week 6 and study arm was not statistically significant ($\chi^2_{\text{trend}} = 0.746$; $df = 1$; $p = 0.388$). The distribution across the two groups is shown in **Table 24** (Ahmed et al., 2015).

From Baseline to Week 6

Table 24: Distribution of level of change in total EQ5D scores from Baseline to Week 6 (Ahmed et al., 2015)

Change in total EQ5D score	N (%)		Total (%)
	Group A (Intervention)	Group B (Control)	Group A plus Group B
Deterioration	15 (32.6)	23 (39.7)	18 (36.5)
No change	16 (34.8)	20 (34.5)	36 (34.6)
Improvement	15 (32.6)	15 (25.9)	30 (28.8)
Total	46 (100)	58 (100)	104 (100)

4.4.15 PEI: Comparison of Groups from Baseline to Weeks 2, 4, and 6

Table 25 shows the distribution of responses for the PEI questions at Baseline and Weeks 2, 4, and 6, respectively, in Groups A (intervention) and B (control) and in the total sample (A plus B). There were no meaningful or significant associations between the PEI responses to the questions for either group or in the total sample at any of the time points (Ahmed et al., 2015).

Table 25: Distribution of responses for the PEI questions at Baseline and Weeks 2, 4, and 6 in the intervention and control groups (Ahmed et al., 2015)

Distribution of PEI Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline, Weeks 2, 4 and 6										Continued							
Question	Response, n (%)	Baseline				Week 2		Week 2		Week 4				Week 6			
		Group A (Intervention)	Group B (Control)	Total	P	Group A (Intervention)	Group B (Control)	Total	P	Group A (Intervention)	Group B (Control)	Total	P	Group A (Intervention)	Group B (Control)	Total	P
Able to cope with life	Much better	8 (10.0)	8 (9.0)	16 (9.5)	0.301	4 (5.8)	9 (12.7)	13 (9.3)	0.693	1 (1.9)	1 (1.8)	2 (1.8)	0.781	2 (3.8)	6 (10.3)	8 (7.3)	0.607
	Better	32 (40.0)	28 (31.5)	60 (35.5)		22 (31.9)	16 (22.5)	38 (27.1)		19 (35.8)	19 (33.3)	38 (34.5)		17 (32.7)	15 (25.9)	32 (29.1)	
	Same or less	40 (50.0)	53 (59.6)	93 (55.0)		43 (62.3)	46 (64.8)	89 (63.6)		33 (62.3)	37 (64.9)	70 (63.6)		33 (63.5)	37 (63.8)	70 (63.6)	
	Total	80 (100)	89 (100)	169 (100)		69 (100)	71 (100)	140 (100)		53 (100)	57 (100)	110 (100)		52 (100)	58 (100)	110 (100)	
Able to understand your illness	Much better	8 (10.8)	14 (15.9)	22 (13.6)	0.662	4 (6.3)	9 (13.0)	13 (13.8)	0.481	2 (3.8)	4 (7.1)	6 (5.5)	0.676	4 (8.0)	6 (10.3)	10 (9.3)	0.346
	Better	30 (40.5)	31 (35.2)	61 (37.7)		22 (34.4)	20 (29.0)	42 (31.6)		19 (35.8)	19 (33.9)	38 (34.9)		11 (22.0)	17 (29.3)	28 (25.9)	
	Same or less	36 (48.6)	43 (48.9)	79 (48.8)		38 (59.4)	40 (58.0)	78 (58.6)		32 (60.4)	33 (58.9)	65 (59.6)		35 (70.0)	35 (60.3)	70 (64.8)	
	Total	74 (100)	88 (100)	162 (100)		64 (100)	69 (100)	133 (100)		53 (100)	56 (100)	109 (100)		50 (100)	58 (100)	109 (100)	
Able to cope with your illness	Much better	6 (7.8)	9 (10.0)	15 (9.0)	0.835	2 (3.0)	7 (10.1)	9 (6.6)	0.989	1 (1.9)	3 (5.1)	4 (3.6)	0.995	3 (5.9)	5 (8.5)	8 (7.3)	0.884
	Better	30 (39.0)	33 (36.7)	63 (37.7)		26 (38.8)	17 (24.6)	43 (31.6)		16 (30.2)	14 (23.7)	30 (26.8)		13 (25.5)	13 (22.0)	26 (23.6)	
	Same or less	41 (53.2)	48 (53.3)	89 (53.3)		39 (58.2)	45 (65.2)	84 (61.8)		36 (67.9)	42 (71.2)	78 (69.6)		35 (68.6)	41 (69.5)	76 (69.1)	
	Total	77 (100)	90 (100)	167 (100)		67 (100)	69 (100)	136 (100)		53 (100)	59 (100)	112 (100)		51 (100)	59 (100)	110 (100)	
Able to keep yourself healthy	Much better	5 (7.1)	6 (7.1)	11 (7.1)	0.721	3 (4.8)	9 (14.1)	12 (9.4)	0.939	2 (3.8)	3 (5.6)	5 (4.7)	0.948	2 (4.1)	5 (8.9)	7 (6.7)	0.446
	Better	23 (32.9)	25 (29.4)	48 (31.0)		21 (33.3)	10 (15.6)	31 (24.4)		12 (23.1)	11 (20.4)	23 (21.7)		10 (20.4)	11 (19.6)	21 (20)	
	Same or less	42 (60.0)	54 (63.5)	96 (61.9)		39 (61.9)	45 (70.3)	84 (66.1)		38 (73.1)	40 (74.1)	78 (73.6)		37 (75.5)	40 (71.4)	77 (73.3)	
	Total	70 (100)	85 (100)	155 (100)		63 (100)	64 (100)	127 (100)		52 (100)	54 (100)	106 (100)		49 (100)	56 (100)	105 (100)	
Confident about your health	Much more	2 (2.7)	3 (3.4)	5 (3.1)	0.687	3 (4.5)	5 (7.0)	8 (5.8)	0.507	1 (2.0)	1 (1.7)	2 (1.8)	0.445	2 (4.0)	3 (5.2)	5 (4.6)	0.319
	More	19 (25.7)	24 (27.6)	43 (26.7)		12 (18.2)	14 (19.7)	26 (19.0)		9 (17.6)	7 (11.9)	16 (14.5)		4 (8.0)	9 (15.5)	13 (12.0)	
	Same or less	53 (71.6)	60 (69.0)	113 (70.2)		51 (77.3)	52 (73.2)	103 (75.2)		41 (80.4)	51 (86.4)	92 (83.6)		44 (88.0)	46 (79.3)	90 (83.3)	
	Total	74 (100)	87 (100)	161 (100)		66 (100)	71 (100)	137 (100)		51 (100)	59 (100)	110 (100)		50 (100)	58 (100)	108 (100)	
Able to help yourself	Much more	7 (9.6)	8 (9.2)	15 (9.4)	0.365	3 (4.5)	5 (6.9)	8 (5.8)	0.305	4 (7.0)	0 (0)	4 (3.6)	0.088	3 (6.3)	3 (5.2)	6 (5.7)	0.625
	More	24 (32.9)	21 (24.1)	58 (66.7)		20 (30.3)	11 (15.3)	31 (22.5)		8 (15.1)	8 (14.0)	16 (14.5)		9 (18.8)	9 (15.5)	18 (17.0)	
	Same or less	42 (57.5)	58 (66.7)	100 (62.5)		43 (65.2)	56 (77.8)	99 (71.7)		41 (77.4)	49 (86.0)	90 (81.8)		36 (75.0)	46 (79.3)	82 (77.4)	
	Total	73 (100)	87 (100)	160 (100)		66 (100)	72 (100)	138 (100)		53 (100)	57 (100)	110 (100)		48 (100)	58 (100)	106 (100)	

4.4.16 Retrospective case note reviews

Hospital admissions and outpatient visits

There was no significant difference between the intervention and control groups in the number of hospital admissions and outpatient visits during the 12 months prior to receiving baseline questionnaires or during the study period (Table 26).

Table 26: Hospital admissions and outpatient visits

Characteristic	Intervention Group A	Control Group B	All patients, n	Notes <i>p</i>
Number of hospital admissions during 12 months prior to receiving baseline questionnaires				
The mean number of hospital admissions during the 12 months prior to baseline data received	6.30 (median = 4; SD = 6.60)	4.45 (median = 3; SD = 5.67)	5.34 (median = 3; SD = 6.19)	No significant difference (Mann-Whitney $Z = -1.593$; $p = 0.111$)
Number of hospital admissions during study (period is 8 weeks from baseline questionnaires received)				
The mean number of hospital admissions during the study period (period is 8 weeks from baseline data received)	0.94 (median = 0; SD = 1.42; n= 87)	0.91 (median = 0; SD = 1.34; n= 95)	0.92 (median = 0; SD = 1.37; n=182)	No significant difference (Mann-Whitney $Z = -0.298$; $p = 0.766$)
Number of outpatient visits during 12 months prior to baseline questionnaires received				
The mean number of outpatient visits during the 12 months before the baseline data were received	14.17 (median = 11; SD = 10.51)	13.44 (median = 11; SD = 9.12)	13.79 (median = 11; SD = 9.79)	No significant difference (Mann-Whitney $Z = -0.334$; $p = 0.738$)
Number of outpatient visits during study (period is 8 weeks from baseline questionnaires received)				
The mean number of outpatient visits during the 8-week study period	1.70 (median = 1; SD = 1.98)	1.87 (median = 1; SD = 1.80)	1.79 (median = 1; SD = 1.89)	No significant difference (Mann-Whitney $Z = -0.912$; $p = 0.362$)
Number of days in hospital during 12 months prior to baseline questionnaires received				
The mean number of days in hospital during the 12 months prior to receiving baseline data	22.15 (median = 14; SD = 26.27)	15.51 (median = 9; SD = 21.05)	18.68 (median = 10; SD = 23.86)	No significant difference (Mann-Whitney $Z = -1.795$; $p = 0.073$)
Number of days in hospital during study duration (period is 8 weeks from baseline questionnaires received)				
The mean number of days in hospital during the 8-week study period from when the baseline data were received	4.21 (median = 0; SD = 9.81)	4.03 (median = 0; SD = 8.38)	4.12 (median = 0; SD = 9.07)	No significant difference (Mann-Whitney $Z = -0.233$; $p = 0.816$)

Summary of key findings from retrospective case note reviews

- 164/182 patients (90.1%) completed a SPARC questionnaire.
- 107/164 (65.2%) patient-completed SPARC forms were filed in the notes (when reviewed at the 8-week point).
- 123/182 (67.6%) patients had progress notes for the duration of study.

- 43/182 (23.6%) patients had no progress notes for the entire duration of the study, a further 16/182 (8.8%) patients did not complete SPARC.
- 30/182 (16.4%) trial participants were discharged during the trial period.
- In 12/182 (6.59%); the prospect of pending discharge was discussed during the trial period.

SPARC referenced in notes: What actions were taken?

Only 5/164=3.0% of patient notes made any direct reference to SPARC. The following actions were taken as a result of participants completing SPARC (as documented in the participants' notes).

BM001 (trial duration period 15.3.11-10.5.11)

This participant was not seen by a palliative care health care professional during the trial duration, in fact the notes suggest that this participant was last seen by the palliative care team in August 2010, and has not been seen since. The notes indicate that the participant has a long-term condition, and has had multiple admissions to the hospital. The notes have documented that the consultant was currently trying to make another appointment to see the participant in the outpatient clinic following high level scoring of SPARC on some issues. In this case the completion of SPARC resulted in the Palliative Medicine Consultant recalling the participant back to the outpatient clinic for further review, who had not been seen in clinic for over 6 months, and for whom appointments seemed to have slipped through the net.

MA006 (trial duration period 24.3.11-19.5.11)

The completion of SPARC by this participant who was seen during the trial duration period, identified various psychological concerns that needed addressing, loneliness was a major cause of unhappiness in this participant, caused by the death of her husband, depression was therefore due to the bereavement. The completion of SPARC by this participant when attending the outpatient clinic resulted in the consultant seeking a referral to a clinical psychologist based in the hospice. In this case the completion of SPARC initiated a referral to a clinical psychologist to address any underlying psychological concerns/issues.

MA015 (trial duration period 12.4.11-7.6.11)

In this case the participant completed SPARC, and informed the clinical nurse specialist that she had been concerned that she may alarm someone when she ticked 'thoughts of suicide'. She said that she often thought of suicide when questioned, and said that it had gone through her mind on a number of occasions. The participant was aware that this was not an 'easy way out' and only contemplates it, and has never developed her thoughts on it. This prompted the health care professional to inform the participants GP, so that the GP was made aware of this.

The health care professional said that she never got the impression that the participant had any intention of following through with these thoughts. When the participant was asked if she would like a referral to psychological support (as done in past), the participant felt that this was not necessary (was open and honest), but will do if she needs more psychological support in future. In this case the completion of SPARC by the participant who had high-level scoring for the ‘thoughts of suicide’ question, prompted the health care professional to immediately contact the participant to see what help if any could be offered.

MA046 (trial duration period 7.6.11-2.8.11)

In this particular case the participant completing SPARC had already been discharged (prior to trial entry). The SPARC questionnaire was returned following patient discharge, and one area highlighted 3 (very much distressed by), however the participant had already been discharged and the health care professional then made a plan to establish contact with the participant. The health care professional made contact with the patient by telephone following receipt of the completed SPARC tool, and checked with the participant if she had been provided support in the area that had been highlighted as 3. The participant stated that she had the opportunity to talk with the health care professional (since completing SPARC) and had been provided with literature (during a subsequent consultation with the health care professional), which had been helpful but she did not feel the need for further support at this time, and said that her illness still had an impact on her sexual life. However, she did not feel that this would change.

MA110 (trial duration period 18.1.12-14.3.12)

The health care professional spoke to the participant about a copy of SPARC form received, the participant informed the health care professional that the information he had required was covered by the last visit (completed SPARC before that visit), he had also asked at that time when he would be able to try his new catheter out, and was advised he should ask Dr ‘E’ at his next outpatient appointment. The participant said that he still has some questions for Dr ‘E’ at his next outpatient appointment. The health care professional encouraged the participant to ask questions.

4.5 Summary

The unexpected negative finding that a higher proportion of patients in the control group (34 of 70; 48.6%) showed a relative improvement in their MYCAW score from Baseline to Week 2 compared with the intervention group (19 of 66; 28.8%) ($P = 0.019$) raises questions about the application of SPARC and possibly other holistic needs assessment questionnaires in the context of a specialist palliative care service. No positive effect of the intervention on either the primary or secondary outcome measures was observed at two, four, or six weeks, suggesting that the intervention did not have a detectable beneficial effect at any point and the difference between arms was obliterated when the control arm received SPARC (Ahmed et al., 2015).

Data which indicate that most patients felt that no particular action or benefit followed from completion of SPARC will be reported in **Chapter 6**. There were no meaningful or significant differences between the control and intervention groups in the scores for health related quality of life as recorded in the general measure EQ-5D. This measure did not significantly change over the six weeks, as would be expected of patients attending a palliative care service. However, in contrast, there appears to be improvement in the most important concern as recorded in the MYCAW; this suggests that usual palliative care is having a beneficial effect in this respect (Ahmed et al., 2015).

This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan (Ahmed et al., 2015). This is supported by review of case notes, and the interview data from patients which indicate that most patients felt that no particular action or benefit followed from the completion of SPARC (Ahmed et al., 2015).

The SPARC pilot trial focused primarily on outcomes, not on the processes involved in implementing the intervention. The Medical Research Council framework requires an evaluation of the pilot study, a process evaluation was undertaken and is reported in **Chapters 5, 6, and 7**, to elucidate the precise mechanism by which this result came about (Ahmed et al., 2015).

Chapter 5

RESEARCH PHASE II: Process evaluation

5 Process evaluation

Evaluating interventions or health care services is an important component of health services research. The new MRC guidance, 2008 provides a framework for conducting and reporting process evaluation studies. A process evaluation is a means by which researchers attempt to better understand why an intervention/program/strategy was or was not successful and how any effects were achieved (Escoffery et al., 2016; Francis et al., 2013; Hanley et al., 2016; Moore et al., 2013a; Moore et al., 2013b; Moore et al., 2015; Munro & Bloor, 2010; Murphy et al., 1998; Norman et al., 2016; O’Cathain et al., 2002; O’Cathain et al., 2009a; Rudolf et al., 2006; Volpe et al., 2013; Wilkinson, 2011). Huis et al., 2013, emphasise the importance of undertaking process evaluations as a means of looking inside the ‘black box to ascertain which components of an intervention work well and which work less well’ (Grant et al., 2013; Pope & Mays, 1993; Riley et al., 2005). That said, there appears to be limited guidance on how to undertake a process evaluation, much of the guidance is on the use of qualitative methods alongside RCTs, rather than on the processes to evaluate (De Silva et al., 2014; Grant et al., 2013; Grimshaw et al., 2007; Moore et al., 2012).

A process evaluation should be an integral element of RCTs (Craig et al., 2008a; Craig et al., 2008b; Ellard et al., 2011; Ezendam et al., 2013; Flottorp et al., 2003; Francis et al., 2013; Grant et al., 2013; Hind et al., 2010; May et al., 2007a; May et al., 2007b; Moore et al., 2015; Toroyan et al., 2004; White, 2013). However, Huis et al., 2013, argue that researchers are more likely to publish RCTs that mainly focus on outcomes data (answering the question ‘does it work?’), and rarely publish process evaluation data answering why or how an intervention/program/strategy was successful or why it failed (O’Cathain et al., 2013; Ellard et al., 2011).

The SPARC pilot trial funded by Macmillan Cancer Support focussed primarily on outcomes, not on the processes involved in implementing the intervention (Ahmed et al., 2015). Macmillan Cancer Support agreed to further fund this process evaluation.

An important part of the MRC framework requires an evaluation of the pilot study (Ahmed et al., 2015; Craig et al., 2008a; Craig et al., 2008b; Grant et al., 2013) and a process evaluation of the trial was undertaken during the period 1st February 2013-14th July 2014, in order to elucidate the precise mechanism by which this result came about in this pilot randomised controlled trial (Ahmed et al., 2015).

Process evaluations of trials are particularly appropriate for complex interventions to examine content, implementation and receipt of intervention in depth and how it was conducted and received (Baranowski & Stables, 2000; Brady et al., 2011; Burr et al., 2011; Chandler et al.,

2013; Craig et al., 2013), and are useful in multi-centre trials where the same intervention may be implemented and received in different ways (Oakley et al., 2006; Verwey et al., 2016).

An outcome evaluation does not provide any information about the causal mechanisms and contextual factors associated with variation in outcomes (Moore et al., 2013a). It is therefore now common practice for process evaluations to utilise qualitative methods alongside RCTs to explore participants' attitudes towards, and experiences of, study interventions (Grimshaw et al., 2007). For this reason, a small scale process evaluation was undertaken to elucidate the underlying mechanisms through which the intervention (SPARC) influences outcomes, for whom, why, and under what circumstances (Hartman et al., 2013).

5.1 The use of a qualitative study running alongside an RCT

The UK MRC updated guidance of complex interventions (2008) recommends 'undertaking qualitative research in the early stages and alongside trials to develop an understanding of the intervention under study, and at a later stage to explore why an intervention did or did not work' and to enhance the inferences and interpretations from the RCT (Craig et al., 2000; Craig et al., 2008a; Craig et al., 2008b). Research in this area has gained momentum, and process evaluations of this nature are now common (Blackwood et al., 2010; Bradley et al., 1999; Campbell et al., 2003; Campbell et al., 2007; Dyson, 2010; Lewin et al., 2009; Oakley et al., 2006; O'Cathain, 2009; Riley et al., 2005; Weaver et al., 1996; Wilkinson, 2011; Young et al., 2013). O'Cathain, 2009, argues that 'the use of qualitative methods alongside an RCT allows researchers to highlight the discrepancies arising between the two methods'. The value of combining qualitative research with RCTs in health services research is now widely acknowledged, researchers often cite 'helping to interpret the results of RCT' as a rationale for using qualitative research with RCTs, this is one of the important contributions of qualitative research (O'Cathain et al., 2013). O'Cathain et al., 2015, explores and report 8 rationales for using qualitative research with RCTs based on findings from the QUART study. There is now growing recognition that 'qualitative research methods can reach the parts other methods cannot reach' (Bradley et al., 1999). In the context of this doctoral study, a mixed methods study was considered appropriate and undertaken for reasons of: 1) triangulation (convergence or corroboration); 2) complementary (qualitative method elaborates, enhances or clarifies results of RCT); 3) offsetting (strengths of one method offset weaknesses of the other method); 4) development/expansion (extends breadth and range of inquiry); 5) development of SPARC (as a HNA tool); and 6) comprehensiveness (issue is addressed more fully than either approach alone) (Creswell, 2009; Creswell & Clark, 2010; Tashakkori & Creswell, 2007a; Tashakkori & Creswell, 2007b).

5.2 The use of qualitative interviews in health services research

There are three main types of qualitative interviews used in health services/medical research, namely: 1) structured interviews; 2) semi-structured interviews; and 3) in-depth interviews. Structured interviews, as the name suggests elicit participants' views using a structured

questionnaire; semi-structured interviews make use of open-ended questions (questions/topics for discussion are drawn up in advance); and in-depth interviews usually involve covering one or two issues in much greater detail (Britten, 1995). Qualitative interviews provide useful insights into the lives, experiences and understandings of research participants. However, as with other methods of research, they may be limited to providing only partial understandings of situations (Cheek et al., 2004).

5.3 Semi-structured interviews

The qualitative component of this mixed methods study comprised of semi-structured interviews with patients and health and social care professionals about their experiences of completing SPARC during the trial. The aim was to determine the reasons why the SPARC intervention did not appear to work. A retrospective case note review was also undertaken (presented in **Chapter 4**). The questions/topic guides were used to guide the research process and ensure that key areas are covered using prompts (probes). Semi-structured interviews do have some degree of structure and the use of open-ended questions allows some flexibility for participants to tell their stories (i.e. their understandings and experiences) spontaneously in their own words. During the interview the researcher is able to pursue topics that are relevant to the research question and are of interest to participants, and can delve deeper by asking further questions (Britten, 2006). Interviews are normally audio-recorded and then transcribed (with participants' consent), a one-hour interview can take up to six hours for a simple transcription, and longer if there are interruptions or long pauses during the interview. Field notes are often taken by the researcher (Ritchie & Spencer, 1994).

Payne, 2007, emphasises the importance of the researchers' skills and experience in making sense of not only 'what is said but how it is said, paying particular attention to both the narrative and the non-verbal communication'. Participants must be encouraged to talk freely, in a comfortable and relaxed way. Therefore, it is essential to develop a good rapport, gain trust and co-operation between the researcher and the researched. The strengths (advantages) and the limitations/weaknesses of semi-structured interviews are summarised in **Table 27**.

Table 27: Semi-structured interviews (strengths/advantages and limitations)

Strengths/advantages	limitations/challenges/weaknesses
<ul style="list-style-type: none"> ▪ ‘Face-face interviews: higher response rate vs. postal questionnaires/postal surveys’ ▪ ‘Loose structure/some degree of structure-open-ended questions allow participants to tell their stories spontaneously and in their own words’ ▪ ‘Can deal with confusing questions and address any misunderstandings during interview’ ▪ ‘Interviews can be conducted in participants own language (for those with language difficulties but this has resource implications)’ ▪ ‘Less missing data vs. postal questionnaires/postal surveys’ ▪ ‘May be less demanding than postal questionnaires (some participants may have difficulty writing/reading)’ ▪ ‘Mainly participant-led’ 	<ul style="list-style-type: none"> ▪ ‘Can place extra burden on participants with an advanced or progressive illness who may be too ill and emotionally upset to participate’ ▪ ‘Relationship between researcher and participant may have an impact’ ▪ ‘Distressed/sensitive patients may decline, and some may not wish to be interviewed’ ▪ ‘Open to selection bias and interviewer bias, may influence interview’ ▪ ‘Sex, race, religion, class and educational experiences of researcher may affect interviews’ ▪ ‘Lack of rapport between researcher and interviewer can hinder research process’ ▪ ‘Good listening skills essential, and researcher must facilitate interview in a non-judgemental and non-directive manner’ ▪ ‘Transcription process: involves some element of interpretation’ ▪ ‘Miss non-verbal communication and non-verbal behaviour omitted in audio-recordings’ ▪ ‘Extensive skill and training required’ ▪ ‘Skill and experience of researchers-determines data quality’
<p>Adapted from Bennett, 2007; Britten, 1995; Edwards et al., 2002; Payne, 2007</p>	

5.3.1 Sample size and the concept of saturation

A number of issues can affect sample size in qualitative research, and this is dependent upon researchers’ methodological and epistemological perspective. Many experts agree that the concept of saturation is central to qualitative sampling, i.e. ‘the point at which no further information or themes emerge or are observed in the data and collecting more data does not necessarily generate more information’ (Baker & Edwards, 2012; Guest et al., 2006; Mason, 2010). Guest et al., 2006, argue that while the concept of saturation is useful and helpful at a conceptual level, it provides no indication or guidance on how to estimate sample sizes. The sample sizes of qualitative studies are typically much smaller than those used in quantitative studies (Guest et al., 2006). Some authors have attempted to estimate sample sizes in qualitative studies. Mason, 2010, study looked at a sample of PhD studies using qualitative approaches, they found that the study mean sample size was 31, some suggest a range between 12-16 interviews. A mean sample of 30 interviews required for saturation has also been cited (Baker & Edwards, 2012).

Chapter 6

6 A qualitative study to elicit the views of patients about their experience of completing SPARC

6.1 Abstract

Background

The findings of a pilot randomised controlled trial of a holistic needs assessment questionnaire in a supportive and palliative care service appear to defy the conventional assumption that the use of a validated multidimensional holistic screening tool for supportive and palliative care needs such as SPARC, will lead to improved health care outcomes for patients (Ahmed, 2010; Ahmed et al., 2015). The results of this trial were counter-intuitive and the trial result identified a potential negative effect of SPARC in specialist palliative care services (Ahmed et al., 2015).

This is a qualitative study embedded and running alongside a randomised controlled trial, to elicit the views of trial participants (patients) about their experience of completing SPARC, to help in the interpretation of the trial result (EAPC abstract, 2015).

Methods

As part of a process evaluation, semi-structured interviews were undertaken with a sub-group of trial participants (n=33) referred to the palliative care service in Sheffield (UK). All patients were interviewed after they had completed the study (i.e. 8 weeks from the date baseline questionnaires were received). The interview schedule was designed to provide a description of patients' experience of completing the SPARC questionnaire during the trial, in particular: how they found completing SPARC; what they thought about the SPARC questions; whether anything changed because of completing SPARC; and whether or not they felt that completing SPARC resulted in any actions being taken. Interviews were digitally recorded and transcribed verbatim and analysed using the framework analysis approach (EAPC abstract, 2015).

Findings

Seven prominent themes emerged from the patient interviews, themes were determined largely by the topics of 'predetermined interest' and guided by the interview schedule, these provided useful insights into why the intervention (SPARC) did not work, and highlighted potential areas for improvement. Prominent themes were identified as: **Theme 1:** Ease of SPARC completion; **Theme 2:** Suitability, relevance and sensitivity of SPARC questions; **Theme 3:** Impact of completing SPARC on clinical practice; **Theme 4:** Usefulness and comprehensiveness of SPARC; **Theme 5:** Follow up and monitoring of patients (timing of administering SPARC); **Theme 6:** Information and communication issues; **Theme 7:** Satisfaction with services or care received. Most patients interviewed [30/33], found SPARC

either quite easy to complete, fairly straightforward, simple or had no problems in completing it. Only a small number of participants found questions on SPARC ‘too sensitive or upsetting’. A crucial finding in the context of the trial was the large proportion of patients interviewed [30/33] who did not experience or report any noticeable change, or beneficial effects after completing SPARC (EAPC abstract, 2015).

Conclusions

Overall, participants considered SPARC to be an acceptable and relevant tool for the clinical assessment of supportive and palliative care needs (EAPC abstract, 2015). However, patients’ reports of a failure to act on identified needs would support the conclusion that holistic needs assessment may be potentially harmful if not integrated with a clinical assessment that informs the care plan.

The potential negative effect of SPARC in a specialist palliative care service could be due to the failure of health care professionals to act on identified needs in a timely manner, or related to the raising of patients’ expectations that are not subsequently met (Ahmed et al., 2015). This qualitative study helps in the interpretation of the outcome results, and provides useful insights into how SPARC might be used in practice (EAPC abstract, 2015).

Key Words: Palliative care, holistic needs assessment, SPARC, process evaluation, semi-structured patient interviews, qualitative study.

6.2 Introduction

In the previous Phase of the study (**Chapter 4: outcome evaluation**), I presented the findings of a pilot study of a pragmatic randomised controlled trial to determine whether the use of SPARC leads to improved health care outcomes (health-related quality of life and self-identified concerns) for patients referred to a supportive and palliative care service (Ahmed et al., 2015).

In this Phase 2 (process evaluation), I will present the findings from semi-structured interviews undertaken as part of the wider RCT.

This Chapter explores trial participants' (patients) (n=33) views of completing SPARC, as a further important aspect of the development of the tool and provides useful insights on the implementation, receipt and setting of the SPARC intervention that would help in the interpretation of the outcome results, and guide the development of a definitive multicentre study (Hughes et al., 2015). This is a qualitative study embedded and running alongside a randomised controlled trial, to elicit the views of trial participants (patients) about their experience of completing SPARC.

This Chapter will also review the feedback from the supplementary question about patients' experience of completing SPARC during the trial (Ahmed et al., 2015).

6.3 Methods

Study design

As part of a process evaluation, semi-structured interviews were undertaken with a sub-group of trial participants (n=33) referred to the palliative care service in Sheffield (UK). All patients were interviewed after they had completed the study (i.e. 8 weeks from the date baseline questionnaires were received). The interview schedule was designed to provide a description of patients' experience of completing the SPARC questionnaire during the trial, in particular: how they found completing SPARC; what they thought about the SPARC questions; whether anything changed because of completing SPARC; and whether or not they felt that completing SPARC resulted in any actions being taken. Interviews were digitally recorded and transcribed verbatim and analysed using the framework analysis approach (EAPC abstract, 2015).

This qualitative methodology is particularly useful in identifying themes on topics of 'predetermined interest' and has the flexibility to capture themes in other related areas of interest.

I developed the patient interview schedule (**Appendix 24**) with help from other members of the research team that comprised of experienced qualitative researchers, a palliative medicine

consultant, and two consumers. The interview schedule was piloted with a member of the research team.

Supplementary question on patient experiences of completing the SPARC questionnaire

As part of the follow up procedure, all patients were asked to complete a supplementary question on their experience of completing the SPARC questionnaire; *“Please tell us about your experience of completing the SPARC questionnaire”* The supplementary question on experience of completing SPARC was part of the questionnaire booklet that was sent out four weeks after completed SPARC questionnaires were received. For the intervention group this was at week 4, and for the control group this was at week 6 (**Table 12**) (Ahmed et al., 2015).

6.3.1 Patient recruitment and demographics

How participants were identified and who was invited to participate

Semi-structured interviews were conducted with a sub-group of trial participants using purposive sampling (i.e. patients who had taken part in the main trial who had been referred to the palliative care service and those that met the study inclusion criteria). The inclusion and exclusion criteria for recruiting patients to this study, is presented below (also presented in **Chapter 4**).

Trial participants

Inclusion criteria

- 1) Any diagnosis (cancer and non-cancer).
- 2) Any referral to the palliative care service in any care setting.
- 3) Patients 18 years old or above.
- 4) Patients able to give informed consent.

Exclusion criteria

- 1) Patients incapable of giving informed consent.
- 2) Patients incapable of completing SPARC even with the help of a relative or informal carer.
- 3) Patients under 18 years old.

The method that I used to identify patients for semi-structured interviews (i.e. how participants were identified and who was invited to participate is described in more detail below).

Patients taking part in the main trial were also invited to take part in a follow-up interview about their experiences of completing SPARC, and reference to this was made in the initial patient information sheet sent out in the study invitation pack (as described in **Chapter 4**).

An invitation letter (**Appendix 25**), a patient opt-in form (**Appendix 26**) for taking part in semi-structured interviews and a consent form (**Appendix 27**) was initially sent to all patients (two weeks after they had completed the SPARC questionnaire) and placed inside the questionnaire pack which contained MYCAW, EQ5D and PEI (2 week questionnaires). For the intervention group this was at week two, and for the control group this was at week four, as shown in **Table 12**.

Table 12: Study follow-up procedure (questionnaire completion at 2-week intervals) (Ahmed et al., 2015, also presented in **Chapter 4**)

Baseline	Randomisation	
	Group A intervention group	Group B waiting-list control
	MYCAW; EQ-5D; PEI SPARC	MYCAW; EQ-5D; PEI
Two weeks	MYCAW; EQ-5D; PEI [Invitation for patient interview]	MYCAW; EQ-5D; PEI SPARC
Four weeks	MYCAW; EQ-5D; PEI plus supplementary question on experience of completing SPARC	MYCAW; EQ-5D; PEI [Invitation for patient interview]
Six weeks	MYCAW; EQ-5D; PEI	MYCAW; EQ-5D; PEI plus supplementary question on experience of completing SPARC
Eight weeks	Case Note Reviews Semi-Structured Interviews with Patients Semi-Structured Interviews with Health Care Professionals	

SPARC: *Sheffield Profile for Assessment and Referral for Care*

MYCAW: *Measure Yourself Concerns and Wellbeing*

EuroQoL (EQ-5D): *Standardised outcome measure of Health Related Quality of Life*

PEI: *Patient Enablement Instrument*

(Ahmed et al., 2015)

The completion of the opt-in form indicated that the participant would be willing to be contacted by a researcher about taking part in an interview, and participants were asked to provide contact details (name, address, phone number, email address) and a good time to contact them. Those patients (inpatients, outpatients and community care patients) expressing an interest in taking part completed the enclosed opt-in form, signed the consent form, and returned them in a freepost envelope provided (addressed to the research team). The consent

form was completed when I went out to interview; for those patients that had not returned the signed and completed consent form in the freepost envelope. Inpatients also had the option of returning the reply form and opt in form to any health care professional that was caring for them, and a procedure was in place so that health care professionals would inform researchers of all completed reply forms and for researchers to collect these forms from the health care professionals. Upon receiving the completed opt-in form, I contacted the participant by phone to arrange a suitable date, time and place that was convenient to the participant to conduct the interview. Recruitment of patients for the purposes of the interview continued until saturation was achieved, and also when sufficient numbers of patients representing the different groups of patients were recruited (i.e. cancer, non-cancer, long-term conditions, and end of life care), at which point no further invitations for interview were sent out. There were no patient drop-outs during this stage. All interviews were audio-recorded with permission of the participants and field notes were kept. All participants had the option of withdrawing from the interviews at any time without giving any reason, and without their medical care or legal rights being affected. Participants were also made aware that researchers would be accessing their clinical/medical records.

Characteristics of patients and their interviews (n=33) are described below.

6.3.2 Setting and sample

Characteristics of patients and their interviews (n=33)

Thirty-three patient interviews were undertaken between May 2011 and February 2012 (Interviews took place between 16/5/2011 and 16/2/2012).

Response saturation was achieved with the interview of thirty-three patients. Interviews were undertaken at a location that was convenient to the participants; all 33 interviews were undertaken at patients' homes (EAPC abstract, 2015).

Nineteen of thirty-three participants were female, and 14/33 participants were male. The mean age of participants was 63 years old (range 34-83 years), the majority of patients had a diagnosis of cancer, with 29/33 participants with a 'cancer/malignant diagnosis', and 4/33 participants with a 'other non-cancer diagnosis' (EAPC abstract, 2015). The year of diagnosis ranged from 1984-2011. I undertook 26/33 of the patient interviews, and my colleague MW undertook 7/33 of the patient interviews. The mean interview duration was 12.95 minutes (range 3.18-46.18 minutes). The majority of participants interviewed were cancer survivors; (19/33); some were categorised as having end of life care cancer; (9/33); and some as having a long-term condition; (5/33). The characteristics of participants and their interviews are summarised in **Table 28**.

Table 28: Characteristics of patients and their interviews (n=33)

Patient ID Number	Gender	National Diagnosis Code	Interviewer's name	Length of interview (minutes)	Care received upon referral: 1. EOLC cancer 2. EOLC non-cancer 3. Cancer survivor 4. Long-term condition
BM001	F	Other Non-Cancer Diagnosis	NA	7.27 minutes	4
BM002	F	Cancer/Malignant Diagnosis	NA	27.33 minutes	3
BM009	F	Cancer/Malignant Diagnosis	NA	6.43 minutes	1
BM021	M	Cancer/Malignant Diagnosis	MW	14.15 minutes	3
BM028	M	Cancer/Malignant Diagnosis	MW	5.05 minutes	1
BM033	F	Other Non-Cancer Diagnosis	NA	12.00 minutes	4
MA001	F	Cancer/Malignant Diagnosis	NA	14.21 minutes	3
MA006	F	Other Non-Cancer Diagnosis	NA	5.48 minutes	4
MA012	F	Cancer/Malignant Diagnosis	NA	15.05 minutes	1
MA014	F	Cancer/Malignant Diagnosis	NA	23.50 minutes	3
MA015	F	Cancer/Malignant Diagnosis	NA	10.57 minutes	3
MA024	F	Cancer/Malignant Diagnosis	NA	18.16 minutes	3
MA025	F	Cancer/Malignant Diagnosis	NA	10.18 minutes	4
MA026	M	Cancer/Malignant Diagnosis	NA	11.36 minutes	3
MA029	F	Cancer/Malignant Diagnosis	NA	10.00 minutes	1
MA033	M	Cancer/Malignant Diagnosis	NA	10.41 minutes	1
MA039	M	Cancer/Malignant Diagnosis	NA	46.18 minutes	3
MA046	F	Cancer/Malignant Diagnosis	MW	13.16 minutes	3
MA047	F	Cancer Malignant Diagnosis	MW	8.38 minutes	1
MA057	F	Cancer/Malignant Diagnosis	NA	13.02 minutes	3
MA058	M	Cancer/Malignant Diagnosis	NA	9.08 minutes	3
MA060	M	Cancer/Malignant Diagnosis	NA	12.30 minutes	3
MA061	M	Cancer/Malignant Diagnosis	NA	3.18 minutes	3
MA064	F	Cancer/Malignant Diagnosis	NA	10.09 minutes	3
MA065	M	Cancer/Malignant Diagnosis	NA	30.42 minutes	1
MA070	M	Cancer/Malignant Diagnosis	NA	14.40 minutes	3
MA071	M	Cancer/Malignant Diagnosis	NA	6.58 minutes	1
MA090	M	Cancer/Malignant Diagnosis	NA	3.53 minutes	3
MA091	F	Cancer/Malignant Diagnosis	NA	8.58 minutes	3
MA093	M	Other Non-Cancer Diagnosis	MW	12.55 minutes	4
MA098	F	Cancer/Malignant Diagnosis	MW	12.24 minutes	1
MA100	F	Cancer/Malignant Diagnosis	NA	6.15 minutes	3
MA102	M	Cancer/Malignant Diagnosis	MW	16.21 minutes	3

NA: Nisar Ahmed, MW: Michelle Winslow

Interview data was examined qualitatively using a Framework Analysis approach (Ritchie & Spencer, 1994), and a summative content analysis was used to analyse feedback from the supplementary question on patients' experience of completing SPARC (Ahmed et al., 2015; Graneheim & Lundman, 2004; Hsieh & Shannon, 2005).

6.4 Data analysis (the framework approach)

The interview schedule was designed to provide a description of patients' views about their experiences of completing the SPARC questionnaire, in particular: how they found completing the SPARC questionnaire; what they thought about the SPARC questions and whether or not they felt that completing the SPARC questionnaire resulted in any change or actions being taken by the clinical staff; as well as any other comments they had about SPARC or in general. Interviews were digitally recorded and transcribed verbatim and analysed using the framework analysis approach (EAPC abstract, 2015). A full description of the framework approach is presented below. An example of a coded verbatim patient interview transcript is presented in **Appendix 28**, the coding framework (theme headings, subheadings and code numbers) is presented in **Table 30**, and an example of a patient thematic Chart is presented in **Appendix 29**. Field notes were also kept.

Some authors support the use and reporting of numbers in qualitative research as these can 'complement and enhance narratives in order to generate significance and meaning' (Olson, 2000; Sandelowski, 2001). The use of numbers is particularly useful in the context of this study (process evaluation).

6.5 Framework analysis

'Framework' analysis is a method for analysing qualitative data that was developed during the 1980's by social policy researchers at the National Centre for Social Research (UK's largest independent not-for-profit research institute) (Ritchie & Spencer, 1994; Smith & Firth, 2011; Ward et al., 2013). This pragmatic analytical approach allows researchers to organise and manage large volumes of qualitative data in a rigorous, transparent and systematic manner, and is used by researchers in a wide range of disciplines, such as health related research, policy development and program evaluation. The systematic process of data sifting, charting and sorting, and the subsequent categorisation of data according to key issues, themes and sub-themes are the key features of this method of analysis, hence giving rise to the term 'framework', which is derived from the term 'thematic framework'. The analytical process comprises of five distinct, but highly interconnected stages of data analysis, leading to the development of a robust and flexible grid structure or matrix, constructed by data that is summarised and presented in the form of themes, sub-themes (in columns), against participants (in rows). Thus, facilitating exploration of complex relational data at many different levels (both within and between comparisons), and allowing research questions to be answered. The 'framework' approach has undergone refinement and further development over the years, but the general underlying principles remain the same (Ritchie & Spencer, 1994). For these reasons, the 'framework' analysis approach was considered the

most appropriate choice for the analysis of the qualitative data generated from the transcripts of the semi-structured interviews of patients and health care professionals, interviewed during the study. The strengths and weaknesses of the ‘framework’ approach are presented in **Table 29**.

Table 29: The strengths and weaknesses of the ‘framework’ approach

Strengths	Weaknesses
<p>‘Relatively straightforward form of qualitative analysis’ (Braun & Clarke, 2006)’. ‘Flexible approach in dealing with large volumes of complex data’. ‘Follows a systematic and well defined procedure, following a particular order and with logic steps, analytical process is documented, accessible, retaining links to original data set’ (Ritchie & Spencer, 1994). ‘Flexibility and good documentation of the procedure offers analyst to revisit, and reconsider or rework earlier or initial ideas’.</p> <p>(Adapted from Gale et al., 2013; Ritchie & Spencer, 1994; Ward et al., 2013).</p>	<p>‘There is a certain degree of subjective judgement required by the analyst about meanings, the importance or prominence and connections that need to be made’. ‘Despite the systematic, rigorous, and disciplined nature, the process does not provide a ‘fool-proof method’ with a guaranteed outcome’. ‘Time-consuming and resource-intensive’</p> <p>(Adapted from Gale et al., 2013; Pope et al., 2000; Ritchie & Spencer, 1994).</p>

A description of each stage in the ‘framework’ analytical process that I followed is described below (Gale et al., 2013; Ritchie & Spencer, 1994; Ward et al., 2013).

6.5.1 Stage 1: Familiarisation

The familiarisation stage is an important first stage which takes place prior to the process of sifting and sorting data. This stage requires the analyst to listen to the interviews and read through the material (transcripts) collected in order to become familiar with the range and diversity of the data collected, hence the name familiarisation stage. During this stage key ideas and initial themes as well as any recurrent themes or emerging concepts are identified (such as attitudes, behaviours, motivations, views etc.). It is not compulsory at this stage to review the entire dataset, however a sufficient examination of the material gives the analyst a more thorough overview and a feel for the material collected as a whole. It is advisable to review the overall aims and objectives of the research at this point (Ritchie & Spencer, 1994).

6.5.2 Stage 2: Identifying a thematic framework

Stage two involves the development of a ‘thematic conceptual framework’ or ‘index’, which is constructed using the recurrent themes identified during the familiarisation stage and/or

issues introduced into the interview using the topic guide/questionnaire. During this stage themes/concepts identified are further sorted and grouped into a smaller number of broader categories ('higher order categories' or 'main themes'), which may be identical to the interview questioning or newly developed from emerging themes and placed within an overall thematic framework. Thus this stage, compared to stage one involves a more careful and detailed examination and arrangement of data by themes/concepts identified. The process of devising and refining a thematic framework typically involves the analyst to draw inferences from the dataset, and making certain level of judgements about the meaning of the data, it's relevance and importance, as well as establishing any connections between emerging themes/concepts and ideas. It is important at this stage to go back to the original research questions, and ensure that they are being fully addressed (Gale et al., 2013; Ritchie & Spencer, 1994; Ward et al., 2013). The final coding framework (theme headings, subheadings and code numbers) that I developed from the patient interviews is presented in **Table 30**.

6.5.3 Stage 3: Indexing (labelling or tagging the data)

The next stage is called 'indexing' and involves labelling or tagging the data on margins of each transcript against each paragraph/sentence using a numerical system, which should link back to the index (similar to an index found at the back of text books). During this stage the transcripts are re-read and numerically coded by themes and the thematic framework constructed in stage two is systematically applied to the entire dataset. This stage, as with stage two is regarded as a highly subjective process and once again the analyst is required to draw conclusions about meaning, importance and significance of material collected prior to applying an index which can be applied either manually or electronically. At this stage it is advisable to review the preliminary thematic framework, which may need further refinement (i.e. addition or deletion/collapsing of categories and subcategories) following initial application to the data. It is advisable to record any revisions made to the index during this stage for consideration during the latter stages of analysis (Ritchie & Spencer, 1994). An example of a patient interview transcript that I coded is presented in **Appendix 28**.

6.5.4 Stage 4: Charting (thematic charting)

Having applied a thematic framework, indexed, labelled and tagged the entire dataset, this stage requires the analyst to explore and review the pattern and range of responses for each issue or theme identified across the whole dataset. 'Charting' or 'thematic charting' involves 'lifting' the data from the original transcript and rearranging it and placing it in a chart according to the appropriate thematic reference. Charts are constructed using the headings and subheadings of the thematic framework or from a priori set of questions which are presented in the columns of the matrix, against each respondent presented in rows in the matrix. This is another critical stage in the analysis, again requiring a certain level of judgement about the amount and content of the material to chart, without losing content, context and importance of the material being charted, and retaining language of the respondent. The content and context of the charted data should be sufficient enough to allow

understanding of the point being made without having to go back to the original transcriptions. At this point it is advisable to make a note of the page number of the transcript against all the data that is ‘lifted’ from the original transcripts, thus allowing the analyst to go back, and so retaining the link to the original dataset should the need arise (Gale et al., 2013; Ritchie & Spencer, 1994; Ward et al., 2013). An example of a patient ‘charting/thematic charting’ table that I developed during this stage is presented in **Appendix 29**.

6.5.5 Stage 5: Mapping and interpretation (mapping, linking and interpreting the whole dataset)

The final stage of the analysis regarded as perhaps the most difficult stage of the analytical process, involves summarising and synthesising or interpreting the whole dataset, this being the stage at which the key objectives of qualitative analysis are addressed. During this key stage the analyst is comparing and contrasting data, highlighting key concepts and ideas, and searching for patterns, connections, motivations, associations and seeking explanations, and taking a step back and looking at the dataset in its entirety in order to draw the necessary conclusions (Ritchie & Spencer, 1994).

The familiarisation phase and the initial thematic analysis, development of themes and sub-themes was conducted by myself, and then examined by another experienced qualitative researcher (KC). I listened to each patient interview audio-recording, checking for any errors in the verbatim transcript; listening to an interview audio-recording also facilitated the analysis.

In order to minimise any bias, and improve the reliability of the analysis, 20% (7 out of 33) of the patient interview transcripts were independently coded and charted by two experienced qualitative researchers (NA and KC). Subsequent detailed discussions of the analysis optimised consistency and agreement within interpretation and the development of themes, as an on-going process throughout the data analysis.

6.6 Transcription conventions

Any words appearing between two square [] brackets indicate where I have added notes of clarification. Ellipsis points [...] indicate where I have abridged a quotation or omitted some words. All quotations presented in the findings section have been indented. Following each quotation, the trial participant’s identification number is reported. This is followed by the page number (s) of the original interview transcript from which the extract/quotation has been ‘lifted’.

6.7 Emergence of seven prominent themes

Initially the coding framework (**Table 30**) identified five main themes and 18 sub-themes headings (determined largely by the topics of predetermined interest). These included: ease of

SPARC completion; suitability, relevance and sensitivity of the SPARC questions; changes or any actions taken as a result of completing SPARC; usefulness of completing SPARC; timing of administering SPARC, and issues relating to follow-up and monitoring of patients and other general comments.

However, upon closer examination the themes and subthemes that were determined largely by the topics of 'predetermined interest' were collapsed into seven prominent themes, which provided useful insights into why the intervention (SPARC) did not work, and other potential areas for improvement.

Theme 1: Ease of SPARC completion;

Theme 2: Suitability, relevance and sensitivity of SPARC questions;

Theme 3: Impact of completing SPARC on clinical practice;

Theme 4: Usefulness and comprehensiveness of SPARC;

Theme 5: Follow-up and monitoring of patients (timing of administering SPARC);

Theme 6: Information and communication issues;

Theme 7: Satisfaction with services or care received.

Table 30: Coding framework (patient interviews): Theme headings, sub-headings and code numbers

PATIENT ID					
EASE OF SPARC COMPLETION	<p>1) <u>Quite easy/fairly straightforward/no problems completing</u> <i>How patients found completing the SPARC questionnaire: easy, straightforward/no problems completing, answered truthfully/dishonestly.</i></p>		<p>2) <u>Quite difficult/difficult</u> <i>How patients found completing the SPARC questionnaire: Quite difficult/difficult, hard to fill in.</i></p>		
SUITABILITY, RELEVANCE AND SENSITIVITY OF SPARC QUESTIONS	<p>3) <u>Suitable/appropriate/relevant</u> <i>What patients thought about the questions: questions were suitable/appropriate/relevant.</i></p>	<p>4) <u>Not relevant/not applicable</u> <i>Felt questions on SPARC/SPARC questionnaire not relevant/not applicable.</i></p>		<p>5) <u>Inappropriate/too personal/sensitive</u> <i>What patients thought about the questions: questions were inappropriate/too personal/sensitive/invasive/offensive/upsetting/bothering</i></p>	
CHANGES OR ANY ACTIONS TAKEN AS A RESULT OF COMPLETING SPARC	<p>6) <u>Actions: referrals/consultations</u> <i>Did completing SPARC result in any actions taken (for the better/for the worse): resulting in referrals being made/consultations being undertaken?</i></p>	<p>7) <u>Actions: interventions (treatment/care)</u> <i>Did completing SPARC result in any actions taken (for the better/for the worse): in relation to changes in intervention/s, treatment/care?</i></p>		<p>8) <u>Nothing changed/no action/no beneficial effect</u> <i>Completing SPARC resulted in no noticeable changes in actions taken (for the better/for the worse) in relation to referrals, consultations, changes in intervention/s, treatment/care?, no beneficial effect/s observed (possible reasons).</i></p>	
USEFULNESS OF COMPLETING SPARC	<p>9) <u>Helpful/worthwhile completing/good idea</u> <i>Reasons why completing SPARC was or could be useful: helpful/worthwhile completing/good idea.</i></p>	<p>10) <u>Unhelpful/not worthwhile completing/not so good idea</u> <i>Reasons why completing SPARC wasn't or could not be useful: unhelpful/not worthwhile completing/not so good idea.</i></p>		<p>11) <u>Impact of completing SPARC on others (e.g. family/carer/s)</u> <i>The impact of completing SPARC on other people (e.g. family/carer/s).</i></p>	
TIMING OF SPARC, IMPORTANCE OF FOLLOW UP AND MONITORING OF PATIENTS	<p>12) <u>Timing of SPARC/who should get it</u> <i>Timing of SPARC: when, how, and to whom SPARC should be given?</i></p>		<p>13) <u>Importance of follow up and monitoring of patients</u> <i>The importance of follow up and monitoring of patients.</i></p>		
OTHER GENERAL COMMENTS	<p>14) <u>Comments on missing questions/depth of questioning/ ambiguous/confusing questions/ SPARC format, categories/scales/layout</u> <i>SPARC missed important things/questions, comment on depth of questioning (too simple/too lengthy), any ambiguous/confusing questions, comments on SPARC format, categories/scales/layout.</i></p>	<p>15) <u>Information and communication issues</u> <i>General information and communication issues arising.</i></p>	<p>16) <u>Comments about service/care received/availability of services</u> <i>General comments about service/care received/availability of services.</i></p>	<p>17) <u>Participated to help others/advance research</u> <i>Motivations/reasons for taking part in the research: to help others/advance research.</i></p>	<p>18) <u>Unsure why patients were asked to take part in the study/what was required/how SPARC would be useful</u> <i>Confusion as to why patients were asked to take part in the study/what was required/how SPARC would be useful.</i></p>

6.8 Findings

6.8.1 Theme 1: Ease of SPARC completion

Most patients interviewed [30/33] said that SPARC was either quite easy to complete, fairly straightforward, simple, or they had no problems in completing it.

'...Perfectly straightforward, ...only took about a minute to complete, ...was a case of tick, tick, tick, scribble that's it, ...tick the boxes it was very, very straightforward, far more straightforward than I anticipated' [Patient ma100, p114].

Several patients [3/33] said that they found the questions quite difficult or emotionally difficult.

'...Very emotionally hard makes you focus on the things that you are concerned about, can't do whatever it is you are finding problematic. So there's two different levels to that so is it difficult?; no, as a task?, it's difficult emotionally?; yes. ...I never thought about that I'm going to lose my independence, what they are saying now?, ...if you are already frightened' [Patient bm033, p19, p20].

Some patients [2/33] in this group indicated that it was difficult to score the questions.

'Sometimes bit hard to fill in the questions, ...how do you feel?, I don't know?, shall I put three or shall I put two cos you are thinking do I really feel like this or that is very much?, quite a bit?' [Patient ma029, p52].

One patient said that although she wasn't troubled by SPARC, there was always the option of not completing it.

'...I wasn't fazed by it, It didn't trouble me...If I found my mind wandering I used to put it in a drawer and close it' [Patient ma024, p42].

6.8.2 Theme 2: Suitability, relevance and sensitivity of the SPARC questions

Over a third of patients [13/33] interviewed regarded the questions on SPARC to be either, suitable, appropriate, or relevant and applicable.

'Yes...it seemed to mention anything anybody might be feeling...you should get a good an all-round picture..' [Patient bm009, p11].

Several patients [5/33] felt that the SPARC questionnaire or questions on it were either not relevant, not applicable, or becoming less relevant.

'Did me head in to be honest, ...some of them don't seem relevant, ...I answered best I can...' [Patient ma064, p88].

Several patients [5/33] found some of the questions (e.g. religious and spiritual issues, worrying thoughts about death and dying) on SPARC too personal, inappropriate or sensitive.

'...I couldn't relate to the one about, religion, religious and spiritual issues; worrying thoughts about death. I suppose there would be some people because they had cancer that's right yes, would think about death' [Patient ma024, p42].

'...I don't like the ones about the dying and they stressed me a little bit, I like to try and keep positive of course and feel that I can beat this hopefully, and not look at that part really. I try not to talk about that much. It was mainly that..., yes you are always thinking about that (death and dying) all the time of course and then you go off the subject and you think no I'm not going to die, I'm going to look positive and I'm going to be okay, to carry on and try to forget it again and keep busy...' [Patient ma029, p52].

Some patients said that they had answered other questionnaires that were a lot more personal than SPARC.

'...I have answered other questionnaires that have been a lot more personal than this, I don't really find this personal in comparison with other things I have done' [Patient bm001, p1, p2].

Those patients that did have thoughts about death and dying talked about the various coping mechanisms or strategies for dealing with those thoughts.

'No (sensitive/personal) ..., I don't mind at all..., yes I'm okay (with being asked about questions on psychological issues)...I have people around me that give me moral support...' [Patient ma098, p112].

'...had I had any thoughts about death or dying?,...I was a Chaplain at the hospice for fifteen years, so I've seen plenty of death and dying and as you can gather by that I'm a very religious man..., well I've had thoughts but it hasn't bothered me. I'm a believer and, I believe that sooner or later whichever one of us goes first we will meet again, and that's why I've written it here not at all, but that doesn't mean I've had no thoughts whatsoever, it just means that I'm happy with my thoughts' [Patient ma102, p116].

In contrast, other patients in this group felt that although some questions might be sensitive and upsetting, this doesn't mean it's wrong to ask them.

'...they might be sensitive and they might be upsetting, that doesn't mean it's wrong to ask them' [Patient bm033, p19].

The consensus view was that these questions do need to be asked in order to learn and to help other people in the future.

'No, no, no (sensitive/personal)...if they don't learn they don't know things do they?, so you know that's alright' [Patient ma014, p32].

'No not really (sensitive), well you need to know them things to help people in future that's why I did it, people must have done things in past to help me, so I just help other people' [Patient ma061, p86].

6.8.3 Theme 3: Impact of completing SPARC on clinical practice

Most patients interviewed as part of the main trial [30/33] felt that nothing had changed as a result of completing SPARC, i.e. patients did not experience any noticeable, beneficial effects after completing SPARC (EAPC abstract, 2015).

'...and for me they don't seem to be doing anything, but if they do I don't know...they don't tell us anything' [Patient bm021, p13].

'Well at the moment I don't really feel anything has changed...I've still got problems (in the arm) which, hasn't been sorted, getting me down a lot...because it won't go down the swelling' [Patient ma029, p53].

Various reasons were given for the perception that nothing had changed or no action had been taken as a result of completing SPARC, these together with illustrated comments are presented in **Table 31**.

Table 31: Possible reasons why no beneficial effect was seen as a result of completing SPARC (patients' views)

Possible reasons why nothing changed, no action taken, or no beneficial effect seen as a result of completing SPARC	Illustrative Comments
Not seen by a palliative care health professional, not heard from anyone, or had no follow-up appointment throughout the duration of the study	<i>'I've not heard anything since I've completed the last form, not heard anything from anybody, no' [Patient ma012, p29].</i>
Didn't want to bother the health professionals (there were more deserving patients than them, or that they didn't consider themselves to be terminal)	<i>'...I wasn't thankfuly terminal last year..., must be more deserving patients: who are needing this time than me, I've been through the whole system before' [Patient ma026, p50, p51].</i>
Saw this as a research study	<i>'Really good idea, ... if it does get followed up,...a lot of questionnaires..., you fill it out and that's it, it's used for research and there's nothing that sort of comes from it..., and people to get help that need help...' [Patient bm001, p3, p4].</i> <i>'...as far as I know these go to the University, so such as Dr S wouldn't have seen this, so there wouldn't be any changes...' [Patient ma058, p81].</i>
Study follow-up period (6 weeks) is too short	<i>'... perhaps six weeks is too short' [Patient ma065, p93].</i>
Discharged from the palliative care service	<i>'... I'm not seeing him anymore now, he's discharged me cos... nothing else, I can have done' [Patient ma061, p86].</i> <i>'... LP (health professional), signed me off, ... she said if we need her at all then she will be there' [Patient ma033, p56, p57].</i>
'Open appointment' system (although patients were discharged from the service, they could still contact the health care professional via the 'open appointment' system)	<i>'...I might go nine months now without seeing him..., I can go whenever I want to see him' [Patient ma057, p78].</i> <i>'... as long as I make an appointment,... having the same conversation every time I go and nothing really is happening, so I did say to him [health professional] we've tried everything, would it be alright if we left things until they may have got an idea of a different avenue to explore and rather than me just go back and have the same old, same old, ... he said just leave the appointment open' [Patient ma057, p78].</i>
Nothing more could be done	<i>'...he basically said there is nothing he could do and he's now passed me back to Dr J..., Dr J... is gonna pass me down to Nottingham... I have sort of come to terms with the fact that I'm not gonna be how I was...' [Patient bm001, p2, p3].</i> <i>'... he ses there was nothing more they could do just yet...' [Patient bm021, p15].</i>
Tried everything	<i>'...It was about December, referred to by the haematologist but tried me on all different things nothing didn't work but prior to that I had been to (hospital name) with NP (health professional), ... so he tried first and tried all things even acupuncture, but then I went and saw A (health professional) and told him everything and he tried virtually everything but nothing you know from</i>

	<p><i>creams to different tablets,... the anti-depressant... didn't work...'</i> [Patient ma060, p83].</p> <p><i>'...he tried a number of things most of which made me iller than I already was...'</i> [Patient bm033, p19].</p>
Any improvements had plateaued	<i>'... I've gradually improved but I've got to a limit, ...but it's plateaued...'</i> [Patient ma039, p60].
Problems untreatable or treatment not available	<p><i>'The biggest...problem I've got which finally stopped me going to work about ten days ago is this chronic perianial pain..., the pain problem it seems to be untreatable...I don't think anything helped apart from the whole half a day of being cared for...'</i> [Patient ma026, p50].</p> <p><i>'... I don't think they can do chemotherapy at the moment because there isn't one available, ... maybe some treatment was available or some trials in the future then maybe I would be able to go on a trial otherwise, there is nothing much they can do really...'</i> [Patient ma029, p53].</p>
Got to a 'dead-end'	<i>'...we've got to dead end... we've tried things that's going round and round in a circle...'</i> [Patient ma029, p54].
Learned to live with it, accepted it, or adapted to illness due to long-standing issues	<p><i>'... I've had fifteen years of learning of in depth looking at myself, learning how to pick myself up and how to kick myself up the backside and make myself shift from the position of, oh woe is me because oh woe is me is for emergency situations, you can't live your life oh woe is me, cos you end up ill, I mean really ill...you have to live with disabilities, and with the on-going side effects...'</i> [Patient bm002, p10].</p> <p><i>'I have sort of come to terms with the fact that I'm not gonna be how I was'</i> [Patient bm001, p3].</p>
Not been that ill, not had any problems, not needing anything, managing illness quite well, or had stable disease	<p><i>'I haven't had a lot of problems (stable disease), perhaps somebody with more problems than me, they might sit up and think, but of course you have got to go across the board when you doing something like this, and of course not everybody will fill it in'</i> [Patient ma024, p43].</p> <p><i>'...my GP who I'm seeing tomorrow, about two months ago said he didn't think I needed to see the palliative care nurse as I was, as he said managing a chronic illness perfectly well...'</i> [Patient ma015, p40].</p>
Health professionals unable to find out what was wrong	<i>'I was going at one stage to about seven or eight different clinics... I was going and a lot of this pain... they couldn't find anything wrong with me, it was just was numb...'</i> [Patient ma025, p47].

Several patients [3/33] said that the completion of SPARC resulted in either, referrals being made or consultations being undertaken in the form of a follow-up call.

For two of the patients in this group, completing SPARC initiated a follow-up call from a Macmillan Nurse or a health care professional following high level scoring of SPARC, which in turn initiated a discussion about the issues raised.

'I said to the palliative care nurse, I told them, I'm thinking about how I'm going to die, I said are they going to be rushing round and get me sectioned for self-harm?' [Patient ma015, p38].

'... I did get a follow-up call from...the Macmillan Nurse contact (for one of the concerns), to discuss some of the aspects on the form,...cos, it raised a red flag because I had marked a number three on the form, so we had a frank discussion about it,...proved to be really helpful,...I probably wouldn't have raised it with a GP but by raising it on the form it did enable me to get some additional help you know which was good. ...yes so something did change, and it made me reflect on what I'd written, enabled me to have some help...' [Patient ma046, p69].

And for one patient in this group this resulted in a request for a referral being made for bereavement support even though the patient didn't think that it would be beneficial.

'Dr N referred me (for bereavement support), Dr N seems to think I should be feeling better than I am, but I don't know what the answer is,...Dr N who is lovely, seems to think it's all from bereavement of my husband, I'm not in agreement with him, I think it's because I'm lonely, that's top and bottom of it. See it's just a flat and no one comes, well I've got family, neighbours, everybody keeps themselves to themselves, you just close the door and it's...but what can they do about it?' [Patient ma006, p27].

Others said that they did not feel neglected, and felt reassured that help would be available if things deteriorated.

'...I'm sure I'm not being neglected' [Patient ma001, p25].

'Well I do believe if your health deteriorates or if I ring them up and say I feel really shocking they may let me go in for respite for a week...' [Patient ma039, p62].

None of the thirty-three patients felt that anything had changed in relation to changes in intervention, treatment or the care that they received following completion of SPARC.

6.8.4 Theme 4: Usefulness and comprehensiveness of SPARC

Just over a half of the sample of patients interviewed [18/33] gave reasons as to why they felt that SPARC was either helpful, worthwhile completing, or a good idea. These are presented below under relevant headings with illustrative quotations.

Adequate questionnaire that covers most things: Most patients within this group talked about SPARC being an adequate and comprehensive needs assessment questionnaire that identifies needs or concerns which perhaps would otherwise not be picked up.

'...I think its brilliant...a professional get to know what the patient needs, there are so many little bits and pieces, personal issues your care your treatment, these depending on the individual, they might need quite a lot of these sort of things...nobody would pick these things up, perhaps things aren't picked up..., perhaps not picked up full stop...' [Patient ma065, p94].

Someone decided to listen, felt like I had been forgotten, and neglected: Some patients within this group who previously felt neglected were pleased that someone was keeping an eye on them, and was listening.

'I couldn't believe somebody is listening to me...I've had my body battered and I'm just left...now and somebody's decided to listen' [Patient ma057, p75].

Time for reflection: For some patients the completion of SPARC was a time for reflection, and made them think more about the illness, or about palliative care and complementary therapy.

'...Made me think more about my illness, and more about palliative care and complementary therapy...' [Patient ma012, p28].

Makes you more interactive/proactive: Several patients among this group said that completing SPARC made them more interactive or proactive, and they were now more likely to get in touch with somebody for help.

'...main thing that's changed is I'm more likely to ring up more if I think I need some help, whereas I've been prone to forget it...I've always been a bit like don't bother anybody...it's made me look at that more but not to leave things, and get you know get in touch with somebody...' [Patient ma012, p29].

Writing things down versus verbal communication: Several respondents talked very positively about being given the opportunity to write things down on paper.

'...I've always been positive and to actually see things like this, and where it's all worded down you know feeling weak, feeling tired you know,...anxious, low mood, confused all these psychological issues, I've got no problems with them at all and it was nice, it was good to see that because I could put down in writing,...it doesn't worry me that side of it...' [Patient ma060, p84].

Some patients among this group said that they found it easier to put down their thoughts (especially about personal issues) and express their concerns on paper rather than speaking to someone.

'...I found it easier to sort of put my thoughts down on paper, rather than speaking to someone about it to be honest with you' [Patient ma046, p69].

'...it just felt easier...to put concerns down, that were quite personal...'[Patient ma046, p69].

While other patients among this group talked about SPARC being a useful prompt or aide-mémoire that was particularly useful for those patients that have undergone intensive treatment.

'Some of the questions you see on here, you kind of forget, my treatment was so intense,...it actually causes memory loss,...it prompts to remind you about things that you have got, pain, loss of memory, dry mouth, sore mouth and all these sort of things...it jogs your memory about things...you might get a truer picture by somebody filling a form in like this than just a one to one consultation', WIFE 'well I think that will encourage people to be more frank...and paint a truer an overall picture of how their life is, whatever their condition might be' [Patient ma065, p94, p95].

Several patients [2/33] talked about the reasons why SPARC was either unhelpful, not worthwhile completing or not so good idea.

'...sometimes they do bring it home to you actually how you do feel, but because you start thinking about it then, cos I tend not to' [Patient ma064, p88].

'... it makes you think about things don't get me wrong, it's like do you worry about death or dying?, and then well yes I do because, its summat that's gonna affect me...' [Patient ma064, p90].

Some patients [2/33] talked about the impact (negative) of completing SPARC on other people (e.g. family or carer/s).

'...People can get someone else to help them fill that in,...they could but a family member might be even more upset about it' [Patient bm033, p21].

Almost a third of patients interviewed [9/33] made specific references to either missing questions on SPARC, depth of questioning, ambiguous or confusing questions, or made comments on SPARC questionnaire format, categories, scales, or about the general layout.

One patient felt that SPARC didn't ask a question about family history.

'I am amazed you don't ask a little bit more about family history, whether that would be an issue or not I don't know. I did think...oh you don't ask about any other conditions or any family histories, obviously not important and passed it off' [Patient ma024, p42].

Several patients felt that the questions on SPARC were ‘too simple’ and ‘too general’, and were expecting a more specific and detailed level of questioning.

‘...I thought it could have asked deeper questions (more in depth),...a lot more invasive questions and it still wouldn’t have been an issue,...wouldn’t be appropriate for somebody who is...yes could have asked an awful lot more, you could have gained a lot more knowledge about what was appropriate for me. But... you have to ask questions which everybody is okay...answering. When I was first referred in, I had my head so far under the quilt, that if you had asked me,... simple question how are you?, I couldn’t answer...’ [Patient bm002, p7].

‘No it was far easier than I expected, I expected some more detailed questions,... possible too simple for my liking, questions perhaps a bit too general,... could have been perhaps a little more specific...’ [Patient ma100, p 114].

6.8.5 Theme 5: Follow-up and monitoring of patients (timing of administering SPARC)

Timing of administering SPARC to patients: Almost a third of patients interviewed [10/33], made some comments about follow-up and monitoring of patients in relation to the timing of administering SPARC; in terms of when, how, and to whom SPARC should be given. Some patients were of the view that SPARC may not be appropriate for newly referred patients, who needed time to accept the diagnosis or those patients going through the very early stages of the illness.

‘...suppose you know you were going to see a consultant for the first time and you were sent this with your letter,...I just wonder if it would be a bit much, at that point...’ [Patient bm033, p20].

‘I think... early on perhaps a couple of months after diagnosis....people, once that you know they have been able to accept the diagnosis themselves and they know what their feelings are around it and then they would be able to put their feelings down on paper. I think if you did it any earlier it might be a little bit too soon and just aren’t interested,...you know be quite reluctant to fill in forms, if it was done much earlier...’ [Patient ma046, p71].

Conversely, other patients felt that it would be most appropriate to administer SPARC either before or after the patient goes to see the consultant, and then again at the 6-month interval.

‘...it would have been better...perhaps if the questionnaires had been done either just before or just after seeing him (health professional) and spread it out perhaps just that little bit longer...’ [Patient ma065, p91].

'Well I think you put this into operation for all the patients you get and six months down the line, same thing again and I think you would find a change...' [Patient ma065, p96].

Several respondents touched on the sensitivity around the timing of SPARC and about how patients should be approached, in terms of who should or shouldn't be given SPARC.

'...I think there are some judgement calls in who you give it to, and where they are at,... and I feel a bit strongly about that because it talks about some quite frightening things in here...' [Patient bm033, p20].

'...only certain kinds of patients can do it because I think people say with mental illness, or a lot of depression they will just go sling it in the corner...' [Patient ma039, p67].

Some respondents within this group talked about the time constraints and the limited amount of time available when patients go to see the doctor in clinic.

'...in all fairness when you go into a clinic or anywhere to talk to anybody you have got five minutes, now how can you get to the bottom of, what most people have suffered is a shock, to start with...' [Patient ma024, p44].

'...I think oh I didn't ask this, I didn't ask that, and what did she say and sometimes...they are so busy the nurses and the doctors that you don't really get a chance to say how you feel so much that way' [Patient ma029, p53].

Almost a third of patients interviewed [9/33] stressed the importance of follow-up and for better monitoring of patients, particularly after completion of questionnaires.

'...really good idea, if it does get followed up, a lot of questionnaires,...you fill it out and that's it, it's used for research and there's nothing that sort of comes from it. And people to get help that need help...' [Patient bm001, p3, p4].

There was however, some degree of scepticism about just how much of this information (on SPARC) will actually be taken on board.

'I would like to think so (when asked if patients would benefit from receiving SPARC), but I'm a bit sceptical. ...I wonder just how much the powers that be will take this on board...' [Patient ma024, p43].

Several patients felt like they had been forgotten or lost in the system, and had not been seen by a health professional for a considerable period of time.

'...the way that I was feeling before this landed on my door step was that I was just stuck, I had nowhere to go, ...it just felt like I had been forgotten, and it was just like I'm gonna be like this forever' [Patient bm001, p2, p3].

Others talked about the need for patients to be seen by a health professional at least once a year.

'It would be nicer to see him (referring to the health professional), once a year or something like that just to keep in touch cos he was very nice, weren't he? ('oh yes smashing'...)' [Patient bm021, p15, p16].

One patient stressed the importance and the need for better monitoring of patients, as soon as a diagnosis is made, and having a follow-up with shorter time-frames.

'...It could if it came earlier and then perhaps do a follow-up...as soon as the diagnosis was made...the disappointing thing for me, and I try not to dwell on it is the fact that it took a long time from me to actually feeling ill to a diagnosis being made, because I was going to the doctors for about four months in severe pain, I could barely walk and being treated for back pain...' [Patient ma046, p70, p71].

6.8.6 Theme 6: Information and communication issues

Almost a third of patients interviewed [10/33] talked about information and communication issues arising. Many of these patients talked about the general lack of information from health care professionals about their illness.

'...can't always find, get as much information from them (referring to health professionals) as you would like...' [Patient ma033, p57].

'...concerns me I don't know what the next stage of my illness will be. And it's very difficult to get the professionals to tell you, they don't want to talk about it. They all say absolutely depends on the individual, but I'm sure there are some generalities...' [Patient ma015, p39].

With some patients even suggesting that they felt like being 'cheated'

'...they don't tell us anything...I mean we are just being fobbed off all the time,... no never said anything what they are going to do or anything whatsoever,... I would like to know what's going off...there's a lack of information for you' [Patient bm021, p13, p14].

'...doctors are very bad at telling you these things,...I am going to become you know unable to work?, unable to walk?, well we don't know. And sometimes that's in brackets but we are not wanting to tell you, so there is another side to this which could open the dialogue...' [Patient bm033, p21].

One patient expressed concern over the lack of information and support from health care professionals, particularly after surgery and at the point of discharge.

'...you are brought out of hospital major surgery, they give you a huge bag of medication they don't know anything about it, some of the stuff I've had, I couldn't read them and they say here you are, tara, best of luck, and we will see you again...'
[Patient ma039, p66].

For those patients that did receive information, concerns were expressed about the approach that was used to convey the information to the patient.

'WIFE...Well it was the wrong approach to go into a consultation unaware of anything to come out having been given that information and you know off you go. Have this done and that done and we will see you on Thursday for a bone marrow'
[Patient ma065, p96].

Some patients felt that communication issues were a real problem that seemed to be getting worse.

'...the communication stuff which is a real problem,...it's a problem that's getting worse for me...' [Patient bm033, p20].

In contrast some patients in this group said that they didn't know much about their illness, and preferred it that way.

'...he said to me then how long have you got S? and I said I don't know and I don't want to know, I really didn't know much about illness except I knew it were terminal...' [Patient ma064, p88, 89].

Others said that they would have benefited from more explanation from health care professionals.

'...I would have benefited from that being explained to me,... and then I think you accept it more,...if you find out at the beginning you find it easier to accept...'
[Patient ma046, p71].

6.8.7 Theme 7: Satisfaction with services or care received

Just over half of the patients interviewed [17/33] made comments about the service, care received, or about the availability of services. Fifteen of the seventeen respondents praised the service, care, or treatment that they received, with many pleased with the level of care that they received, particularly at the hospice.

Praise for Macmillan Nurses

Several patients specifically praised the Macmillan Nurses for the excellent care that they provided.

'...we had a Macmillan Nurse, didn't we?, and you know they were smashing, whereas here you are just a number at... (hospital name)...' [Patient bm021, p14].

'...they've been fantastic to me and my Mrs, they are like family, I mean the Macmillan Nurse, she is bringing my medication here on...because they don't want me going in with big groups of people so you can't ask for better than that' [Patient ma058, p81].

Some patients in this group went on to praise the availability of services at the hospice.

'...if my pains not very good I can go there for the day or the night (hospice), and I can have my pain sorted,...and I know that I can ring them for that...' [Patient ma014, p33].

Most patients praised the hospice and all the staff.

'...I think that service from the...(hospice name) has made this whole experience immeasurably more satisfactory than it might have been...(comparing it to without the visits of the palliative care nurse)' [Patient ma015, p40].

'...It's a great pity that more people can't go to (hospice name)...had I not gone to... (hospice name), I would have really been left in the lurch...' [Patient ma024, p43, p44].

There was also praise for the palliative care nurses.

'...and I feel that the palliative care nurse understands me, and is sympathetic to the problems of my life...' [Patient ma015, p40].

'...L (health professional's name) who is extremely helpful, very good indeed, she is the only sort of professional that I have seen isn't she?' [Patient ma033, p57].

Some patients within this group praised the doctor or their GP, and the care received particularly after discharge.

'...my doctor is absolutely fantastic, ...I've got a marvellous GP, ...I've had absolutely fantastic treatment in all the different departments...' [Patient ma025, p48].

'...do you know I worship him he's my god (referring to the hospital doctor), and I'm not saying that because you are here, ...I do feel proud of them...' [Patient ma057, p76, p78].

'...my doctor is very good, he's excellent, but I don't think he knows a lot about this sort of situation...and they don't just stop there, when the patients discharged a lot of these things are on-going' [Patient ma024, p43, p44].

Others went on to praise the NHS service, and all the departments.

'...I'm a hundred percent in I think the National Health is absolutely brilliant, I've had fantastic treatment wherever I've been in (two hospital names). ...I've had absolutely fantastic treatment in all the different departments...' [Patient ma025, p48].

On the whole there was all round praise for the palliative care service provision in Sheffield, with some describing the service and care received as excellent, compared to other towns.

'...the hospice Macmillan Nurse,...everybody is so helpful there, absolutely marvellous, no complaints with anyone, even the food was good...so I'm very grateful, fantastic service in Sheffield, It really is because I know other towns aren't so good' [Patient ma047, p73,74].

In contrast, some patients in this group made some negative comments about their National Health Service (NHS) experience, making reference to a lack of empathy in hospitals, and expressing concerns over a deteriorating NHS system.

'...I think this would have all been very, very much more difficult for me, ...when you go to the hospital however good they are, you are just a person with cancer, you are not a person per se...' [Patient ma015, p40].

'...I would say it's a reflection on how the NHS is currently working (laughing), it's just rubbish at the moment,...there is nobody at all who has a grasp of you as a person, and I think that's an increasing problem, I don't think its necessarily me, I think...the system is deteriorating' [Patient bm033, p20].

Several patients commented on the lack of out of hours, evening and weekend availability of services and were unsure about who to contact at evenings and at the weekend.

'...If anything goes wrong it's evening and weekend, and then you sort of left with who can talk?, who do I ring up?, ...who do I get in touch with at evening and weekend? ...' [Patient ma012, p30].

One patient was unsure about how someone would get hold of a Macmillan Nurse and also commented on the lack of general information for the public about the availability of services in hospitals.

'...until you are poorly like this you don't realise anything that's out there, ...or who can help you or anything, ... we were at the hospital and then my daughters talked and said, how do you get a Macmillan Nurse,...so we wouldn't know which phone number...' [Patient ma014, p35].

6.8.8 Supplementary question on patients' experience of completing the SPARC questionnaire

As part of the follow up procedure, all patients were asked to complete a supplementary question on their experience of completing the SPARC questionnaire; *'Please tell us about your experience of completing the SPARC questionnaire'*. Patients in both groups completed this supplementary question 4 weeks, after receiving the SPARC intervention (for patients in Group A; intervention arm, this was at Week 4, and for patients in Group B; control arm, this was at Week 6). Patients of all ages responded. The age range of respondents to this question was 34-87 years old, thirty of the seventy-one respondents were male and forty-one female. Sixty-three respondents had a cancer/malignant diagnosis, seven with other non-cancer diagnosis, and in one patient the diagnosis was unknown. Thirty-three respondents were in the intervention arm, and thirty-eight respondents were in the control arm of the study (Ahmed et al., 2015). The question generated a variety of responses, some relating to SPARC and some general comments. A thematic content analysis was undertaken (summative content analysis) (Ahmed et al., 2015; Graneheim & Lundman, 2004; Hsieh & Shannon, 2005).

Several 'prominent themes' were identified, and illustrative quotations are presented under the relevant themes, both negative and positive feedback on the use of SPARC in this trial is presented in **Table 32**.

Overall most respondents [53/71] considered SPARC to be acceptable, easy to complete and understand, relevant and useful tool for the holistic assessment of supportive and palliative care needs. Several patients [9/71] reported some negative feedback, or did not find completing SPARC useful or beneficial.

Table 32: Supplementary question on patients' experience of completing SPARC questionnaire

Theme	Illustrative Quotation
Explicit, easy to understand and complete, fairly straightforward or very clear and straightforward [6/71]	<i>'Have found questionnaire explicit and easy to complete' (bm009, Intervention)</i> <i>'I found the questionnaire easy to understand and complete. Very clear and straightforward. Generally my situation has not altered much but there has been an improvement in my mood' (ma095, Intervention)</i>
No problem or no trouble completing the SPARC questionnaire [4/71] One patient commenting on how basic the questions were and was expecting more in-depth questions	<i>'No problems at all although the questions seemed very basic. I was expecting more in-depth details to be requested' (ma100, Intervention)</i>
Someone was interested in problems, issues or concerns, and felt like being listened to [3/71]	<i>'Made me feel appreciative that someone was interested in how I was feeling/coping. It also gave me a kick to try and fight back against my illness' (bm001, Intervention)</i> <i>'Although things at the moment remain 'the same'. In some ways I do feel that the current 'problems' are being listened to. Whether anything can be gained from this only time will tell' (ma057, Control)</i>
Brings home reality of illness, and brings issues to the fore to address realities of coping, accepted what the future holds [4/71]	<i>'It has made me aware that my health has to come first. Not feeling great keeps you feeling low. Slowly but surely things will get better and your questionnaire has helped bring the issues to the fore' (ma108, Control)</i> <i>'Completing may have helped me understand what has happened to me. Writing things down makes things more real. I am just hoping that treatment has worked and that I can get to get on with life as I was before. I am not very good at explaining myself so I hope this will be alright' (ma092, Intervention)</i> <i>'I have found it satisfying that such a study is taking place. I have tried to be accurate in my answers. I have been very happy with the palliative care I have been given and have with the help of...accepted the future I face' (ma102, Control)</i>
Good diary of condition, state of current health, or a useful MOT [4/71]	<i>'A useful MOT' (bm014, Intervention)</i> <i>'The questionnaire is a good diary of my condition. Unfortunately, this condition has deteriorated since the start of it' (ma071, Intervention)</i>
Helpful in allowing to focus and reflect on issues [7/71]	<i>'It was a useful way at looking at my situation and, as such, somewhat depressing' (bm033, Control)</i> <i>'I found completing the SPARC questionnaire quite useful in that it made me think more deeply about my personal condition and how it would/is affecting my family' (bm046, Control)</i> <i>'Some of the questions made me think of before all my problems began. Mainly trying to remember what it was like to be 'normal', not in pain 24-7' (ma060, Control)</i>

<p>Useful actions resulted from completing SPARC: helped patient communicate with doctor, prompted patient to visit their GP, enquire about palliative care services, realise the importance of family and religion, adopt a healthy lifestyle and to think more positively [6/71]</p>	<p><i>'Helped me to communicate with Dr about pain and medication and to accept physical limitations due to illness. Treatment has been excellent. Thank you' (bm032, Control)</i></p>
	<p><i>'The questionnaire was easy enough to complete but it made me realise I ought to visit my GP. She is sending me for tests' (ma062, Intervention)</i></p>
	<p><i>'Completing the questionnaire has made me think more about my illness and find out more about palliative care and any complementary therapy that may help. My way of dealing with my illness was to try and ignore it and not talk about it' (ma012, Control)</i></p>
	<p><i>'It has made me more aware of how much my family and my religion mean to me. How patient and understanding my palliative care doctors are. And how important it is for me to work harder in looking after my own health by trying to exercise more and eat more healthy' (ma067, Control)</i></p>
<p>Negative aspects relating to SPARC completion: Opened up certain issues, problems, or concerns best left, better to block out/didn't want to talk about, increased awareness of issues, problems or concerns and how awful life is, initiated a physical/emotional response, highlighted patients limited control over illness or disease progression and a comment on SPARC box categories [9/71]</p>	<p><i>'My experience in completing the questionnaire is to look at myself generally, both physically and mentally, realise my condition generally and make a more determined effort, to be if possible to maintain a more positive attitude and avoid thinking negatively' (ma005, Control)</i></p>
	<p><i>'Completing the questionnaire made me think more about my health and mental state as usually I find it better to block it all out otherwise I get depressed and I can't talk about my health or illness to anyone. I just tell everyone I'm ok. So people don't go on about it. It's easy for people who have not had cancer to talk about it, wait till it gets them, then they play a different tune on the fiddle' (ma061, Control)</i></p>
	<p><i>'My wife has completed the form indicating my views/feelings etc. otherwise I would not have bothered. it has however opened up certain issues best left' (ma075, Intervention)</i></p>
	<p><i>'The questionnaire in some ways made me feel worse because putting the problems down in writing makes them look more real, but also shows one that over time they can bother you a bit less just by the passage of time. I've had no treatment during this study but some issues, like anxiety and guilt, they're still there but less all 'consuming' (bm002, Control)</i></p>
<p>Felt like writing about someone else: someone they didn't know [2/71]</p>	<p><i>'Completing the SPARC questionnaire made me even more aware of how awful my life is at the moment due to my health' (bm001, Intervention)</i></p>
	<p><i>'I have found it hard completing this questionnaire. It's as though I'm writing about someone else' (ma013, Intervention)</i></p>
	<p><i>'Writing down how I feel about problems seemed to me someone I don't know, helped me get my feelings out into open. Thank you for this chance to voice my feelings. My family and husband are fantastic, but can all do without my worries, especially my husband. This week he was diagnosed with angina. He hasn't got to have any more stress' (ma084, Control)</i></p>

General/other comments

Theme	Illustrative Quotation
<p>Study-timeframe: too short of a time frame to detect a difference [2/71]</p> <p>Study questions (SPARC and other study questionnaires) were either too close together with appointments less frequent than the questionnaire, not seen anyone from the palliative care team, study duration simply too short of a timeframe to detect any change or difference in health status or quality of life</p>	<p><i>'Too short of time to let you know about the difference in the change of medication' (bm038, Intervention)</i></p> <p><i>'But I do think that they were too close together as appointments were less frequent than the questionnaire. The problems still exist and I am making a slow recovery' (ma065, Control)</i></p>
<p>Not seen anyone from palliative care team [2/71]</p>	<p><i>'I don't mind helping out if it has some benefits. I don't mind telling you how I feel but some of the questions seem a bit odd, especially when it's so long since I've seen anyone from the Palliative Care Team. Keep sending 'em though' cos I really don't mind helping out' (ma064, Intervention)</i></p>
<p>Timing of questionnaires: Problems, concerns, and issues change over time: the need to capture these changes [3/71]</p>	<p><i>'Some worries can vary during the day e.g. pain is worse at night and evening and less in the day time. Limitation of function is there all the time but reduced further by pain. Therefore, answers may vary according to the time of day or night!' (ma091, Intervention)</i></p> <p><i>'Did not realise that the first 2 issues would continue in this survey. Things change-issues/concerns come and go. I have suggested before that concerns change over time, but you do not change your questionnaire. Your research might be better if you took changes into account' (ma099, Intervention)</i></p>
<p>Confused as to how this will help/not relevant or of any benefit/can't remember [5/71]</p> <p>Expressed confusion as to how their participation will help, one patient didn't feel SPARC was of any particular benefit to them at that particular moment in time, and one patient didn't remember much of the SPARC questionnaire</p>	<p><i>'Didn't mind completing the questionnaires but I'm puzzled as to how this can help' (ma124, Control)</i></p> <p><i>'I'm dying of cancer, am virtually blind and very deaf. I don't see where I fit in with your questionnaire' (bm017, Intervention)</i></p> <p><i>'I don't feel that it is of particular benefit to me. As at the moment I am quite well. My only concern being that I am unable to see how things are progressing' (ma082, Intervention)</i></p> <p><i>'Can't remember much of SPARC questionnaire. However, I feel about the same as a few months ago' (bm006, Intervention)</i></p>
<p>Participated in study to help research and other people, or others in the future in a similar situation [9/71]</p> <p>Hope participation would help research and other people, or others in the future in a similar situation</p>	<p><i>'I just hope by completing these questionnaires it will help others in the future' (ma070, Control)</i></p> <p><i>'I am very pleased to help you in your study. If it helps other people to get more support in the beginning' (ma118, Intervention)</i></p> <p><i>'If completing these questionnaires has helped some way to understanding patients' needs and understanding of living with cancer then I am happy to have taken part' (ma074, Control)</i></p>
<p>Physical symptoms are often well catered for, but not the psychological symptoms [1/71]</p>	<p><i>'I am finding that physical symptoms are well catered for, care, pain relief etc. but little exists for the psychological effects. Support groups are in place, but they are a two edged word' (ma022, Intervention)</i></p>

6.9 Summary and discussion

This qualitative study concerning the views of patients about their experiences of completing SPARC was conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for developing and evaluating complex interventions, it may help in the interpretation of the trial outcome results (EAPC abstract, 2015). Eliciting the views of patients represents an important phase in the development of SPARC (Hughes et al., 2015).

Seven prominent themes emerged from the patient interviews. Most patients interviewed [30/33], found SPARC either quite easy to complete, fairly straightforward, simple or had no problems in completing it. Only a small number of participants found questions on SPARC ‘too sensitive or upsetting’. A crucial finding in the context of the trial was that almost all of the patients interviewed [30/33] did not experience or report any noticeable change, or beneficial effects after completing SPARC (EAPC abstract, 2015).

Overall, most participants found SPARC quite easy to complete, simple, and fairly straightforward and most participants did not have problems completing it. In fact it was considered to be more straightforward than some participants had originally anticipated. That said, some participants found it difficult and emotionally challenging, because it made them focus on things that were problematic in their lives. This could be due to the fact that participants were recruited from a wide range of settings, patients seen by the supportive and palliative care service are a very varied group and are at various stages of illness, they include those with long-term conditions and cancer survivors as well as those needing end of life care, as a result some of these patients may still be coming to terms with the illness, losing their independence or already frightened about what will happen to them. Hence, the process and the prospect of completing SPARC for these patients can be quite daunting. Participants felt consoled that they had the option of not completing or finishing SPARC on the off chance that it turned out to be excessively disquieting or troubling, making it impossible to finish.

Overall most patients also regarded the questions on SPARC to be either suitable, appropriate, or relevant and applicable, and the questions seemed to mention anything anybody might be feeling, thus providing a good all round picture of the patients current state of health and well-being. For some patients, again as one would expect in this type of service, that deals with a varied group of patients, the SPARC questionnaire or questions on it were either not relevant, not applicable, or becoming less relevant. This does raise important questions about who should receive SPARC, and more importantly when patients should be asked to complete it. The supplementary question on SPARC, endorsed the overall view that the questions were clear, well written, easy to understand and complete, and appropriate and relevant.

It is inevitable, as we found in this study that holistic needs assessment questionnaires of this nature, will ask questions about religious and spiritual issues, worrying thoughts about death and dying, and other questions related to psychological issues, which are regarded by some patients as sensitive, inappropriate or too personal. Some participants said they were reluctant to talk about some of these issues, because they felt that patients are always thinking about these issues anyway, but try to remain positive, others valued these questions as they provided them with an opportunity to talk about them with their health care professionals. Some strategies presented by some participants for dealing with these thoughts included having good moral support from family and friends and other people around them, being religious, keeping busy and generally thinking positive about what the future holds. It was however, reassuring to hear that overall most patients didn't really find SPARC too personal or sensitive in comparison with other questionnaires that they had completed. The consensus view appears to be that questions of this nature should be included in questionnaires despite their sensitive and personal nature.

It is also important to take note of the way that somebody has scored something on SPARC as distressing or bothering them. A low score on any item or question doesn't necessarily imply that they don't have that issue, problem or concern. It might imply that they are content with it or not bothered by it, so for this reason it is vital to cross check this information during a clinical consultation.

I have presented the reasons why most participants interviewed as part of the main trial felt that nothing had changed or no action had been taken as a result of completing SPARC; patients did not experience any noticeable, beneficial effects after completing SPARC and this is a critical finding in the context of the trial. What is concerning here is that some patients felt that health care professionals did not appear to be doing anything, or if they were, then the patient wasn't aware of it, because some of the problems hadn't been sorted or patients still had those same problems. None of the thirty-three patients felt that anything had changed in relation to changes in intervention, treatment or care they received following completion of SPARC, and a retrospective review of the case notes (**Chapter 4**), appears to support these findings (i.e. only 5/164=3.0% patient notes made any direct reference to SPARC, and 43/182; 23.6% patients had no progress notes for the entire duration of the study).

The information derived from both the patient interviews and the case note reviews seem to suggest that a large proportion of patients were not seen by a palliative care health professional, not heard from anyone, or did not have a follow-up appointment throughout the duration of the study. Many of these patients were scoring high (i.e. high levels of distress) on many of the items on SPARC. The precise reasons, as to why this may be the case requires attention, and further investigation.

There is an urgent need to review how often and when patients are followed-up by reviewing the follow-up period. Participants described how they were having the same conversations each time with their health care professionals, and that nothing more could be done because

they had tried virtually everything, sometimes this was detrimental to their health, resulting in some participants being discharged. Others reported that improvements had either plateaued, the problems were untreatable or treatment was not available, they got to a dead end or were going round in circles.

While some patients said that they had learned to live with the illness, accepted or adapted to the illness due to long standing issues, patient perceptions from the sample of participants interviewed is a true reflection of their clinical situation. The information derived from patient interviews was verified and cross checked with clinical information from a note review of the whole patient sample, and we can conclude with some degree of confidence that the findings are generalisable to the whole study sample.

There is a strong case here of the need for more adequate assessment of patients' holistic needs in a timely manner, not only when a patient enters the service, but also at regular intervals, at different stages of the illness or treatment and at the point of discharge. What is of great concern, is that some participants were being discharged from the service and placed on an 'open appointment system', many of these patients reported high levels of distress in many areas, but failed to contact their health care professionals, and the health care professionals failed to re-engage with these patients. Others said that they did not feel neglected, and felt reassured that help would be available if things deteriorated.

Some patients viewed this as a research study and therefore didn't expect to see any improvements in their health and well-being, but rather saw this as an opportunity to help the research study and others in the future. However these patients felt that this was a really good idea/concept, provided it does get followed up, and others felt that the study period (6 weeks) was simply too short to notice any changes in improvement. Only a small number of patients that scored high on some of the SPARC items were contacted and recalled by the service and reassessed.

For the small number of patients where completion of SPARC resulted in either referrals being made or consultations being undertaken in the form of a follow-up call, these took place after the study duration period, so one would not expect to see any changes in health outcomes during the first six weeks of the study. These are very important considerations that one must consider when designing any future study of the clinical utility of SPARC.

The Sheffield Palliative Care service is well established in Sheffield, and it was reassuring to hear about the high levels of patient satisfaction with services or care patients received, particularly at the hospice. Further work must focus attention on improving out of hours access i.e. improving evening and weekend availability of services, and on improving information and communication issues.

In summary the results of this study, and our earlier work (Hughes et al., 2015), indicate that SPARC is a suitable, relevant, applicable, comprehensive and useful tool for the holistic assessment of supportive and palliative care needs, with the potential to improve health professionals' understanding of patients' needs (Hughes et al., 2015). Participants' reports of

a failure to act on identified needs, in other words the raising of patients' expectations that are not subsequently met, would lend support to the conclusion that holistic needs assessment may be counterproductive if not integrated with a clinical assessment that informs the care plan (Ahmed et al., 2015). This qualitative study helps in the interpretation of the trial outcome results and provides useful insights into how SPARC might be used in practice (EAPC abstract, 2015).

Chapter 7

7 A qualitative study to elicit the views of supportive and palliative care health care professionals about the use of SPARC

7.1 Abstract

Background

This is a qualitative study embedded in a randomised controlled trial, to elicit the views of supportive and palliative care health care professionals about their experiences of using SPARC during the trial, to help in the interpretation of the trial result (EAPC abstract, 2015).

Methods

As part of a process evaluation, semi-structured interviews were undertaken during a randomised controlled trial with supportive and palliative care health care professionals [n=20]. All participants were interviewed after they had some experience of using SPARC. The interview schedule was designed to provide a description of health care professionals' views about their experience of using the SPARC questionnaire during the trial. Interviews were digitally recorded and transcribed verbatim and analysed using the framework analysis approach (Burnard, 1991; EAPC abstract, 2015; Ritchie & Spencer, 1994; Smith & Firth, 2011; Ward et al., 2013).

Results

Ten prominent themes emerged from the health care professional interviews, themes were largely determined by topics of predetermined interest and guided by the interview schedule. These provided useful insights into why the intervention (SPARC) did not work and highlighted potential areas for improvement. Prominent themes were identified as: **Theme 1:** Holistic assessment of patients' needs (methods and tools used); **Theme 2:** Awareness and previous experience of using SPARC; **Theme 3:** Patient feedback on SPARC; **Theme 4:** Impact of completing SPARC on clinical practice; **Theme 5:** Usefulness of completing SPARC; **Theme 6:** Sensitive, inappropriate or personal questions; **Theme 7:** Barriers to the relief of distress; **Theme 8:** Timing of administering SPARC; **Theme 9:** Education, training and skills issues around the use of SPARC; **Theme 10:** Future utilisation of SPARC. Most health care professionals had something positive to say about SPARC and had previous experience of using SPARC, and most professionals were considering using SPARC at some point in the future. A number of barriers were identified to the relief of distress highlighted by SPARC. Lack of professional action and the numerous barriers identified following high level scoring of SPARC has revealed useful insights into how SPARC might be used in practice (EAPC abstract, 2015).

Conclusions

Overall, supportive and palliative care health care professionals considered SPARC to be an acceptable and relevant tool for the clinical assessment of supportive and palliative care needs (EAPC abstract, 2015). However, the intervention was not sufficiently integrated within existing holistic needs assessment practice to impact on health care professionals' perceptions of their patients' needs, and therefore would not in itself prompt action. The effective integration of SPARC into routine care and standard operating systems requires further investigation.

7.2 Introduction

In this Chapter, I will present the findings from semi-structured interviews that I conducted with supportive and palliative care health care professionals. This is component two of the process evaluation, and follows on from the semi-structured interviews that I conducted with a subgroup of trial participants (patients) in **Chapter 6**.

Chapter 7 explores the views of supportive and palliative care health care professionals (n=20) about the use SPARC during the trial, and is a qualitative study embedded in an RCT. This component, as with component one (patients' semi-structured interviews) is a further important aspect of the development of the tool (Hughes et al., 2015), and provides useful insights on the implementation, receipt and setting of the SPARC intervention, that would help in the interpretation of the outcome results (Oakley et al., 2006). To my knowledge, this is the first study of its kind to elicit the views of supportive and palliative care health care professionals about the use of SPARC since development of the tool (Hughes et al., 2015).

7.3 Methods

Study design

Semi-structured interviews were undertaken to elicit the views of supportive and palliative care health care professionals (n=20) concerning the use SPARC during the trial.

I developed the interview schedule (see **Appendix 30**), with the help of other members of the research team; including experienced qualitative researchers; a palliative medicine consultant; and two consumers. The interview schedule was piloted with one health care professional.

7.3.1 Health care professional recruitment and demographics

A purposive sample of health care professionals was selected for interviews because they were working in the supportive or palliative care service, and were caring for the patients that had participated in this study. The purpose of the semi-structured interview was for health care professionals to talk about their experience of using SPARC, and to give the research team a better understanding of the current methods of assessing patients' holistic needs in a supportive and palliative care service.

Health care professionals were interviewed at the end of the study (i.e. 8 weeks after baseline questionnaires were received), and only after they had some experience of working with SPARC. Health care professionals received an invitation pack consisting of the following: invitation letter (**Appendix 31**); information sheet (**Appendix 32**); an opt-in form (**Appendix 33**) inviting them to take part in the study; a consent form (**Appendix 34**); and a freepost envelope. Those health care professionals expressing an interest in taking part in the interview completed the opt-in form with their contact details and suggested a suitable time to contact them. All completed consent forms were returned to the research team in the freepost envelope. I then contacted the health care professional who had expressed an interest in taking part in the interview by telephone to arrange a suitable date, time and location for the interview that was convenient to the health care professional.

I ensured that the consent form was completed when I went out to interview; for those health care professionals that had not returned the signed consent form in the freepost envelope. All interviews were audio-recorded with permission of the participants and field notes were kept. Health care professionals were given the option to have their interview either face-face or over the telephone, however all agreed to have face-face interviews. The characteristics of participants (HCPs) and their interviews are presented below.

7.3.2 Setting and sample

Characteristics of health care professionals and their interviews [n=20]

A total of 20 supportive and palliative care health care professionals, working in the service that hosted the study, were invited to take part in semi-structured interviews and all 20 agreed to participate. Purposive sampling technique ensured that I interviewed Clinicians (Consultants in Palliative Medicine), Clinical Specialist Palliative Care Nurses, Macmillan Palliative Care Nurses, Specialist Registrars, Lead Nurse and a Senior Sister. This group comprised mostly of females [15/20], with fewer males [5/20]. Of the 20 health care professionals interviewed, eleven were Clinical Specialist Palliative Care Nurses [nine from hospice, and two from Sheffield Teaching Hospitals, STH]; one lead nurse [hospice]; one senior sister [therapies and rehabilitation at hospice]; two Macmillan Palliative Care Nurses [hospital support team]; four consultants in Palliative Medicine [two from hospice, and two from STH]; and one Specialist Registrar in Palliative Medicine [STH].

Nineteen participants were part of the original main trial, and one participant was already using SPARC, and wasn't included in the main trial but included in this part of the study for comparative purposes. I undertook all twenty interviews. Interviews took place between 7/12/2011 and 21/2/2012, and were conducted in locations that were convenient to the health care professionals. The mean interview duration was 13.75 minutes (range 7.59 minutes-26.14 minutes). Most of the interviews were undertaken at the offices of the research team [Sykes House/Centre] and only a few were undertaken at the health care professionals' workplace/office. Response saturation was achieved with the interview of 20 health care

professionals. There were no drop-outs or withdrawals. The characteristics of participants (HCPs) and their interviews are summarised in **Table 33**.

Table 33: Characteristics of health care professionals and their interviews [n=20]

Health care professional ID Number	Gender	Health care professional occupation	Length of interview (minutes)
HCP 1	F	Clinical Specialist Palliative Care Nurse	12.20
HCP 2	F	Lead Nurse	11.41
HCP 3	F	Clinical Specialist Palliative Care Nurse	26.14
HCP 4	F	Clinical Specialist Palliative Care Nurse	20.04
HCP 5	F	Clinical Specialist Palliative Care Nurse	9.33
HCP 6	F	Clinical Specialist Palliative Care Nurse	16.20
HCP 7	F	Clinical Specialist Palliative Care Nurse	15.14
HCP 8	F	Clinical Specialist Palliative Care Nurse	10.32
HCP 9	F	Clinical Specialist Palliative Care Nurse	19.27
HCP 10	F	Clinical Specialist Palliative Care Nurse	11.29
HCP 11	M	Macmillan Nurse Part of Hospital Support Team	19.45
HCP 12	M	Consultant in Palliative Medicine	14.01
HCP 13	F	Macmillan Palliative Care Nurse	11.26
HCP 14	F	Clinical Specialist Palliative Care Nurse	7.59
HCP 15	M	Consultant in Palliative Medicine	13.35
HCP 16	F	Clinical Specialist Palliative Care Nurse	12.09
HCP 17	M	Specialist Registrar in Palliative Medicine	15.37
HCP 18	F	Senior Sister, Therapies and Rehabilitation Centre	12.46
HCP 19	F	Consultant in Palliative Medicine	17.26
HCP 20	M	Consultant in Palliative Medicine and Professor	13.09

7.4 Data analysis (the framework approach)

Interview data was examined qualitatively using a Framework Analysis approach (Ritchie & Spencer, 1994). A full description of the Framework approach is presented in **Chapter 6**.

The interview schedule (**Appendix 30**) was designed to provide a description of supportive and palliative care health care professionals' views about the use of SPARC during the trial, in particular; the current method of assessing patients'/families' holistic needs; awareness and previous experience of using SPARC; whether anything changed because of patients filling in the SPARC questionnaire; and whether or not they felt this resulted in any actions being taken; as well as any other comments they had about SPARC or in general.

Interviews were digitally recorded and transcribed verbatim and analysed using the Framework analysis approach (EAPC abstract, 2015). Field notes were also kept. Twenty health care professional interviews were undertaken. An example of a coded verbatim health care professional interview transcript is presented in **Appendix 35**, the coding framework (theme headings, sub-headings and code numbers) is presented in **Table 34**, and an example of a health care professional thematic chart with illustrative quotations is presented in **Appendix 36**.

The familiarisation phase and the initial thematic analysis, development of themes and sub-themes was conducted by myself, and then examined by another experienced qualitative researcher (KC). I listened to each health care professional interview audio-recording, checking for any errors in the verbatim transcript, listening to an interview audio recording also facilitated the analysis.

In order to minimise any bias, and improve the reliability of the analysis, 20% (4 out of 20) of the health care professional interview transcripts were independently coded and charted by two experienced qualitative researchers (one clinical and one non-clinical). Subsequent detailed discussions of the analysis optimised consistency and agreement within interpretation and the development of themes, as an on-going process throughout the data analysis.

7.5 Emergence of ten prominent themes

Initially the coding framework (**Table 34**) identified five main themes and fourteen subthemes that were determined by topics of predetermined interest. These included the following: current method of assessing patients'/families' holistic needs; awareness and previous experience of using SPARC; whether anything changed/any actions taken as a result of completing SPARC; usefulness of completing SPARC; and other comments.

However, upon closer examination these themes and subthemes were collapsed into ten prominent themes, which provided useful insights into why the intervention; SPARC did not work and highlighted other potential areas for improvement.

Prominent themes are presented below.

Theme 1: Holistic assessment of patients' needs (methods and tools used);

Theme 2: Awareness and previous experience of using SPARC;

Theme 3: Patient feedback on SPARC;

Theme 4: Impact of completing SPARC on clinical practice;

Theme 5: Usefulness of completing SPARC;

Theme 6: Sensitive, inappropriate or personal questions;

Theme 7: Barriers to the relief of distress;

Theme 8: Timing of administering SPARC;

Theme 9: Education, training and skills issues around the use of SPARC;

Theme 10: Future utilisation of SPARC.

Table 34: Coding framework (HCP interviews): Theme headings, sub headings and code numbers

HCP ID				
CURRENT METHOD OF ASSESSING PATIENTS/FAMILIES HOLISTIC NEEDS	<p>1) <u>Description of current method of assessing patients'/families' holistic needs</u></p> <p><i>A description of the current method of assessing patients'/families' holistic needs</i></p>		<p>2) <u>Tools used</u></p> <p><i>Any tools used when assessing patients' needs? (value/usefulness, benefits/ barriers)</i></p>	
AWARENESS AND PREVIOUS EXPERIENCE OF USING SPARC	<p>3) <u>Awareness</u></p> <p><i>Awareness of what SPARC questionnaire is used for (before, during or after the study?, any expectations?)</i></p>	<p>4) <u>Previous experience of using SPARC</u></p> <p><i>Do you have any previous experience of using SPARC?</i></p>	<p>5) <u>How SPARC results are feedback or discussed with patients</u></p> <p><i>How SPARC results are feedback or discussed with patients (by telephone, letter, face to face), what feedback have they had?</i></p>	
HAS ANYTHING CHANGED/ANY ACTIONS TAKEN AS A RESULT OF COMPLETING SPARC	<p>6) <u>Yes: Actions (or considering taking action): referrals/consultations/interventions</u></p> <p><i>Did completing SPARC result in any actions taken (for the better/for the worse): resulting in referrals being made/consultations, intervention/s, treatment/care, being undertaken?</i></p>		<p>7) <u>No: Nothing changed/no action</u></p> <p><i>Completing SPARC resulted in no changes in actions taken for the better/for the worse (possible reasons). Nothing new/no surprises.</i></p>	
USEFULNESS OF COMPLETING SPARC	<p>8) <u>Helpful for patients to have completed SPARC</u></p> <p><i>Reasons why completing SPARC was or could be useful: helpful/worthwhile completing/good idea.</i></p>	<p>9) <u>Unhelpful/not worthwhile for patients to have completed SPARC</u></p> <p><i>Reasons why completing SPARC was or could not be useful: unhelpful/not worthwhile completing/not so good idea.</i></p>	<p>10) <u>Inappropriate/ too personal/ sensitive/invasive/offensive/upsetting/bothering?</u></p> <p><i>Any questions considered to be inappropriate/sensitive/upsetting/personal?</i></p>	
OTHER COMMENTS	<p>11) <u>Barriers to the relief of distress highlighted by SPARC</u></p> <p><i>Were there any barriers to the relief of distress highlighted by SPARC?</i></p>	<p>12) <u>Timing of SPARC/who should get it</u></p> <p><i>Timing of SPARC: when, where, how often, and who should receive it?, follow up?</i></p>	<p>13) <u>Education, training and skills issues around the use of SPARC</u></p> <p><i>General comments about education and training and skills issues around the use of SPARC?</i></p>	<p>14) <u>Do you plan to use SPARC in the future?</u></p> <p><i>Do you think using SPARC will help you in your work, and do you plan to use it in the future?</i></p>

7.6 Findings

7.6.1 Theme 1: Holistic assessment of patients' needs (methods and tools used)

All health care professionals provided some form of description about their current method of assessment. Analysis of the descriptions of the current method of assessing patients' needs revealed some similarities, particularly amongst the staff working at the hospice.

There appears to be no definitive method, or any particular model or tool used for doing a holistic needs assessment.

'The current methods that I use for assessing patients holistically is not a definitive, it's not a particular model as such. It's a tool that we've used as specialist palliative care nurses, so it covers every aspect of the patient. So it tends to be an assessment ...for looking at diagnosis and physical needs, psychological elements, and social circumstances' [Health care professional 9, p38].

Most participants interviewed [13/20], mostly the hospice staff said that they were using the holistic needs assessment format developed by senior members of the team (hospice document, covers all systems).

'When I first started in the team, I was shown...a brief outline of all the things that you needed to cover when assessing patients...and used that as guide really. It was put together by...senior members in the team...and...you make sure when you go to see a patient that you cover all aspects of what's there, physical, psychological, social, spiritual...just a holistic needs assessment' [Health care professional 5, p22].

Health care professionals described the assessment as 'fairly structured', with some degree of structure (but not entirely structured).

'...But it's as I say it's something that isn't done in a very structured way...you go to see the patients introduce yourself. I normally just ask how they have ended up coming into hospital, and then the conversation takes off from there and whatever the patient focuses on...' [Health care professional 16, p67].

Several health care professionals within this group talked about how the interviews would start off with introductions and roles being explained as well as obtaining patient consent in order to do the assessment and for sharing of information, which was followed by a general question about the impact of the illness on the patient.

'Well I start off by saying you have been referred to me...tell them who I was and why I was going to be coming, what my role is.....and then say would they tell me a little bit about what's happened to them and...why we are where we are now, and then sometimes they go right back to the beginning of diagnosis. And that's a good way of,

cos I often say to them you know I've got some medical information about you but that doesn't tell me about how it's impacting on your, how you are feeling?' [Health care professional 3, p9].

Participants said that the assessment process often involved undertaking a routine clinical or medical interview (referring to the assessments undertaken in outpatient clinics, and on the wards). The use of informal interviews with the patient in a conversational style using open questions as well as closed questions appears to be the preferred method of assessing patients' and families' needs.

'I suppose my assessment style has been for a long time, has been a conversation style which is course is all the latest guidance anyway, we shouldn't be just going for a proforma...as a student nurse I remember you just sort of went through the tick box list really. But rather because your assessment is not just ... finding out information but is also getting to know the person. It's the support that we are giving people so you want that to be a conversational style and supportive style as well' [Health care professional 11, p47].

'It is primarily through informal interviews with the patient, through open questions as well as closed questions about the patients', psychosocial background and other needs, physical aspects, family backgrounds, financial issues, any other psychosocial concerns with the family as well as with the patient' [Health care professional 17, p71].

The use of more structured interviews with an examination (medical clerking) appears to be the common approach used for assessing patients on the wards.

'...Apart from well of course the...medical clerking which we designed for palliative care, is really also a category of holistic assessment as well, and I would do that if I'm filling in for the juniors when I assess a patient on the ward, and that's a more structured interview with...examination in it' [Health care professional 15, p63].

Most health care professionals said that they took a very systematic approach to assessing patients' needs and described the assessment process as having a professional agenda as a structure, but one which was mainly patient-led and patient focussed. Health care professionals said that during their assessment they would prioritise what was important to the patient. Most health care professionals within this group described the assessment process as being holistic, and having a whole person focus. Referral forms or discharge summaries from the wards were often used to initiate further discussions.

'My current way of assessing somebody would be to take a very systematic approach, to assessing their physical needs, psychological needs, social and spiritual needs, and with physical needs I think there's always a tendency for that to dominate ... but I would take a very systematic approach sort of to the systems. So although it's kind of a professional

agenda as a structure, I would only focus on the things that the patient identified as being problematic' [Health care professional 2, p5].

Health care professionals said that the 'full holistic needs assessment' was undertaken mainly on the first contact or appointment with the patient, and patients were reviewed during follow-up appointments.

'...Well when I first get a referral, when I first meet a patient for the first time I do a full holistic needs assessment, and then at each follow-up appointment I will go over certain areas. I probably won't cover every single area every time I see the patient, so the main holistic assessment is done on the first contact' [Health care professional 13, p56].

Several health care professionals stated that many patients were too ill to do a complete holistic needs assessment, therefore sometimes much of the work they do is with the family rather than the patient, but in some instances families do not wish to be contacted by the health care professionals.

'...A lot of the patients we see, we can't complete a holistic assessment because they are too unwell, and although we do try to make contact with families, some families don't want to be contacted directly by us, or don't want to meet with us...so in some circumstances we don't meet the family, in other circumstances a lot of the work we do is more with the family than with the patient them-self' [Health care professional 14, p60].

The responses varied about the types of tools used when assessing patients' needs. Most health care professionals [13/20], particularly at the hospice were using an aide-mémoire/ model/template developed by the team (hospice staff), that was developed from the holistic needs assessment document, and most were guided by or followed the holistic needs assessment [HNA] framework/document produced by Richardson and colleagues (Richardson et al, 2007).

Aide-mémoires

'I use an aide-mémoire that I've taken from the holistic needs assessment document. [referring to the holistic needs assessment document developed by Alison Richardson and colleagues] ...myself and one of my colleagues...hopefully cover all the bases, but I usually start off by saying, I suppose a bit like Maguire and Faulkner; can you tell me about what's been going on?, and then let them tell me... story, very open question. Let them tell their story and then if something key comes up that I think is an issue, then I might stop them there and focus on that and then hopefully go back, so I do have some degree of structure, but quite open' [Health care professional 3, p9].

Other tools and methods cited included SPARC, a Proforma, and some HCP's were guided by other nursing models (e.g. Roper Logan Model).

SPARC

'The only sort of formal way I have is of using SPARC, if I'm gonna use it, if I'm going to do it at all, I would use SPARC. I have to say to be honest I don't use SPARC for every one of my patients, by no means, but if I wanted to do what I would call a holistic needs assessment then I have to use SPARC...well I'm aware obviously the distress thermometer, concerns checklist, and other variations of those, people have used but clearly I would only use SPARC' [Health care professional 20, p85].

However, health care professionals expressed some reservations about using SPARC with certain types of patients (i.e. with those lacking mental capacity, those with dementia, elderly frail patients, and those who are imminently dying).

'It depends on their mental capacity, if they have got dementia then it's totally different, you can't work with SPARC,...I will if the patient's got full mental capacity and they are able to talk and they have got the ability to answer the questions...Again it will depend on the patients. It literally is depending and if they are elderly frail, sometimes it's too much to ask them, and you actually go in and prioritise what's important at that particular moment in time. And if they are in a nursing home sometimes they are imminently dying, so again some of the things aren't always appropriate' [Health care professional 6, p25].

Proforma, or guided by other nursing models [e.g. Roper Logan model]

'I think this is probably based on many years of different nursing really. I have done numerous nursing training and specialist training and each of those you come across new ways of assessing, I think my background in nursing focused on a sort of nursing process model based on nursing models of alleged holistic assessment, there's very well-known models Roper Logan model, and so all these models that nursing which over twenty-six years I've been a nurse have kind of been embedded, so, those are all things that give you I suppose a framework to hang your assessment on really' [Health care professional 11, p47].

Some health care professionals stated that they would use tools or methods that they felt most comfortable with using (i.e. no set thing or particular tool used for assessment).

'I wouldn't say that they were sort of you know a set thing but it's kind of what I guess I'm comfortable with having done the same...way for a long time' [Health care professional 2, p5].

7.6.2 Theme 2: Awareness and previous experience of using SPARC

Awareness: Almost all of the health care professionals interviewed [18/20] said that they were aware of SPARC before the study.

'Yes, although I have had little use of it, I am aware that it is about looking at people's concerns, and then ways of addressing, looking, find ways of addressing those concerns' [Health care professional 14, p60].

'...When I first started as a consultant...I attended [health professionals name] clinic ... I sat in for a few times with him and he was using it at that point with all of his... although the way he used it was he would ask an SpR to go and give the patient the questionnaire while they were waiting, so just my experience of observing how useful that was with [health professionals name], I've used it ever since in my clinic but I decided I wouldn't get the patients to fill it out when they came, I would send it out with the clinic letter. So I've used it since 2006' [Health care professional 19, p81].

Some health care professionals [2/20] said that they were not aware of SPARC before the study.

'...I wasn't really aware of it until [Health Professionals name] spoke to us which will be quite a long time ago now' [Health care professional 13, p56].

There was some variation in health care professionals' views and expectations on what SPARC was used for, these are listed below.

- 1) as a holistic needs assessment tool/screening tool;
- 2) as a guide for health care professionals/as a trigger/flagging up referrals;
- 3) for administering outside the specialty;
- 4) to be used during initial assessment, and as a discharge tool;
- 5) not used as an outcome measure.

One health care professional talked about the limitations of using SPARC in relation to the difficulties in trying to triangulate the assessment between the patients, their families and health care professionals.

'...And I guess...that's where I perceive the limitations with it, it's when I'm trying to triangulate the assessment between the patient and the perception of what the issues are, their own issues and then the nurses or the professional team's issue, the perception of what the person and all the problems are and their own problems. It's kind of...a useful, it would be useful there, but...I think how you triangulate those' [Health care professional 11, p49].

Only one health care professional was unsure about what SPARC was originally developed for.

'...Although I knew it [referring to SPARC] was a tool, I didn't actually know what it was originally developed for no. I wasn't aware of that originally' [Health care professional 9, p38].

A half of the sample of the respondents interviewed [10/20], said that they had some previous experience (sometimes limited) of using SPARC, three health care professionals [3/20] said that their colleagues had experience of using SPARC, and only two health care professionals [2/20] said that they had no previous experience of using SPARC. Most health care professionals went on to describe some of their positive experiences of using SPARC.

'...I'm quite interested in SPARC because we have as a service used...and found it quite beneficial as...a structured tool to do assessments with, and it gave us a far more patients' centred assessment, which was quite surprising, because people felt that they already did patient centred assessments, but actually it brought up things that were unexpected' ...And...as a professional you can become very, almost kind of over confident that you know what the patient's problems are going to be...I think for me it showed that various professionals had not been asking the right questions perhaps. ...We had a sense that we knew, we know all about it, but actually, it did throw up some surprises...' [Health care professional 2, p5, p6, p8].

At least three health care professionals [n=3/20] talked about their positive experiences of using SPARC as part of a service evaluation done at the hospice with ten hospice community patients, and described how SPARC helped patients talk about issues (sensitive) that would otherwise not have come up until the second or third visit.

'...We did ten patients here...and one of the things that was quite obvious was that it brought up the more sensitive or the more important issues to the patient...we would give it to the patient to do here, we'd then in the afternoon do the assessment interview...but what did happen was that some of these issues that came up would be issues that perhaps wouldn't have come up to the second or third visit...so I think what it did, was to raise surface issues that would otherwise not have come' [Health care professional 18, p77].

Several health care professionals within this group [3/20], based on their previous experiences of using SPARC, stated the reasons as to why they were reluctant to use SPARC with inpatients (with acute problems).

'...we know that we have got a cohort of quite a lot of older patients on this site than there are at the Central site. We have got patients with dementia here, and you know those kind of issues, as well so that's a problem. A lot of patients come in the initial point aren't probably well enough...sometimes we do have patients that would be well

enough probably to sit and fill one of these questionnaires in, but they are coming in with quite acute problems initially...’ [Health care professional 16, p68].

7.6.3 Theme 3: Patient feedback on SPARC

Just over a half of the sample of health care professionals interviewed [13/20] said that they had limited or no feedback from patients about using SPARC or had not discussed it with them; with some even suggesting that because the research study was done ‘remotely’, patients didn’t necessarily connect with it.

‘For the SPARC tools, didn’t do it...no-ones mentioned it and I’ve not mentioned it to them either, discussed it with them’ [Health care professional 8, p36].

‘I don’t think many of the patients who’ve actually filled in questionnaires in the study have actually mentioned them to us, we have seen them...I haven’t had anybody say to me, oh I’ve sent that questionnaire or anything, now I don’t know if it was because that was done remotely, so they didn’t connect with it necessarily, because a lot of the patients who have done questionnaires from here have done them via the community visit...so I think they may have associated it with the community, and didn’t mention it to us...’ [Health care professional 18, p77].

From the very limited feedback received by health care professionals from patients [4/20], generally the feedback was positive, and patients found it very useful to have completed SPARC, and weren’t put off by it, as it brings their problems, issues and concerns to the fore, but for some completion can be quite a challenge.

‘I think on the whole the patients that I know, that have filled it in have found it very useful and found although it can be quite a challenge for them, It focuses the interest on their problems. So although it’s not an easy thing for somebody to fill in, it’s actually very productive in that it shows them as well what they’re worried about’ [Health care professional 2, p6].

Sometimes the feedback received [4/20] from patients was more about the research study than about the process of using SPARC.

‘...I’ve had a few patients that said they have received this in the post [not sure about it, the word research]...and I’ve had patients that have said...do I have to go somewhere to be interviewed?...because I don’t feel I can do that...so I’ve had those sort of comments...’ [Health care professional 1, p2, p3].

‘...The letters yes, patients often shown me and say this has come from you and well it’s actually from me but it’s part of a research project that’s happening...’ [Health care professional 4, p17].

Interestingly, two health care professionals stated that they didn't really expect to have received any feedback as they didn't specifically invite it.

'...patients just see it as a normal thing to do. So they don't make a big deal out of it...I don't specifically invite feedback, because I don't want to make it look as if it's something special we're doing, it's just a part of our assessment...' [Health care professional 20, p86].

Health care professionals said that they used a combination of methods (by telephone, letter, or face to face) depending on the circumstances to discuss SPARC results with patients, however the preferred method appears to be a face to face consultation rather than a phone discussion with patients.

'...That might have been a combination of those things [by telephone, letter, or face to face] and depending on what...the plans were for them in terms of being seen again, or being referred to other people, or you know it became part of their sort of management plan' [Health care professional 2, p6].

'My personal preference is to actually bring the patient back to clinic and discuss it face to face, that's my preference, there is a particular patient...I'm thinking about bringing back where the patient has been discharged from the clinic, and in order to re-engage with them, I am going to have to call them and so the SPARC tool that they sent plus other letters, I may...need to raise those as an issue. So I might end up having a telephone consultation although I would rather see him and speak to him face to face' [Health care professional 12, p53].

7.6.4 Theme 4: Impact of completing SPARC on clinical practice

Almost half of the respondents interviewed [9/20] stated the following things happened as a result of patients completing SPARC; on most occasions [7/10] this initiated another discussion with the patient.

- 1) SPARC highlighted issues/areas: plan to phone patient and discuss further;
- 2) Phoned a lady to discuss issues she raised with another health care professional;
- 3) Initiated a discussion around thoughts about ending it all, and about the future of her disease (highlighted on SPARC);
- 4) Encouraged HCP to re-ask question later on but didn't feature as something that required attention;
- 5) Nothing really that needed action apart from involving another discussion around psychological issues;
- 6) Patient was called back to the clinic for further discussion.

Some HCP's felt that SPARC has an important role in monitoring patients, particularly those patients that they were not seeing.

'...Well I called them into clinic, and that's been the pattern with about half the patients that I've had SPARC information back on...but because the process is relatively slow, I don't know whether that will actually you know change the patients position for some time. I think it's useful because it does show you things that you weren't aware of...but I think its common enough now for me to get a SPARC form from somebody back particularly from clinic who are more distressed than I thought they would be by this stage. I conclude...it has got a role in maybe sort of monitoring patients who I'm not seeing...well only the opportunity to see them. I don't think SPARC tells you what to do at all, all it does is, it says look there is an issue here that you haven't addressed. And you need to get on to it. I don't think actually SPARC replaces anything that I do in clinic, it merely adds a sort of warning, it sort of highlights an issue, so I think it's a trigger to sort of going back to my usual assessment methods, this time focus on what we've found on SPARC' [Health care professional 15, p64].

Most health care professionals [16/20] stated possible reasons as to why no action had been taken (for the better or for the worse) during the study, and why no beneficial effect was seen as a result of patients completing SPARC. The main reasons are presented in **Table 35** together with illustrative quotations.

Table 35: Possible reasons why no beneficial effect was seen as a result of completing SPARC (HCP views)

Possible reasons why nothing changed, no action taken i.e. no beneficial effect seen as a result of completing SPARC	Illustrative Comments
Treated SPARC like any other correspondence [correspondence that wasn't requested] [n=1]	'...I think I was led to believe for this research purposes that we were to regard the SPARC tools that we got back like any other kind of correspondence that we hadn't requested...' [Health care professional 8, p36].
Didn't expect anything to change [n=7]	'The last patient I used it on, he very much answered the questions in the way that, there was no surprises on it...everything that he answered was what I already knew, so there were no surprises...just reinforced the assessment I had done. On a couple of occasions, I have been surprised by what the patients have actually scored, maybe there was more distress for the patient than I actually thought there was. It was more about psychological....' [Health care professional 5, p22, 23].
Tried everything; long-standing problems; nothing more could be done/got to a dead end [n=1]	'... the SPARC's I've had back, there has been a number which I have kind of already discharged. So what it's doing it's come after a point where we have either recognised the limitations of our intervention and we've discussed that with the patients. So even though a patient might score relatively highly on some of the features, we have kind of got to point that we have agreed that we haven't been able to make progress beyond that..., and the patient has had the opportunity to decide whether they want more intervention or not. At that point elected not to receive anything else...' [Health care professional 12, p52, p53].
Patient had moved on to another setting (no follow-up) [n=3]	'Have to say, that the SPARC patients that I carried out SPARC with, when the results actually came back to me, they were in another part of the service. So...like the last gentleman's now an inpatient, so I've taken the SPARC tool up there...when they go to another area of care then they have another primary nurse looking after them so...politically correct is that they follow that through ...' [Health care professional 5, p23].
Health care professionals wanted more ownership of the study in order to be more pro-active, seen as a third party [n=1]	'I think that's the nature of how the study has been set out because it's not us that are generating SPARC. And actually if I was a patient filling that out, I would expect somebody to be engaging with me...because it's been done as the third party...I don't think we have been engaging with it in the same way because we haven't been proactive in saying have you filled your SPARC form in and because that's not in the nature of the thing to do that...I think we have been like a third party' [Health care professional 3, p14].
Some problems/issues cannot be completely resolved/patient has adjusted to live with it [n=4]	'...I think sometimes its, people, you know you have dealt with the problem but there may still be some degree of pain that they have adjusted to live with if you like' [Health care professional 1, p2]. '... We can't always resolve all symptoms or all problems, but what we want to do is resolve the ones that are important to the patient' [Health care professional 12, p54].
Patient previously discharged from service/referred elsewhere /open appointment (no follow-up call), or even died [n=7]	'...As I say they've been, I've discharged them. You know when we discharge people we usually leave it for them to... contact us if they feel they need us...' [Health care professional 1, p3].

<p>Limited number of completed SPARC forms received/only recently received completed SPARC forms [n=6]</p>	<p><i>'I've some sent back but not very many... I've not had many back...I think I've only seen about four returned on my desk' [Health care professional 1, p2].</i></p> <p><i>'...And I've only received them fairly recently. I do feel I want to make contact with them to see if they are okay' [Health care professional 1, p3].</i></p>
<p>Saw this as a research study run by the research team, done as a third party, not in the loop, been happening in isolation, or wasn't aware of consenting patients [n=5]</p>	<p><i>'... In terms of it impacting on our assessment, because it's not done in conjunction, by ourselves, in other words we are not leading it, we are not in control of it, you haven't been able to engage with the patient about it, particularly either, you can't sort it, unless they chosen to talk to us about it...' [Health care professional 3, p11].</i></p> <p><i>'I'm not in the loop... I would say that yes. It's like, it's been happening in isolation...' [Health care professional 3, p14].</i></p> <p><i>'Well to be honest I haven't been looking at those forms formally because they not necessarily all patients who are coming back to me...so I have tended to regard those as separate, as a research exercise, I've not been using those clinically, if I have been wanting to use SPARC clinically with my patients I have used it anyway...no the ones that come back I mostly keep to myself, I mean I might share it with someone else a member of the team. But I keep them myself...' [Health care professional 20, p85].</i></p> <p><i>'I can see the benefits, and I think I'm a little bit confused...because it's almost as though we should have been incorporating this into our practice and really using it more. My understanding of the trial was that we would just identify patients who might be able or willing to fill it out and it was more like your study and...we weren't... incorporating it into the feedback, and it was more for our interest to look at the SPARC tools, so maybe that's a lack of understanding on my part...I don't think I probably engaged with it as much as...' [Health care professional 8, p37].</i></p>
<p>Originally thought HCPs weren't to address any highlighted issues only if something jumped out that needed addressing [n=1]</p>	<p><i>'I thought originally we weren't there to address some of the issues, but also I think if something jumped out then obviously it needed addressing. I'm not sure because there is a confidentiality...does the patient know that they are coming back to us?...' [Health care professional 6, p28].</i></p>
<p>Not timely enough to have an impact on HCP assessment, feedback needed much quicker (time delay/time-lag) [n=4]</p>	<p><i>'...I think it's helpful but it would be helpful if you had the feedback much quicker, in relation to your contact with the patient, in other words because it's been done as a research and you have only been given SPARC two or three weeks into your contact with them... I think it may be the delay in the patients returning it to you...yes, so it's not timely...in terms of it impacting on our assessment...' [Health care professional 3, p11].</i></p> <p><i>'...I think sometimes when we looked at it, because there would be a time-lag, I think that's the issue that when the questionnaires came back to us there would be time-lag between the patients starting here and probably doing that questionnaire and us seeing the questionnaire' [Health care professional 18, p77].</i></p>
<p>Not sure whether HCP was meant to be re-engaging with patients, unsure about the extent of involvement [n=2]</p>	<p><i>'...If patients had consented to being part of the study, maybe if we had known about that...but then I'm not sure we're meant to be re-engaging with them about it, so in other words I don't think we, I don't think that's been clear' [Health care professional 3, p14].</i></p> <p><i>'...I know that patients have received it. It's very difficult because it's been addressed to them directly...I didn't want to sort of have an influence on the study if you like really...you are obviously the ones who are doing the study. I don't know how much you wanted us to be part of that, or if it was supposed to be them' [Health care professional 4, p17].</i></p>

Notes may have gone somewhere else (for discharged patients and those in other settings)	<i>'...The only ones that I've had back they have both been discharged and then, do you phone them, do you not?, you know, how do you manage that? ...But the notes have already gone somewhere else by the time...yes, so when you discharge a patient then notes go....well I wonder if that's because we get them back so late...'</i> [Health care professional 3, p14].
Not seen patient for a while/during study/no discussion with patients	<i>'The last two that I've seen within the study, one-and it reflects the pattern, I think one ticked concerns which I was aware of in the severity that were indicated. And it didn't give me any extra information. The other one, however, ticked a couple of concerns that were outside what I expected, and it reflected the fact that the patient was in distress that I wasn't aware of and that's probably because I hadn't seen them for a little while. So from that I concluded that the review period that I had put into that outpatient was too long'</i> [Health care professional 15, p64].
Can't sort it unless patient choses to talk about it	<i>'...You haven't been able to engage with the patient about it, particularly either, you can't sort it, unless they chosen to talk to us about it...'</i> [Health care professional 3, p11].
Concerns on SPARC forms have been taken seriously but not sure if they have been referenced back to SPARC: loop needs closing	<i>'I think when the SPARC's have come back their concerns have been taken seriously. But I'm not sure that has been referenced back to SPARC, I think that's probably just a loop that needs closing really'</i> [Health care professional 2, p7].
Patient had died. Institution wasn't able to meet patient's needs at the time	<i>'I've had one and unfortunately by the time I had it returned to me, the patient had died. But, it was actually quite interesting, his response to some of the questions and I'm not quite sure how I would have dealt with them, Because of his character as well. And it was actually quite sad seeing it in a way. It was emotional, which I think identified the type of people we are seeing is that we don't do enough on the psychological support...the physical is easy...A lot of the issues I have are not the physical which you can probably treat easily it's the psychological side, the loss of independence, the loss of having been taken out of your own home, and some of them maybe acceptance of dying, but it's the stages that they go through, through losing their independence, of dying. And that's ...where it, sometimes it's quite difficult. He [referring to the patient] wanted to be respected and wanted to be independent and do things, which the institution at that time, wasn't meeting those needs. He felt he was being treated like a child as well. Unfortunately, as I said, it would have been interesting to have gone back and discussed it with him but he had died'</i> [Health care professional 6, p26].
Correspondence that HCP had not requested, didn't tend to respond too much to the SPARC tools	<i>'...And...that's the way I kind of looked at it really and it was interesting to look at it but I perhaps went by my own assessment more than, I didn't tend to respond too much to the SPARC tools'</i> [Health care professional 8, p36].
It's not incorporated into HCP role yet. SPARC was not seen as part of routine clinical practice Just viewed it as another piece of information, like getting a letter from a GP/clinic	<i>'For the SPARC tools, didn't do it...no because I didn't feel that was...no because it's not incorporated into my role yet. I just viewed it as another piece of information. Like if I got a letter from the GP or a letter, clinic letter, I wouldn't ring the patient up and discuss the results. I wouldn't discuss...and I viewed the SPARC tool in that same, in this instance, if we were using it day to day as part of our culture if you like then I perhaps then I might yes'</i> [Health care professional 8, p36].
HCP not mentioned/discussed it with the patient	<i>'No-ones mentioned it and I've not mentioned it to them either, discussed it with them...no nothing that, no action that I've taken is as a result of SPARC'</i> [Health care professional 8, p36].
Assessor may have felt it's not the right time to address unresolved/outstanding issues or problems but these could be addressed	<i>'The only thing that I would like to think if there are issues that aren't addressed it's because the person that's done the assessment doesn't believe it's been the right time at that time, and it might be something that might have been picked up later down the line or, when there is a bit more of a relationship formed...I would like to</i>

<p>later down the line when a better relationship is formed with the patient</p>	<p><i>think in my experience that's...what might have happened, some patients deteriorate quite rapidly' [Health care professional 10, p45].</i></p> <p><i>'...I suppose I found it really interesting actually...I think two of the patients particular things that had come up that I hadn't addressed at all, there was one there was a sexuality one, and I hadn't addressed that at all with the patient, having said...on that one, I had only seen the patient once. And unless that patient had probably brought the sexuality issue up, that wouldn't have been necessarily something I would have gone straight into on my first assessment, so it was sort of interesting things that were brought up' [Health care professional 9, p38, p39].</i></p>
<p>Nothing that needed action/addressing something that's not addressable</p>	<p><i>'...I don't think, anything sort of came to mind that it was really something that I needed to sort out, or if it did it might have been things that I thought well you know if somebody like circled feeling very weak. And yet they were very poorly and there was not perhaps a lot that I could do about that, so how do you address something that's not addressable, those kind of issues' [Health care professional 8, p36].</i></p>

7.6.5 Theme 5: Usefulness of completing SPARC

All health care professionals interviewed [20/20] had something positive to say about the usefulness of SPARC, comments on the usefulness of SPARC are summarised in **Table 36** together with illustrative quotations, these were in the majority.

Table 36: Usefulness of completing SPARC (HCP views)

Usefulness of completing SPARC	Illustrative comment
1) Writing things down: allows patients to communicate (sometimes uncomfortable/difficult things) in a different way, without having to say something out aloud [n= 6]	<i>'...I think it allows a patient to communicate in a different way. So to be able to communicate without having to say something out loud. So if something feels a bit uncomfortable to say they can let you know they want to talk about it' [Health care professional 2, p7].</i>
2) Very helpful tool to use where time and interaction with patient is very limited e.g. in outpatients [n= 3]	<i>'...I think probably in areas where there is probably limited contact especially in an outpatients setting, It is probably where SPARC is very helpful where, because your time is limited and because the interaction with the patient is limited, SPARC is where you can actually use it as something to prioritise your consultation, maybe not in the first interview but subsequent consultations...' [Health care professional 17, p72].</i>
3) Sometimes SPARC confirms and reinforces what we had done in the initial assessment. Sometimes gives new information that health care professionals were not aware of [n= 4]	<i>'...Seeing it in writing and hearing it just reinforces it' [Health care professional 6, p26].</i> <i>'...There are times obviously when it gives new information I didn't know about before then it's very helpful. Sometimes it just confirms the information I had or thought I had...It's often been very useful...when it gives some new information which I wasn't aware of cos it clearly asks about a lot of areas which I don't normally do in my clinical assessments' [Health care professional 20, p86].</i>
4) Cuts to the chase with patients about their real problems and their perceptions of what their problems are in a patient-led way [shift from a very medically-driven agenda to a patient agenda] [n= 6]. Patients are in control	<i>'...I think it's good because I think it sometimes cuts to the chase. Certainly have one experience of looking after a young woman who I was doing first visit. And ...it enabled her to talk about end of life care issues in relation to her family and her children and what she wanted for them. Whereas I might have been a bit more gentle and not gone there in the initial assessment. So in a way it opened up a dialogue really quickly which was really important because she didn't have that much time. So in that sense I've had positive outcomes from it...' [Health care professional 3, p11, p13, p14].</i> <i>'...I guess what it does it gives you the patient's agenda. And that for me is extremely useful because all from my personal view is what we are here for is really about trying to ensure that the patients' major concerns are being addressed. We can't always resolve all symptoms or all problems, but what we want to do is resolve the ones that are important to the patient. And this is what it does rather than us going from a very medically driven agenda...' [Health care professional 12, p53, p54, p55].</i>

<p>5) Useful guide/prompt, reminder-helps prioritise, sets the scene, and stimulates further discussion [n= 5]</p>	<p><i>'...Looking at SPARC when you look at it, I mean these are exactly the kind of things that you know I was saying this is what we'd cover, so I would hope you know our role doing a holistic assessment that we would cover these things. However, I don't think it does any harm to have a tool to guide you, to remind...to remember to...so it's a guidance...' [Health care professional 4, p18].</i></p> <p><i>'I think it can be a useful tool to stimulate some further discussion, and I think people can look at these in their own time...' [Health care professional 11, p49, p50].</i></p>
<p>6) Brings up the unexpected, things-important to the patient you weren't aware of, forgotten to ask, missed, or things you don't ask in clinical assessments [n= 8]</p>	<p><i>'...It gave us a far more patients' centred assessment, which was quite surprising, because people felt that they already did patient centred assessments, but actually it brought up things that were unexpected...I think what's interesting is that it brings up, the unexpected. And you, as a professional you can become very, almost kind of over confident that you know what the patient's problems are going to be. And actually...I can recall somebody who appeared to be very calm on the outside and had been seen by a number of health professionals and assessed. And nothing had been raised about anxiety but actually when she completed the SPARC she scored very highly on that. And it opened a door to a lot of things that she hadn't discussed before, and I think for me it showed that various professionals had not been asking the right questions perhaps' [Health care professional 2, p5, p6].</i></p>
<p>7) Simple, short (not too lengthy), useful tool, fairly compact and concise, very streamline, structured mental checklist [n= 5]</p>	<p><i>'...I do like the set-up of it; I must admit...I think its self-explanatory really...quite simple isn't it. It's not rocket science tool' [Health care professional 4, p18].</i></p> <p><i>'... I think the nice thing about it is it's not too lengthy and it's fairly compact isn't it and concise?...I think it's two A4 and that's pretty okay isn't it?...I think it's a useful tool...' [Health care professional 9, p42].</i></p>
<p>8) Part and parcel of our assessment, useful addition to HCP's normal practice [n=1]</p>	<p><i>'...I have quite a clear opinion that I think having something like this as part and parcel of our assessment would be helpful' [Health care professional 4, p19].</i></p>
<p>9) SPARC gives permission to ask patients again, message is that health care professionals are taking all patients' concerns seriously and want to help [n=2]</p>	<p><i>'...What SPARC did was almost give me permission to ask the patient the question again, but you think you have covered it, you think patients have given you a clear answer, and you think that's the end of that particular discussion or it's reached a negotiated point where that's where it's been left. But the fact that the patient has still identified it as an ongoing problem really invites you in a kind of patient-led way to re-challenge that and just be sure that you've reached an acceptable compromise, or that the problem has been resolved...' [Health care professional 12, p53, p54].</i></p> <p><i>'...I think the message that it gives is you know I'm taking all your concerns seriously. I want to help so generally very positive...' [Health care professional 19, p82, p54].</i></p>

10) Can home in on highlighted issues, problems, concerns (smartly and quickly) [n= 2]	<i>'Well I mean I suppose we are coloured a bit by previous experience with using SPARC. I think I would like to believe that the assessment that we do is robust enough that issues come up and that the relationship that develops between the key worker and the patient, issues will come up. But I suspect we just would not have addressed them as smartly, as quickly without using the SPARC' [Health care professional 18, p78].</i>
11) Could be helpful in a limited number of patients particularly in patients with lots of on-going issues, helping them to focus [1]	<i>'I think that in a limited number of patients it could be very helpful, the lady that I've seen this morning has got a lot of anxieties and I just wonder now, with hindsight if giving her something like this may help her to focus on the way she's feeling cos there is so much going on, and it maybe that this helps her to focus...' [Health care professional 14, p61].</i>

7.6.6 Theme 6: Sensitive, inappropriate or personal questions

Of the 16 health care professionals that responded to this question, just over a half of the sample of health care professionals interviewed [12/20] stated reasons as to why SPARC could be potentially unhelpful or not worthwhile for patients to have completed. A few health care professionals [2/20] said that some patients might be alarmed at receiving SPARC because of its association with palliative care, and with the prospect of being defined as a 'palliative patient'. There was also the worry expressed by some health care professionals [2/20] that patients would have to complete a questionnaire with lots of questions, and the perception that this would take a lot of time to complete. There was a concern amongst some health care professionals [4/20] that SPARC might be burdensome for some patients, particularly those patients who were unwell, or had cognitive impairments, those experiencing a change in circumstances due to illness (e.g. profound fatigue, loss of independence) and those coming to terms with the illness. Some health care professionals [2/20] felt that SPARC could reinforce the situation the patient was in (e.g. losing independence), and you then run the risk of reinforcing problems that can't be solved.

Some health care professionals [n=2/20] felt that the questions that made reference to the patient's sexual problems were considered to be either inappropriate too personal, or too sensitive.

'...I don't think I would have used a direct enough question like you know is your illness impacting on your sexual life?, I'm not sure I would have gone there. And I think as professionals we are not very good at covering, I tend to talk about it in terms of sexuality, it will be about body image, rather than about the...' [Health care professional 3, p12].

And one health care professional said that as a health care professional you have got to be comfortable addressing and talking about sexual issues.

'As a health professional say the sexual issues...you have got to be comfortable addressing those issues, and I feel that ... in our field we should be able to do that so, but perhaps it allows them to put it down...' [Health care professional 9, p40].

In contrast, others felt it was useful to ask about sexual problems as it can be a useful prompt to check on things that sometimes are difficult to talk about.

'...I think when patients identify...sexual problems for instance, I think that's very useful thing about the SPARC tool because I think patients aren't always very comfortable talking about that...other colleagues have said....the return of the SPARC tool has identified concerns that maybe they haven't expressed verbally, so that's very, very useful, and I think the fact that they've written that on the form hopefully will help enable them to maybe you know feel more comfortable about discussing it and bringing up concerns. It's how we then address it you know' [Health care professional 1, p3].

Some health care professionals [2/20] found discussing of end of life care issues, dying, death and life is not worth living questions distressing and sensitive. The issue around timing of asking these questions was considered important.

'And you know questions about death or dying, although we do try and touch on them in an assessment you get a feel for if somebody wants to talk about it or not, whereas if you know, and then we can sort of pursue it or not, back away or leave it. You know its timing isn't it?, but that maybe a question that...people might find distressing to answer, yeah it's a bit different when it's seen there in black and white. I mean they may sort of think oh am I dying [when this may not necessarily be the case]....' [Health care professional 7, p33].

Several health care professionals reflected on their positive experience of using SPARC in relation to asking these questions [i.e. about death and dying].

'...I think...as nurses...we've just sort of had a more tentative approach to maybe discussing death or discussing...peoples' views about how they wanted things to be, we would sort of hold off and wait till we had got to know them a bit better...whereas what was interesting was that people wanted to talk about that right away. So we would make that assumption quite incorrectly, you know...' [Health care professional 2, p6].

'I think it's good because I think it sometimes cuts to the chase. Certainly have one experience of looking after a young woman who I was doing first visit. And...I think it enabled her to talk about end of life care issues in relation to her family and her children and what she wanted for them. Whereas I might have been a bit more gentle, ... and not gone there, in the initial assessment...so in a way it opened up a dialogue

really quickly which was really important because she didn't have that much time. So in that sense I've had positive outcomes from it' [Health care professional 3, p12, p13, p14].

Other potentially sensitive/distressing questions include: questions about psychological issues, because patients are not always ready to talk about them; loss of independence and questions about long-term effects of treatment.

'I think the only thing about the tool is ... there are going to be some aspects of it that the patient might not be ready, able to talk about, you know when it comes to things like, some of the psychological issues...' [Health care professional 9, p40, p41].

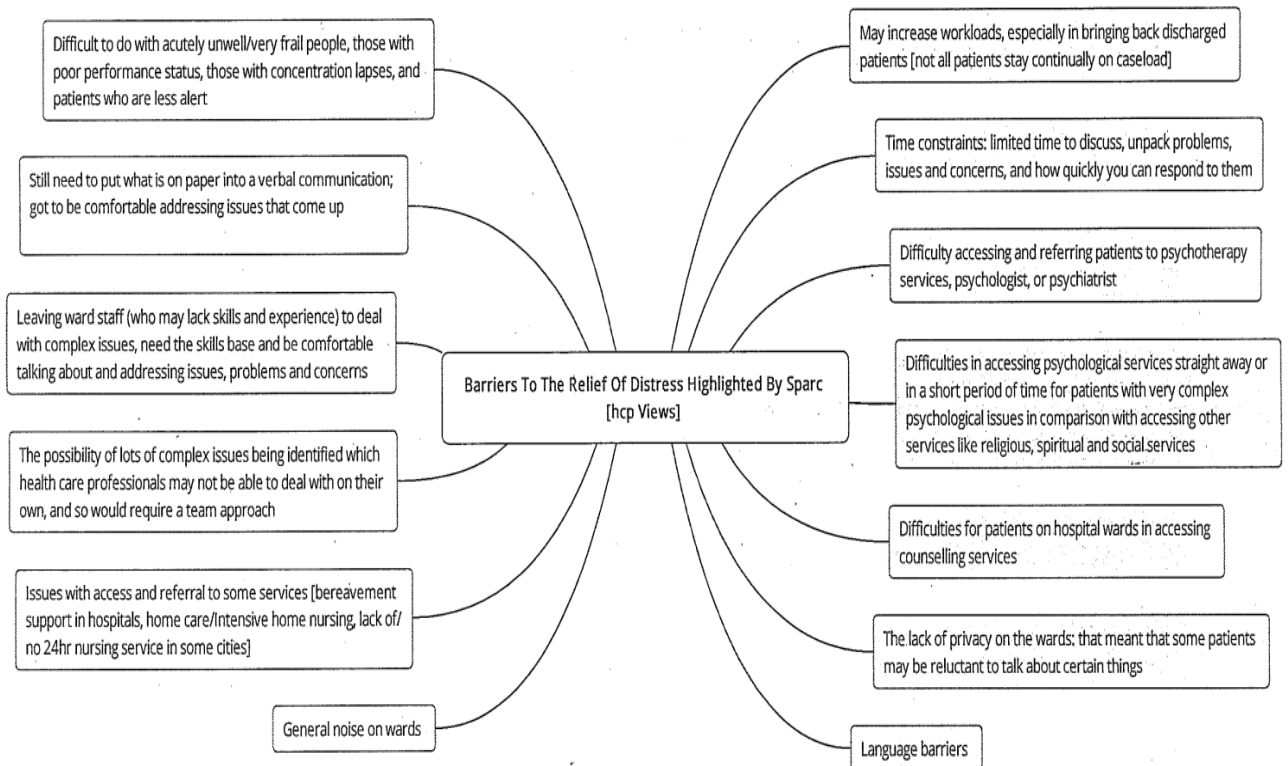
On the whole HCP's felt that including upsetting questions may be potentially useful because patients may feel reassured that someone was looking into addressing their issues or problems.

'... I suppose quite a lot of the things that we ask patients can be upsetting, ...but in the long-term of course these may be things that patients may find upsetting but have wanted to talk about but never had an opportunity to discuss with, so in a way, it may actually become a relief there is someone actually looking into these issues, because that's something that can get side-lined in especially hospital environment. So no I think on the whole it's very helpful' [Health care professional 17, p73, p74].

7.6.7 Theme 7: Barriers to the relief of distress

Several barriers were identified by health care professionals [15/20] to the relief of distress highlighted by SPARC, these are presented below with illustrative quotes/comments and summarised in **Figure 11**.

Figure 11: Barriers to the relief of distress highlighted by SPARC (HCP views)



Just over a third of the sample of health care professionals interviewed [7/20] commented on the limited resources available and the difficulty with accessing and referring patients to psychotherapy services (psychologist, or psychiatrist) as potentially a barrier to addressing the psychological issues. Several health care professionals [4/20] commented on the time constraints, limited time to discuss, unpack problems, issues and concerns particularly with regards to addressing patients’ psychological needs in the clinic context/outpatients setting.

‘...But the clinic context doesn’t give you a lot of time to unpack those problems. So then you need to be confident that you can refer onto a colleague in psychology and if a patient doesn’t want to be identified as having a psychological or psychiatric problem, that in itself can act as a barrier to addressing the issues, as well as having the resource of having a psychologist to refer to...’ [Health care professional 12, p54].

‘...I suppose timing is an issue for us...I mean it’s not like an outpatients where you have got a very specific slot. And if you have created sort of problems that you can’t

address, then you are going to go home with those problems...we have got more time' [Health care professional 18, p78].

Health care professionals talked about the difficulties in accessing psychological services straight away or in a short period of time for patients with very complex psychological issues in comparison with accessing other services like religious, spiritual and social services.

'Well psychology not good, you see...we waited quite a long time sometimes for a psychologist or psychiatrist, It's easier to refer patients to a physio or a dietician that's quite easy. Chaplain is quite easy yes, so the psychologist is probably one of the most difficult ones' [Health care professional 20, p86].

There were some health care professionals who felt it was not possible to deal with all the issues at once, and there was a need to prioritise. However, on the contrary, there were some health care professionals [2/20] who felt that completing SPARC may be a more efficient and effective way of identifying problems, concerns, or issues and may actually save time in the long run, because SPARC helps patients focus on things that matter or bother them most.

'I can see that for some professionals they may think, oh my goodness they have ticked three for everything, but if they have ticked three for everything actually that gives you I suppose a lot of information as to how they are feeling emotionally, I think there is a worry that if they do [tick 3 for everything] ...given our time limitations how are we going to, what ones do you want time to address?. So I wouldn't feel threatened by it...I can see that it may be seen as time consuming but actually doing a full holistic needs assessment does take time, but I mean the other thing is it does allow you to be focused, so in some ways it might save time' [Health care professional 19, p83].

Health care professionals expressed concerns about SPARC identifying problems, issues, or concerns that other HCP's couldn't 'fix', but at the same time said that they could refer patients to someone who could help.

'...I can see having spoken to some of the neurology clinical nurse specialists that they worry they are going to identify something that they then can't fix, I suppose I don't personally have any concerns about.... if I've identified there is a problem with their sexual life I'm not the right person to help sort that but I know who is...' [Health care professional 19, p83].

Other general barriers identified by a very small number of health care professionals included the following: 1) the lack of privacy on the wards; that meant that some patients may be reluctant to talk about certain things; 2) language barriers; 3) general noise on the wards; 4) lack of bereavement support in the general hospitals; 5) difficulties of accessing home care/intensive home nursing/ no 24hr nursing service in some cities; 6) the possibility of lots

of issues being identified which health care professionals may not be able to deal with on their own, and so would require a team approach.

Several health care professionals [3/20] said that completing SPARC may increase workloads, especially in bringing back discharged patients (because not all patients stay continually on a caseload).

'...We are busy, we have limited time with patients and if someone were to complete the form and highlight a lot of issues, I need to have factored that into my visit, that I may go and there be no issues, but I may go and there may be lots of issues and that may then have a knock on effect in terms of how my visits proceed from then on...and it also I guess could create more work in that I may need to make referrals to other teams, ...it's not just a paper exercise is it?, It's not just a case of giving it to someone to fill in, its dealing with the fall out' [Health care professional 14, p61].

'The only issue that I could see there is that if...perhaps I have discharged a patient then I get a form back and there are lots of issues there, I think crikey they never said that. And then I might think I have got to get back in touch with this patient again...it wouldn't be a barrier but that might be a clinical issue...it just might make our workloads a bit more' [Health care professional 8, p37].

At least one health care professional was concerned that she wouldn't have the skills to deal with the issues, problems, concerns identified, and that SPARC may bring up issues, concerns, problems that they nor the patient was ready to talk about. Another health care professional said off-tape that he was concerned about leaving ward staff who may not have the necessary training or skills to deal with the complex issues identified.

'I worry that if it highlighted lots of issues that I wouldn't have the skills then to deal with those issues, but I also worry that if a patient has lots of issues and is unable to decide which ones are the most pressing that they need to deal with first, that then may be left to me to decide which I address first, and it may be that I don't know and that I don't do that in a manner in which they would want me to do' [Health care professional 14, p61].

'I think my worry is that I open a can of worms that I then am not equipped to deal with or not ready to deal with, or that it opens a can of worms for the patient that they weren't ready to open' [Health care professional 14, p62].

Several health care professionals said that you would still need to put what is on paper into a verbal communication.

'I suppose the barrier though is then that you still putting it into a verbal communication ... they identified it, haven't they on paper. And I suppose by doing

that they are saying this is something I wanted to discuss and is a concern' [Health care professional 9, p40].

7.6.8 Theme 8: Timing of administering SPARC

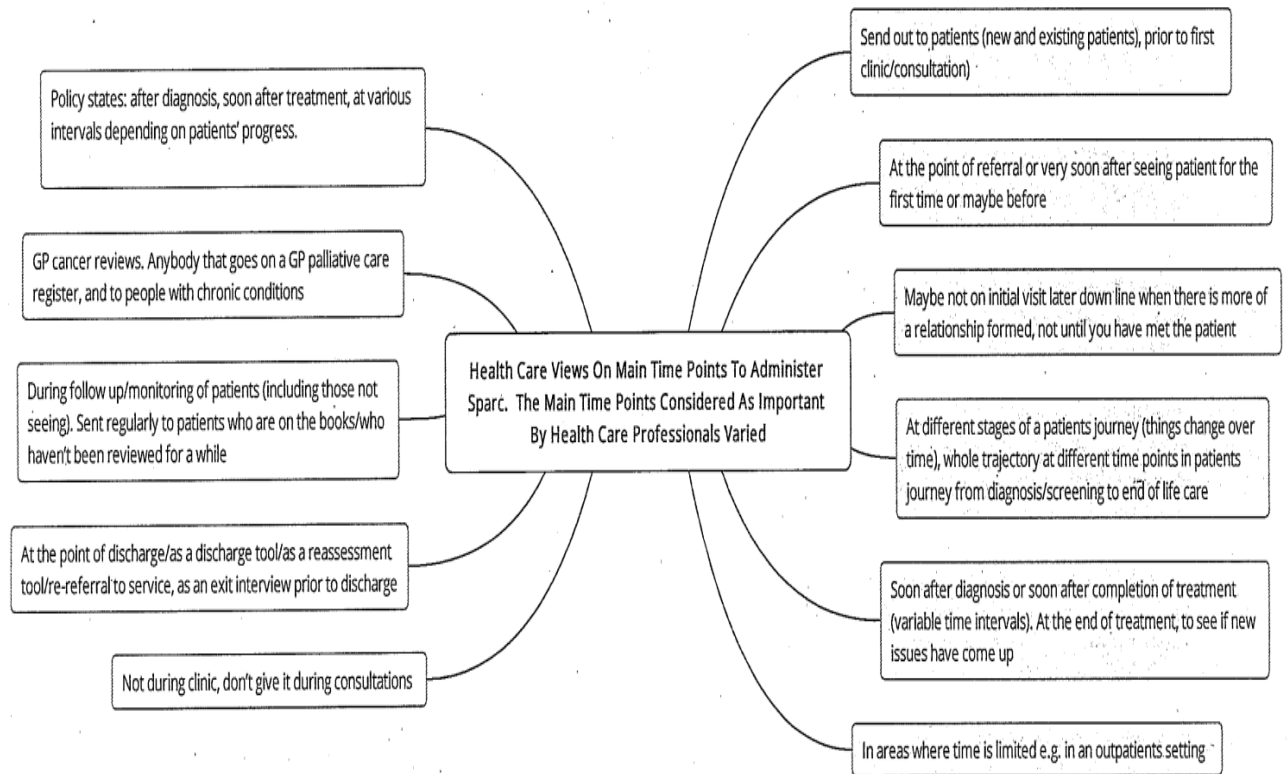
Most health care professionals [18/20] commented on the timing of administering SPARC to patients, the main time points considered as important by health care professionals varied and are presented below with illustrative comments and are summarised in **Figure 12**.

Several health care professionals [5/20] strongly felt that SPARC should be used as an initial assessment or as an early holistic needs assessment tool, early on in the course of the illness, and then perhaps again at discharge, or as a reassessment tool. Participants stated that you need to be careful when SPARC is sent out because usually when these go out they coincide with lots of other things going on. And some health care professionals [n=2] said that SPARC should be used judiciously, and then repeated or used more routinely, with a particular time-frame. A small number of health care professionals initially thought of SPARC as something that would be particularly useful for health care professionals to use in primary care (outside the specialty) and that could help point health care professionals to which patients require extra attention or referral to specialist palliative care (for people referring to the palliative care service e.g. District Nurses or General Practitioners). Others felt it could be a re-usable tool that could be used at different stages in the patient's illness/journey.

Health care professionals said that the timing depends on the client that they are dealing with (i.e. whether the patient was in a nursing home, at home or in an inpatient unit etc.), and that you need to strike a balance between the burden you put someone under and the benefit you get out of it, and it was difficult weighing this up, as some patients that are on general hospital wards are acutely unwell. And others said that SPARC should be completed when you are seeing the patient so that you could 'capture the moment'.

Figure 12: HCP views on the main time points to administer SPARC

The main time points considered as important by health care professionals varied



7.6.9 Theme 9: Education, training and skills issues around the use of SPARC

Almost a third of health care professionals interviewed [6/20] talked about the need for education, training and skills issues around the use of SPARC.

'...It maybe that we just need more education in its use...it would be good to have that evidence really...' [Health care professional 11, p51].

'...We might need to consider the skills of the people using it...I think as well that you have...got to be comfortable to talk about the things that might come up, or know where to go with them and I think...there is some work to do around that. And I think around a process for using it' [Health care professional 2, p7].

For some it was more about receiving education and training around confidence building and on introducing and using something like SPARC.

'...I think you have got to have some thought process behind it. And a way of introducing it and maybe some you know education and training or you know just confidence building about using something' [Health care professional 2, p8].

'...I understand what it's for, but explaining that to patients and whether they will get any benefit from it. I don't know if I feel confident doing that...' [Health care professional 13, p58].

Some health care professionals [2/20] expressed concern about how they would deal with and address any concerns or issues highlighted by the patient.

'I worry that if it highlighted lots of issues that I wouldn't have the skills then to deal with those issues...' [Health care professional 14, p61].

'...Yes I think that would help [education and training on using SPARC], yes, cos it's not just a paper exercise is it?, It's not just a case of giving to someone to fill in its dealing with the fall out...' [Health care professional 14, p61].

However, some [2/20] felt that health care professionals should have received sufficient training to be able to tackle a lot of these issues anyway.

'...I think that's something that we would be expected to learn from our training for example things like bowel problems, constipation you would expect a Registrar in Palliative Medicine to know about how to deal with....of course...' [Health care professional 17, p74].

'As a health professional say the sexual issues...you have got to be comfortable addressing those issues...in our field we should be able to do that...but perhaps it allows them to put it down...' [Health care professional 9, p40].

One health care professional commented on how SPARC would be beneficial for physicians and consultants, especially those who were in the initial stages of their training.

'...And probably good thing about SPARC of course, it is very streamline it is kind of.....it's a very structured way, so it would be definitely helpful for physicians especially those who were in the initial stages of their training, and for consultants...even a consultant can make mistakes' [Health care professional 17, p74].

Another health care professional was very supportive of using SPARC, providing it was not too burdensome for the patient.

'...I think anything that is gonna help people and really provide a good benefit that's not burdensome to the person, I think I would be supportive of that. I just think it's ... striking this balance between the burden that you perceive you put someone under

and the benefit that you get out of it, it is difficult and it's weighing this up [burden vs. benefit]' [Health care professional 11, p51].

The same health care professional said the following 'off-tape'

***Off tape:** '...Concerned about leaving ward staff to deal with complex issues identified, as ward staff may not be skilled or trained to deal with such complex issues' [Health care professional 11, p51].*

Another health care professional said that if they found difficulty dealing with issues, they could always get help from one of their colleagues.

'...And if we are finding difficulty, we can always get help from our colleagues, so I think on the whole it will be helpful. I mean I think yes we would be expected to be able to tackle quite a lot of these issues, but if we can't then at least in a way it can be also used as an early opportunity...' [Health care professional 17, p74].

7.6.10 Theme 10: Future utilisation of SPARC

All health care professionals interviewed said that they would either use SPARC in the future or consider using it. It is fair to conclude that the majority of health care professionals interviewed in this study support the use of SPARC, and there seems to be a lot of enthusiasm amongst teams and individual members of staff about using SPARC in the future, particularly amongst staff working at the hospice.

'I think it certainly helps in our work with assessing patients. And we are very interested in using it in the future...there is a lot of enthusiasm amongst particularly the community team to use this...as part of their, as an assessment tool' [Health care professional 2, p7].

'I'm a big fan and like I say I've never used anything like this before I came to Sheffield and I see it as a really useful addition to our normal practice...we all like to think we do a very thorough needs assessment when we assess patients but I know I don't always, there are always things I miss out, so I think what it does is it gives the patient's permission that...all of these are issues that we consider important and it just makes sure that we don't miss anything. I find it very help to prioritise as well as to what we are going to concentrate on now and what we can afford to leave till perhaps a bit later. So I'm a big fan' [Health care professional 19, p83, p84].

Some health care professionals [2/20] said that they were considering using SPARC, but put it on hold due to the ongoing research.

'...I would like to start using it ... although the research is really important we've sort of put it on hold...I think that's a shame. But I understand...it's good to get proper evidence behind using something. But I would certainly look to use it in the future, myself... as a way of doing holistic needs assessment' [Health care professional 3, p15].

'...We did have really positive experience of it when we used it that time. And we haven't used it any further because effectively you are doing the study...didn't want to do sort of the same at the same time. But yes. I think we would use it' [Health care professional 18, p79].

Other health care professionals stated reasons as to why they considered SPARC to be useful.

'...It...compartmentalises things but in a negative way but quite a constructive way...rather than a ream of stuff and then you are trying to sort of work out which bits you need to address it's quite simple...I have quite...a clear opinion that I think having something like this as part and parcel of our assessment would be helpful' [Health care professional 4, p19].

'...It seems to me that if fulfils the assessment, a paper assessment which is awfully good a screening for the things that clinicians don't do naturally...I would certainly use it in our service and I think something like it should be used and I think SPARC is as good as anything else I've seen...I think it's much more useful than a global measure ... and the good thing about SPARC is it tells you whether it is the thing you know about, whether it's something else' [Health care professional 15, p65, 66].

A few health care professionals suggested that the use of SPARC should not become obligatory or be seen as an enforcement but instead it should become part and parcel of what you are doing.

'...I don't necessarily think they...should be seen as an enforcement you know we have to do this. Because if something becomes obligatory people think of it as like oh it's extra work, and we have got to start messing about filling this in and doing this. Whereas if it becomes part of parcel of what you are doing, or this is just a bit of a guidance to help you... I think it works much better...I think it's got a place, ...there are mixed views in our team but you will get that back when you talked to everybody, there are some people who are really keen on its use...' [Health care professional 4, p20, p21].

One health care professional said that she would use part of SPARC, but wouldn't go through it all in one go.

'I could use part of it. I wouldn't say I would go through the whole framework or maybe I would over a period of time with the patient. But maybe not on one initial visit, it maybe something I would use there and pick in on that assessment, so if I had it there then yes...I think it's a good framework...but it's maybe something that you come in and out of because...depending on the mood of the patient at the time' [Health care professional 6, p29].

Some health care professionals said that they would be happy to use SPARC in the future, but for them it was more important to know when it was used.

'I would be quite happy to use it in the future...but again for me it's actually about when it's used' [Health care professional 12, p54].

One health care professional commented on the difficulties of trying to convince other colleagues to using SPARC, despite the fact that the hospital Trust had put SPARC on the intranet and promoted SPARC as the leading official holistic needs assessment tool.

'...I suppose my concern is I am working in a team, where the team itself doesn't use SPARC. They use a different holistic needs assessment, it's not even a formal tool. They have just got like a check-list of things, topics and that's in a sense my biggest failure that I haven't even convinced my own team, that's the nursing team to use SPARC, now that's more to do with you know politics and the fact that...I don't run the team I work with them, but with nursing team managed by a different management. But having said that, I'm very pleased that the Trust has now put SPARC on...it's intranet. It's become established as the leading, the official holistic needs assessment tool, so if anyone is going to do it properly they have to use SPARC, and the Trust is supporting that, but trouble is some of the individual nursing teams are opting not to do it and that is a problem and that is something we have to take up with the Trust' [Health care professional 20, p88].

The same health care professional quoted a recent study presented at the British Thoracic Oncology Group meeting in Dublin that supports the use of SPARC.

'...I came across a good piece of research recently, the British Thoracic Oncology Group meeting in Dublin in January a nurse from Rotherham, lung cancer nurse from Rotherham, had done a study where she'd compared SPARC with I think normal assessment. And she had found that patients all liked using SPARC, and the staff that have used SPARC also found that it was very helpful as well. So again that was an area where people were a bit resistant to using something new, but once they used it they found it very good' [Health care professional 20, p88].

7.7 Summary and discussion

This qualitative study was undertaken to elicit the views of supportive and palliative care health and social care professionals about their experiences of using SPARC during the trial. The study was conducted within the context of a pragmatic RCT and nested within the MRC framework for developing and evaluating complex interventions, in order to help in the interpretation of the trial outcome results. Eliciting the views of health and social care professionals represents an important phase in the development of SPARC (Ahmed et al., 2009; Hughes et al., 2015).

Ten prominent themes emerged from the health care professional interviews. Most health care professionals had something positive to say about SPARC and had previous experience of using SPARC, and most were considering using it at some point in the future. A number of barriers were identified to the relief of distress highlighted by SPARC. Lack of professional action and the numerous barriers identified following high level scoring of SPARC has revealed useful insights into how SPARC might be used in practice (EAPC, 2015).

The usefulness of completing SPARC has been discussed in **Chapters 6 and 7**. Patient and health care professional views are very similar on this matter. All health care professionals interviewed had something positive to say about the usefulness of SPARC, and patients gave reasons as to why they felt that SPARC was either helpful, worthwhile completing, or a good idea.

The findings suggest that health care professionals could benefit from using a more structured holistic needs assessment tool like SPARC to assess patients' holistic needs, alongside their normal face to face consultation with the patient on the wards (e.g. at bedside), in the outpatient clinic or during home visits. The findings support the use of both open-ended and closed questions. SPARC can help to structure and guide a consultation, and clinicians may benefit from reviewing a patient completed SPARC form alongside any physical examination that they undertake to assess patients' holistic needs. This approach appears to be the preferred method of assessing patients' needs.

SPARC was developed by our team of researchers based at The University of Sheffield and as one would expect, most health care professionals interviewed were aware of SPARC and had some previous experience of using SPARC before the study. This is largely due to the fact that much of the earlier development work on SPARC was undertaken in Sheffield at the same study sites. I also presented the study to colleagues and widely disseminated the interim findings at local meetings and at national and international scientific conferences in the fields of supportive care, palliative care, cancer care and end of life care.

Some of the more positive experiences of using SPARC, included how SPARC helped patients talk about issues, often sensitive and personal issues that would otherwise not have come up until the second or third visit.

Health care professionals' perceptions and expectations about what SPARC was actually used for varied, this was partly due to the fact that SPARC could either be used as a screening tool, as a guide for referral of patients to specialist palliative care, or as a holistic needs assessment tool. SPARC can also be used at different stages and phases of a patients' illness trajectory and at different time points (i.e. during referral, initial assessment, follow-up, discharge, or re-entry to the specialist palliative care service as a reassessment tool). SPARC may have some role in helping to triangulate an assessment between patients, their families, carers and their health care professionals, but this requires further work.

Most health care professionals and patients failed to connect with the study and viewed it primarily as a research study that was done 'remotely' to help the researchers. This became apparent from the limited feedback that health care professionals received from patients about using SPARC, and health care professionals did not discuss SPARC with them either. This points to an implementation failure of the intervention rather than failure of the SPARC intervention itself. It is possible that a standardised intervention such as SPARC will never supplement the quality of care unless it is properly integrated with the clinical methods and routine care planning procedures of the clinical team.

Due to the nature and sensitivity of some of the questions, it is recommended that completed SPARC forms should be discussed during a face to face consultation with the patient rather than over the phone. However, a combination of methods could be employed (e.g. letter, telephone and face to face consultation), this would largely depend on the type of issues, concerns or problems that need to be addressed, as well as the time and resources available.

With regards to the impact of completing SPARC on clinical practice, the findings suggest that there were only a very limited number of occasions when SPARC appears to have had an impact on clinical practice, and on most occasions this initiated a further discussion with the patient, often resulting in health care professionals having to call patients back to the clinic, but this did not take place during the study duration period. Therefore, one would not necessarily see any immediate impact on clinical practice or any improvement in patient health-related outcomes during the first six weeks of the study. This suggests that SPARC does have a role in the long-term monitoring and follow-up of patients.

There are similarities and parallels in the type of questions that both patients and health care professionals perceive to be sensitive, personal and potentially distressing. These include questions about: sexual problems; death and dying; end of life care issues; life is not worth living; and psychological issues. It is also worth noting that we need to take account of the concerns expressed by some practitioners about SPARC being potentially too burdensome for some patients, particularly those patients who are unwell and those coming to terms with the

illness, and there is also a genuine concern that you run the risk of raising patient expectations and reinforcing problems, issues and concerns that can't be solved. These concerns are well founded. Thus, the timing of asking these questions and the type of patients approached to complete SPARC is an important consideration. We must also consider how to help health care professionals become more comfortable in addressing and talking about some of these issues.

On a more positive note, this study reveals that SPARC can be a useful prompt to check on things that sometimes are difficult to talk about, and practitioners reflected on their positive experiences of using SPARC in relation to asking these questions. While there was some resistance initially to ask these questions, the consensus view was that it was ok to include them on a questionnaire, and some patients felt reassured that someone was looking into addressing their issues, problems or concerns.

There is some consensus around using SPARC as an initial assessment or as an early holistic needs assessment tool, preferably early on in the course of the illness, and then perhaps again at discharge, or as a reassessment tool. SPARC could be used outside the specialty and in primary care for referring patients into specialist palliative care. The precise timing of SPARC and how often it is administered requires careful consideration, this will no doubt depend on the type of patient being asked to complete SPARC, the setting in which they are located, and the stage and nature of their illness.

The findings support the need for health care professionals to receive education, training and skills around the use of SPARC, particularly around confidence building and on introducing and using SPARC, which were identified as important areas for further development. This is further supported by the finding that some practitioners working within specialist palliative care expressed concern about how they would deal with and address any concerns or issues highlighted by the patient. There were genuine concerns about leaving ward staff to deal with complex issues identified, and others who may not be skilled or trained to deal with such complex issues. This raises some very important questions. It demonstrates that even those practitioners working within specialist palliative care and considered to have expertise in this line of work, may need help, support and further guidance on how to use SPARC, and on how to deal with the complex issues and problems that are identified. We need to ensure that health care professionals receive sufficient education and training, and have the necessary skills to be able to tackle these complex issues. Education and training should also extend to the generalists and other practitioners who do not have the expertise within specialist palliative care, and the adoption of a more shared-care approach to caring for patients is recommended. Education, training and skills programmes should perhaps be delivered by more senior and experienced members of the supportive and palliative care team.

Holistic needs assessment methods (e.g. for identifying and addressing supportive and palliative care needs) training should also be incorporated further into training and education

programmes for future nurses, doctors and other allied health and social care professionals, which should continue during the initial stages of their training after they have qualified.

This study has demonstrated that health care professionals interviewed are very supportive of and receptive to the idea of using SPARC in the future, and the enthusiasm amongst teams and individual members of staff for using SPARC in the future, particularly amongst staff working at the hospice is very encouraging and reassuring. It is also worth noting that for SPARC to become widely adopted it must become embedded in health care professional roles (i.e. become part and parcel of their role) rather than become 'obligatory' or be seen as an 'enforcement'. There will of course be many obstacles and challenges in trying to convince all practitioners to use SPARC and this requires further investigation. There is a need to undertake further research on the clinical utility of SPARC in order to build a strong evidence base.

What are the underlying issues and reasons for little or no follow-up (patient versus practitioner views)?

In this section, I will present the underlying issues and reasons that attempt to explain why nothing appears to have changed, or no action taken i.e. why no beneficial effect was seen as a result of completing SPARC, and why there was little or in some instances no patient follow-up. I will also be comparing and contrasting patient and practitioner views.

When we presented the study to health care professionals during our initial site visits we asked them to treat completed SPARC questionnaires like any other correspondence (i.e. similar to correspondence that they may receive from a general practitioner or any other health care professional, that informed them of clinical issues). Unfortunately, this approach appears to have backfired and had a detrimental effect on the study design and on the outcome. Findings from case note reviews, patient interviews and health care professional interviews all confirm that on most occasions SPARC was filed away with no further action taken. As a result, practitioners took the view that this was only for research purposes, a view that was echoed by some patients. Although most practitioners said that they found SPARC interesting to look at, they were more inclined to go with their own assessment. Thus they treated SPARC tools that they got back as information they had not requested, and didn't tend to respond to the issues highlighted by SPARC.

The study suggests that practitioners felt that the research team did not provide clear guidance about what they should do once patients had completed the SPARC forms. Others felt that they weren't to address any highlighted issues, unless something jumped out that needed addressing, and some were unsure whether a health care professional was meant to be re-engaging with patients and unsure of the extent of this involvement. Practitioners were worried that their involvement may have an influence on the research study.

At the start of the study we did consider providing health care professionals with a clinical guide for SPARC, to help them make decisions about what actions they should take when

issues, problems and concerns are identified. However, our clinical colleagues felt that this was not necessary, because those working within supportive and palliative care service already had previous experience of using SPARC in the clinical service. The clinical teams had specialist knowledge, training, skills and the expertise to deal with these complex issues. For this reason, we designed the trial with the assumption that practitioners would act on the information elicited by SPARC. However, our findings suggest that it would have been useful to have developed a clinical guide or manual to accompany SPARC. This is an important consideration for the design of any future study of the clinical utility of SPARC, and equally important is the need for full cooperation, support and engagement of health care professionals with the design of any future study.

Practitioners wanted more ownership of the study and viewed this as a research study run by the research team (a view that was also shared by some patients), and felt that it was done as a third party, and they were not in the loop. Lack of engagement with patients and little or no follow-up of patients who had completed SPARC, seems to be a direct result of the belief held by practitioners that it was not them generating SPARC, and as a result of this, many of them did not engage with patients in the same way, and did not pro-actively follow-up patients to ask them about SPARC completion. Some patients specifically went on to say that they participated in the study to help the research and other people, or help others who might be in a similar situation in the future. Thus, both patients and health care professionals failed to connect and engage with clinical information generated by the study, and it seems that the only time health care professionals talked about SPARC, was when the patient chose to talk about it. For these reasons the completion of SPARC by patients may have raised their expectations that were not subsequently met. Practitioners nevertheless acknowledged that if they were a patient completing SPARC, then they would have expected somebody to have engaged with them.

It is important to point out that in some cases practitioners were receiving completed SPARC forms outside of the study period, or had only recently received them when I went out to interview them, and so one would not expect to see any immediate impact on clinical practice or changes in patient outcomes during the first six weeks of the study. This suggests that, despite hand-delivering completed SPARC forms to the health care professionals immediately upon receiving them, there is a need to review methods employed of relaying this information back to health care professionals much quicker, and we need to put appropriate systems and procedures in place that would allow one to track the journey of completed SPARC forms (i.e. from the point a researcher receives a completed SPARC form to the point where the health care professional has acknowledged receipt and beyond).

The study also suggests that when patients were discharged or moved from one setting to another, there was little or no follow-up during the study i.e. practitioners describe how on a number of occasions when SPARC results came back to them, the patient was in another part of the service or discharged and was referred back to primary care, and some patients died, so they didn't feel the need to take any action, with some still pondering over whether or not it

was ‘politically correct’ to contact the patient because they were under the care of another health care professional, a view held by both patients and health care professionals.

Some practitioners felt that by the time that they had received completed SPARC forms, it was simply ‘too late’ to take any action and the patient notes had gone somewhere else because as mentioned earlier, the patient was either discharged or had moved to other settings. It is true that in some cases, as practitioners pointed out, the process of getting SPARC forms back to health care professionals was not timely enough to have had an impact on health care professional assessment, and there is clearly a need for feedback much quicker (i.e. time delay/time-lag). The lateness of information accessed by SPARC was in part due to the timing of recruitment into the study. Participating nursing teams had been reluctant to approach or inform patients about the study until their second visit, after their own assessment had taken place.

The delay in patients returning the completed SPARC forms to the research team, and the further delay in the research team and site administrators returning them to practitioners caring for the patient (i.e. time lag between the patients starting the study and probably doing that questionnaire and health care professionals seeing the questionnaire), has meant that in some instances there was not enough time for SPARC to have had an impact on health care professionals’ assessment. This does raise some very important questions about the continuity of care, and follow-up of patients. This whole procedure of relaying information back to practitioners needs careful consideration. One option would be to have information i.e. the completed SPARC forms and the results relayed back to practitioners in ‘real time’.

For those patients that were discharged during the study, or previously discharged prior to completing SPARC or on an ‘open appointment’, it appears that the onus was on the patient to contact the health care professional if they felt the need to do so. This study demonstrates a failure of this system, and even patients with high levels of distress for a number of symptoms, issues and problems as evident from the completed SPARC forms, failed to contact and re-engage with their practitioners. Some patients even citing that they did not want to bother their practitioners because they didn’t consider themselves as ‘terminal’ and felt there were more deserving patients than them. Others felt that there was nothing more that could be done, or that no treatment was available and that they had reached a ‘dead-end’ and any improvements in their health had plateaued, or that they had ‘learned to live with the condition’ ‘adapted’ or ‘come to terms with the illness’ due to the long-standing issues. This view was held by both patients and practitioners. This may well be a true reflection of the clinical situation for many patients, particularly in the late advanced or terminal stages of the illness, and for some symptoms, problems and concerns there is only so much that could be done to help. However, I believe that better methods of assessment, monitoring and earlier management of patients may go some way in alleviating some of these problems and the distress that they cause, but this has yet to be established.

It is important to recognise the limitations of any intervention or treatment, and equally important is for this to be discussed with patients and their families or carers in a timely

manner. It is inevitable that even though a patient might score relatively highly on some of the items (i.e. for levels of distress), there will come a point when practitioners and patients will have to reach a mutual agreement that no further progress is likely beyond that point, as was the case in this study, a view shared by both patients and practitioners. It is also worth noting that some patients may have elected to receive no further treatment beyond this point despite being given the opportunity to continue with the treatment or intervention. We can conclude from these findings that there may come a point when it may not always be possible to resolve all symptoms, problems or concerns, and it becomes important to try and resolve the ones that are important to the patient in order to improve the patients' overall quality of life.

What also emerges is that some patients taking part in the study were not seen for a considerable amount of time, some were recalled back to the clinic as a result of completing SPARC, what is alarming is that many of these patients appeared to be in a much more distressed state than their health care professionals had originally anticipated. So from that one can conclude that the review period especially in an outpatient setting was too long, and needs to be reviewed urgently, this of course may have resource implications, for a service that is already stretched, and operating on limited resources, and on limited government funding.

Interestingly, some practitioners felt that concerns on the SPARC forms were taken seriously but were not sure if they have been referenced back to SPARC. This may well be the case, but I was unable to find any evidence of this when I reviewed the case notes, because not all symptoms, concerns and problems, treatments and clinical interventions are documented in the notes, thus making it difficult to cross check them with what patients identify on SPARC. SPARC could be used to improve the documentation of symptoms, issues and problems, and it is important to then link SPARC results with a care plan, i.e. holistic needs assessment questionnaires should be integrated with a clinical assessment that informs a care plan.

Some practitioners suggested that they had only recently received a limited number of completed SPARC forms, therefore not yet had a chance to follow them up.

A view that was shared by both patients and practitioners was that the study duration was too short of a time frame to detect any changes or differences in health status or quality of life. The study questionnaires (SPARC and other study questionnaires) were either too close together with appointments less frequent than the administration of the questionnaires i.e. they were not timely enough to have had an impact on health care professionals' assessment, and feedback is needed much quicker. From this, it can be concluded that the study follow-up period (i.e. 6 weeks) was too short. This could explain why there were no significant differences (no detectable effect) between the control and intervention groups in the scores for EQ-5D and Patient Enablement Instrument scores at two, four and six weeks follow-up.

I can draw from at least one example in the study where a nursing home patient scored high ('very much distressed by') for nearly all of the items on SPARC, and was in an extremely

distressed state. However the health care professional caring for the patient said that the institution wasn't able to meet the patients' needs at that time, and the practitioners and nursing staff were aware of this. The patient wanted more independence and didn't want to be in a nursing home in the first place, but for a patient to suffer from this level of distress is of great concern. The precise reasons why this may be the case is unknown as the patient died during the study, and I was unable to interview him. This finding suggests that SPARC does have a role in identifying holistic needs of patients in nursing homes, but how we then address these concerns for this group of patients and those in other care homes and institutionalised care settings requires urgent attention. Patients in these settings may benefit from a timely shared-care model approach to care with a much greater involvement of the palliative care team, but this is likely to have resource implications.

There has been an independent evaluation of SPARC by staff at the Sheffield Hospice prior to this study, and the results were positive and encouraging. However at the time of this study SPARC was not incorporated into practitioners' role, and this accounts for one of the main underlying reasons as to why there was little or no patient follow-up following completion of SPARC. SPARC was not seen as part of routine clinical practice, and practitioners just viewed it as another piece of information, like getting a letter from a GP/clinic, thus they wouldn't ring the patient up and discuss the results. There was a suggestion that if SPARC was used on a day to day basis as part of the culture, then perhaps practitioners may have been more proactive.

The findings also seem to suggest that some assessors felt that it was not the right time to talk about and address unresolved or outstanding issues or problems, and felt more comfortable with addressing these later on down the line when a better relationship was formed with the patient. I can draw from one specific example in the study where a patient had brought up the sexuality issue, but the practitioner caring for this patient said that this wouldn't necessarily have been something that she would have gone straight into talking about on her first assessment of the patient. It was interesting and very useful for practitioners that these issues were brought up much earlier on than would otherwise have been the case if they hadn't used SPARC.

Many patients had not seen anyone from the palliative care team for a considerable amount of time or not heard from anyone, and did not have any follow-up appointments throughout the duration of this study. This study has demonstrated that some of these patients were in a distressed state and should have been recalled back to the service. Some patients seem to suggest that their practitioners were unable to find out what was wrong with them, and therefore it was not much point going back to them. Both patients and practitioners suggested that problems, concerns, and issues change over time and that there is a need to periodically review patients and capture these changes, this is where SPARC would be a very useful safety net, if acted upon in a timely fashion.

There is a genuine and well-founded concern and belief that SPARC may increase workloads, especially in bringing back discharged patients, because not all patients stay continually on

the caseload. This has resource implications. That said, there is all round agreement that SPARC may be a more efficient and effective way of identifying problems, concerns, or issues and may actually save time in the long run, because SPARC helps patients focus on everything that distresses them. The cost-effectiveness of using SPARC needs to be established.

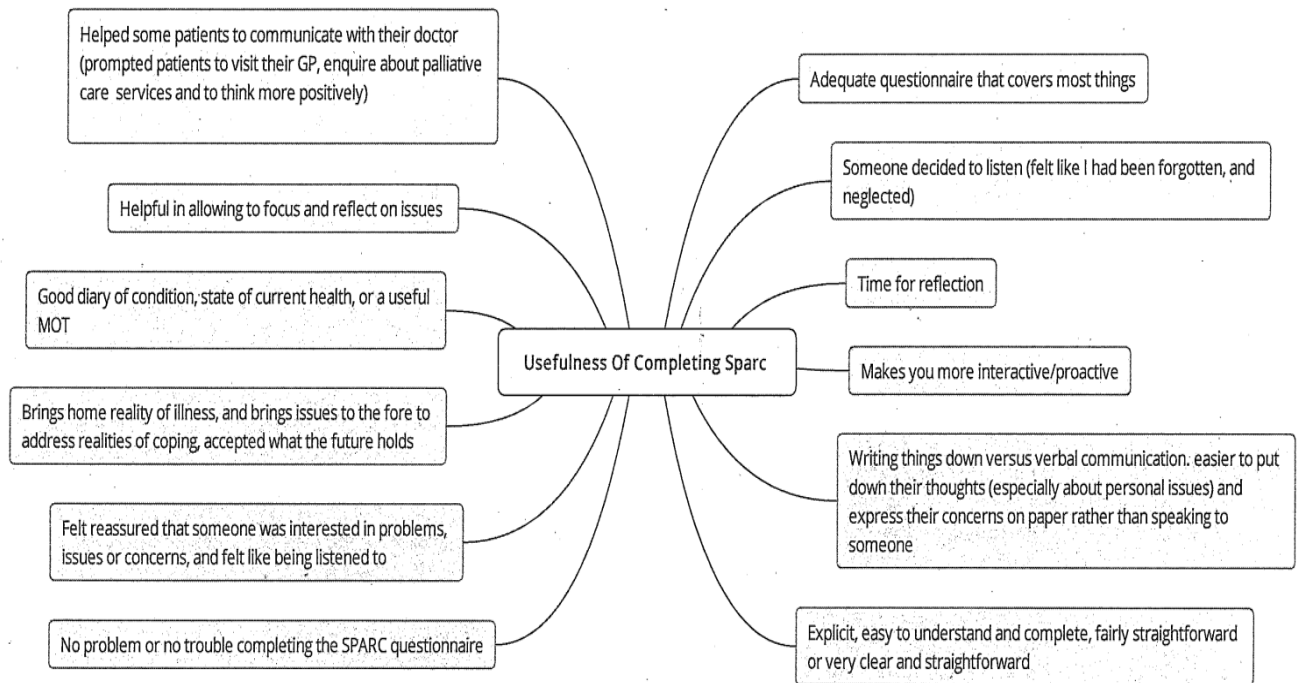
There was considerable discussion around barriers to the relief of distress highlighted by SPARC. There are concerns over limited resources available, time constraints i.e. limited time to discuss, unpack problems, issues and concerns, and difficulties with accessing and referring patients to psychotherapy services (e.g. psychologist, or psychiatrist). There are also difficulties with accessing home care/intensive home nursing/24hr nursing service, as well as other services. This is an accurate reflection of the kind of barriers to the relief of distress in the service, and one must be mindful of these when using SPARC. There is more work that needs to be done in order to identify these barriers and how best to overcome them.

Overall, supportive and palliative care health care professionals and patients considered SPARC to be an acceptable and relevant tool for the clinical assessment of supportive and palliative care needs (Ahmed et al., 2009; EAPC abstract, 2015; Hughes et al., 2015). However, the intervention was not sufficiently integrated within existing holistic needs assessment practice to impact on health care professionals' perceptions of their patients' needs, and therefore would not in itself prompt action. There is compelling evidence here to suggest an implementation failure, with little disagreement between practitioners and patients views on the underlying reasons for the lack of patient follow-up after the completion of SPARC. The effective integration of SPARC into routine care and standard operating systems requires further investigation, and systems and services must be in place to meet those needs in a timely manner.

A direct comparison of HCPs' views with patients' views on: 1) the usefulness of completing SPARC is summarised in **Figure 13**; and 2) the possible reasons why no beneficial effect was seen as a result of completing SPARC is summarised in **Figure 14**.

Figure 13: Usefulness of completing SPARC (Patient vs HCP views)

Patient views



HCP views

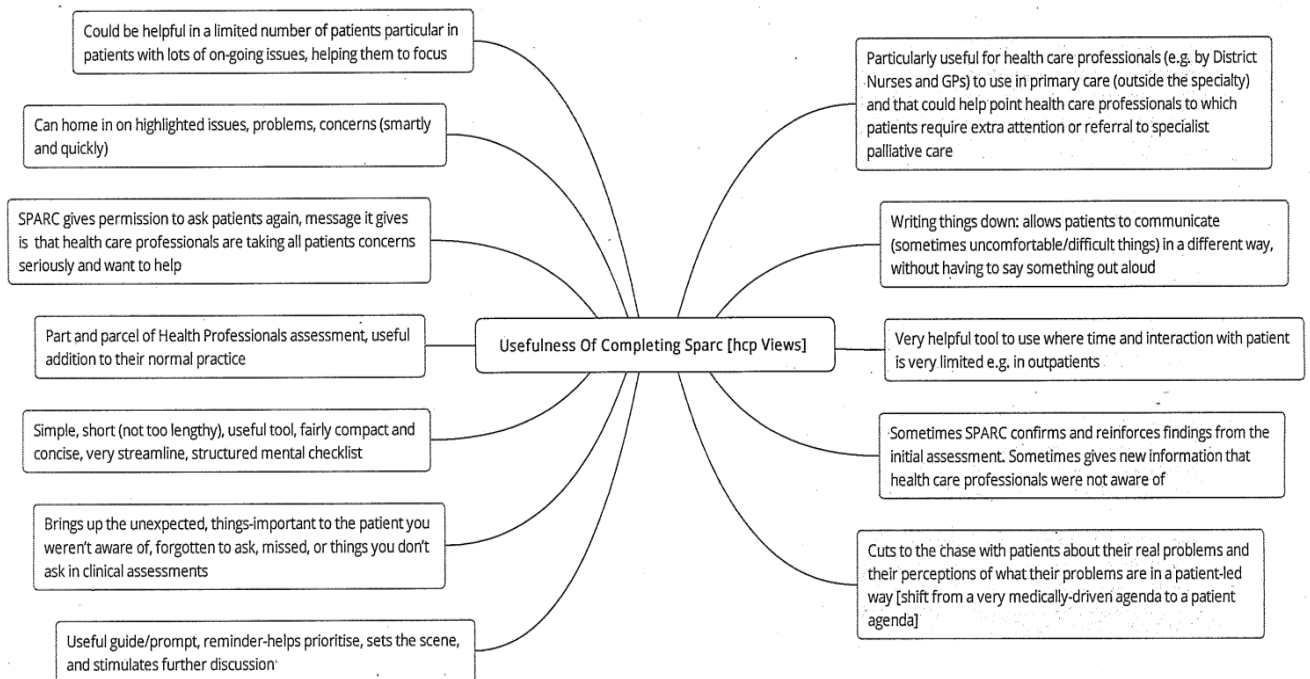
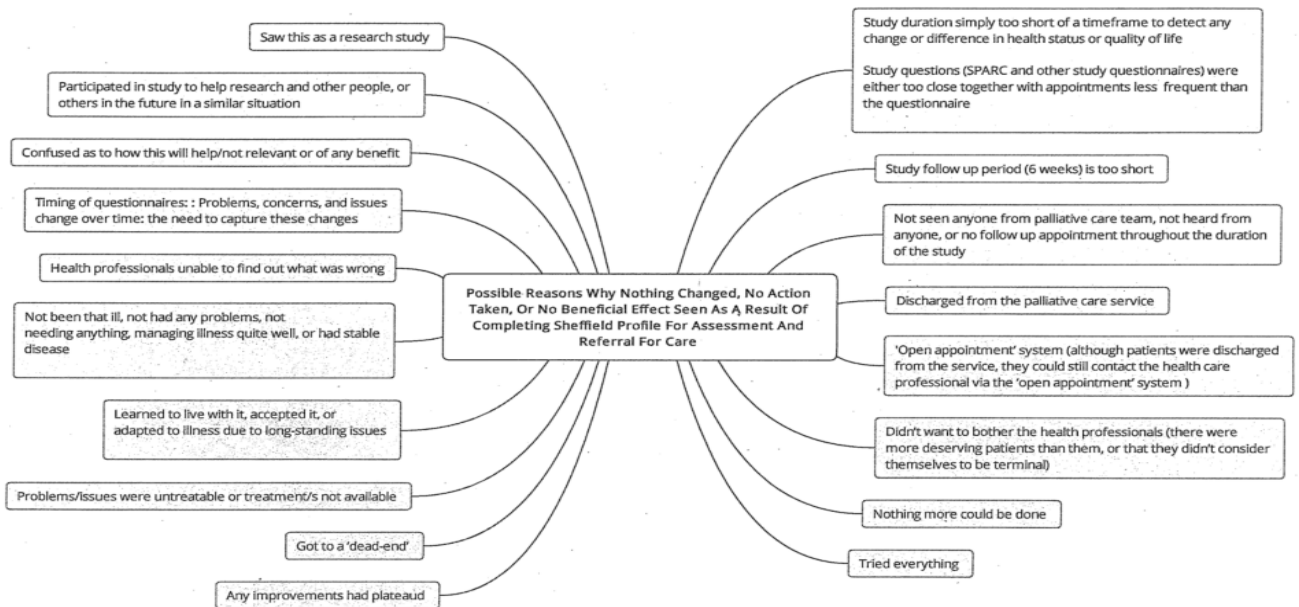
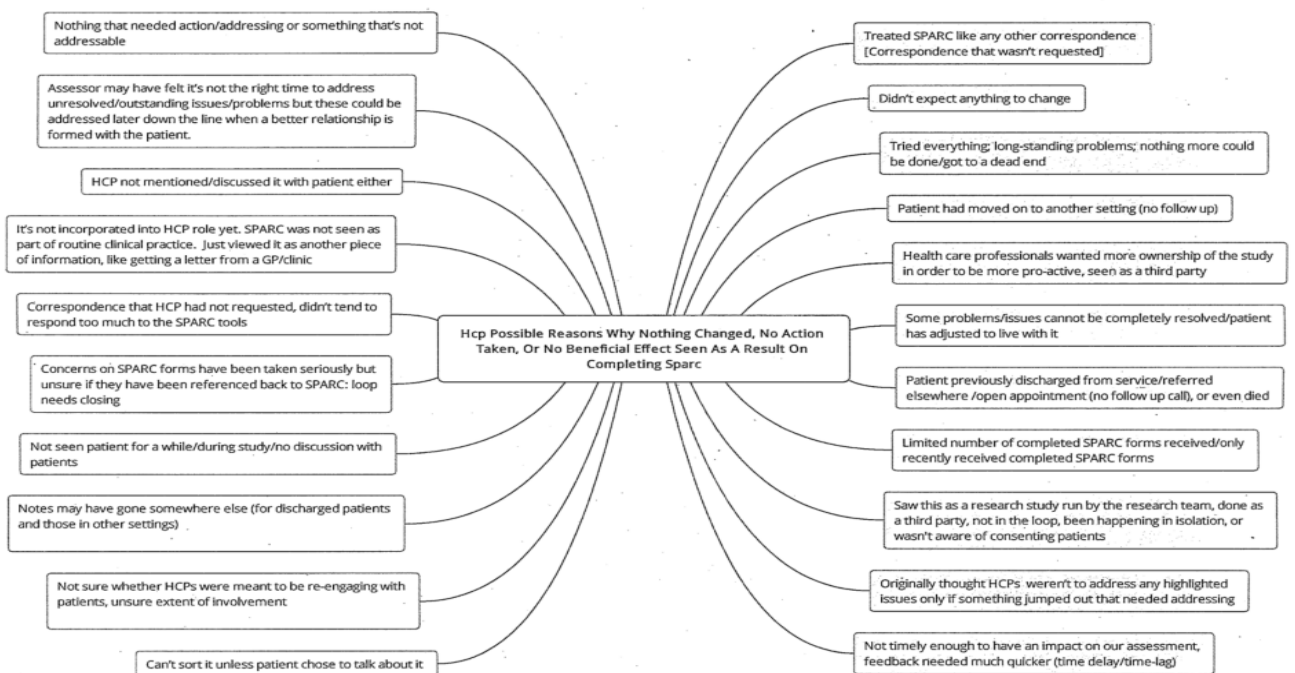


Figure 14: Possible reasons why no beneficial effect seen as a result of completing SPARC (Patient vs HCP views)

Patient views



HCP views



Chapter 8

8 Thesis summary and discussion

In this concluding chapter, I will start by synthesising and discussing the key findings across the thesis chapters, including conclusions about the assessment and when it does and does not work. I will discuss some of the methodological and ethical challenges that were encountered and the strengths and limitations of this study. Next, I will discuss the findings of this study in the context of other studies, and what insights implementation theories/ models may add (e.g. Normalization Process Theory and PARiHS). I will then discuss the implications for future research and practice, which is followed by a separate conclusion section. Finally, I present the main clinical, methodological and theoretical contributions that this doctoral thesis makes to the existing knowledge and literature in this field.

8.1 Discussion of results of pilot RCT

This doctoral study was conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for evaluating complex interventions. An embedded (or nested) concurrent mixed methods design was considered the most appropriate design for this study. The rationale for this design is discussed within this thesis. The primary objective was to design and undertake a pilot study to evaluate clinical outcomes associated with the use of SPARC. The trial itself focussed primarily on outcomes, not on the processes involved in implementing the intervention.

The purpose of this PhD and a secondary objective of the trial, was to undertake a process evaluation. On reviewing the literature, it became increasingly apparent of the importance of combining quantitative and qualitative research methods approaches in the development and evaluation of complex interventions in palliative care research. The process evaluation study comprised of three additional strands of work namely: 1) analysis of semi-structured interviews with patients; 2) analysis of semi-structured interviews with health care professionals; and 3) retrospective case note reviews (presented under findings and analysis of Phase I: outcome evaluation, **Chapter 4**). The use of qualitative and secondary quantitative analysis approaches alongside randomised controlled trials of complex healthcare interventions, in order to gain a better understanding of '*whether and how an intervention works (or does not work) and inform the design of subsequent studies*' is highly recommended (Craig et al., 2008a; Craig et al., 2008b; Ellard et al., 2011; Ezendam et al., 2013; Farquhar et al., 2011; Flottorp et al., 2003; Francis et al., 2013; Grant et al., 2013; Hind et al., 2010; Moore et al., 2015; Toroyan et al., 2004; White, 2013).

This study provided an opportunity to 'test-drive' SPARC with patients that have supportive and palliative care needs. The hypothesis was that the use of a validated multidimensional holistic screening tool for supportive and palliative care needs, namely; SPARC would lead

to improved recognition of supportive and palliative care needs, and improved health care outcomes for patients (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

This was an open, pragmatic, randomised controlled trial. Patients (n=182) referred to the palliative care service were randomised to receive SPARC at baseline (n=87) or after a period of two weeks (waiting-list control n=95). Primary outcome measure is the difference in score between Measure Yourself Concerns and Wellbeing (MYCAW) patient-nominated Concern 1 on the patient self-scoring visual analogue scale at baseline and the two-week follow-up. Secondary outcomes include difference in scores in the MYCAW, EuroQoL (EQ5D), and Patient Enablement Instrument (PEI) scores at Weeks 2, 4, and 6. As part of a process evaluation, case notes were reviewed at week 8, and semi-structured interviews were undertaken with a sub-group of patients and health care professionals (Ahmed et al., 2015).

In this pragmatic randomised waiting-list controlled trial, a higher proportion of patients in the control group (34/70; 48.6%) showed an improvement in their MYCAW score from baseline to Week 2 compared with patients in the intervention group (19/66; 28.8%) (p=0.019). There was no positive effect of the intervention on either the primary or secondary outcome measures at two weeks. This was an unexpected finding and raises questions about the trial design, application of the intervention and the context in which SPARC is used (Ahmed et al., 2015). The secondary outcome measure of quality of consultation similarly failed to detect any effect of the intervention. This is supported by the interview data from patients that indicate that most patients felt no particular action or benefit followed from the completion of SPARC (Ahmed et al., 2015). Only a few patients who had no recent contact with palliative care service and scored high for some SPARC items were recalled by the service and reassessed.

There were no meaningful or significant differences between the control and intervention groups in the scores for EQ5D and PEI at 2 weeks, 4 weeks or 6 weeks, suggesting that the intervention did not have a detectable effect.

When data that applies to the study overall population (intervention plus controls) was considered, health-related quality of life as recorded in the general measure EQ5D is changing for the worse in this study population as would be expected of patients attending a palliative care service. However, the most important issue for patients as recorded in MYCAW appears to be improving suggesting that usual palliative care is having a beneficial effect in this respect. No change is observed in the quality of consultations as recorded in PEI throughout the duration of the study (Ahmed et al., 2015).

A number of barriers were identified to the relief of distress highlighted by SPARC: these have been presented in considerable detail in **Chapter 7**. Only 5/164=3.0% patient notes made any direct reference to SPARC. This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical

assessment that informs the care plan (Ahmed et al., 2015). Overall, participants and health care professionals considered SPARC an acceptable and relevant tool for the clinical assessment of supportive and palliative care needs (EAPC abstract, 2015). The supplementary question on SPARC, endorsed the overall view that the questions were clear, well written, easy to understand and complete, appropriate and relevant. The underlying issues and reasons for little or no follow up; patient views (**Chapter 6**); and practitioner views (**Chapter 7**); and a comparative analysis has been presented in considerable detail in **Chapter 7** (patient vs. practitioner views). For the small number of patients where completion of SPARC resulted in either referrals being made or consultations being undertaken in the form of a follow-up call, these took place after the study duration period, so one would not expect to see any changes in health outcomes during the first six weeks of the study. These are very important considerations that one must consider when designing any future study of the clinical utility of SPARC.

8.2 Strengths and limitations of the study

The main strength of this trial was that it was undertaken in a real setting rather than artificially controlled conditions or settings. When considering data quality, it can be concluded that the study design and methods were appropriate to the study population. The 26.5% (225/850) recruitment rate is one indicator of this, as is the fact that out of 225 patients that consented, only 7 withdrew for reasons of burden of research assessments. The lack of differences between study arms for either demographic factors or baseline research assessment values is another indicator of good data quality and a successful randomisation. The strategy of stratification for baseline quality of life was added to the design to ensure equivalence between trial arms. It appears that this was successful with the exception of the number of hospital admissions in the 12 months prior to baseline. The difference was not statistically significant but may have had a bearing on changes in MYCAW scores; Group A (intervention) was 6.30 (median 4; SD =6.60) and in Group B (control) was 4.45 (median 3 SD = 5.67), (Mann-Whitney $Z = -1.593$; $p = 0.111$). This is reflected in the difference in the mean number of days in hospital in that time; Group A (intervention) 22.15 versus Group B (control) 15.51. This raises the question of using patients' history of admission as a criterion for stratification.

Although recruitment rates were very close to estimates in the study protocol, these tailed off towards the end of the data collection period. A total of 850 invitations were sent out, leading to consent obtained from 225 patients (225/850=26.5% response rate) and 182 patients returning baseline data. 152 patients completed the 2-week questionnaires as against 128 required to achieve adequate power.

In relation to the aim of the study concerning the feasibility of an RCT of early holistic needs assessment, using SPARC; it can be concluded that the estimates of recruitment rates were broadly correct. Instead of an estimated 75% attrition rate limiting the data returned at two weeks, a 32.4% attrition rate was observed from consent to two-week follow up in a

population largely made up of home care and out-patient clinic patients. This limited study population required the continuation of trial recruitment for a period of 5 months to allow data collection to the required power achieved with data from 128 patients at the crucial analysis of the primary outcome.

The lack of success in recruiting patients within the hospital support service meant that the study sample had fewer patients with conditions other than cancer and a smaller proportion of patients acutely ill than the whole population of patients referred to the palliative care service (Ahmed et al., 2015). In fact, the poor recruitment in the hospital support team was due to a lack of credibility of the process amongst clinical team members, they were concerned that SPARC raised problems and expectations that could not be resolved. The consequence was that attrition in this study population was rather less than expected and it is possible that we missed an opportunity to allow the intervention longer to achieve an effect in individual patients. It would be recommended that future trials of SPARC carry out a first research assessment significantly later than two weeks following baseline assessment to allow clinical intervention related to SPARC returns.

The lack of recruitment of patients with conditions other than cancer, in large numbers, has meant that the aim of comparing their difference in quality of life at baseline was impractical. However, it was possible to compare patients identified as cancer survivors with those cancer patients receiving end of life care. A significant difference was detected only in the EQ5D thermometer score, with cancer survivors reporting a better quality of life than those receiving end of life care. This finding is consistent with previous studies measuring a deteriorating quality of life as death approaches and highlights the continuing and increasing need to relieve distress in the terminal phase of cancer. However, no difference was detected between groups in the MYCAW first concern score, PEI or other EQ5D scores, suggesting that it is the quantity of distressing symptoms, rather than the intensity of particular concerns that worsens as life comes to an end.

It is possible that the context of a specialist palliative care service is the most difficult environment to test a new holistic needs assessment technology, in that the existing assessments used by the trained clinicians may well be sufficient to detect all the issues that require attention and there are the skills within the service to do what can be done in terms of improving quality of life, with or without using SPARC (Ahmed et al., 2015).

A further aspect of the design of the intervention, already identified as a possible weakness of the study, is that it was confined to administering the SPARC questionnaire and informing the attending health care professional of the results. It is possible that this is insufficient to change practice within a service; and without a change in behaviour (Campion-Smith et al., 2011), no effect is possible. It was assumed that benefits follow from actions prompted by SPARC returns. The intervention may not have been sufficiently integrated within existing holistic needs assessment practice to impact on health care professionals' perceptions of their patients' needs, and therefore would not in itself prompt action. It is recommended that future

trials should link the revelation of SPARC data to the consultation, thus facilitating action on issues identified by the assessment. An alternative recommendation is for trials of SPARC in primary care or general hospital ward populations. Patients might also benefit from receiving SPARC at the point of referral to the palliative care service and at the point of discharge.

It is also possible that a standardised intervention such as SPARC, will never supplement the quality of care unless it is properly integrated with the clinical methods and routine care planning procedures of the clinical team. Scandrett et al., 2010, propose that new methods to achieve practice change should be considered and evaluated when assessing such interventions (Ahmed et al., 2015).

8.3 Results in context of other studies

Several lines of research suggest that there is a wide variety of assessment tools currently used by health care professionals to assess patients' needs, and there appears to be a considerable amount of questionnaire/tool validation research already undertaken (Ahmed et al., 2014; Richardson et al., 2007). Many of these tools have been developed primarily to address the needs of cancer patients. The feasibility and acceptability of these tools (i.e. patients' views on being asked to complete an assessment questionnaire/tool, reasons for non-response, time needed to complete or administer, and practitioners' views) to both patients and practitioners for use in routine clinical care is lacking, and identified as a severe limitation of all the cancer needs assessment tools (Richardson et al., 2007).

There is a lack of good quality prospective trials in this area which is in need of urgent attention. Richardson et al., 2007, recommend that we now shift the focus of our attention on establishing the effectiveness and clinical utility of these tools i.e. how one might integrate these tools into routine care and practice and determine what impact these tools have on care processes and service utilisation.

There is a need for greater transparency and documentation of the process of tool development, and all key stakeholders (e.g. health and social care professionals, patients, and relevant consumer groups) must be involved in all stages of tool development, to ensure that tools are not only feasible, relevant and acceptable but also 'fit for purpose'. There must also be evidence that they are effective i.e. produce measurable beneficial outcomes in a broad range of patients (Cancer Action Team Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer: Assessment Guidance, 2007; Richardson et al., 2007).

There are a number of assessment tools e.g. Problems and Needs in Palliative Care instrument (PNPC), SPARC, symptoms and concerns checklist and Needs at the End-of-life Screening Tool (NEST) that have been specifically developed to meet the needs of advanced cancer patients. These tools were developed for use in an outpatient clinic, with a few exceptions; the Needs Evaluation Questionnaire (NEQ) and the NEST, which were designed

for hospitalised cancer patients and the SPARC and symptoms and concerns checklist can also be used in a primary care setting (Richardson et al., 2007).

It is important to recognise that not all of these tools will cover all of the domains considered important for a ‘holistic assessment’. We know from previous work undertaken in this field that the degree of coverage varies widely. The most comprehensive instruments with respect to health status (defined as covering to some degree the full range of needs related to health status) include the Problems and Needs in Palliative Care instrument (PNPC), Oncology Clinic Patient Checklist (OCPC), symptoms and concerns checklist, Supportive Care Needs Survey (SCNS), the Distress Management Tool and SPARC (Richardson et al., 2007).

The importance of improving methods for the recognition of supportive and palliative care needs is widely acknowledged by the research community, however Richardson et al., 2007, argue that this does not necessarily lead to improved patient management or improved patient outcomes, without careful care planning, in other words systems and services must be in place to meet those identified needs in a timely manner. Furthermore, there appears to be a lack of coordination between the different practitioners both within and across disciplines for sharing of patient information leading to repeated and sometimes ‘unnecessary assessments’, or ‘duplication of efforts’ (Richardson et al., 2007).

In the field of supportive and palliative care, it is important to improve clinical or patient-centred outcomes which may include one or more of the following: improving a patients’ quality of life; reducing their levels of unmet need; improving patient–practitioner communication; and improving a patients’ well-being; or their satisfaction with the care received.

The practitioners interviewed in this study were using assessment tools that they felt most comfortable using, or ones that had been developed ‘in-house’ or ‘custom designed’ by the team. There is some concern over this practice as not all of these tools have undergone rigorous psychometric testing and validation, and for some the clinical utility has not been established. There is a need to build the evidence base prior to using tools in routine care.

To my knowledge, only two published studies have examined the clinical utility of holistic needs assessment tools. These two tools are: 1) The Initial Health Assessment (IHA), designed to improve the recognition and documentation of a patients’ supportive care needs (Crooks et al., 2004; Richardson et al., 2007); and 2) NEST13+ (Needs of a social nature; Existential concerns; Symptoms; and Therapeutic interaction), a screening tool for advanced illness care needs (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Richardson et al., 2007; Scandrett et al., 2010). Although these two studies have measured changes in clinical outcomes following needs assessment, to my knowledge no controlled study has demonstrated an improvement in clinical or patient reported outcomes as a result of the intervention (administration of the tool) (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

The Initial Health Assessment (IHA)

The IHA is designed to improve the recognition and documentation of a patients' supportive care needs. The form comprises of twenty-two supportive care items under eight domains of need: physical; psychological; daily living; social; financial; informational; special needs and personal resources.

Crooks et al., 2004, undertook a study to determine whether the introduction of the IHA into clinical practice leads to an improvement in the assessment of a patients' needs, personal resources available to meet the needs identified (primary outcome) and documentation of a management plan of care (secondary outcome) to meet unresolved needs as compared to routine practice. The IHA was introduced during a patients' first visit to a comprehensive cancer centre (Hamilton Regional Cancer Centre). A before (i.e. pre-intervention evaluation; T1 over a 3-month period) and after (post-intervention evaluation; T2 over a 3-month period) study design was employed. The Charts of consecutive patients (n=306 charts evaluated; 153 each in T1 and T2) with newly diagnosed cancer were randomly selected.

The authors describe how the introduction of IHA significantly increased the mean documentation of supportive care needs and resources from 26% in T1 to 49% in T2 ($p=0.001$), significant improvements were seen in all domains of need and this was most evident for psychological needs, increasing from 9% in T1 to 49% in T2 ($p=0.0001$). However, there was no significant improvement in the documentation of the management plan (outcome of secondary importance) for supportive care services delivery to meet unmet needs (28% in T1 versus 32% in T2, $p=0.10$). This was identified as one of the major limitations of the IHA. The authors concluded that while the results were encouraging and promising with respect to improving documentation of supportive care needs and resources, further work was necessary to establish the clinical utility of IHA. The authors argue that clinician behaviour is complex, and certain factors may have influenced this (e.g. their knowledge, attitudes and ability), and the introduction of the IHA into clinical practice and routine care is unlikely to change or motivate practitioners' values, behaviours or practices without further support, training and education. Further support and training sessions (given to staff to complete the IHA, especially in the area of planning of supportive care service delivery), better time allocation for those who undertake an assessment and endorsement of IHA may help to improve the documentation, assessment and outcomes. These findings are not dissimilar from the findings of this doctoral study. The authors point out several other potential limitations, these include relying on a documentation in the patients' chart as an indicator of assessment of patients' supportive care needs, and not all needs are documented, and lack of need is just as important to document as the presence of a need, this is where a tool like SPARC would be useful. The before-after design was chosen to evaluate the IHA over an RCT design, mainly due to 'logistic' limitations in performing an RCT at a single centre (Crooks et al., 2004; Richardson et al., 2007).

NEST13+ (Needs of a social nature; Existential concerns; Symptoms; and Therapeutic interaction)

Scandrett et al., 2010, assessed the feasibility and effectiveness of the NEST13+ (Needs of a social nature; Existential concerns; Symptoms; and Therapeutic interaction) as a screening tool for advanced illness care needs. The tool comprises of 13 initial screening questions and depending on the answers, the tool has the ability to evaluate identified needs in more detail with a potential to ask 48 questions. The authors describe the tool as a ‘comprehensive’ needs assessment tool, but brief enough for bedside administration. A controlled trial with 451 patients hospitalised for cancer care at a comprehensive cancer center was undertaken. The primary objective of this study was to determine whether the introduction of NEST13+ into clinical practice, would lead to an improvement in the documentation of patients’ needs (e.g. social, emotional, physical, and care-system needs), and an improvement in clinical outcomes for cancer patients in tertiary care.

Patients were asked 13 initial screening questions (intervention arm), followed by more in-depth level of questioning (only asked if individuals exceeded a certain threshold level for the screening questions). In the intervention arm, clinical recommendations were generated for each dimension of need and results were conveyed to the clinical team caring for the patient. Subjects were assigned to either the intervention or control arm (subjects were blinded).

A baseline assessment was undertaken in both groups, and further assessments undertaken at the pre-intervention phase and then again at the post-intervention stage, patients received usual care plus NEST13+ (yes and no answers, items rated 0-10 scale; 10 highest severity rating) and 48 follow-up evaluation questions (intervention arm), this was compared with usual care alone (control arm). Patients in the control arm were asked twelve questions about satisfaction with facilities and admission process (Control arm Sham interview), measurements included: documented needs; clinician response; patient perception of goals alignment; and overall quality of palliative care. The main finding from this study was that the introduction of NEST13+ tool in the clinical setting facilitated greater documentation of illness-related needs than routine clinical assessment i.e. significantly more needs were documented in the intervention group patients compared with patients in the control group (in 7 content areas), with physical needs being documented highly in all groups. The authors concluded that NEST13+ tool facilitated identification of a much wider range of important needs as compared with the ‘existing or traditional evaluation’. Interestingly, NEST13+ identified several important psychosocial needs. This led them to conclude that the ‘existing or traditional’ evaluation of patients’ needs may be in need of improvement. The quality of care as judged by expert chart review showed no significant differences between the two groups i.e. the intervention did not lead to any detectable improvements in care, changes in the clinician response were described as ‘modest’, and changes in outcomes were not significant (Scandrett et al., 2010).

One major limitation identified relates to the generalisability of the results to other patient settings because patients were recruited from a tertiary cancer inpatient center. There was also the possibility of some cross contamination of subjects in control and intervention groups (patients recruited from each of 4 oncology units treated by same clinical teams), and a large number of patients were ineligible due to the study inclusion criteria.

The findings from this study, in many ways resemble and mirror the findings of this doctoral study. Firstly, uptake of recommendations from NEST13+ intervention was described as poor, secondly, the integration of identified problems, concerns and issues into a comprehensive care plan was incomplete, and thirdly, the outcomes of care remain unchanged, and like SPARC the clinical effectiveness of NEST13+ remains to be established.

Limitations of these studies may include inadequate power to detect a change, the tools may not be appropriate or not comprehensive enough for holistic needs assessments, or the outcomes chosen may have been inappropriate (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Hales et al., 2010; Salisbury et al., 1999; Zimmermann et al., 2008). Although many of these studies have shown an improvement in the documentation of needs, uptake of any recommendations from the intervention and assessment of needs have been described as poor, with no significant overall improvements in care outcomes (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

The precise reasons for these findings are unclear, but may be related to health care professionals' attitudes, knowledge or skills, as well as timing of the recommendation and the availability or non-availability of services (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Scandrett et al., 2010). As stated above, it is possible that a standardised intervention such as SPARC, will never supplement the quality of care unless it is properly integrated with the clinical methods and routine care planning procedures of the clinical team (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

8.4 Discussion of patient semi-structured interviews

A qualitative study concerning the views of patients about their experiences of completing SPARC was conducted within the context of a pragmatic randomised controlled trial and nested within the MRC framework for developing and evaluating complex interventions, it may help in the interpretation of the trial outcome results. Eliciting the views of patients represents an important phase in the development of SPARC (Hughes et al., 2015).

In terms of ease of completion, appropriateness and relevance of SPARC, overall most patients interviewed found SPARC either quite easy to complete, fairly straightforward, simple, or they had no problems in completing it (EAPC, 2015), and many patients regarded the questions on SPARC to be either, suitable, appropriate, or relevant and applicable. Additionally, qualitative comments (supplementary question on SPARC) endorsed the overall

view that the questions were clear and well written, easy to understand and complete, appropriate and relevant.

Only a small number of patients considered the questions on either religious and spiritual issues, worrying thoughts about death and dying, some family and social issues questions, and the psychological questions to be sensitive or too personal. However other patients valued these questions and the consensus view appears to be that these questions should be included, despite the sensitive or personal nature.

Although the experiences of patients completing SPARC generated a wide variety of responses, overall most patients considered SPARC to be helpful, worthwhile completing, or generally a good idea or concept. Only a small minority of patients considered SPARC to be unhelpful, with some patients making reference to the negative impact of completing SPARC on other people, such as on family or carer/s.

On the issue of timing of administering SPARC to patients, most patients appear to be in favour of SPARC being administered before or just after the patient goes to see the doctor or consultant; at the very beginning (perhaps not on the very first visit) or early stages of the illness; and perhaps then again at regular intervals as a follow-up. Many patients cited time constraints/limited time available to see a doctor or a health care professional in clinic.

On the contrary, some patients felt that SPARC may not be entirely appropriate for newly referred patients, or for those patients going through the first or very early stages of the illness, with some suggesting that a more appropriate time to consider administering SPARC, would be after the patients have had a chance to accept the diagnosis and have had some time to come to terms with their illness. The sensitivity around which type of patients, in particular how and when patients should be approached requires careful consideration.

A crucial finding in the context of the trial (EAPC abstract, 2015), was that most patients felt that no particular action or benefits followed from the completion of SPARC (Ahmed et al., 2015; EAPC, 2015). Only a small number of patients that scored high for some SPARC items were contacted or recalled by the service and reassessed, there are numerous possible reasons as to why most patients interviewed felt no improvement or beneficial effect following SPARC administration, and these have been presented in considerable detail.

What is clear from this interview data is that there is an urgent need to improve the way patients' needs are identified and managed in a timely manner, in particular how best to follow-up patients discharged from the service. Furthermore, there are resource implications that one must also consider.

Many patients talked about the general lack of information and poor levels of communication from health care professionals about their illness, treatment or care, with some patients suggesting that they would have benefited from more explanation from health care

professionals about their illness, that said, fifteen of the seventeen respondents praised the service, care, or treatment that they received, with many pleased with the level of care they received, particularly at the hospice.

Although patients with a cancer diagnoses were the largest single category, previous work has demonstrated acceptability and relevance of SPARC across a range of disease and conditions (Hughes et al., 2015).

This qualitative study has revealed useful insights into how SPARC might be used in practice (EAPC, 2015), and to the best of our knowledge is the first to explore the reasons as to why we may have observed no significant overall improvements in care outcomes following the administration of SPARC from the patients' perspective (Ahmed et al., 2015). The results of this study, and others (Hughes et al., 2015), indicate that SPARC is a suitable, relevant, applicable and useful tool for the holistic assessment of supportive and palliative care needs, with the potential to improve health care professionals' understanding of patients' needs (Hughes et al., 2015).

The availability of services and resources to respond to any identified needs requires careful consideration (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Pollock, 2015). Systems and services must be in place in order to address any identified needs in a timely and sensitive manner (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Barclay & Maher, 2010; Bristowe et al., 2015), and we must consider and evaluate new methods to achieve practice change.

Taken together, the findings from this component of the study, together with the qualitative feedback about patients' experience of completing SPARC, would strongly point to an implementation failure rather than failure of the SPARC intervention itself (Ahmed et al., 2015). The potential negative effect of SPARC in a specialist palliative care service could be due to the failure of health care professionals to act on identified needs in a timely manner, or related to the raising of patients' expectations that are not subsequently met (Ahmed et al., 2015). Further research is also needed on the effective integration of these tools into routine clinical care. Future work must therefore address these issues. The findings from this work serves as a useful guide for researchers designing future supportive and palliative care complex trials.

8.5 Discussion of health care professional semi-structured interviews

A qualitative study was undertaken to elicit the views of supportive and palliative care health and social care professionals about their experiences of using SPARC during the trial. The study was conducted within the context of a pragmatic RCT and nested within the MRC framework for developing and evaluating complex interventions (EAPC abstract, 2015), in order to help in the interpretation of the trial outcome results (Craig et al., 2008a; Craig et al.,

2008b). Eliciting the views of health and social care professionals represents an important phase in the development of SPARC (Ahmed et al., 2009; Hughes et al., 2015).

Although there are some similarities, particularly amongst the hospice staff in assessing patients'/families' holistic needs, there appears to be no definitive method, model or any particular set of tools used for assessing patients'/families' holistic needs. Assessment often involved a routine clinical/medical interview undertaken in a 'conversational style' that had a professional agenda as a structure, but was mainly described as being 'patient-led'. Referral forms and discharge summaries from the wards were often used by health care professionals as guides and starting points for undertaking a holistic needs assessment. An holistic needs assessment document (covering all systems) appears to be the most commonly used model/template used by the hospice staff. Nearly all of the health care professionals interviewed were aware of SPARC before the study, and most had some experience of using SPARC prior to study commencement.

Interestingly, just over half of the sample of health care professionals interviewed said that they had limited or no feedback from patients about using SPARC, or had not discussed it with them, generally the feedback received from those patients that gave it was positive. Health care professionals said that they used a combination of methods (by telephone, letter, or face to face) depending on the circumstances to discuss SPARC results with patients, however the preferred method appears to be face to face rather than phone discussion/consultation with patients. Health care professionals said that on most occasions the completion of SPARC by the patient often initiated another discussion with the patient. The majority of health care professionals stated reasons as to why completing SPARC resulted in no changes in actions taken for the better or for the worse. All 20 health care professionals taking part in the study had something positive to say about the usefulness of SPARC, comments on usefulness of SPARC were in the majority. Most participants welcomed this as another way for patients to communicate their problems, issues and concerns, with some suggesting that writing things down on a form may help patients feel more comfortable discussing and bringing up concerns, particularly in discussing the more sensitive issues/personal issues that they would have otherwise felt uncomfortable talking about. Just over a half of the sample of health care professionals interviewed stated reasons as to why it is, or why it could be potentially unhelpful or not worthwhile for patients to have completed SPARC, with some saying that you run the risk of reinforcing the situation and problems that can't be solved, and others saying that sometimes it just adds to the burden to what patients are having to cope with anyway.

The majority of health care professionals commented on the most inappropriate/too personal/sensitive/invasive/offensive/upsetting/bothering questions on SPARC. These questions were identified as being the following: talking about sexual problems; questions about death or discussing death; end of life care issues; psychological aspects; the loss of independence; feeling that life is not worth living; advanced care planning; treatment issues; and the long-term effects of treatment.

The main barriers identified by most health care professionals to the relief of distress highlighted by SPARC were as follows: the availability of resources; referral to psychotherapy services/psychiatrist/psychological support; availability of time to discuss things/time to unpack problems in the outpatients setting; increased workloads; privacy on the wards; access to home care; availability of intensive home care nursing/24hr nursing support; the worry that if SPARC highlighted lots of issues; the health care professional wouldn't have the skills to deal with those issues; identifying something that they can't then fix; and opening up a can of worms that the health care professional is not equipped to deal with; or that it opens up a can of worms that the patients weren't ready to open were some of the barriers identified. The majority of health care professionals commented on the timing of giving SPARC to patients, the main time points considered as important by health care professionals varied and have been presented. Some health care professionals made reference to the need for more education, training and skills around the use of SPARC. All 20 health care professionals said they would either use SPARC in the future or consider using it. It is fair to conclude that the vast majority of health care professionals interviewed in this study support the use of SPARC and there seems to be a lot of enthusiasm amongst teams and individual members of staff about using SPARC in the future.

8.6 Implementation of SPARC into routine clinical practice

What insights implementation theories/ models may add (e.g. Normalization Process Theory, and PARIHS)?

There are numerous factors affecting implementation that require further exploration, these include: clinician attitudes; knowledge and skills; presence of local champions, timing of recommendation/s; and systemic barriers to responding clinically. There is a need to understand, identify and overcome barriers to change (NICE Guidance, 2013).

The NICE guidance, 2013, recognises that certain factors/conditions may be more conducive to facilitating change than others. These include organisations with strong leadership, and motivated staff, where the focus and desire is on the continuous improvement of patient care (Rycroft-Malone, 2004; Rycroft-Malone et al., 2013). I have identified certain barriers during this study e.g. lack of credibility of SPARC amongst some practitioners and concerns over changing established practice, which may prevent or impede progress in all organisations. In order to develop a successful strategy for change, we must understand all the different types of barriers identified during this study, and there is a need to put a clear system in place to support the implementation of evidence-based guidance (Rycroft-Malone, 2004; Rycroft-Malone et al., 2013). This may require a tailored approach to overcoming these barriers depending on the organisation, in order to encourage changes in behaviour, but this requires further work (NICE guidance, 2013).

The process evaluation guidance recommends the development of a logic model or explanatory model of an intervention i.e. more details about the intervention components and

pathways are required in order to deliver the desired outcomes (May et al., 2009; Rycroft-Malone et al., 2013; Murray et al., 2010).

It is important to engage with key stakeholders including trialists, trial designers, recruiters, intervention developers, patient and public representatives, patients and health care professionals, and qualitative researchers, throughout the process of development of an intervention. Involving users in the design and conduct of evaluations may contribute to a better understanding of the processes by which change is achieved (MRC Guidance, 2008). The introduction of SPARC into clinical practice does not require a fundamental change from usual practices because most practitioners were using some form of assessment tool/guide on which to base their assessment process. Therefore one should not experience any major challenges in its implementation. However, it is important to consider the wider context in which a trial operates, because the context in which the intervention is implemented, economic climate, staff shortages, media scares, resources and structures required to achieve practice change and the services available to meet identified needs may have an impact on the implementation of an intervention (Rycroft-Malone, 2004; Rycroft-Malone et al., 2013).

Despite the challenges faced, and concerns about the appropriateness of using RCT methodology particularly in palliative care research, the RCT methodology, provided it can be ethically justified, remains the best means of establishing whether an intervention like SPARC has a measurable impact (Bennett, 2007; Grande & Todd, 2000). However the importance of undertaking further feasibility work around the use of SPARC and implementation is urgently needed prior to embarking on a large scale costly study. Further work should focus more on intensive practitioner directed interventions and we must consider what insights implementation theories/ models may add (e.g. Normalization Process Theory and PARiHS). Additional research on the effective integration of SPARC into routine care is the vital next step (May et al., 2009; Murray et al., 2010; Rycroft-Malone et al., 2013).

There has been considerable interest in the development and evaluation of complex interventions to improve health and the MRC complex interventions framework provides a useful framework for conducting and reporting of complex interventions (MRC Guidance, 2008). However, as we have found during this study, for SPARC to have any significant impact on the health and well-being of patients and on healthcare, we have to demonstrate that SPARC is effective when tested and that it is capable of being widely implemented and 'normalized' into routine care (May et al., 2009; Murray et al., 2010).

The Normalization Process Theory

The Normalization Process Theory (NPT) is considered to be an important and useful sociological action theory of the implementation, embedding, integration and evaluation of complex interventions, new technologies and organisational innovations. It was developed by Carl May, Tracy Finch, & colleagues between 2000 and 2009, and is one of the more popular theories in implementation science that can be applied to understanding implementation problems (May et al., 2009; Murray et al., 2010). NPT is concerned with what people actually

do and how they work (i.e. individual and group behaviour) as opposed to their attitudes, beliefs or organisation culture. Thus, the NPT focuses on how interventions or practices can become 'routinely embedded or normalized' in social contexts, hence the name 'normalization process theory' (May et al., 2009; Murray et al., 2010).

May et al., 2009, outline the four main NPT constructs that represent the different kinds of work that people do to implement an intervention/new practice/some new technology. These four key concepts are: 1) coherence of intervention (i.e. does it make sense?, how does it fit?); 2) cognitive participation of target group (i.e. how engaged and committed are providers?); 3) collective action to implement innovation (i.e. how will change occur and who will do what?); and 4) reflexive monitoring regarding use of innovation (i.e. appraisal work that people do to assess what change occurred?, why or why not?, and how it will affect them and others around them?). The gap between research and implementation remains problematic and the use of theories such as NPT could be used to address the factors needed for successful implementation and integration of interventions such as SPARC into routine work (May et al., 2009; Murray et al., 2010).

The PARIHS framework (Promoting Action on Research Implementation in Health Services)

The PARIHS framework (Promoting Action on Research Implementation in Health Services), is a multi-dimensional framework that was developed by The Royal College of Nursing Institute, UK, during the 1990's to address the complexities of change processes and variability in success of implementation, and for guiding practitioners and researchers with implementing research evidence into routine clinical practice (Rycroft-Malone et al., 2004; Rycroft-Malone et al., 2013). The three main elements of the PARIHS framework that are known to play an important role in successful implementation are: 1) Evidence (sub-elements: research evidence, clinical experience, patient preferences and experiences, and the local knowledge/information); 2) Context (sub-elements: culture, leadership, and evaluation); and 3) Facilitation (sub-elements: characteristics of the facilitator, role, and style). The interaction and association of these elements (i.e. evidence, context and facilitation) will determine the overall success of the implementation (Rycroft-Malone et al., 2004; Rycroft-Malone et al., 2013).

The PARIHS framework makes reference to certain conditions that are necessary and more conducive to facilitating change and integrating evidence into practice (weak to strong support for implementation). Successful implementation is most likely to occur when the conditions set out in **Table 37** are met (Kitson et al., 1998; Rycroft-Malone et al., 2004; and Ullrich, 2016).

Table 37: Conditions that are considered to be more conducive to integration of evidence into practice (Table Adapted from Kitson et al., 1998; Rycroft-Malone et al., 2004; and Ullrich, 2016)

Elements	Sub-Elements	Criteria	
		Strong support for implementation	Weak support for implementation
1) Evidence <i>‘Scientific research evidence must be sound and fit in with professional and patient beliefs’</i> <i>‘Well-conceived, designed and executed research’</i>	Research evidence	‘RCT, evidence-based guidelines’	‘Anecdotal evidence, descriptive’
	Clinical experience	‘Consensus’	‘Expert opinion is divided’
	Patient preferences and experiences	‘Partnership with patients and HCPs, seen as part of a decision’	‘Patients not involved’
	Local information	‘Information from the local context collected and analysed systematically and rigorously’	‘Local information not collected and analysed’
2) Context <i>‘The health care context must be receptive to implementation of the intervention, and this requires supportive leadership, culture, and evaluative systems’</i>	Culture	‘Learning organisation, patient-centred creating learning cultures’ ‘Receptiveness to change’	‘Task-driven, low morale’
	Leadership	‘Clear roles, effective teamwork and effective organisational structures’ ‘Transformational leaders (ability to transform cultures or create), as opposed to those who command and control’ ‘Enabling/empowering approach to teaching/learning/ managing’	‘Poor organisation, diffuse roles, no role clarity’
	Evaluation	‘Routine audit and feedback’ ‘Feedback on individual, team, and system performance (from multiple sources of information and use of multiple methods)’	‘Absence of audit and feedback’
3) Facilitation <i>‘Appropriate mechanisms must be in place to facilitate implementation’</i>	Characteristics (of the facilitator)	‘High respect, credibility, empathy, enabling others, adult learning approach to teaching’	‘Low respect, credibility, empathy’

	Role	‘Clear roles’	‘Lack of role clarity’
	Style, skills and attributes	‘Flexible, consistent’ ‘Project management skills’ ‘Technical skills’ ‘Marketing skills’ ‘Subject/technical/ clinical credibility’	‘Inflexible, sporadic’

8.7 Implications for future research and practice

There are a number of feasibility questions that should be addressed prior to undertaking any further large-scale study using SPARC, preferably using qualitative research methods to explore further some of the uncertainties around using SPARC in clinical practice. Further qualitative work should address issues concerning SPARC acceptability, implementation, practicality and expansion to other contexts and different patient sub-groups. Some of these questions have been addressed during the course of this doctoral study and during the previous work undertaken by the team (Ahmed et al., 2009; Ahmed et al., 2014; Bestall et al., 2004).

O’Cathain et al., 2015, have identified a range of issues and questions that qualitative research can address in a feasibility study for a future trial or study. The authors emphasise the importance of considering the context in which an intervention is delivered during both a feasibility study and in the full trial. They argue that addressing these issues during the feasibility stage may help to optimise a pilot trial conduct and intervention rather than simply identifying problems with it. A process and resource assessment may also be necessary. Many of these questions should have been addressed in a feasibility type study and prior to undertaking this pilot study, and this perhaps was one of the main limitations of this study, while some issues and questions have been addressed as a result of undertaking the pilot study on the effectiveness of SPARC, some key questions remain unanswered and may have been overlooked. The key issues that any future feasibility study should address include: 1) intervention content and delivery (e.g. intervention development, intervention components, mechanisms of action, perceived value, benefits, harms or unintended consequences of the intervention, acceptability of intervention in principle, feasibility and acceptability of intervention in practice, fidelity, reach and dose of intervention); 2) trial design, conduct and processes (e.g. recruitment and retention, diversity of participants, trial participation, acceptability of the trial in principle, acceptability of the trial in practice, ethical conduct, adaptation of trial conduct to local context, impact of trial on staff, researchers, participants and the health system, patient and public involvement); 3) outcomes (e.g. breadth and selection of outcomes); 4) measures (e.g. accuracy of measures, completion of measures, development of measures).

The problems with the implementation of SPARC; experienced during this study are not dissimilar to those associated with the use of the Liverpool Care Pathway (LCP). The LCP

was developed in the UK, to support patients as they near death (Ellershaw, et al., 2010), in some circumstances the system was found to involve inappropriate withdrawal of medication, food and fluids, with poor communication and consultation with patients, their families and carers. (Neuberger, 2013). It can offer a peaceful and dignified death but there were problems with its implementation, the system requires a lot of training and education to put it in place and make it work properly (Chinthapalli, 2013; Hodgkinson et al., 2016; O', Halloran, 2016; Sykes, 2015). My study has shown that there is a risk that without appropriate education and training and formal systems in place to act on assessments, SPARC could also potentially lead inadvertently to negative effects.

This work supports the need to establish an effective holistic needs assessment system. Any discussions with palliative care and end of life care patients must take place in a timely and sensitive manner, preferably earlier on in the course of the illness, and be patient-led and patient-centred, as one size does not fit all. Hence, there is a need for more individualised, personalised care, needs-driven care tailored to meet individuals' needs, and it is important to set realistic hopes and goals in a way that doesn't raise patient expectations (Barclay & Maher, 2010; Bristowe et al., 2015). This could potentially lead to better patient outcomes, and improved patient satisfaction. This work also supports the need to undertake holistic needs assessments throughout the course of illness or disease trajectory (i.e. from the point of diagnosis, before and after treatments and during follow-up), and not just confined to any one point in the pathway (NICE Guidance, 2004; Snowden et al., 2015), as per guidance 2004; recommendations from the work commissioned by the Cancer Action Team (Richardson et al., 2007, Kings College London). Furthermore, it is important to emphasise that the use of holistic needs assessment tools; such as SPARC should complement and not replace the face-to-face clinical assessment by healthcare professionals (Hughes et al., 2015). There is an urgent need to develop a system that allows 'real time' screening for supportive and palliative care needs (Ramchandran et al., 2015), potentially streamlining the process. One approach may be to make use of technology or an electronic holistic needs assessment system that would allow information from an electronic HNA to be relayed back to health care professionals in 'real time' i.e. a system that would flag up or raise red flags against problems, issues, or concerns that patients identified as most upsetting or distressing, this may go some way in reducing the delays in addressing patients' needs. We also recommend that future trials should link revelation of SPARC data to consultations which should then be incorporated into a care plan, thus facilitating actions on issues identified by the assessment. For those patients that are in the community or that have been discharged or placed on an open-appointment system, better supported self-management and remote surveillance is needed (Nanton et al., 2016). However, this requires further investigation.

It is possible that a standardised intervention such as SPARC, will never supplement the quality of care unless it is properly integrated with the clinical methods and routine care planning procedures of the clinical team (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015). Scandrett et al., 2010, propose that new methods to achieve practice change should be considered and evaluated when assessing such interventions (Ahmed et al., 2015). The

findings from this work serves as a useful guide for researchers designing future supportive and palliative care complex trials. The availability of services and resources to respond to any identified needs requires careful consideration (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Pollock, 2015). Systems and services must be in place in order to address any identified needs in a timely and sensitive manner (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015; Barclay & Maher, 2010; Bristowe et al., 2015), and we must consider and evaluate new methods to achieve practice change. Furthermore, there are resource implications that one must also consider.

SPARC could be used to improve the identification and documentation of symptoms, issues, concerns and problems. SPARC guidance, 2004 needs updating, which should be periodically reviewed and updated to reflect the findings of this important piece of work. I would also recommend moving towards developing and testing an electronic version of SPARC ('e-SPARC').

This study has generated findings of more than local importance, and I have presented this study and the research findings at local meetings and at national and international scientific conferences in the fields of supportive care, palliative care, cancer care and end of life care. This work has so far resulted in a number of reports submitted to Macmillan Cancer Support and a number of publications in international peer reviewed journals, and there are plans to disseminate further.

8.8 Conclusion

Studies suggest that cancer and non-cancer patients have needs which are not being met fully at the moment. At present, there is no widely used systematic, evidence-based holistic approach to screening patients for supportive and palliative care needs. There is evidence to indicate a lack of studies on the clinical utility of tools. SPARC is a multidimensional holistic tool which provides a profile of needs (i.e. physical, psychological, social, and spiritual) to identify patients who may benefit from additional supportive or palliative care regardless of diagnosis or stage of disease.

Despite rigorous psychometric development, preliminary field-testing, and validation, the clinical utility of SPARC has yet to be established. The study findings indicate no positive effect of the intervention on either the primary or secondary outcome measures at two, four or six weeks. The study findings indicate that the primary outcome was affected adversely by the intervention within two weeks.

This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardised holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan. It may raise patient expectations that are not subsequently met.

This trial result calls into question the utility of SPARC in specialist palliative care services and raises important questions regarding the application as well as the context in which the SPARC intervention is used. It can be concluded that a larger trial with more power to detect an effect is highly unlikely to be positive. A larger trial in specialist outpatient or home care services, employing the same design and outcome measures is not feasible and unlikely to demonstrate any benefit without a different method of administering the intervention (SPARC) (Ahmed et al., 2015). It is nevertheless possible that SPARC has utility as a screening tool in primary care or general medical care for selection of patients who may benefit from a referral to specialist palliative care (Ahmed et al., 2015). Therefore an alternative recommendation may be to undertake trials of SPARC in primary care or with general hospital ward populations, as a screening tool for palliative care needs in a population before referral to specialist palliative care services (Ahmed, 2010; Ahmed et al., 2014; Ahmed et al., 2015).

8.9 Contribution to knowledge

The main contribution to knowledge is that this study demonstrates that an assessment that is not linked to clinical method and care plan can be potentially harmful and detrimental to patient outcomes.

In terms of methodological contributions to knowledge the use of qualitative and secondary quantitative analysis approaches alongside an RCT of a complex healthcare intervention (concurrent mixed methods research) worked well, to provide a better understanding of whether and how SPARC works (or does not work) to inform the design of subsequent studies and provided useful insights into how SPARC could be used in practice.

The use of quality of life instruments where the most troublesome concern is nominated and scored, in this study e.g. MYCAW, appears to be more sensitive to changes than a generic multidimensional measure of health-related quality of life namely; EQ5D. EQ5D may be the standard in health economic evaluations (i.e. to assess the value for money of medical interventions), but not as sensitive to changes as a result of interventions. It is questionable whether health economists are using the correct tools in the context of palliative care. The MRC should set standards of how an intervention should be designed. The study provides a useful lesson for researchers.

In terms of theoretical contributions to knowledge, theory has an important role when planning implementation research, and we should give more consideration and attention to the components of the intervention and the systems into which complex interventions are placed. We should focus more on the development of interventions and implementation phases, as well as on evaluation and also consider the social, political and geographical context in which interventions take place. While some aspects of good practice are clear, methods for developing, evaluating and implementing complex interventions are still being developed, and on many important issues there is no consensus yet on what is best practice.

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10 Appendices

Appendix 1: Publication Number 1 (Ahmed et al., 2015)

Original Article

A Pilot Randomized Controlled Trial of a Holistic Needs Assessment Questionnaire in a Supportive and Palliative Care Service

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Abstract

Context. At present, there is no widely used systematic evidence-based holistic approach to assessment of patients' supportive and palliative care needs.

Objectives. To determine whether the use of a holistic needs assessment questionnaire, Sheffield Profile for Assessment and Referral for Care (SPARC), will lead to improved health care outcomes for patients referred to a palliative care service.

Methods. This was an open, pragmatic, randomized controlled trial. Patients ($n = 182$) referred to the palliative care service were randomized to receive SPARC at baseline ($n = 87$) or after a period of two weeks (waiting-list control $n = 95$). Primary outcome measure is the difference in score between Measure Yourself Concerns and Wellbeing (MYCAW) patient-nominated Concern 1 on the patient self-scoring visual analogue scale at baseline and the two-week follow-up. Secondary outcomes include difference in scores in the MYCAW, EuroQoL (EQ-5D), and Patient Enablement Instrument (PEI) scores at Weeks 2, 4, and 6.

Results. There was a significant association between change in MYCAW score and whether the patients were in the intervention or control group ($\chi^2_{trend} = 5.51$; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in the control group had an improvement in MYCAW score from baseline to Week 2: control (34 of 70 [48.6%]) vs. intervention (19 of 66 [28.8%]). There were no significant differences (no detectable effect) between the control and intervention groups in the scores for EQ-5D and Patient Enablement Instrument at 2-, 4-, or 6-week follow-up.

Conclusion. This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardized holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan. J Pain Symptom Manage 2015;50:587–598. © 2015 The Authors. Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Key Words

Palliative care, holistic needs assessment questionnaire, SPARC, MYCAW, EQ-5D, PEI

Introduction

The Sheffield Profile for Assessment and Referral for Care (SPARC) (Appendix I, available at jpsmjournal.com) is a multidimensional holistic needs assessment questionnaire, designed to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of

disease. SPARC is intended for use by primary care, hospital teams, or other services to improve patient management, either by current professional carers or by referral to a specialist team. The patient-rated (self-complete) 45-item questionnaire reflects nine dimensions of need and as such represents a comprehensive early needs assessment or holistic

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Accepted for publication: May 23, 2015.

Table 1
Follow-Up Procedure

Questionnaire Completion (at 2-week intervals)	Randomization	
	Group A (Intervention Group)	Group B (Waiting-List Control Group)
Baseline	MYCAW, EQ-5D, PEI, SPARC	MYCAW, EQ-5D, PEI
Two weeks	MYCAW, EQ-5D, PEI [Invitation for patient interview]	MYCAW, EQ-5D, PEI, SPARC
Four weeks	MYCAW, EQ-5D, PEI plus supplementary question on experience of completing the SPARC	MYCAW, EQ-5D, PEI [Invitation for patient interview]
Six weeks	MYCAW, EQ-5D, PEI	MYCAW, EQ-5D, PEI plus supplementary question on experience of completing the SPARC
Eight weeks		Case note reviews Semistructured interviews with patients Semistructured interviews with health care professionals

MYCAW = Measure Yourself Concerns and Wellbeing; EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life; PEI = Patient Enablement Instrument; SPARC = Sheffield Profile for Assessment and Referral for Care.

Those patients who consented were randomized to receive the SPARC questionnaire at baseline (intervention group) or after a two-week waiting-list period (control group).

questionnaire.¹ It is capable of being completed by patients unassisted, or, for those prevented by disability from reading or writing responses, with the help of their informal or professional carers.² Despite rigorous psychometric development, preliminary field testing, and validation,¹⁻⁶ the clinical utility of SPARC has yet to be established, either as an aid to specialist clinical assessment or as a screening tool.⁷

There is evidence to suggest that patients with cancer and nonmalignant chronic progressive illnesses may experience distressing symptoms and concerns, which may remain unrecognized.⁷⁻¹⁰ Previous research has highlighted that distressing symptoms and concerns can be managed, provided they are identified in a timely manner and systems are in place for a prompt referral to specialist teams.¹¹⁻¹⁶ The timely identification of needs and prompt referral to specialist teams could reduce the burden of suffering and lead to earlier discharge. Similarly, earlier detection of these problems in outpatients or the community might prevent unnecessary admissions. These potential health gains may accrue for a relatively small investment.⁷ However, at present, there is no widely used systematic evidence-based holistic approach to assessing patients for supportive and palliative care needs. There is a lack of studies on the clinical utility of tools.^{1,7}

We conducted a pilot pragmatic randomized controlled trial to determine whether the use of SPARC leads to improved health care outcomes (health-related quality of life and self-identified concerns) for patients referred to a palliative care service, to guide the development of a definitive multicenter study. This study represents a development of SPARC for use as an early holistic needs assessment questionnaire within a specialist service. This study does not test the utility of SPARC as a screening questionnaire for specialist palliative care. Palliative care interventions are complex, and in light of this, the SPARC study was developed, piloted, evaluated, reported,

and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions (new guidance).¹⁷⁻¹⁹

Methods

Trial Design and Recruitment

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement²⁰ and was registered (International Standard Randomised Controlled Trials Number [ISRCTN] 25758268). This open randomized controlled trial used a waiting-list control design.²¹ All patients referred to the supportive and palliative care service who met the study inclusion criteria were invited to take part in the study. Invitations to participate were sent by post (outpatients and those in the community) or given face to face (inpatients and day care patients). Patients who consented to taking part in the study were randomized to receive the SPARC questionnaire at baseline (intervention group) or after a two-week period (control group).

The study received approval from the Bradford Research Ethics Committee, U.K. Multicentre Research Ethics Committee (MREC) reference number 10/H1302/88 on January 14, 2011 and received research and development permission from local trusts. Participants' inclusion criteria were 1) any diagnosis (cancer and noncancer), 2) any referral to the palliative care service in any care setting, 3) 18 years or older, and 4) able to give informed consent. Exclusion criteria included 1) incapable of giving informed consent, 2) incapable of completing SPARC even with the help of a relative or informal carer, and 3) younger than 18 years.

Stratification

Baseline quality of life may confound response to an intervention by reversion to the mean, so patients

Table 2
Research Questionnaires: Rationale for Choice of Outcome Measures

MYMOP	MYCAW Slightly Modified Version of MYCAW Used	EQ-5D	PEI Slightly Modified Version of PEI Used
<ul style="list-style-type: none"> ■ A precursor of MYCAW ■ Demonstrated sensitivity to change ■ Used in a range of contexts ■ Patient self-complete, outcome questionnaire, problem specific (includes general well-being) ■ Applicable to all symptomatic patients ■ Brief and simple questionnaire to administer ■ MYCAW used in preference to MYMOP because concerns raised could be of any kind and not restricted to symptoms or activity (may be of significance when comparing the information from the three groups: cancer survivors, people with long-term conditions, and people needing end-of-life care) ■ For the purposes of this study, it was important to use an outcome measure that covered the diversity in the patient group ■ A slightly modified version of MYCAW was used (the sentence "Please write down one or two concerns or problems which you would most like us to help you with" was replaced with "Please write down one or two concerns or problems that bother you most") <p>References: ²⁴⁻²⁶</p>	<ul style="list-style-type: none"> ■ Developed from a validated tool, MYMOP, simple to use, and sensitive enough to show any changes with time ■ Patients nominate concerns, which may or may not be medical (MYCAW) or symptoms (MYMOP) of importance to them (two concerns/symptoms can be identified) ■ They then score these on a scale of 0 (not bothering me at all) to 6 (bothers me greatly) ■ Patients are also asked to rate their general feeling of well-being on a scale of 0 (as good as it could be) to 6 (as bad as it could be) ■ The follow-up form asks patients to rescore the concerns/symptoms and rate their general feeling of well-being they previously nominated, thus capturing any changes over time that are important to the patient ■ However, HRQoL may not be sensitive enough to changes in the short term, possibly because people adjust their expectations ■ Work by Guyatt et al.²⁷ indicates that in seven-point scales of this kind, a shift of one point corresponds to a moderately important change for a patient ■ Is an additional element of needs assessment, stated concerns, are truly patient generated, reflecting an accurate expression of need at that time <p>References: ²⁵⁻²⁷</p>	<ul style="list-style-type: none"> ■ Outcome measure of health-related quality of life ■ Patient self-complete ■ Five questions (three varying response categories): on mobility, self-care, usual activities (e.g., work, study, housework, family, or leisure activities), pain/discomfort, and anxiety/depression ■ A further question (EQ-5D thermometer scale) asks people to mark their current health status on a scale of 0 (worst imaginable health state) to 100 (best imaginable health state) ■ Used extensively in studies where quality of life is compared between patient groups <p>References: ^{23,28}</p>	<ul style="list-style-type: none"> ■ Outcome measure of a patient's ability to cope with life and their illness and the confidence and ability to help themselves (as a result of visiting a doctor or health professional) ■ Patient self-complete ■ One main question "thinking about the last time you saw a doctor or nurse from palliative care, do you feel you are: ... (6 subquestions with four varying response categories) ■ Studies in general practice to assess quality of consultations using PEI have shown it to be a crucial outcome measure, with enablement correlating best with the length of consultation and how well the patient knew the doctor ■ PEI scores consultations in cancer clinics, independently of quality of life and scores higher when sufficient time is allocated or when staff have communication skills training (our own unpublished work) ■ PEI may detect an effect of SPARC (if any) on the quality of subsequent consultations with the clinical team ■ A measure of consultation quality was included to detect an effect on communication between patients and professionals. However, we overestimated the intensity of contact between patients and professionals and palliative care services in the duration of this trial <p>References: ^{29,30}</p>

MYMOP = Measure Yourself Medical Outcomes Profile; MYCAW = Measure Yourself Concerns and Wellbeing; EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life; PEI = Patient Enablement Instrument; HRQoL = health-related quality of life.

were stratified for baseline EQ-5D (standardised outcome measure of health-related quality of life) thermometer score. Thus, patients completing the consent form also were asked to complete the EQ-5D thermometer score before randomization. Based on previous work,^{22,23} the research team set the EQ-5D thermometer score at 40. Patients scoring 40 or above at baseline were placed in the median and above group, and those scoring less than 40 were placed in the below median group.

Sheffield Palliative Care Service Context and Settings

Patients were recruited from the whole range of settings (inpatients, outpatients, day care, and from the

community), which included the two hospitals within the city, a palliative care unit, a hospice, and from the community via a team of community specialist nurses. More than 2000 patients a year are referred to these services, including those with long-term conditions and cancer survivors as well as those needing end-of-life care.

Intervention (SPARC)

Those patients who consented were randomized to receive the SPARC questionnaire (Table 1) at baseline (intervention group) or after a two-week waiting-list period (control group). All patients received ongoing care as usual. A completed paper copy of

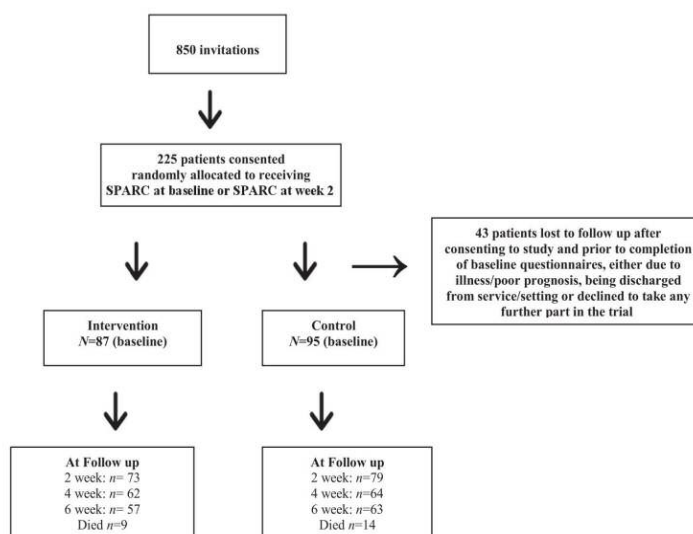


Fig. 1. Summary of recruitment for the Sheffield Profile for Assessment and Referral for Care (SPARC) trial. There was no significant difference in the number of deaths between the intervention and control groups. In Group A (intervention), nine people (10.3%) died within the eight-week study period and in Group B (control), 14 people (14.7%) died within the eight-week study period ($\chi^2 = 0.445$; degrees of freedom = 1; $P = 0.504$).

SPARC was sent to the health care professional (HCP) caring for the patient to prompt action on needs identified by SPARC. The SPARC questionnaire data also were kept in the patients' notes, and a copy was kept on the electronic clinical record. Follow-up study questionnaires were administered either face to face or by post. Two weeks was selected as the crucial follow-up time after baseline to minimize attrition.

Outcome Measures

Study participants were required to complete three validated brief self-complete research outcome measures: the Measure Yourself Concerns and Wellbeing (MYCAW), the EuroQoL (EQ-5D) (measure of health-related quality of life), and the Patient Enablement Instrument (PEI) at baseline, Week 2, Week 4, and Week 6 (Appendix II, available at jpsmjournals.com). The rationale for the choice of outcome measures is presented in Table 2.²⁴⁻³⁰

The primary outcome was the change in MYCAW score between the first MYCAW patient-nominated concern at baseline and the two-week follow-up. This is the nominated first concern. Secondary outcomes included 1) the change in scores in the EQ-5D at the two time points; 2) changes in the PEI at the two time points; 3) comparisons of MYCAW patient-nominated concerns, EQ-5D, and the PEI at baseline between patient groups; and 4) the pattern of actions taken and referrals made as a result of administering the SPARC screening tool were

examined by analysis of the clinical record (to be reported elsewhere).

Randomization

A set of sequentially numbered, opaque, sealed, A4 envelopes containing all study documents were set up for each care setting (henceforth called the study pack). The randomization process was undertaken by a member of the study team (M.W.), who then identified which study packs were for the intervention arm and which were for the control arm. A copy of the SPARC questionnaire (Appendix I) was added to the study packs for the intervention arm, and 182 patients were randomized with computer-generated random numbers in prepaid sealed envelopes to receive SPARC at baseline ($n = 87$) or after a period of two weeks (waiting-list control $n = 95$).

Recruitment

For inpatients and day care patients, a HCP informed the patients about the study and asked whether they were willing to participate. Contact details of those patients willing to participate were passed to a member of the study team. Community patients and outpatients were sent study packs via medical secretaries (the list of patients was first agreed with the HCP with responsibility for the care of these patients). On receiving consent, the researcher (N.A.), who was blinded to the study, collected the next sequentially numbered, opaque, sealed envelope and hand delivered it to inpatients

Table 3
Baseline Demographic Characteristics of Participants in Group A (Intervention), Group B (Control), and Total Sample (A + B)

Characteristic	n (%)			Notes A vs. B <i>P</i>
	Intervention Group A (87)	Control Group B (95)	All Patients (182)	
Age (mean age in yrs) on registration	63.90 years (median = 65.00 years; SD = 11.68; minimum age = 28 years; maximum age = 87 years)	64.99 years (median = 67.00 years; SD = 13.34; minimum age = 27 years; maximum age = 90 years)	64.47 years (median = 66.00 years; SD = 12.57; minimum age = 27 years; maximum age = 90 years)	No significant difference (Mann-Whitney $Z = -0.865$; $P = 0.387$)
Gender				No significant difference ($\chi^2 = 1.183$; degrees of freedom = 1; $P = 0.277$)
Male	36 (41.4)	48 (50.5)	84 (46.2)	
Female	51 (58.6)	47 (49.5)	98 (53.8)	
Partnership/marital status				No significant difference ($\chi^2 = 1.706$; degrees of freedom = 3; $P = 0.636$). Most patients were married ($n = 118$; 64.8%)
Married	56 (64.4)	62 (65.3)	118 (64.8)	
Single	10 (11.5)	7 (7.4)	17 (9.3)	
Divorced/parted/separated	5 (5.7)	9 (9.5)	14 (7.7)	
Widowed	15 (17.2)	15 (15.8)	30 (16.5)	
Ethnicity				The low numbers in many of the groups meant that it was not possible to test for differences
White—British	83 (95.4)	90 (94.7)	173 (95.1)	
White—other background	2 (2.3)	0 (0)	2 (1.1)	
Black or Black British	1 (1.1)	0 (0)	1 (0.5)	
Caribbean				
Asian or Asian British-Indian	0 (0)	1 (1.1)	1 (0.5)	
Information withheld/not documented	1 (1.1)	4 (4.2)	5 (2.7)	
Living arrangements				Most patients were living at home ($n = 177$; 97.3%), three patients were living in a care or nursing home (1.6%), and for two patients (1.1%) it was not known where they were living
Home	83 (95.4)	94 (98.9)	177 (97.3)	
Care home/nursing home	3 (3.4)	0 (0)	3 (1.6)	
Patient lives alone				No significant difference in the proportions of patients living alone ($\chi^2 = 0.020$; degrees of freedom = 1; $P = 0.887$)
Living alone	15/73 (20.5)	20/88 (22.7)	35 (19.2)	
Religion				Most patients ($n = 115$; 63.2%) gave their religious denomination as Church of England
Church of England	56 (64.4)	59 (62.1)	115 (63.2)	
Roman Catholic	6 (6.9)	5 (5.3)	11 (6.0)	
Christian	5 (5.7)	7 (7.4)	12 (6.6)	
Jewish	2 (2.3)	2 (2.1)	4 (2.2)	
Methodist	3 (3.4)	4 (4.2)	7 (3.8)	
Protestant	1 (1.1)	1 (1.1)	2 (1.1)	
Humanist	1 (1.1)	0 (0)	1 (0.5)	
Anglican	1 (1.1)	0 (0)	1 (0.5)	
Agnostic	0 (0)	2 (2.1)	2 (1.1)	
Quaker	1 (1.1)	2 (2.1)	3 (1.6)	
Church of Scotland	1 (1.1)	0 (0)	1 (0.5)	
None	10 (11.5)	13 (13.7)	23 (12.6)	

or sent it via post to community patients and outpatients.

Statistical Methods and Analysis

Primary Endpoint Analysis. The primary outcome measure was the difference in score between the patient-nominated concern (MYCAW, Concern 1) on the self-scored visual analogue scale at baseline and at the two-week follow-up. Assuming the changes in the score (baseline to Week 2) would be normally distributed, we had planned to carry out a *t*-test to test the null hypothesis that the difference between the intervention and control groups in the mean score on the first symptom nominated on the scale at baseline and two weeks is 0. However, because the data were not normally distributed, the Mann-Whitney test was used to test for difference in the two groups in the rankings of Weeks 2, 4, and 6 scores and the rankings of the change in scores from baseline to Weeks 2, 4, and 6.

Statistical Power. To detect a medium-sized difference between two independent sample means at alpha = 0.05 and beta = 0.80, required a minimum of 64 individuals in each group with scores at baseline and two weeks.³¹ Therefore, a total of 128 patients would need to be recruited. The power of the study was based on the randomized controlled trial with the group of patients from whom it would be possible to obtain follow-up data. Differences between the control and intervention groups were tested using *t*-tests to compare the mean scores at Weeks 2, 4, 6, and the mean change in scores from baseline to Weeks 2, 4, and 6.

Secondary and Exploratory Analyses. Statistical analysis of the comparisons between patient groups for the secondary outcomes involved both descriptive analyses and statistical tests. A qualitative content analysis^{32,33} of the nominated first concern and the nominated second concern was undertaken at baseline. The concerns named in MYCAW were analyzed qualitatively using a summative content analysis approach. Stated concerns were examined for key words and themes, with the context taken into account for the final interpretation. Analysis of the data from patient semistructured interviews, HCP interviews,³⁴ case note reviews, and from the supplementary question about patients' experience of completing the SPARC will be presented elsewhere.

Results

Recruitment and Attrition Rates

A total of 850 patients were invited to take part in the study, of whom 225 consented to take part

Table 4
Distribution of Scores for MYCAW Concern 1 at Baseline and at 2-, 4-, and 6-Week Follow-Up in Group A (Intervention), Group B (Control), and for the Total Sample (Group A + Group B)

MYCAW Concern 1 Score	Baseline		Week 2		Week 4		Week 6		Total
	A	B	A	B	A	B	A	B	
	n (%)		n (%)		n (%)		n (%)		
0	2 (2.5)	3 (3.2)	2 (2.9)	2 (2.9)	3 (5.1)	6 (10.0)	2 (3.6)	3 (5.6)	5 (4.6)
1	1 (1.2)	4 (4.3)	1 (1.4)	8 (11.4)	2 (3.4)	3 (5.0)	3 (5.5)	4 (7.4)	7 (6.4)
2	6 (7.4)	6 (6.5)	6 (8.7)	11 (15.7)	4 (6.8)	4 (6.7)	4 (7.3)	4 (7.4)	8 (7.3)
3	7 (8.6)	9 (9.7)	14 (20.3)	11 (15.7)	9 (15.3)	10 (16.7)	11 (20.0)	11 (20.4)	22 (20.2)
4	20 (24.7)	20 (21.5)	13 (18.8)	11 (15.7)	14 (23.7)	14 (23.3)	9 (16.4)	15 (27.8)	24 (22.0)
5	19 (23.5)	21 (22.6)	16 (23.2)	11 (15.7)	11 (18.6)	13 (21.7)	10 (18.2)	7 (13.0)	17 (15.6)
6	26 (32.1)	30 (32.3)	17 (24.6)	16 (22.9)	16 (27.1)	10 (16.7)	16 (29.1)	10 (18.5)	26 (23.9)
Total	81 (100)	93 (100)	174 (100)	70 (100)	59 (100)	60 (100)	55 (100)	54 (100)	109 (100)

MYCAW = Measure Yourself Concerns and Wellbeing.

Table 5
Frequency of EQ-5D Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline and Weeks 2, 4, and 6

Domain	Statement	Baseline Response, n (%)			Week 2 Response, n (%)			Week 4 Response, n (%)			Week 6 Response, n (%)		
		A	B	Total	A	B	Total	A	B	Total	A	B	Total
Group Mobility	I have no problems in walking about	13 (15.7)	9 (9.5)	22 (12.4)	11 (15.1)	10 (13.0)	21 (14.0)	10 (16.9)	8 (12.5)	18 (14.6)	8 (14.3)	5 (7.9)	13 (10.9)
	I have some problems in walking about	66 (79.5)	85 (89.5)	151 (84.8)	60 (82.2)	64 (83.1)	124 (82.7)	48 (81.4)	53 (82.8)	101 (82.1)	45 (80.4)	56 (88.9)	101 (55.5)
Self-care	I am confined to bed	4 (4.8)	1 (1.1)	5 (2.8)	2 (2.7)	3 (3.9)	5 (3.3)	1 (1.7)	3 (4.7)	4 (3.3)	3 (5.4)	2 (3.2)	5 (2.7)
	Total	83 (100)	95 (100)	178 (100)	73 (100)	77 (100)	150 (100)	59 (100)	64 (100)	123 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with self-care	43 (53.1)	43 (45.3)	86 (48.9)	37 (51.4)	36 (46.8)	73 (49.0)	34 (57.6)	28 (44.4)	62 (50.8)	31 (55.4)	27 (42.9)	58 (48.7)
	I have some problems washing or dressing myself	33 (40.7)	48 (50.5)	81 (46.0)	31 (43.1)	36 (46.8)	67 (45.0)	22 (37.3)	33 (52.4)	55 (45.1)	20 (35.7)	33 (52.4)	53 (44.5)
Usual activities	I am unable to wash or dress myself	5 (6.2)	4 (4.2)	9 (5.1)	4 (95.6)	5 (6.5)	9 (6.0)	3 (5.1)	2 (3.2)	5 (4.1)	5 (8.9)	3 (4.8)	8 (6.7)
	Total	81 (100)	95 (100)	176 (100)	72 (100)	77 (100)	149 (100)	59 (100)	63 (100)	122 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with performing my usual activities	7 (8.4)	6 (6.5)	13 (7.4)	7 (9.7)	8 (10.3)	15 (10.0)	3 (5.1)	8 (12.5)	11 (8.9)	4 (7.4)	7 (11.1)	11 (9.4)
	I have some problems with performing my usual activities	54 (65.1)	59 (63.4)	113 (64.2)	46 (63.9)	49 (62.8)	95 (63.3)	40 (67.8)	38 (59.4)	78 (63.4)	31 (57.4)	40 (63.5)	71 (60.7)
Pain/discomfort	I am unable to perform my usual activities	22 (26.5)	28 (30.1)	20 (28.4)	19 (26.4)	21 (26.9)	40 (26.7)	16 (27.1)	18 (28.1)	34 (27.6)	19 (35.2)	16 (25.4)	35 (29.9)
	Total	83 (100)	93 (100)	176 (100)	72 (100)	78 (100)	150 (100)	59 (100)	64 (100)	123 (100)	54 (100)	63 (100)	117 (100)
	I have no pain or discomfort	11 (13.3)	9 (9.8)	20 (11.4)	9 (12.5)	10 (13.2)	19 (12.8)	6 (10.3)	3 (4.8)	9 (7.5)	8 (14.8)	4 (6.6)	12 (10.4)
	I have moderate pain or discomfort	59 (71.1)	72 (78.3)	131 (74.9)	55 (76.4)	55 (72.4)	110 (74.3)	44 (75.9)	54 (87.1)	98 (81.7)	34 (63.0)	53 (86.9)	87 (75.7)
Anxiety/depression	I have extreme pain or discomfort	13 (15.7)	11 (12.0)	24 (13.7)	8 (11.1)	11 (14.5)	19 (12.8)	8 (13.8)	5 (8.1)	13 (10.8)	12 (22.2)	4 (6.6)	16 (13.9)
	Total	83 (100)	92 (100)	175 (100)	72 (100)	76 (100)	148 (100)	58 (100)	62 (100)	120 (100)	54 (100)	61 (100)	35 (29.9)
	I am not anxious or depressed	34 (42.0)	29 (31.9)	63 (36.6)	31 (43.1)	23 (29.9)	54 (36.2)	23 (40.4)	18 (29.0)	41 (34.5)	19 (34.5)	23 (37.7)	42 (36.2)
	I am moderately anxious or depressed	42 (51.9)	55 (60.4)	97 (56.4)	37 (51.4)	52 (67.5)	89 (59.7)	31 (54.4)	41 (66.1)	72 (60.5)	29 (52.7)	34 (55.7)	63 (54.3)
Anxiety/depression	I am extremely anxious or depressed	5 (6.2)	7 (7.7)	12 (7.0)	4 (5.6)	2 (2.6)	6 (4.0)	3 (5.3)	3 (4.8)	6 (5.0)	7 (12.7)	4 (6.6)	11 (9.5)
	Total	81 (100)	91 (100)	172 (100)	72 (100)	77 (100)	149 (100)	57 (100)	62 (100)	119 (100)	55 (100)	61 (100)	116 (100)

EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life.

Table 6
Distribution of PEI Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline, Weeks 2, 4 and 6

Question	Response, n (%)	Baseline			P	Week 2	
		Group A (Intervention)	Group B (Control)	Total		Group A (Intervention)	Group B (Control)
Able to cope with life	Much better	8 (10.0)	8 (9.0)	16 (9.5)	0.301	4 (5.8)	9 (12.7)
	Better	32 (40.0)	28 (31.5)	60 (35.5)		22 (31.9)	16 (22.5)
	Same or less	40 (50.0)	53 (59.6)	93 (55.0)		43 (62.3)	46 (64.8)
	Total	80 (100)	89 (100)	169 (100)		69 (100)	71 (100)
Able to understand your illness	Much better	8 (10.8)	14 (15.9)	22 (13.6)	0.662	4 (6.3)	9 (13.0)
	Better	30 (40.5)	31 (35.2)	61 (37.7)		22 (34.4)	20 (29.0)
	Same or less	36 (48.6)	43 (48.9)	79 (48.8)		38 (59.4)	40 (58.0)
	Total	74 (100)	88 (100)	162 (100)		64 (100)	69 (100)
Able to cope with your illness	Much better	6 (7.8)	9 (10.0)	15 (9.0)	0.835	2 (3.0)	7 (10.1)
	Better	30 (39.0)	33 (36.7)	63 (37.7)		26 (38.8)	17 (24.6)
	Same or less	41 (53.2)	48 (53.3)	89 (53.3)		39 (58.2)	45 (65.2)
	Total	77 (100)	90 (100)	167 (100)		67 (100)	69 (100)
Able to keep yourself healthy	Much better	5 (7.1)	6 (7.1)	11 (7.1)	0.721	3 (4.8)	9 (14.1)
	Better	23 (32.9)	25 (29.4)	48 (31.0)		21 (33.3)	10 (15.6)
	Same or less	42 (60.0)	54 (63.5)	96 (61.9)		39 (61.9)	45 (70.3)
	Total	70 (100)	85 (100)	155 (100)		63 (100)	64 (100)
Confident about your health	Much more	2 (2.7)	3 (3.4)	5 (3.1)	0.687	3 (4.5)	5 (7.0)
	More	19 (25.7)	24 (27.6)	43 (26.7)		12 (18.2)	14 (19.7)
	Same or less	53 (71.6)	60 (69.0)	113 (70.2)		51 (77.3)	52 (73.2)
	Total	74 (100)	87 (100)	161 (100)		66 (100)	71 (100)
Able to help yourself	Much more	7 (9.6)	8 (9.2)	15 (9.4)	0.365	3 (4.5)	5 (6.9)
	More	24 (32.9)	21 (24.1)	58 (66.7)		20 (30.3)	11 (15.3)
	Same or less	42 (57.5)	58 (66.7)	100 (62.5)		43 (65.2)	56 (77.8)
	Total	73 (100)	87 (100)	160 (100)		66 (100)	72 (100)

(26.5% response rate), 182 patients completed baseline questionnaires, 152 completed the two-week questionnaires, 126 completed the questionnaires at four weeks, and 120 completed the six-week questionnaires. The critical point in the analysis was the two-week point, the point at which patients in Group A (intervention arm) had already received the SPARC intervention and patients in Group B (control arm) had not yet received the SPARC intervention. Seven patients did not complete the trial, citing questionnaire completion and taking part in the trial too burdensome as reasons for not continuing. Two patients expressed concern around issues of data collection and had anticipated more face-to-face contact visits as opposed to receiving postal questionnaires. At the end of the trial (eight weeks after completion of baseline questionnaires), 23 patients had died and 159 patients were alive. There was no significant difference in the number of deaths between the intervention and control groups. In Group A (intervention), nine people (10.3%) and in Group B (control), 14 people (14.7%) died within the eight-week study period. A summary of the recruitment is presented in Fig. 1.

Baseline Data

Of the 182 study participants, 84 were males (46.2%) and 98 were females (53.8%). The mean age of the participants on trial registration was

64.47 years (median 66.00 years; SD 12.57; minimum age 27 years; and maximum age 90 years). There were 87 (47.8%) participants in the intervention arm (Group A) and 95 (52.2%) participants in the control arm (Group B); there was no significant difference in the partnership status of patients in Group A vs. Group B. Most patients were married ($n = 118$; 64.8%) and of White-British ethnicity ($n = 173$; 95.1%). No significant differences were observed between the intervention and control groups with respect to age distribution, gender distribution, in the baseline scores for MYCAW, EQ-5D, and PEI, or in any other study parameters. Demographic characteristics of participants are summarized in Table 3.

MYCAW: Comparison of Groups From Baseline to Weeks 2, 4, and 6

The mean MYCAW Concern 1 score for both groups improved over six weeks (Table 4). The overall mean change in score from baseline to Week 2 was 0.368 (median 0; SD 1.39); from baseline to Week 4 was 0.430 (median 0; SD 1.66); and from baseline to Week 6 was 0.462 (median 0; SD 1.59). There were no significant differences (no detectable effect) between the control and intervention groups in the change in mean MYCAW 1 scores at two-, four-, or six-week follow-up.

There was, however, a significant difference in the rankings for the change in MYCAW Concern 1 score

Table 6
Continued

Week 2		Week 4				Week 6			
Total	P	Group A (Intervention)	Group B (Control)	Total	P	Group A (Intervention)	Group B (Control)	Total	P
13 (9.3)	0.693	1 (1.9)	1 (1.8)	2 (1.8)	0.781	2 (3.8)	6 (10.3)	8 (7.3)	0.607
38 (27.1)		19 (35.8)	19 (33.3)	38 (34.5)		17 (32.7)	15 (25.9)	32 (29.1)	
89 (63.6)		33 (62.3)	37 (64.9)	70 (63.6)		33 (63.5)	37 (63.8)	70 (63.6)	
140 (100)		53 (100)	57 (100)	110 (100)		52 (100)	58 (100)	110 (100)	
13 (13.8)	0.481	2 (3.8)	4 (7.1)	6 (5.5)	0.676	4 (8.0)	6 (10.3)	10 (9.3)	0.346
42 (31.6)		19 (35.8)	19 (33.9)	38 (34.9)		11 (22.0)	17 (29.3)	28 (25.9)	
78 (58.6)		32 (60.4)	33 (58.9)	65 (59.6)		35 (70.0)	35 (60.3)	70 (64.8)	
133 (100)		53 (100)	56 (100)	109 (100)		50 (100)	58 (100)	109 (100)	
9 (6.6)	0.989	1 (1.9)	3 (5.1)	4 (3.6)	0.995	3 (5.9)	5 (8.5)	8 (7.3)	0.884
43 (31.6)		16 (30.2)	14 (23.7)	30 (26.8)		13 (25.5)	13 (22.0)	26 (23.6)	
84 (61.8)		36 (67.9)	42 (71.2)	78 (69.6)		35 (68.6)	41 (69.5)	76 (69.1)	
136 (100)		53 (100)	59 (100)	112 (100)		51 (100)	59 (100)	110 (100)	
12 (9.4)	0.939	2 (3.8)	3 (5.6)	5 (4.7)	0.948	2 (4.1)	5 (8.9)	7 (6.7)	0.446
31 (24.4)		12 (23.1)	11 (20.4)	23 (21.7)		10 (20.4)	11 (19.6)	21 (20)	
84 (66.1)		38 (73.1)	40 (74.1)	78 (73.6)		37 (75.5)	40 (71.4)	77 (73.3)	
127 (100)		52 (100)	54 (100)	106 (100)		49 (100)	56 (100)	105 (100)	
8 (5.8)	0.507	1 (2.0)	1 (1.7)	2 (1.8)	0.445	2 (4.0)	3 (5.2)	5 (4.6)	0.319
26 (19.0)		9 (17.6)	7 (11.9)	16 (14.5)		4 (8.0)	9 (15.5)	13 (12.0)	
103 (75.2)		41 (80.4)	51 (86.4)	92 (83.6)		44 (88.0)	46 (79.3)	90 (83.3)	
137 (100)		51 (100)	59 (100)	110 (100)		50 (100)	58 (100)	108 (100)	
8 (5.8)	0.305	4 (7.0)	0 (0)	4 (3.6)	0.088	3 (6.3)	3 (5.2)	6 (5.7)	0.625
31 (22.5)		8 (15.1)	8 (14.0)	16 (14.5)		9 (18.8)	9 (15.5)	18 (17.0)	
99 (71.7)		41 (77.4)	49 (86.0)	90 (81.8)		36 (75.0)	46 (79.3)	82 (77.4)	
138 (100)		53 (100)	57 (100)	110 (100)		48 (100)	58 (100)	106 (100)	

(baseline to Week 2) of patients in Group A (intervention: mean rank of patients: 61.21) and Group B (control: mean rank of patients: 75.37) (Mann-Whitney $Z = -2.192$; $P = 0.028$; $n = 136$). Overall, patients in Group B (control) showed greater improvement or less deterioration in the MYCAW score than patients in Group A (intervention). The mean change in MYCAW Concern 1 score (baseline to Week 2) in Group A (intervention) was 0.15 (SD 1.32; median 0) (a small improvement) vs. Group B (control) 0.57 (SD 1.44; median 0). When the scores for changes in MYCAW Concern 1 score for the patients were recoded (baseline to Week 2) into groups for deterioration/no change/improvement, there was a statistically significant association between the change in MYCAW Concern 1 score and study arm ($\chi^2_{trend} = 5.51$; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in Group B (control: 34 of 70 [48.6%]) had an improvement in the MYCAW Concern 1 score (baseline to Week 2) compared with patients in Group A (intervention: 19 of 66 [28.8%]). A higher proportion of patients in Group A (intervention: 16 of 66; 24.2%) showed a deterioration in the MYCAW Concern 1 score (baseline to Week 2) compared with patients in Group B (control: 10 of 70; 14.3%). There was no significant difference in the rankings for the change in MYCAW Concern 1 score from baseline to Week 4 or from baseline to Week 6.

MYCAW Concerns at Baseline

Of the 182 patients completing baseline questionnaires, 173 (95.1%) respondents nominated and scored a primary concern and 125 (68.7%) nominated and scored a secondary concern. For both MYCAW primary and secondary concerns, physical symptoms, condition and disability predominated, but other concerns, such as apprehension for themselves or others, concerns about disease progression and dying, feelings of loss of function or purpose, and about help needed, also were prominent. Similarities were marked, in that for all groups, symptoms, condition, and disability featured most strongly. For cancer survivors, and those receiving end-of-life cancer care, all concerns were named: apprehension for themselves or others; concerns related to the progression of disease; psychological concerns; concerns related to loss or existential issues; concerns about needing help; the effect on their social life; work or financial issues; and treatment effects.

EQ-5D Variables: Comparison of Groups From Baseline to Weeks 2, 4, and 6

There were no meaningful or significant associations between any of the EQ-5D domains for Groups A (intervention) and B (control) at baseline, Weeks 2, 4, or 6. Table 5 shows the frequency of responses for the EQ-5D domains at all of the time points. It is

also worth noting that, in this analysis, the mean EQ-5D scores did not change in any significant or meaningful way.

PEI Scores: Comparison of Groups From Baseline to Weeks 2, 4, and 6

Table 6 shows the distribution of responses for the PEI questions at baseline and Weeks 2, 4, and 6, respectively, in Groups A (intervention) and B (control) and in the total sample (A+ B). There were no meaningful or significant associations between the PEI responses to the questions for either group or in the total sample at any of the time points.

Discussion

The unexpected negative finding that a higher proportion of patients in the control group (34 of 70; 48.6%) showed an improvement in their MYCAW score from baseline to Week 2 compared with the intervention group (19 of 66; 28.8%) ($P = 0.019$) raises questions about the application of SPARC and possibly other holistic needs assessment questionnaires in the context of a specialist palliative care service.

No positive effect of the intervention on either the primary or secondary outcome measures was observed at two, four, or six weeks, suggesting that the intervention did not have a detectable beneficial effect at any point and the difference between arms was obliterated when the control arm received SPARC.

Data that indicate that most patients felt that no particular action or benefit followed from completion of the SPARC will be reported elsewhere. There were no meaningful or significant differences between the control and intervention groups in the scores for health-related quality of life as recorded in the general measure EQ-5D. This measure did not significantly change over the six weeks, as would be expected of patients attending a palliative care service. However, in contrast, there appears to be improvement in the most important concern as recorded in the MYCAW; this suggests that usual palliative care is having a beneficial effect in this respect.

Results in the Context of Other Studies

Several other studies have examined the clinical utility of some holistic needs assessment tools. These tools include 1) Palliative Care Assessment Tool,^{35,36} 2) the Initial Health Assessment,³⁷ and 3) Needs at the End of Life Screening Tool.³⁸ Although the studies have measured changes in clinical outcomes after needs assessment, no controlled study has demonstrated an improvement in clinical or patient-reported outcomes as a result of the intervention. Although many of these studies demonstrated an

improvement in documentation of needs, uptake of findings and action after the assessment of needs have been described as poor, with no significant overall improvements in care outcomes. The reasons for these results are unclear but could be a result of inadequate power to detect a change; the tools not being comprehensive enough for holistic needs assessments; outcomes chosen may have been inappropriate; HCPs' attitudes, knowledge, or skills; and timing of and the availability/nonavailability of services.³⁸ It is also possible that standardized needs assessments will never supplement the quality of care unless properly integrated with the clinical methods and routine care planning procedures of the clinical team. Scandrett et al.³⁸ proposed that new methods to achieve practice change should be considered and evaluated when assessing such interventions.⁷

Limitations of the Study

Our poor recruitment of patients within the hospital support service meant our study sample had fewer patients with conditions other than cancer and a smaller proportion of patients acutely ill than the whole population of patients referred to the palliative care service.

The context of a specialist palliative care service is possibly the most difficult environment to test an assessment intervention in that the existing holistic needs assessments may be sufficient to detect all issues that require attention. The SPARC pilot trial focused primarily on outcomes, not on the processes involved in implementing the intervention. The Medical Research Council framework requires an evaluation of the pilot study, and a process evaluation is underway and will be reported elsewhere, to elucidate the precise mechanism by which this result came about.

Conclusions

This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardized holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan. It may raise expectations that are not subsequently met.

We can, however, conclude that a larger trial with more power to detect an effect is highly unlikely to be positive. A larger trial in specialist outpatient or home care services using the same design and outcome measures is unlikely to demonstrate any benefit. It is nevertheless possible that SPARC has utility for the original purpose for which it was designed, as a screening tool, in primary care or general

medical care for selection of patients who may benefit from a referral to specialist palliative care. It is also possible that, were SPARC to be included in the routine clinical assessment that informs a care plan within a specialist service, then immediate benefit might follow within an effective supportive or palliative care service.

Disclosures and Acknowledgments

This study was funded by Macmillan Cancer Support (U.K.). This work was undertaken as part of a doctoral study and was written by N. Ahmed. The co-authors made suggestions for improvement to the article. The development of SPARC was previously funded by the Elizabeth Clark Charitable Trust.⁴ The authors were part of a team that were involved with the development of SPARC.^{2,4,7,8} The authors declare no conflicts of interest.

The authors acknowledge the patients and HCPs who kindly and generously agreed to give their time and participate in this study. They also thank the members of the research cooperative, The Macmillan Palliative and Cancer Care Research Collaborative, for advice and discussion of the analysis, and consumer representatives Ms. Jacqui Gath and Ms. Alison Morton for their contributions to the study. Thanks to the funders, Macmillan Cancer Support (U.K.), for funding all aspects of this work.

Supplementary Data

Supplementary data related to this article can be found online at <http://dx.doi.org/10.1016/j.jpainsymman.2015.05.010>.

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Consumer views on a new holistic screening tool for supportive and palliative-care needs: Sheffield Profile for Assessment and Referral for Care (SPARC): a survey of self-help support groups in health care

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Abstract

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Accepted for publication

21 January 2013

Keywords: advanced illness, consumer views, holistic needs assessment, relevance and acceptability, SPARC, supportive and palliative care

Background Sheffield Profile for Assessment and Referral for Care (SPARC) was developed in response to concerns that palliative care may not be reaching all people who could benefit from it. Acceptability of the tool is an important step in developing its future use.

Aims To elicit the views of a wide variety of members of consumer and self-help support groups concerned with health care on the relevance, acceptability and the overall perception of using SPARC as an early holistic needs assessment tool in supportive and palliative care.

Methods This study was conducted in South Yorkshire and North Derbyshire (UK). Ninety-nine consumer and self-help groups were identified from information in the public domain. Thirty-eight groups participated. Packs containing study information and self-complete postal questionnaires were distributed to groups, and they were asked to circulate these to their members. Completed questionnaires were returned in pre-paid envelopes to the research team.

Results 135 questionnaires and feedback forms were returned. The majority of respondents found SPARC easy to understand (93% (120/129; 95% Confidence Interval 87% to 96%) and complete (94% (125/133; 95% CI: 88% to 97%). A minority, 12.2% (16/131), of respondents found questions on SPARC 'too sensitive'.

Conclusions Overall, respondents considered SPARC an acceptable and relevant tool for clinical assessment of supportive and

palliative-care needs. Whilst a small minority of people found SPARC difficult to understand (i.e. patients with cognitive impairments), most categories of service user found it relevant. Clinical studies are necessary to establish the clinical utility of SPARC.

Background

Sheffield Profile for Assessment and Referral for Care (SPARC) is a multidimensional screening tool to assess the supportive care and palliative-care needs of patients with advanced illnesses, regardless of diagnosis. The questionnaire is a comprehensive and holistic self-assessment tool that gives a profile of needs to identify patients who could benefit from additional supportive or palliative care. No questionnaire of this type has been fully evaluated in terms of its validity and clinical utility.

The World Health Organisation (WHO) has defined palliative care as: 'an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual'.¹ This definition recognizes the value of early application of palliative-care principles, rather than a narrower view which identifies palliative care solely as care at the end of life. The term 'supportive care' has been used by some as a wider term intended to include palliative care, and there is continuing debate on terminology. In this paper, we follow the WHO definition, which suggests the early introduction of palliative care.

Sheffield Profile for Assessment and Referral for Care has been developed over a 5-year period by the Academic Unit of Supportive Care, The University of Sheffield,² in response to concerns that palliative care may not be reaching all people who could benefit from it.³ A systematic review of the literature confirmed the potential unmet need in this area and identified several barriers to referral, including professionals' lack of knowledge and absence of standard referral criteria. Some groups of peo-

ple, including the elderly, those from ethnic minorities and those with non-cancer conditions appeared to be particularly likely not to receive timely referral.³ SPARC has been subjected to rigorous psychometric development, consultation with professionals and patients, and extensive field-testing.²⁻⁵

The questionnaire is relevant to most categories of health service user at some point in their disease. It is designed to complement and not replace face-to-face clinical assessment by health-care professionals. It can be combined with a holistic needs assessment consultation, or used as a preliminary to such a consultation, or as screening tool to identify those requiring further help. SPARC can point to a category of need that a GP or other health-care professional can follow-up by making an action plan which could include a specific intervention or referral to another service. This represents enormous potential for identifying need and therefore improving the situation for patients and also for their carers.

SPARC is a patient-rated 45-item tool with nine dimensions.² Domains addressed in SPARC include communication and information; physical symptoms; psychological issues; religious and spiritual issues; independence and activity; family and social issues; treatment and personal issues (see Appendix 1).

Assessment tools and instruments

Richardson *et al.*, 2007⁶ undertook a review of 15 patient assessment tools in cancer care. SPARC was one of only a few tools designed for patients with any serious illness, which can be used to assess needs in patients with chronic, progressive diseases. SPARC was considered one of the most comprehensive tools (according to the author's classification, covering all dimensions of need and in relation to health status).

Patient and public involvement in the further development of SPARC

In the United Kingdom and elsewhere the involvement of consumers in health and social care is recognized in both health service development and research.^{7,8} In the United Kingdom, a national advisory group, INVOLVE, was set up by the Department of Health to support patient and public involvement in research and development and improve the way that research is prioritized, commissioned, undertaken, disseminated and used.⁹

The North Trent Cancer Network's Consumer Research Panel (a group of 30 former and current cancer and palliative-care patients and carers) were involved in all stages of the research.^{7,8,10} The group was involved in the initial development of the SPARC questionnaire and the study feedback form. Two members of the member also formed part of the study steering group and provided useful input and contributions throughout the course of the study.

Richardson *et al.* (2005)¹¹ have reported on patients' assessment tools in cancer care and state that the principal function of these tools is to improve clinicians' understanding of patients' needs, and therefore, their ability to respond to them. Work to-date suggests that assessment tools improve doctor-patient communication. However, the impact of assessment tools on patient outcomes is less clear.

As the scope of palliative care moves beyond being identified solely with cancer care, there has been a wider awareness of the supportive and palliative-care needs of those with other diagnoses. Chronic illnesses in particular have been the subject of review, which has included the understanding of some cancers as chronic illness. Three typical illness trajectories have been described for patients with chronic illness: cancer trajectory (a short period of decline); organ failure trajectory (long term with intermittent serious episodes) and the frail elderly or dementia trajectory (prolonged dwindling). Awareness of these trajectories helps clinicians meet patients' multidimensional needs better and helps patients and carers cope with their

situations.¹² Extensive evaluation and development of SPARC has allowed patients and carers to use the instrument as a self-rated questionnaire. In order for a screening tool to function well as a self-rated instrument, it is important that a wide variety of views are taken into account to ensure that it is acceptable and relevant to the needs of a broad sector of potential users/consumers of health-care services. In view of this, we designed a study which would explore the views and perceptions of people with a range of conditions who might be those who would encounter the SPARC questionnaire if it came to be widely used by health professionals as part of an assessment of need, or in screening for potential but hitherto unidentified need. This paper reports on respondents' views of SPARC, as a further important aspect of the development of the tool. However, review of individual replies to items within SPARC was beyond the scope of this study. We regarded testing the acceptability of SPARC as an important requisite before carrying out studies in wider populations not currently in contact with supportive and palliative-care services.

Aim and Methods

The aim of the study was to elicit the views of a wide variety of members of consumer and self-help support groups on the relevance, acceptability and the overall perception of using SPARC as an early holistic needs assessment tool in supportive and palliative care.

Part of SPARC's purpose is to identify people who might benefit from palliative-care services, but who so far have not been considered, or have not considered themselves as within its remit. If SPARC is to function in this way, as screening tool, we needed to feel confident of its acceptability to those completing it. For this reason, we wanted to assess the response to its questions in a group of people not already known to palliative-care services. There were two main reasons for choosing to recruit from self-help support groups for this survey. Firstly, we wanted to assess the response from

people who were already dealing with chronic and serious illness and would therefore not be considering for the first time the issues raised by SPARC. Secondly, recruiting through self-help support groups would mean that potential participants would have an existing support network for discussing whether or not to participate, and in which to address any concerns raised by the survey.

Identifying user and self-help groups

Self-completion postal questionnaires were posted to self-help support groups concerned with serious and life-threatening disease. Contact details of groups approached were all in the public domain. The groups were concerned with a broad range of illnesses including cancer, mental disorders and other medical conditions. The study entailed contacting named contacts within the support groups and, with consent, subsequently forwarding the SPARC questionnaires and the evaluation questionnaires for distribution to group members.

The questionnaire requested brief information about the respondent's particular knowledge and use of health-care services and focused on their views and perceptions of the screening tool. Other issues that users considered important were incorporated using an open question response.

The project was conducted within the requirements of local ethics regulations. NHS Research Governance approval was unnecessary, as user groups were not accessed through NHS services, nor did it involve researchers in their capacity as NHS employees. This study was conducted in South Yorkshire and North Derbyshire (UK). Within this region which covers approximately 1.8 million population, users of health-care services were contacted via their membership of support and self-help groups.

Sheffield user and self-help support groups were identified via the Sheffield City Council 'Help Yourself Database' and the 'Princess Royal Trust Sheffield Carers Centre database'.^{13,14} Additional groups were identified via Google search engine. The groups were con-

tacted initially by phone. Members of the groups represented a broad range of illnesses (serious and life-threatening diseases): Alzheimer's/dementia, arthritis/osteoporosis, cancers, including breast and prostate, heart disease, respiratory disease, kidney disease, lymphoedema, mental health, substance abuse, neurological conditions (multiple sclerosis, Parkinson's disease, brain injury/stroke, epilepsy), other medical conditions: (human immunodeficiency virus (HIV), sickle cell anaemia, migraine, diabetes, myalgic encephalomyelitis (ME), lupus erythematosus), as well as groups specific to carers, and to particular ethnic minorities.

The most appropriate method of distributing the information packs and the SPARC feedback form was discussed with each group, as were other channels (e.g. newsletters) to publicize the study.

User and self-help support groups circulated information packs (information sheet, SPARC, and SPARC feedback form) inviting their members to complete SPARC and the feedback form. We invited completion of SPARC as the most effective route for participants to be able to understand and report their own views on it and their responses to it. We explained that participating in the research would not alter any clinical care they might or might not be receiving. The feedback form consisted of a semi-structured questionnaire with questions on demographics as well as on views and perceptions of the SPARC questionnaire. Demographic questions included age, gender and ethnicity, alongside name of the support group and the disease condition with which it was concerned. Views and perceptions of the SPARC questionnaire were sought, with questions on ease of understanding and completion, whether questions were well written, whether they were too sensitive, relevance of the questionnaire to the respondent now and in the future and its name. Other questions were on which professionals would find it useful, and which patients should be completing it. Ten questions were phrased as open questions with a space for free-text comments, four offered a choice from given responses, and two offered a

choice of responses, followed by an invitation for comments. A copy of the feedback form can be seen at appendix 2.

Completed feedback forms commenting on the SPARC questionnaire were sent back to the research team in pre-paid envelopes. Responses were analysed at both individual and group level. This enabled us to review free-text responses in the light of replies to an accompanying question offering a choice of replies, informing our assessment of validity and trustworthiness of the findings.

A total of ninety-nine user and self-help support groups were identified via information in the public domain. Of these, thirty-four groups were excluded from the study after initial phone contact; twenty-four of these were excluded due to either (i) the group considering it inappropriate to be involved with the research and/or (ii) they had links with the NHS. A further ten groups contacted did not respond to the invitation.

A total of thirty-eight groups eventually participated in the study and distributed information packs to their members; $n = 135$ questionnaires and feedback forms were completed and returned to the research team and underwent data analysis.

Data analysis

Qualitative data were entered into Excel and quantitative data onto Statistical Package for Social Scientists (SPSS Version 18, SPSS Inc., Chicago, IL, USA). Free-text open question responses have been interpreted using methods appropriate to the material generated. This can be described as a summative content analysis approach, which incorporated review of themes where more complex material was supplied.^{15,16} Analysis of free-text open question responses offers insight and information about issues that impact on the acceptability and relevance of specific user groups. In considering issues of reliability and trustworthiness, we were guided by Graneheim *et al.*¹⁷ However, in our study, free-text comments were given in the context of a structured questionnaire, and we have

reported them in this way. Initially, one researcher (MW) carried out the analysis of the qualitative material: this was then reviewed by a second researcher (PH).

Analysis of the qualitative and quantitative data shed light on the relevance and acceptability of SPARC for the specific groups studied. The statistical analysis of the quantitative data was mainly descriptive with point estimates, and 95% confidence intervals reported for the various binary outcomes such as difficulty in completing the SPARC (yes or no) or difficulty in understanding the SPARC (yes or no). We looked at the various characteristics of respondents shown in Table 1 and explored possible associations. Associations between binary variables such as difficulty of understanding the SPARC or difficulty in completing the SPARC and continuous variables such as age were examined by a two-independent samples *t*-test, and associations between cate-

Table 1 Baseline demographics

	<i>n</i>	Median	Range
Age (years)	131	60	16–85 (58.8% aged 55–74)
	Unknown: 4		
	<i>N</i> = 135		
	<i>n</i>	Valid%	
Role in group			
Patient	88	65.2	
Carer	32	23.7	
Professional	4	3.0	
Other	7	5.2	
Unknown	4	3.0	
<i>N</i>	135		
Gender			
Male	42	31.8	
Female	90	68.2	
Unknown	3		
<i>N</i>	135		
Ethnic Origin			
White-British	123	92.5	
Black or Black British-Caribbean	4	3.0	
Black or Black British-African	3	2.3	
Chinese or other ethnic background-Chinese	3	2.3	
Unknown	2		
<i>N</i>	135		

gorical variables (e.g. sex, role, ethnicity, etc.) were examined with a chi-squared test. A *P*-value of <0.05 was regarded as statistically significant.

Results

Overall item completion rates for SPARC were good with very few missing responses. Completion rates for items (for all but one) ranged between 95.6% (129/135) and 100% (135/135). The item that scored slightly lower was '*How relevant might SPARC be in the future?*', which had an 87.4% completion rate.

Individual/group response

Of the 135 respondents, 98.5% (133/135) were individual responses, and 1.5% (2/135) were group responses to SPARC. Therefore, the majority of responders who completed SPARC were individuals. Table 1 shows baseline demographics (based on questions 2–5).

'What disease condition are you concerned with?'/How long did it take you to complete the form?

Respondents were associated with a wide variety of conditions, including cancers; cardiovascular disease; brain injury; Alzheimer's disease; multiple sclerosis; diabetes; mental illness; substance abuse; arthritis; and osteoporosis. 120 respondents stated disease condition (15 respondents did not provide this information). More respondents were associated with cancer (24/135) than any other disease group; however, these still represented a minority of the total respondents. The time taken to complete SPARC ranged from 5 to 45 min; the majority of responders (81.3%: 100/123) cited completion in 15 min or less.

'How easy was it to fill in SPARC?' (easy/ok/moderately difficult/difficult)

Overall 93% (120/129; 95% confidence interval 87–96%) of respondents to this question found

the SPARC questionnaire 'easy' or 'ok' to complete.

'In general, was the SPARC questionnaire easy to understand?' (yes/no)

Overall 94% (125/133; 95% CI: 88–97%) of respondents gave a 'yes' response to this question.

There were 52 comments from respondents. Most comments endorsed ease of understanding the questionnaire. Issues raised included matters such as providing other reply options and proxy completion, for example:

Very simple terms of language

A patient with dementia would have difficulty after the early stages of the illness, as a carer I could only try to assess the patient's feelings due to communication difficulties

Occasionally it would have been nice to have a "not sure" or "don't know" box

'How do you feel about the way the questions are written?'

There were 113 responses to this question. The great majority of comments approved of the way the questions were written, in particular their being clear and to the point, but a minority made suggestions for change including increasing print size, and the specific needs of some disease conditions: for example:

Very good – clear and concise

The easiest questionnaire I've ever completed

Well written and easy to follow

Writing a bit small. Questions close together

Ok. But other questions are needed to cover some aspects of dementia

'Were any questions too sensitive?' (yes/no)

Most respondents did not find any questions too sensitive. Some SPARC questions were considered too sensitive by 12.2% (16/131) of respondents.

There were 24 comments in this section. We looked particularly at the 15 comments from those who had answered 'yes' to the item on sensitivity of questions. Nine of these were patients, 3 were carers, and 3 had other roles. Patients highlighted the following questions as sensitive and intrusive questions: Q29 (feeling that life is not worth living: 1 patient); Q30 (thoughts about ending it all: 2 patients); Q31 (the effect of your condition on your sexual life: 5 patients); and Q38 (worrying about the effect that your illness is having on your family and other people: 1 patient). One patient did not wish to declare their age, and one commented that the issue was the amount of detail asked. The carer who commented said that questions on sexual life or on thoughts of ending it all were difficult for a carer to answer on a patient's behalf. Those in other roles speculated that the questions might be found too personal or intrusive.

However, there were respondents whose comments showed they had found these questions helpful. Patients commented: 'More questions on sex might be helpful especially for males e.g. would you like specialist treatment for your condition?' and 'It was good to admit to myself how I sometimes feel'. One comment from another respondent suggested that it might be useful to ask, rather than avoid, potentially sensitive questions:

A useful and non-threatening tool in highlighting problem areas where a patient may feel uncomfortable in asking for further help and information

'How relevant is the SPARC form to you at the moment?' (very relevant/moderately relevant/not very relevant/totally irrelevant)

There were 132 responses to this question. At the time of completion 59.1% (78/132) of respondents found the SPARC questionnaire 'very relevant' or 'moderately relevant'. 40.9% of respondents (54/132) found the SPARC questionnaire 'not very relevant' or 'totally irrelevant' at the time of completion.

'How relevant might it be in the future?' (very relevant/moderately relevant/not very relevant/totally irrelevant)

There were 118 responses to this question. 83.1% of respondents (98/118) found the SPARC questionnaire to be 'very relevant' or 'moderately relevant' in the future ('very relevant' = 47.5%; 'moderately relevant' = 35.6%). 13.6% of respondents (16/118) found the SPARC questionnaire to be 'not very relevant' and 3.4% (4/118) 'totally irrelevant' in the future. Two of the four were patients, and two were carers.

'Which health-care professionals would find the questionnaire most useful? For example, GP, practice nurse, hospital consultant, other?'

There were 126 responses to this question. In general, the answers supported questionnaire use by any/all professionals involved with the patient.

Any health worker involved in care of patients and other carers

All of above

[Need a] guarantee that information is taken seriously and dealt with, not just stored and nothing happening

'In your opinion, which patients should fill in this type of questionnaire?'

There were 111 responses to this question. In general, comments supported its use for all patients. There were particular references to serious, chronic and terminal illness.

All

Long term illness patients

May be useful on discharge from acute treatment to pick up issues

Anyone who has just developed or living with a life changing condition

'What else would you like to tell us about this SPARC questionnaire?'

There were 50 responses to this question. Several areas were highlighted by respondents.

Seventeen made reference to the value of SPARC in enhancing communication:

A good initiative to be more objective about the needs of patients (and consistent)

Like the way it includes questions about how you are feeling, not just about physical symptoms

One of these respondents raised a point about whether SPARC went far enough:

As a first probe to obtain basic information it is fine. Some may find it does not delve deep enough to give any significant information as to the type of assistance is being sought

The question of use of the information by professionals was referred to by 10 respondents:

I found this an easy but thorough questionnaire, which I feel could be of value in planning care programmes – a useful tool in possibly highlighting problem areas or concerns which may not be apparent with clinical consultation alone

This might be seen as a first step. Bridging the gap between the needs identified by this questionnaire and the means to satisfy them is a major task indeed

Nine comments endorsed the value of the questionnaire:

Good

Quick and easy to complete

Five respondents gave negative comments; for example:

I don't like filling in any questionnaire, looking after my wife is all I am interested in

Nine respondents raised other issues, such as family involvement in questionnaire completion, or suggestions for further questionnaire items.

Discussion

As a screening tool, it is possible that SPARC might serve as a first point of contact with a professional or a service offering supportive or

palliative care. It might also be used by a health professional in primary or secondary care, highlighting the need for such care for the first time. It is important that it is not only acceptable, but that it also asks questions in a suitable way, that respondents feel they can understand and answer. It is important therefore to understand what the response of someone might be to seeing a questionnaire such as SPARC for the first time, and being asked to address the items within it.

We have considered acceptability and relevance of the questionnaire and reviewed the study findings in this light of this. Overall, 93% of respondents (120/129) found SPARC 'easy' or 'ok' to complete, and 94% (125/133) found SPARC easy to understand. Additionally, qualitative comments endorsed the view that the questions were clear and well written and suggested that the questionnaire would be suitable for all patients and useful for all professionals involved in their care. Most (87.8%) did not think the questions were too sensitive. Completing the questionnaire took fifteen minutes or less for 81.3% (100/123) respondents. We considered the matter of the minority (12.2%) who thought some questions too sensitive. Not all of these were patients. In considering whether such potentially sensitive questions should be avoided, we noted that other responses valued the questions, despite their sensitive nature. We suggest that omitting questions because some respondents might find them sensitive runs the risk of reducing the value of the questionnaire for others, where these very questions are valued ones. Taken together, we felt that these quantitative and qualitative data endorsed the SPARC questionnaire as acceptable to patients.

With regard to relevance, 59.1% of respondents (78/132) found the SPARC questionnaire 'very relevant' or 'moderately relevant' at the time of completion. This is unsurprising, given that we were recruiting from self-help groups, and many members of these may not have had supportive and palliative-care needs at that time. However, 83.1% of all respondents (98/118) considered the SPARC questionnaire

could be 'very relevant' or 'moderately relevant' in the future. Coupled with the qualitative comments on clear well-written questions and respondents' suggestions that SPARC could be used by all patients and their professionals, we felt that the data supported the relevance of the SPARC questionnaire.

Respondents were associated with a wide variety of conditions, including cancers; cardiovascular disease; brain injury; Alzheimer's disease; multiple sclerosis; diabetes; mental illness; substance abuse; arthritis; and osteoporosis. Although respondents with cancer diagnoses were the largest single category, they were a minority of the total at 20% (24/120 who provided this data), suggesting acceptability and relevance across a range of disease and conditions.

Strengths and limitations of the study

To the best of our knowledge this study is the first of its kind to elicit the views of a wide variety of users of services concerning the relevance, acceptability and the overall perception of using an early holistic needs assessment tool, in this case SPARC. However, caution is required in interpreting and generalizing from this data. A low response rate, and thus the representativeness of the sample, may be a limitation for this study. Although we included representatives of a broad spread of self-help support groups and conditions, the study sample included many people who did not have supportive and palliative-care needs at that time. Future studies should therefore include patients with supportive and palliative-care needs. As all data collection was carried out in the northern part of England, findings may not be generalizable to other regions of England (UK) and to other countries. While supportive and palliative care are international in scope, service provision itself and the cultural context in which it is delivered are different in different areas of the globe. This may mean that issues of acceptability and relevance may also be altered in different parts of the world.

Conclusions and implications for future research and practice

Review of the literature³ shows the existence of unmet needs in patients, which could be addressed if patients were identified as in need of care and referred to supportive and palliative-care services. Needs assessment tools have been used in cancer care and found to improve health professionals' understanding of needs.⁶ The potential benefit from a comprehensive assessment tool with good acceptability for patients is very great.

Findings from the study sample indicate that SPARC is a relevant and acceptable tool for the holistic assessment of supportive and palliative-care needs. Respondents found it easy to understand; well written and easy to follow; and relevant to patients with a wide range of diagnoses in need of supportive care and palliative care now or in the future. Patients of all ages responded. SPARC contains some sensitive questions but overall it is worthwhile to ask these questions.

There is, however, a challenge inherent in any work on identifying needs, and that is the response to addressing the need once identified. This challenge was referred to by more than one respondent in this survey, and it underlines the need for further studies which look at outcomes following the use of SPARC.

Eliciting the views of members of self-help support groups from a wide range of disease categories represents an important phase in the development of SPARC. However, clinical studies are required to establish the validity and utility of the screening tool. A randomized controlled trial is currently underway to test the clinical utility of SPARC. This feasibility study has been developed and implemented in accordance with the Medical Research Council (MRC) framework for developing and evaluating complex interventions.¹⁸ It will allow us to test procedures, estimate recruitment/retention and determine sample size.

Acknowledgements

The authors would like to express their gratitude to The Supportive and Primary Care Oncology Research Group (SPORG), for the grant which made this study possible, to all user groups who participated in the study and to the late Karen Wilman (Consumer Representative of NTCRN Consumer Research Panel). Thank you for your time and valuable contributions to the study.

Contributors

All members of the research team contributed to the design of the study. Michelle Winslow, Karen Collins and Philippa Hughes undertook the data collection. Kate Walsh, an undergraduate student on research placement (School of Health and Related Research, University of Sheffield) inputted the data for analysis. Nisar Ahmed undertook the secondary data analysis as part of his doctoral study (PhD). Stephen Walters (Professor of medical statistics and clinical trials, School of Health and Related Research, University of Sheffield) undertook a more detailed statistical analysis. Michelle Winslow and Nisar Ahmed wrote the first draft of the paper (equal contribution). Dr Bill Noble is the principal investigator for the study, led the analyses presented in this paper and commented on the draft versions. All co-authors commented on the first and subsequent drafts of the paper. Nisar Ahmed prepared the final draft for submission, and Philippa Hughes revised the paper following the reviews. All co-authors reviewed the final revised draft. Dr Bill Noble is guarantor.

Funding

The study was funded by The Supportive and Primary Care Oncology Research Group (SPORG). The views and opinions expressed herein are those of the authors and do not necessarily reflect those of SPORG. All authors declare independence from the study funders.

Competing interests

All authors declare: no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work and no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval

This study was approved by the School of Medicine and Biomedical Sciences Research Ethics Review Panel (University of Sheffield, UK), in December 2005.

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1. Appendix SPARC*

SPARC*

We would like to know a bit more about you and your concerns. Please fill in this questionnaire (with help from a relative or carer if needed) and return it with the study questionnaire booklet. There are no "right" or "wrong" answers. If you are unsure of a question, please leave it blank. THANK YOU.

COMMUNICATION AND INFORMATION ISSUES		
1.	Have you been able to talk to any of the following people about your condition?	Yes No
a.	Your doctor	<input type="checkbox"/> <input type="checkbox"/>
b.	Community nurse	<input type="checkbox"/> <input type="checkbox"/>
c.	Hospital nurse	<input type="checkbox"/> <input type="checkbox"/>
d.	Religious advisor	<input type="checkbox"/> <input type="checkbox"/>
e.	Social worker	<input type="checkbox"/> <input type="checkbox"/>
f.	Family	<input type="checkbox"/> <input type="checkbox"/>
g.	Other people (please state) _____	<input type="checkbox"/> <input type="checkbox"/>

PHYSICAL SYMPTOMS					
Please circle one answer per line					
	Not at all	A little bit	Quite a bit	Very much	
<i>In the past month have you been distressed or bothered by</i>					
2.	Pain?	0	1	2	3
3.	Loss of memory?	0	1	2	3
4.	Headache?	0	1	2	3
5.	Dry mouth?	0	1	2	3
6.	Sore mouth?	0	1	2	3
7.	Shortness of breath?	0	1	2	3
8.	Cough?	0	1	2	3
9.	Feeling sick (nausea)?	0	1	2	3
10.	Being sick (vomiting)?	0	1	2	3
11.	Bowel problems (eg constipation, diarrhoea or incontinence)?	0	1	2	3
12.	Bladder problems (urinary incontinence)?	0	1	2	3
13.	Feeling weak?	0	1	2	3
14.	Feeling tired?	0	1	2	3
15.	Problems sleeping at night?	0	1	2	3
16.	Feeling sleepy during the day?	0	1	2	3
17.	Loss of appetite?	0	1	2	3
18.	Changes in your weight?	0	1	2	3
19.	Problems with swallowing?	0	1	2	3
20.	Being concerned about changes in your appearance?	0	1	2	3
21.	Feeling restless and agitated?	0	1	2	3
22.	Feeling that your symptoms are not controlled?	0	1	2	3

PSYCHOLOGICAL ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
23.	Feeling anxious?	0	1	2	3
24.	Feeling as if you are in a low mood?	0	1	2	3
25.	Feeling confused?	0	1	2	3
26.	Feeling unable to concentrate?	0	1	2	3
27.	Feeling lonely?	0	1	2	3
28.	Feeling that everything is an effort?	0	1	2	3
29.	Feeling that life is not worth living?	0	1	2	3
30.	Thoughts about ending it all?	0	1	2	3
31.	The effect of your condition on your sexual life?	0	1	2	3

*Sheffield Profile for Assessment and Referral for Care
SPARC-45(clinic) v1 July 2005 © The University of Sheffield - Academic Unit of Supportive Care

RELIGIOUS AND SPIRITUAL ISSUES					
Please circle one answer per line					
	Not at all	A little bit	Quite a bit	Very much	
<i>In the past month have you been distressed or bothered by</i>					
32.	Worrying thoughts about death or dying?	0	1	2	3
33.	Religious or spiritual needs not being met?	0	1	2	3

INDEPENDENCE AND ACTIVITY					
<i>In the past month have you been distressed or bothered by</i>					
34.	Losing your independence?	0	1	2	3
35.	Changes in your ability to carry out your usual daily activities such as washing, bathing, or going to the toilet?	0	1	2	3
36.	Changes in your ability to carry out your usual household tasks such as cooking for yourself or cleaning the house?	0	1	2	3

FAMILY AND SOCIAL ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
37.	Feeling that people do not understand what you want?	0	1	2	3
38.	Worrying about the effect that your illness is having on your family or other people?	0	1	2	3
39.	Lack of support from your family or other people?	0	1	2	3
40.	Needing more help than your family or other people could give?	0	1	2	3

TREATMENT ISSUES					
<i>In the past month have you been distressed or bothered by</i>					
41.	Side effects from your treatment?	0	1	2	3
42.	Worrying about long term effects of your treatment?	0	1	2	3

PERSONAL ISSUES				
			Yes	No
43.	Do you need any help with your personal affairs?		<input type="checkbox"/>	<input type="checkbox"/>
44.	Would you like to talk to another professional about your condition or treatment?		<input type="checkbox"/>	<input type="checkbox"/>
45.	Would you like any more information about the following?			
a.	Your condition		<input type="checkbox"/>	<input type="checkbox"/>
b.	Your care		<input type="checkbox"/>	<input type="checkbox"/>
c.	Your treatment		<input type="checkbox"/>	<input type="checkbox"/>
d.	Other types of support		<input type="checkbox"/>	<input type="checkbox"/>
e.	Financial issues		<input type="checkbox"/>	<input type="checkbox"/>
f.	Other (please state) <input style="width: 150px;" type="text"/>		<input type="checkbox"/>	<input type="checkbox"/>

Are there any other concerns you would like us to know about?

<p>This form was completed by: Name [Please print] Patient / Carer / Professional* *circle as appropriate Date</p>	<p>FOR OFFICE USE ONLY</p>
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2. Appendix Feedback questionnaire form for SPARC

Please tell us about yourself?

1. What is the name of the user group that you are a member of?

2. What is your role in the user group e.g. patient, carer, etc?

3. How old are you?

4. What is your ethnic origin? Please tick

White - British	Chinese or other ethnic background – Chinese		
White - Irish	Asian – other background		
White – other background	Mixed – White and Black Caribbean		
Black or Black British - Caribbean	Mixed – White and Black African		
Black or Black British – African	Mixed – White and Asian		
Black – other background	Mixed – other background		
Asian or Asian British - Indian	Other ethnic background		
Asian or Asian British - Pakistani	Information Withheld		
Asian or Asian British – Bangladesh			

5. What is your gender? (please circle) Male / Female

6. What disease condition are you concerned with?

Your views and perceptions of the SPARC questionnaire

7. How easy was it to fill in the form? (please circle)

Easy OK Moderately difficult Difficult

8. How long did it take you to complete the form?

9. In general, was the SPARC questionnaire easy to understand?

Yes / No (please circle)

Please comment

10. How do you feel about the way the questions are written?

11. Were any questions too sensitive? Yes / No (please circle)

If yes, please give details

12. How relevant is the SPARC form to you at the moment? (Please circle)

very relevant moderately relevant

not very relevant totally irrelevant

13. How relevant might it be in the future?

very relevant moderately relevant

not very relevant totally irrelevant

14. What do think of the name of the screening tool? Is SPARC a good name?

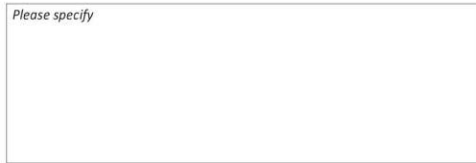
15. Which health care professionals would find the SPARC questionnaire most useful? E.g. GP, practice nurse, hospital consultant, other

Please specify

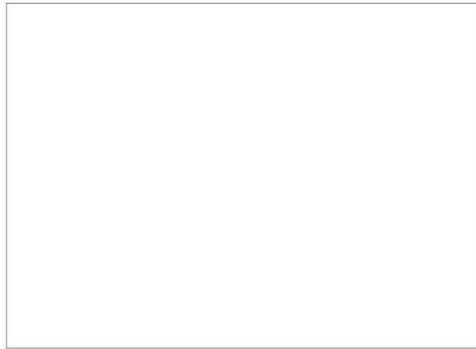


16. In your opinion, which patients should fill in this type of questionnaire?

Please specify



17. What else would you like to tell us about this SPARC questionnaire?



Thank you for taking the time to complete this questionnaire.

Please return it in the pre-paid envelope provided.

Holistic assessment of supportive and palliative care needs: the evidence for routine systematic questioning

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Received 17 July 2012

Revised 6 November 2012

Accepted 21 October 2013

ABSTRACT

There is evidence to suggest that patients with cancer and other non-malignant chronic progressive illnesses can experience distressing symptoms, or concerns, which can often remain unrecognised. There is little disagreement that routine systematic questioning is useful in identifying supportive or palliative care needs that would otherwise not be identified. The purpose of this article is to provide an overview of holistic needs assessment in the fields of supportive and palliative care and to present evidence of the value of routine systematic questioning. Systematic questioning allows needs to be identified and addressed. There is at present no standardised systematic, evidence-based holistic approach to screening patients for supportive and palliative care needs.

INTRODUCTION

Working definitions of 'assessment' and 'needs'

The following working definitions of 'assessment' and 'needs' were part of a Report to the National Cancer Action Team on Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer (January 2007).¹

Assessment: is the overall process for identifying and recording the health and social care needs of an individual and for evaluating their impact on daily living and quality of life so that appropriate action can be agreed and planned with the individual.

Needs: are what an individual requires to be met in order to maintain or improve current states of well-being or to anticipate and manage their deterioration. Areas of supportive and palliative care needs include physical, emotional,

spiritual, environmental, social, sexual, financial and cultural.

Concept of holistic assessment ('medical vs holistic model of care')

The holistic model of care is often described as 'patient-centred', 'whole-person' and 'whole-situation' (mind, body and spirit approach to care where each domain assessed is given equal importance). This approach challenges the traditional 'medical model of care' that is primarily 'disease-focused'. The 'holistic model of care' recognises that any changes or disturbances to either the mind, body or spirit can have an effect on the overall health and quality of life of an individual and the family. These concepts are closely allied to Cicely Saunders' concept of total pain that underpins palliative care practice and comprises the notions of physical, emotional, social and spiritual pain.²

The National Institute for Health and Care Excellence (NICE) guidance on improving supportive and palliative care for adults with cancer set out a series of recommendations based on research evidence and was thus a major policy document in England and Wales. Service users, professionals and policymakers were consulted during the development phase.³ The NICE guidance recognises the need for patients and their families to have their needs assessed on a regular basis and throughout the course of their illness by a multidisciplinary team.

In response to the NICE guidance recommendation 2, the Cancer Action Team commissioned the Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with

To cite: Ahmed N, Ahmedzai SH, Collins K, et al. *BMJ Supportive & Palliative Care* Published Online First: [please include Day Month Year] doi:10.1136/bmjspcare-2012-000324

Features

Cancer-Assessment Guidance (2007).¹ A report by Kings College London accompanied this guidance, which called for a more unified approach to the assessment and recording of patients' needs (setting out the main features of holistic assessment and providing the core content of the assessment).

The authors of a UK nursing paper present the 'tangled web of cause and effect' theory, which proposes that without a comprehensive holistic assessment of an individual the root cause of a problem is unlikely to be identified. In order to 'unpack' the complex nature of problems in patients, it is important to undertake a thorough holistic assessment. A poor or inadequate assessment can result in unnecessary distress and suffering.² A good assessment would inform others providing care from that moment forward, thereby improving continuity of care.

With these considerations in mind, the aim of this feature article is to provide an overview of holistic needs assessment in the fields of supportive and palliative care demonstrating the evidence of the value of routine systematic questioning. We undertook a narrative literature review (not a systematic review) concerning holistic needs assessment in the fields of supportive and palliative care, including both published and unpublished materials. The literature was identified in a systematic manner using an all-inclusive approach with no research methods excluded. A detailed search strategy used to identify the literature and the evidence base is presented in box 1. The following sources were searched: electronic databases, key websites, grey literature sources, hand-searching key journals and contacting experts in the field.

The results of this review are presented in relation to the research aims. The thematic synthesis of evidence led to the emergence of six themes:

1. prevalence of concerns, problems and issues in palliative care patients
2. the need for systematic holistic questioning in palliative care
3. main features of assessment and core content of assessment
4. assessment tools and instruments
5. studies examining the clinical utility of tools
6. implications for future research and practice.

1. Prevalence of concerns, problems and issues in palliative care patients

There is evidence to suggest that patients with cancer and other non-malignant chronic progressive illnesses can experience distressing symptoms and concerns, which can often remain unrecognised. For this reason, the extension of supportive and palliative care to patients with other non-malignant progressive diseases is pressing, irrespective of diagnosis or prognosis. Previous research has highlighted that distressing symptoms and concerns can be managed and treated, provided they are identified in a timely manner and systems are in place for a prompt referral to

appropriate specialist teams.⁴⁻⁸ If these symptoms and concerns are identified early and successfully managed, quality of life and satisfaction with care may be improved. This may also have implications for the configuration and funding of services.

2. The need for systematic holistic questioning in palliative care

There is little disagreement that routine systematic questioning is useful in identifying symptoms, problems and issues that would otherwise not be identified by routine medical and nursing assessment or by using open-ended questions.⁵⁻⁹ For example, Shah *et al*⁷ describe how a study using single open-ended questions that asked palliative care patients *what bothers you most* during the initial consultation generated a variety of patient concerns. The authors propose the use of 'single open-ended' questions to identify 'most pressing needs'. However, this has the potential to exclude less urgent concerns that are nevertheless important for health professionals' understanding of a clinical case. This is illustrated by their finding that "physical distress (44%) was reported more often than emotional, spiritual, existential or non-specific distress (16%)".

For this reason, the 'total symptom experience' is best captured using a more systematic holistic assessment. A study that examined symptom evaluation in palliative medicine found that the frequency of symptoms identified during a systematic assessment (using 48-item symptom checklist) were tenfold higher ($p < 0.001$) than those that were volunteered during open-ended questioning. Arguments against using systematic questioning are usually based on the time it takes to complete an assessment, which can be burdensome for this group of poorly and fatigued patients.⁵

White *et al*⁸ described a retrospective chart review study of 50 patients admitted to a specialist palliative care unit. They found that on average eight further symptoms were detected per patient by systematic questioning than self-report (approximately 66% of symptoms were detected by systematic questioning). Pain was the most commonly self-reported symptom in this study. The authors propose a number of reasons that may account for this. Shorthose and Davies¹⁰ also cite several reasons for under-reporting of symptoms. The main findings from these two studies are summarised below.

A. Why patients may under-report symptoms

Symptom "is not considered severe, considered unimportant, and reporting or under-reporting is influenced by reason for referral, or referrer" have been cited.⁸

Symptom is "inevitable, no treatment is available, perception that health care professional will see it as unimportant, and presence of other more important symptoms" have been cited.¹⁰

Box 1 Literature review methodology: search strategy for identification of studies

The following sources were searched (which involved searching electronic databases and key websites, grey literature sources, hand-searching key journals and contacting experts in the field).

Electronic databases searched

No limits were applied to the years searched.

Medline. In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), British Nursing Index and Archive, PsycInfo, Allied and Complementary Medicine Database (AMED), Cochrane Database of Systematic Reviews (CDSR), Cochrane Controlled Clinical Trials Register (CCTR), Centre for Reviews and Dissemination Databases, Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) Database, Cumulative Index to Nursing & Allied Health Literature (CINAHL), the British Library Database (ZETOC), System for Information on Grey Literature in Europe (OpenSIGLE), Scopus, Google Scholar, National Research Register, PubMed U.S. National Library of Medicine, National Institutes of Health, Web of Knowledge (includes Web of Science-Social Sciences Citation Index), Index to thesis, National Institute for Health and Care Excellence, Department of Health, The National Library for Health (<http://www.library.nhs.uk>), NHS Evidence—Supportive and Palliative care formerly a Specialist Library of the National Library for Health, American Society of Clinical Oncology (ASCO), BIOSIS, NHS Evidence—National Library of Guidelines.

Keywords used to search the literature

Set 1

Palliative Care OR Supportive Care OR Specialist Palliative Care OR Terminal Care OR Hospice Care OR End of Life Care.

AND

Set 2 and 3

Access OR Assessment of need OR Assessment OR Care planning OR Case notes OR Clinical assessment OR Common approach to assessment OR Consultations OR Doctor-patient interaction OR Evaluation OR evaluation tools OR evaluation methods OR History taking OR Holistic assessment OR Holistic needs assessment OR Holistic self-assessment tools OR Interviews OR Measures OR Medical assessment OR Medical clerking OR Medical history OR Medical interview OR Narrative Analysis OR Narrative Medicine OR Narrative synthesis OR Needs assessment OR Nursing assessment OR Oral history OR Patient-physician OR clinician communication OR Questionnaires OR Referral OR Routine assessment OR Scales OR Screening tools OR Standardised holistic assessment OR Symptom assessment OR Symptoms OR Systematic holistic approach OR Systems OR Toolkit OR Tools OR Unmet need OR Validated assessment.

AND

Set 4

Clinical outcomes OR Improved Health OR health care outcomes OR Improved patient management OR Improved patient well being OR Patient centred care OR Patient Experience OR Patient outcomes OR Psychological morbidity OR anxiety OR depression OR distress OR Quality of life OR Relief of suffering OR Satisfaction with care OR Service utilisation OR Survival OR Survivorship OR Uptake OR Well being.

Hand-searching

The following five key journals were hand-searched in an attempt to identify articles that may not have been identified through electronic searches of databases. Hand-searches were limited to journals covering last 10 years (1999–January 2010).

1. Palliative Medicine
2. Supportive Care in Cancer
3. Journal of Pain and Symptom Management
4. Quality of Life Research
5. Psychooncology

Key websites searched

Centre for Reviews and Dissemination (<http://www.york.ac.uk/inst/crd/>)

Cochrane Collaboration (<http://cochrane.co.uk/en/index.html>)

Health Information Resources formerly National Library for Health (<http://www.library.nhs.uk/>)

Department of Health (<http://www.dh.gov.uk/en/index.htm>)

National Institute for Health and Care Excellence (<http://www.nice.org.uk/>)

Contacting experts in the field

Time constraints limited the number of experts contacted. Professor Alison Richardson (Clinical Professor of Cancer Nursing and End of Life Care) and Mathew Fry (Programme Manager Common Assessment Framework Adults), both UK-based, were the two experts that were contacted.

Results of searches

The search strategy generated 35 000 hits and several sifts of published and unpublished abstracts. We obtained 200 full paper copies of articles and on closer examination included and reviewed 63 papers, of which 21 key papers are reported here. The results of this review are presented in relation to the aims.

B. Why healthcare professionals may not enquire about some symptoms

Perception that “symptom is uncommon, considered unimportant, no treatment is available and ‘time constraints’ have been cited”.¹⁰

It must be stressed, however, that the precise reasons are unclear and require further investigation. It would also be interesting to explore reasons why some concerns, problems and issues may be ‘over-reported’.

Features

Hoekstra *et al*⁴ argue that the most 'severe' symptom is not necessarily the same as the 'most troublesome' and stress the importance of assessing both for an individual patient. Kirkova *et al*⁶ report some complexities and challenges of symptom assessment in palliative medicine and highlight the importance of supplementing the clinical interview with validated multisymptom instruments and giving priority to 'total symptom experience'.

It should be noted that Bruera⁹ stresses that early identification of and monitoring of symptoms is only useful if effective treatment programmes are in place. He argued that continued repeated assessments of patients' needs when no systems/treatments are in place to meet those identified needs could be considered unethical.

3. Main features of assessment and core content of assessment

Dunn¹¹ describes assessment as a *staging procedure* for the dimensions of distress. This paper discusses nine dimensions of whole patient assessment for palliative care: (1) illness/treatment summary, (2) physical, (3) psychological, (4) decision making, (5) communication, (6) social, (7) spiritual, (8) practical and (9) anticipatory planning for death. This paper addresses the duration of the assessment (20–30 min), who should be present at the assessment, and discusses the nine dimensions in considerable detail. Although this was developed by the authors of the American Medical Association's Education for Physicians on End-of-Life Care Curriculum and is aimed primarily for surgeons to aid comprehensive assessment, this model could easily be applied to patients earlier in the disease trajectory. It is debatable whether the full assessment as described by Dunn could be successfully completed in 20–30 min, but this very much depends on the patient and the skills of the assessor.

The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer-Assessment Guidance (2007)¹ was developed by a team led by Richardson. The initial stages of development involved a scoping exercise that comprised (1) a literature review to identify tools for holistic assessment, (2) a survey of current practice in cancer networks and (3) an appraisal of the Single Assessment Process for older people. This work led to the development of a specification for assessment and a report that set out the main features of an assessment and core content of the assessment. The recommendations are presented in box 2. Although the guidance was written for the assessment of cancer patients, the principles of assessment could easily be applied to other chronic progressive illnesses.

These recommendations carry implications for resources required to achieve adequate assessment. The recommendation that physical issues be addressed

first should be acceptable to the majority of patients since it is in accordance with the finding that physical symptoms, notably pain and fatigue, are the most frequently identified as the most important problems.⁷ Other recommendations include the proposal that the assessment can continue over many sessions and should supplement routine clinical review.

4. Assessment tools and instruments

Richardson *et al*¹² undertook a review of the tools for patient assessment in cancer care; they found and

Box 2 Recommendations from The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer-Assessment Guidance (2007).¹ (work commissioned by The Cancer Action Team)

The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer-Assessment Guidance (2007)¹ was developed by a team led by Professor Alison Richardson (Kings College, London, UK). This work led to the development of a specification for assessment and a report that set out the main features of an assessment and core content of the assessment.

1. Makes reference to five domains of assessment: background information and assessment preferences, physical well-being, social and occupational well-being, psychological well-being and spiritual well-being. The guidance recommends that physical issues are addressed first, and spiritual and psychological issues towards the end.
2. Holistic assessment is a process that should ideally 'capture full range of needs'; the use of more than one tool is recommended for this purpose since research suggests that no one tool is capable of 'capturing full range of needs'.
3. Holistic assessment should take place throughout the course of the illness (from time of diagnosis, before and after treatments and during follow-up).
4. Unnecessary repeated assessments should be avoided.
5. Assessment should be done over several sessions.
6. Appropriately trained professionals, who have knowledge about the illness, and local services available, should undertake the assessment/s.
7. Assessment of needs should be seen as 'patient-led', 'patient-centred', continuous and supplement but not replace day-day assessment.
8. The guidance recommends that summary records of assessments should be first agreed with patients. This process must take place prior to any further actions being undertaken.
9. The guidance recommends that records of assessment should be well documented and easily accessible to other professionals within and across settings (though patient consent may be required).

Table 1 A summary of the characteristics of some of the key assessment tools used in supportive and palliative care

Instrument, country of origin and reference	Patient group	Clinical purpose	Self complete? (yes/no)	Number of items, domains	Response format	Evidence of clinical utility	Validation work undertaken (yes/no/unknown)
Oncology Clinic Patient Checklist (OCPC), USA, Romsaas <i>et al</i> ¹⁴ and Richardson <i>et al</i> ¹²	Cancer	'Assessment of problems relating to cancer and its treatment- in adult patients in outpatients clinics'	Yes	86 items, 15 domains Information, fatigue, pain, nutrition-related, speech and language, breathing, bowel and bladder related, transportation, mobility, self-care and home care, vocational and educational related, interests and other activities, emotional, family related, interpersonal relationships and three open-ended questions.	Checklist for each item: single or multiple response selections (indicating prevalence of problem). Plus three open-ended questions	Further studies needed to evaluate clinical use	Unknown/absent
Palliative Care Assessment Tool (PACA), UK, Ellershaw <i>et al</i> ¹⁵ and Richardson <i>et al</i> ¹²	'Hospital inpatients with malignant disease (also, assessing the effectiveness of the multidisciplinary team)'	'Developed to assess the outcome of interventions, delivered by a hospital palliative care team'	Administered by health professional	12 items, 3 domains: ► Symptom control (pain, nausea, vomiting, constipation, anorexia, dyspnoea, immobility, insomnia) ► The insight of patients and relatives regarding the diagnosis ► Placement	► Symptoms: four-point scale (0-3) ► Insight of patients and relatives: five-point scale (1-5) @ T1 and T2 (2 weeks) ► Placement: four-point scale (1-4) The scales above are incorporated into a palliative care assessment (PACA) form that includes patient details, relevant medical and social histories, and interventions carried out by the team	PACA 'easy to complete', added to the evidence regarding the effectiveness of palliative care intervention in the hospital setting Significant improvement in some symptoms following referrals: statistically significant improvements in pain (p<0.001), nausea (p<0.009), insomnia (p<0.004), anorexia (p<0.001) and constipation (p<0.02) Staff: completion of symptom forms added significantly to the length of assessments PACA could not easily be incorporated into standard clinical practice	Yes
Supportive Care Needs Survey (SCNS), long form (LF59) and short form (SF-34). Developed based on an existing Cancer Needs Questionnaire, Australia, Bonevski <i>et al</i> ¹⁶ and Richardson <i>et al</i> ¹²	Cancer	'To provide a direct and comprehensive assessment of the multidimensional impact of cancer (including assessment of health services and treatment and delivery) on the lives of cancer patients'	Yes	59 items, six domains: (a) psychologic (needs relating to emotions and coping); (b) health system and information: needs related to the treatment centre and for information about the disease, diagnosis, treatment, and follow-up; (c) physical and daily living needs; (d) patient care and support and (e) sexuality, plus additional items	Five-point response scale: No need 1. Not applicable 2. Satisfied Some need 3. Low need 4. Moderate need for help 5. High need for help	Further studies needed to evaluate clinical use	Yes

Continued

Table 1 Continued

Instrument, country of origin and reference	Patient group	Clinical purpose	Self complete? (yes/no)	Number of items, domains	Response format	Evidence of clinical utility	Validation work undertaken (yes/no/unknown)
Distress Management Tool, USA, Richardson <i>et al</i> ¹² and National Comprehensive Cancer Network (NCCN) ¹⁸	Cancer	'Screening tool-rapid assessment—in cancer patients—made for the clinical setting'	'Simple verbal enquiry or patient self-report'	36 items, five domains Practical problems, family problems, emotional problems, spiritual/religious concerns, physical problems, plus one general distress item	One rating scale (distress thermometer 0-10) extreme distress to no distress, plus 33 statements (yes/no)	Further studies needed to evaluate clinical use	Unknown/absent
Symptoms and Concerns Checklist, UK, Lidstone <i>et al</i> ¹⁵ and Richardson <i>et al</i> ¹²	Advanced cancer	'To determine prevalence and severity of symptoms and concerns in patients with advanced cancer (has been used in the outpatient setting as a supplement to clinical assessment)'	Yes	29-32 items, 4 domains cover physical symptoms, cognitive/emotional/psychological issues, information and communication, treatment related, self-care, social, family and relationships, finances, work and the future, spiritual and religious issues and other concerns plus one open-ended question	Rating scale: 'how much of a problem' (0-3) 'Not at all, a little, quite a bit, very much'	Further studies needed to evaluate clinical use	Yes
Initial Health Assessment Form (IHA), Canada, Crooks <i>et al</i> ²⁰ and Richardson <i>et al</i> ¹²	Patients with newly diagnosed cancer	'To aid clinicians in recognition and documentation of supportive care needs- of patients with newly diagnosed cancer during their first visit to a comprehensive cancer centre' 'Made for use as a multidisciplinary tool in the clinical setting. Used mostly by nurses'	Checklist prompts-facilitating discussion, plus space for management plan	Unclear, common supportive care needs in the following domains: physical (fatigue, pain, breathing, appetite, bowel), psychological (anxiety, depression, sleep disturbance, concentration, appearance), daily living (personal hygiene, managing home), social (caring for the family, concerns relating to others), financial, informational, other special needs and resources (someone to help with; physical needs, psychological needs, social needs, financial needs and spiritual needs)	Checklist prompts (facilitating discussion), plus space for management plan	Introduced in practice and evaluated IHA Form intervention improved documentation of supportive care needs and resources but NOT documentation of the management plan. Currently being used in clinical practice	Unknown/absent
Problems and Needs in Palliative Care Instrument (PNPC), The Netherlands, Osse <i>et al</i> ¹³ and Richardson <i>et al</i> ¹²	Advanced cancer	'A comprehensive checklist of the problems patients experience in palliative care, and their needs for care'	Yes	138 items, 13 domains Quality-of-life aspects: Activities of daily living and instrumental activities of daily living, physical symptoms, role activities, financial and administrative issues, social issues, psychological issues, spiritual issues, autonomy, informational needs Quality-of-care aspects: Problems in consultations, overriding problems in quality of care,	Two questions for each item 1. Is this (item) a problem? Yes—somewhat—No 2. Do you want (professional) attention for this (item)? Yes, more—As much as now—No Informational needs questions (only addressed yes/no) Concerning the GP and concerning the specialist questions: Do you want his/her attention for this? Yes, more—As much as now—No	Further studies needed to evaluate clinical use	Yes

Sheffield Profile for Assessment and Referral for Care (SPARC), UK, Ahmedzai <i>et al</i> ¹⁷	Advanced illness It has found to be acceptable and relevant to patients with a wide range of diagnoses	'A comprehensive, multidimensional and holistic self-assessment tool that provides a profile of needs to identify patients who could benefit from additional supportive or palliative care. It is designed to complement and not to replace the face-to-face clinical assessment by healthcare professionals. SPARC is intended to highlight need, in order to improve patient management, either by the current professional carers, or by referral to specialist supportive and palliative care services'	Yes	concerning the GP, concerning the specialist SPARC is a patient-rated 45-item tool with nine dimensions of need, representing a comprehensive early holistic needs assessment Domains in SPARC include ► Communication and information issues ► Physical symptoms ► Psychological issues ► Religious and spiritual issues ► Independence and activity ► Family and social issues ► Treatment issues ► Personal issues Plus one open-ended question	SPARC is designed to give a clinical profile and NOT a single index score. Each item is regarded on its own merit. Currently the authors do not recommend attaching any clinical significance to the total score or sum of scores in any category. A sample of how some questions on SPARC are scored is presented below. <i>In the past month, have you been distressed or bothered by (symptom/issue/problem)?</i> : Not at all—A little bit—Quite a bit, —Very much: 0, 1, 2, 3 Response formats: Items: communication and information issues (yes/no), Not at all—a little bit—quite a bit—very much (0–3) for the following domains: ► Physical symptoms ► Psychological issues ► Religious and spiritual issues ► Independence and activity ► Family and social issues ► Treatment issues Personal issues (yes/no), plus one open-ended question about any other concerns	Study to assess clinical utility in progress	Yes
Needs at the End-of-Life Screening Tool (NEST), USA, Scandrett <i>et al</i> ¹¹ and Richardson <i>et al</i> ¹²	Framework-based on patients' experiences (subjective) and perspectives regarding their care at the end of life	'Screening tool—clinical setting, possibly assess impact of interventions'	Can be administered by health professional (bedside assessment) or self-complete	13 items, 10 dimensions: Financial burden, access to care, social connectedness, caregiving needs, psychological distress, spirituality/religiousness, personal acceptance, sense of purpose, patient clinician relationship, clinician communication, plus two additional items	Five-point Likert scale (strong agreement—strong disagreement) or discrete responses	The use of NEST 13+ tool resulted in identification of a wide range of important needs vs traditional evaluation; however, care outcomes NOT improved (unchanged) Uptake of recommendations from NEST 13+ intervention—described as poor Clinical effectiveness—yet to be established	

Assessment tools in supportive and palliative care (identified by Richardson *et al*¹² and during our searches).

critiqued 15 tools. Table 1 gives a summary of some of these assessment tools used in supportive and palliative care. Their findings indicate that of the 15 tools identified only 6 were considered to be comprehensive with respect to health status. These included (1) Problems and Needs in Palliative Care Instrument, designed for advanced cancer patients and developed in The Netherlands;^{12 13} (2) Oncology Clinic Patient Checklist (OCPC), designed for cancer patients and developed in the USA;^{12 14} (3) Symptoms and Concerns Checklist, designed for advanced cancer patients and developed in the UK;^{12 15} (4) Supportive Care Needs Survey (SCNS), designed for cancer patients and developed in Australia;^{12 16} (5) Sheffield Profile for Assessment and Referral for Care (SPARC), designed for patients with an advanced illness and developed in the UK;¹⁷ and (6) the Distress Management Tool, designed for cancer patients and developed in the USA.^{12 18} SPARC and the Distress Management Tool were considered to be the most comprehensive tools identified, according to the author's classification, covering all dimensions of need and in relation to health status. Most tools were developed with specific patient groups in mind such as those with cancer or those at the end of life. SPARC and the Symptoms and Concerns Checklist could be used in primary care. SPARC is a multidimensional holistic tool that provides a profile of needs (including physical, psychological, social and spiritual) to identify patients who may benefit from additional supportive or palliative care regardless of diagnosis or stage of disease. SPARC provides a comprehensive early needs assessment.

5. Studies examining the clinical utility of tools

Several studies have examined the clinical utility of some holistic needs assessment tools. These tools include (1) Palliative Care Assessment Tool (PACA),^{12 19} (2) The Initial Health Assessment (IHA)^{12 20} and (3) Needs at the End of Life Screening Tool (NEST).^{12 21} Although the studies have measured changes in clinical outcomes following needs assessment, few have shown an improvement in clinical or patient-reported outcomes as result of the intervention (administration of the tool). Limitations of these studies may include inadequate power to detect a change, the tools not being comprehensive enough for holistic needs assessments or the outcomes chosen may have been inappropriate. Although many of these studies have shown an improvement in documentation of needs, uptake of any recommendations from the intervention and assessment of needs has been described as poor with no significant overall improvements in care outcomes. The precise reasons for these findings are unclear but could include healthcare professionals' attitudes, knowledge or skills, as well as timing of and the availability/non-availability of services.²¹ Scandrett *et al*²¹ propose that new methods to achieve practice change should be considered and evaluated when assessing such interventions.

6. Implications for future research and practice

This article has presented a strong argument in favour of the need for a comprehensive holistic assessment of supportive and palliative care needs. Recommendations for conducting a holistic assessment are also presented. There is a lack of studies on the clinical utility of tools.¹² Systems and services must be in place in order to address any identified needs in a timely manner, and we must consider and evaluate new methods to achieve practice change. Further research is also needed on the effective integration of these tools into routine clinical care. Future work must therefore address these issues.

Acknowledgements The authors would like to express their gratitude to Ms Vicky Grant (Information Specialist, The University of Sheffield) for all the help and advice given on literature search methodology.

Contributors This work was undertaken as part of a doctoral study and is written by NA. The coauthors are supervisors that made suggestions for improvement to the paper.

Funding Macmillan Cancer Support and The University of Sheffield.

Competing interests The authors were part of a team that were involved with the development of an holistic needs assessment questionnaire in a supportive and palliative care service namely; the Sheffield Profile for Assessment and Referral for Care (SPARC).

Provenance and peer review Not commissioned; externally peer reviewed.

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CHAPTER 14

The Organisation of Palliative Care in England*

NISAR AHMED, BILL NOBLE, SAM AHMEDZAI

Epidemiological data of palliative care patients and place of death

Over the past 100 years, there has been an increase in the number of people who are surviving longer with chronic illnesses (such as cancer, stroke, chronic respiratory disease, neurological disease or dementia). Advances in care and treatment have resulted in people living longer, recent figures indicate that two thirds of people that die in England are over the age of 75 years.¹

The United Kingdom population in 2008 was 60,975,000 (Office for National Statistics: ONS figures August 2008). The 2001 census indicate that the population of England was 49,138,831, and in 2008 it was approx 51,000,000 (ONS figures August 2008). The number of deaths registered in England and Wales in 2007 was 504,052, and in 2008 it was 509,090 respectively (1% increase).² The ONS data for 2008 reveal that circulatory diseases (which include deaths from ischaemic heart disease and strokes, 33% of all deaths), cancers (neoplasms, 28% of all deaths) and respiratory diseases (including deaths from pneumonia, 14% of all deaths) account for the largest number of deaths.²

The preference is usually to be cared for and to die at home, however

* UK data presented where available

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this often changes as disease progresses. Although the preference is to die at home, research suggests that many people die in an acute hospital, which often is not their preferred place of care or preferred place of death. Across England, there is evidence to suggest that most people die in places other than their home (Table 1).^{1,3,4}

The approximate number of deaths per setting in England is presented in Table 1. Data indicates that most deaths (58%) in England occur in NHS hospitals.

Table 1: Breakdown of approximate number of deaths per setting in England:^{1,4}

Setting	Approximate number of deaths
NHS Hospitals	58%
Home	18%
Care Homes*	17%
Hospices	4%
Elsewhere	3%

*based on Office for National Statistics figures 2004

The primary aim of the End of Life Care (EOLC) Strategy, which received government funding of £286m, was to help people approaching end of life to die in a setting of their choice, surrounded by their loved ones.^{1,4} Experts are of the opinion that more people would want to die in hospital or hospice if the situation at home was not conducive. Figures quoted for peoples' preferences to be cared for and die at home vary, but the EOLC Strategy 2008 states 'Most people would prefer to be cared for at home, as long as high quality care can be assured and as long as they do not place too great a burden on their families and carers'.^{1,4,5}

In 2004, the Marie Curie Cancer Care Delivering Choice Programme was set up to improve the way palliative care is delivered and to support patients to die in their place of choice.⁶ End of life care registers were set up to ensure that organisations caring for people were made aware of patients' preferences. The EOLC Strategy (2008) highlights the importance of assessing the needs, wishes and preferences of all those patients approaching end of life, and documenting and implementing these preferences in a care plan.^{1,4}

The preferences to be cared for and to die at home often change as disease progresses and as death approaches. The most common reasons cited in the literature, which shed some light as to why patients' priorities and preferences change include: improving symptom control (most common reason cited by staff), patients becoming too ill, and relatives needing relief (provide respite care).⁷

A national telephone survey for England, Wales and Scotland of preferences versus reality where patients want to be cared for, their preferred place of death and where they actually die across the various settings, revealed that 56% of patients had a preference to die at home, but the actual place of death at home was only 20% (all causes) and 25% (cancer principal cause). This survey indicated that most people died in places other than their home.^{3,8}

The long-term projections by Gomes and Higginson 2008, based on the current trend is that less than one in ten (9.6%) of people will die at home by 2030, institutional deaths will increase by over 20%, and people will die at increasingly older ages.⁹

National Health System with regard to palliative care and needs assessment

The National Health Service in the UK was established in 1948. In the UK there are four publicly funded healthcare systems, with each system operating independently and politically accountable to relevant devolved government of 1) Scotland (Scottish Government), 2) Wales (Welsh Assembly Government), 3) Northern Ireland (Northern Ireland Executive), and 4) to the Government for England. The UK NHS funds only 25-30% of specialist palliative care funding, this varies greatly between countries.^{10,11} Political decision making within NHS occurs at every level from governmental through national (devolved) regional, local, NHS trust and general practice level. Appendix 1 presents a summary of the key facts and figures for the NHS.^{10,11}

It is well documented that the needs of patients and their carers/families are often not adequately assessed and addressed.^{1,12} There are new initiatives in the UK. General Practitioners (GP's) use registers for palliative care and systems of assessment and review. In the UK, the Gold Standards Frame-

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work (GSF) is 'A framework to enable a gold standard of care for all people nearing the end of life'. In a recent survey, 61.5% (2096 of 3495) of UK general practices reported an involvement with the GSF initiative.¹³

Family needs assessment is less well developed, probably by 20% in the UK. There are some questionnaires (to support holistic assessment) e.g. the Sheffield Profile for Assessment and Referral for Care (SPARC), for holistic needs assessment, the Single Assessment Process (SAP) for older people, and the Department of Health is developing a Common Assessment Framework for adults.^{12,14,15} Individual preferences regarding type of care and setting/location are documented in the Advanced Care Pathway (ACP).¹⁴

The National Council for Palliative Care (NCPC) collects a minimum data set from specialist services.⁵ The NCPC produces a Population Based Needs Assessment for Palliative and End of Life Care compendium which comprises a set of tables of comparative end of life care need for Primary Care Trusts (PCTs), Cancer Networks and Strategic Health Authorities. The methodology for compiling the Tables is derived from *Population based Needs Assessment for Palliative Care*. This was published jointly in 2004 by the NCPC and the Cancer Action Team. It has been employed in nearly all Cancer Networks in both England and Wales to inform strategic review and planning of palliative care services.⁵ All PCTs in England were required in April 2008 to complete a needs assessment for EOLC in their population. The focus was on clinical need, not diagnosis (cancer and non cancer).¹⁶

At present, in the UK no specific laws for palliative care exist. The Palliative Care Bill is currently going through the Parliament. Laws which impact on palliative care include: The National Health Service Act 2006, NHS Act 1977, Mental Capacity Act 2005 (England and Wales), and National Framework for NHS Continuing Healthcare and NHS-funded nursing care (into effect from Oct 2007, England).⁵ In the UK, palliative care has gained important recognition within the policy arena, various policies and initiatives have raised the importance and recognition of palliative care and end of life care; these include, The 1980 Wilkes Report (Care of the terminally ill), The Calman-Hine Report (1995), NHS Cancer Plan (Sep 2000), End of Life Care initiative in England launched in 2003 (implementation 2004), NHS Cancer Plan for England (2004), End of Life Care Strategy (July 2008), and National Strategy on Children's Palliative Care launched 2008.¹⁷ Euthanasia and assisted suicide remain illegal in the UK (currently being reviewed).¹⁸ After

the 1980 Wilkes report, the first major policy document to impact on supportive and palliative care was the The National Institute for Clinical Excellence (NICE) Guidance on Supportive and Palliative Care for Adults with Cancer (2004).

The following are the main national and/or regional health policies regarding palliative care: National Institute for Clinical Excellence Supportive and Palliative Care Guidance 2004 for adults with cancer (England),¹⁹ Next stage review, Darzi report March 2008 (England), End of Life Care Strategy for England (2008), and the All Wales Integrated Care Pathway for the last days of life (1997). Better Care: Better Lives Improving outcomes and experiences for children, young people and their families living with life-limiting and life-threatening conditions (Feb 2008), sets future direction for children's palliative care services.⁵

Implementation of palliative care policy has often been at local level and is sometimes unclear and variable. Implementation depends on local interpretation by PCTs in response to regional strategic reviews. These are new arrangements. Until now implementation of end of life care policy has been through incentives offered to GP's and alongside targeted funding from central sources. Cancer service policies are implemented via cancer networks. PCTs commission from generalist and specialist services.

Funding and financing of palliative care

Palliative care was pioneered in the voluntary sector since late 1960's (refer to Appendix 2, History of hospices and palliative care in the UK) and initially was not part of remit of NHS. Hospices were funded entirely through voluntary contributions. As the hospice movement has grown, the NHS contributes towards some funding. However current level of state funding is inadequate to provide even a basic level of universal palliative care.^{1, 5, 16} Both supportive and palliative care in the UK, rely heavily on the voluntary sector and charitable funding.^{10, 11} In the NHS Cancer plan (year 2000), the government pledged it would increase NHS investment in specialist palliative care by £50 million by the end of 2004 to address inequalities in access to specialist palliative care services.^{3, 20} The Department of Health EOLC

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Strategy was launched July 2008.¹ Its funding was £88m in 2009/10, and will be £198m in 2010/11. Private health insurance rarely funds palliative care. Hospices in the UK receive mainly voluntary funding, community funding is mixed, and hospitals are mainly NHS funded. The approximate breakdown of services funded by the government is illustrated in Table 2. Hospital support receives the greatest percentage funding, and day care the least percentage funding from the government. A summary of some other initiatives for palliative care funding are summarised in Table 3.²¹ There are over 200 local charities that provide the majority of hospice care in the UK.²² ²³ In the UK, there is a medical specialty in Palliative Medicine, and money is spent (from the total spend on palliative care) on training doctors to become consultants in it.

Because of these different inputs, funding for palliative care and end of life care in the UK is not straightforward. PCT budgets never ‘ring fence’, i.e. protect, anything. Audits have revealed that total funding that has been pledged by the government has not been spent on palliative and end of life care and probably never will be. According to the NCPC and Help the Hospices, additional funds allocated for 2009/10, have not reached front line services in many areas.⁵

Table 2: Funding differences between care settings: ¹⁷

Care setting	Approximate breakdown of services funded by government
In-patient care	30%
Home care	59%
Day care	23%
Hospital support	83%

In the UK, palliative care can be provided in the following settings: hospitals (in-patient and out-patients units), hospital-based services (palliative care services working alongside other health professionals), hospices (in patient units), day care hospices, at home and in the community. Some prisons and secure hospitals can offer palliative care and end of life care. A brief description of palliative care settings in the UK can be found in Appendix 3. Pal-

Table 3: Other initiatives for palliative care funding in the UK²¹

New Opportunities Fund (NOF) (funded by National Lottery)	New Opportunities Fund (NOF) 2001 onwards	Building on the Best: White paper 2003
£70 million made available to Palliative Care in England (£48 million developing children's palliative care services, £22 million developing home care services for adults in areas of need).	£23.25 million allocation by NOF for the Living with Cancer Initiative-providing palliative care, home care support, support for carers, information about cancer and cancer services. Black and minority ethnic communities and socially deprived groups, projects running by 2001.	Commitment to spend £12million over 3years to improve end of life care (2004-2007). NHS end of life Programme: encourage local adoption and development of end of life care models (e.g. GSF, Liverpool Care Pathway for the dying patient, and Preferred Place of Care).

liative care provision for older people, homeless, minority ethnic communities and those with non malignant conditions requires further development.^{1,12}

Number of in-/out-patient palliative care services including number of beds dedicated to palliative care

The approximate number of palliative care beds in UK is 3180 (population 59.8million) and 882 palliative care services.¹⁷ For cancer patients there are about 52 beds/million, and for non-cancer patients 26 beds/million.³ The Hospice and Palliative Care Directory (2009-2010), has this figure as n=3217 total number of adult in-patient beds (in the UK), and n=315 total number of children's in-patient beds (in the UK) for year 2008.²³ Table 4 contains the most recent data for 2008/2009 for hospice and palliative care in-patient units and beds in the UK.²³ The voluntary adult units include 9 Marie Curie Hospices with 228 beds and 6 Sue Ryder Hospices with 107 beds. The remainder are independent local charities including two services exclusively for HIV patients with 18 beds.²³ This data was published in the *Hospice and Palliative Care Directory United Kingdom and Ireland 2009-2010*.²³

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Table 4: Hospice and palliative care in-patient units in the UK:²³

	Adult in-patient units						Children's in-patient units	
	Total units	NHS units	Voluntary units	Total beds	NHS beds	Voluntary beds	Units	Beds
London	16	6	10	359	86	273	4	30
Midlands & East of England	45	15	30	646	182	464	11	87
North	60	8	52	851	79	772	12	81
South	52	11	41	773	143	630	9	71
England	173	40	133	2629	490	2139	36	269
Scotland	24	10	14	355	96	259	2	17
Wales	15	9	6	143	65	78	2	15
N Ireland	5	1	4	67	4	63	1	10
Channel Islands	2	0	2	11	0	11	0	0
Isle of Man	1	0	1	12	0	12	1	4
Total	220	60	160	3217	655	2562	42	315

Table 5 provides a summary of information that is derived from the UK Hospice and Palliative Care Directory 2008, and summarises: who provides palliative care, the different kind of services, and who the referring services and caregivers are.²²

National/regional palliative care associations

There are a number of national associations for different professional groups working in palliative care. The National Council for Palliative Care (NCPC) website and Hospice and Palliative Care Directory 2008, and 2009-2010, publish a comprehensive list of palliative care organisations in the UK.^{5,22,23} The NCPC is the umbrella charity that supports all those involved in providing, commissioning and using palliative and end of life care services in England, Wales and Northern Ireland.⁵ The NCPC helps to coordinate developments, and strategic health authorities oversee regional developments. Each area and country has its own representative for NCPC,

Table 5: A summary of information that is derived from the UK Hospice and Palliative Care Directory 2008:²²

Who provides hospice or palliative care?	What kind of services are part of hospice or palliative care?	Where is hospice or palliative care provided?	Referral to hospice/palliative care?
<p>General level of palliative care provided by</p> <ul style="list-style-type: none"> • GPs and district nurses, social service carers, health and social care staff in hospitals and nursing homes. <p>Specialised help</p> <ul style="list-style-type: none"> • provided by hospices run by charities (including Marie Curie Cancer Care and Sue Ryder Care) NHS hospices or palliative care units specialist community palliative care nurses (including Macmillan nurses) hospital palliative care teams (or support or symptom control team) hospice at home teams. 	<p>Full range of services may differ from place to place-</p> <ul style="list-style-type: none"> - specialised medical and nursing care - pain and symptom management - rehabilitation - practical and financial advice - spiritual support - physiotherapy and occupational therapy - lymphoedema service (form of chronic swelling) - respite care to give carers a break - sitting service for patients at home - bereavement support - complimentary therapies. 	<ul style="list-style-type: none"> • At home, • in hospice day centres, • on specialist hospital wards, • in nursing homes, • in hospices and palliative care centres, • provided by a team of specially trained staff which is likely to include doctors, nurses, physiotherapists and occupational therapists, chaplains and social workers. • volunteers are also an important part of the team. 	<p>Referral</p> <ul style="list-style-type: none"> • To hospice/palliative care service usually arranged by patient's own GP or hospital doctor, • Some hospices take self referrals. • A district nurse may also make a referral to a specialist community care or Macmillan nurse and Marie Curie nurses. • Patients usually referred to their nearest hospice or palliative care service-in special circumstances out-of-area referrals may be considered.

elected by local subscribers, who act as local point of contact. They help disseminate information and feedback local concerns and issues to NCPC. Each area covers a small number of Cancer Networks, Cardiac Networks, and other critical care networks. Other palliative care organisations include Association for Palliative Medicine of Great Britain and Ireland (APM), The Royal College of Nursing (RCN-Palliative Care Group), Help the Hospices (HtH), Palliative Care Research Society (PCRS), and the Palliative Care Congress (PCC).^{5,22,23} The Scottish Partnership for Palliative Care provides a similar role for Scottish palliative care.⁵

Education in palliative care

The UK was the first country in the world to recognise palliative medicine as a formal speciality.^{22,23} Palliative Medicine has been recognised as a specialty by The Royal College of Physicians since 1987.^{24,25} In the UK there are wide variations across medical schools with regards to the time allocated for palliative care and end of life care training.¹ In 1985 the peer-reviewed journal *Palliative Medicine* was launched; in 2010 it became the official journal of the Association for Palliative Medicine in the UK.^{24,25} There is a distinct nursing specialisation in palliative care, but no formal accreditation. The College of Nursing was established in 1916, receiving the 'Royal' part of the title in 1939 (RCN). The RCN is a UK organisation and has officially represented the nursing profession in the UK at an international level since 1963. The RCN has a Palliative Care Group (RCN Palliative Care Forum). According to the data published in 2007, in Britain (England, Scotland and Wales), there are nine Chairs in Palliative Medicine, and approximately twelve Chairs for Palliative Nursing.²⁶ There is now a drive for research and professional training.

Research in palliative care

In the UK, there is a structured national research programme. The National Cancer Research Institute (NCRI) is a UK-wide partnership between the government, charity and industry which promotes co-operation in cancer research among the twenty-one member organisations for the benefit of patients, the public and the scientific community.²⁷ In response to the recommendations of the NCRI's Strategic Planning Group on actions to strengthen research into Supportive and Palliative Care (SuPaC) in the United Kingdom, two NCRI Research Collaboratives have been established and funded through a competitive bidding process.¹⁷ The two NCRI Supportive and Palliative Care Research Collaboratives are COMPAS and CeCo (the Cancer Experiences Collaborative). However private and voluntary contributions contribute towards much of the funding for palliative care research in the UK.

The Capacity Building Grant Scheme (CBGS) is aimed specifically at supporting isolated or new investigators in achieving their research potential

and addressing some of the gaps in the evidence base. SuPaC each of awards are in the region of £80,000 or less and a total sum of £800,000 is available.²⁷

A summary of NCRI and NCRN

National Cancer Research Institute (NCRI)

Takes lead in identifying areas where further research initiatives are needed and most likely to lead to progress, provides focus for cancer research conducted across the country.

National Cancer Research Network (NCRN)

Across England integral part of new NCRI, support for the infrastructure for clinical research into cancer. Fully established 2003.

There are many academic organisations across the UK doing independent research – usually through oncology or other university departments. The Trent Palliative Care Centre (Sheffield), was the first purpose-built palliative care research, education and audit unit in the UK. There has also been a recent launch of Cicely Saunders Research Unit at Kings College, London (Cicely Saunders Institute).

The Medical Research Council and Economic and Social Research Council, fund variable amounts of palliative care research. Major research centres in the UK undertaking palliative care research are based in Bristol, Cambridge, Edinburgh, London, Lancaster, Leeds, Liverpool, Manchester, Sheffield, Southampton and Warwick.^{22, 23} The Macmillan Cancer Support also funds research, and there are other disease-specific charities such as the British Heart Foundation. Research is also commissioned by Marie Curie Cancer Care: The Marie Curie Palliative Care Research and Development Unit undertakes research in order to improve care of those people with life threatening illnesses.

Volunteers in palliative care

In many settings volunteers work alongside paid staff. About 6000-7000 professionals in the field including nearly 5000 nurses, and about 750 physicians are supported by a vast network of some 70,000 volunteers.¹⁷ However clinical care is not dependent on volunteers. Hospices and Palliative care services in the United Kingdom are largely developed by charities. Hospices are more dependent on the presence of volunteers, but the National Health Service (NHS) is less dependent. Volunteers are particularly active within voluntary hospice settings.^{22,23} Whilst there is an Association of Voluntary Service Managers which provides a network for those managing volunteers in palliative care, experts and national palliative care organisations contacted were not aware of network (s) for volunteers themselves.^{22,23} Volunteers often have a brief induction and occasional training, e.g. volunteer bereavement counsellors providing counselling under close supervision. However training varies according to role and setting.^{22,23}

Barriers or incentives

The main barrier to palliative care in the UK is failure to recognise need and variable availability of services, to counteract this, incentives for GP's for providing palliative care now exist within their remuneration.^{12,28} In 2004 Ahmed et al, undertook an extensive systematic review of the problems and issues of accessing specialist palliative care by patients, carers and health and social care professionals.¹² Their findings, published in *Palliative Medicine*, indicate that the rapid and unplanned growth of hospices and other palliative care services has led to several problems in the way that these services are perceived by both the public and professionals and therefore accessed. These problems include: heterogeneity in what palliative care services in different localities offer (a form of 'postcode lottery'); lack of understanding amongst professionals about whom to refer, and when; resistance by some professionals to share with or hand patients over to palliative care services, even when it would be in the patients' interest; reluctance by many patients and family carers to be referred for palliative care, because of misunderstandings of what it offers, or fear of its association with imminent dying; perception that palliative care is only for cancer patients;

and missed opportunities resulting from patients having certain cultural backgrounds, or being in institutional care.^{12,14}

There is also a lack of information about palliative care by professionals and patients with poor equity of access to services. There are currently no standardised criteria in the UK to determine when a referral should be triggered (standardised referral criteria need to be developed).^{12,14} There is a need to improve education and knowledge about specialist palliative care and hospice care amongst health and social care professionals, patients and carers. Further work is also needed to assess the needs of those not currently accessing palliative care services.^{12,14}

The availability of drugs, in particular opioids, are described in the literature as having good availability during standard working hours, with some reluctance to prescribe morphine from GPs.²⁹ However, there is a lack of availability of controlled drugs outside of standard working hours.^{25, 29}

Appendix 1: NHS (key facts and figures)^{10, 11}

NHS (facts and figures)

- ▶ Fully funded-launched 60 years ago-established 1948 (NHS in UK).
- ▶ Palliative care funding-mainly voluntary.
- ▶ Free health care to all UK permanent residents at point of need-paid for from general taxation- NHS Act 1946-5th July 1948-(exception charges for prescriptions, dentistry and ophthalmology, but free to children, elderly, unemployed and those on low incomes).
- ▶ Private health care (private insurance)-parallel to NHS/top up to NHS-used by ~8% of population
- ▶ UK 4 publicly-funded healthcare systems (collectively or individually)-only health service in England uses name 'NHS'
- ▶ Health devolved matter-considerable differences between the systems in different countries.
- ▶ Each system operates independently-politically accountable to relevant devolved government of 1) Scotland (Scottish Government), 2) Wales (Welsh Assembly Government) 3) Northern Ireland (Northern Ireland Executive), and 4) to the Government for England.

Budget:

- ▶ 1948: £437 million (roughly £9 Billion at today's value).
- ▶ 2007/2008 ▶ £90 Billion

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NHS employs

- 1.5 million people (<50% clinically qualified)-
- Most expenditure of Department of Health (£98.6 Billion in 2008/09) is spent on NHS-
- World's largest health service- world's 4th largest employer.

NHS-sections: Primary, secondary and tertiary care.

- Primary care (community care)-'frontline' service-first point of contact for most people-delivered by a wide range of health professionals.
- Secondary care-acute health care -can be either elective care (planned) or emergency care. Usually referral from a primary or community health professional such as a GP.
- Tertiary care- (e.g. specialist cancer care): specialised consultative care-usually referral from primary or secondary medical care,

Primary Care Trusts (PCTs)-

- In charge of primary care-local organisations-
- PCTs centre of NHS controlling approx. 80% NHS budget-
- 35,000 GPs, 90,000 hospital doctors, 400,000 nurses and 16,000 ambulance staff.

290 NHS Hospital Trusts-

- Oversee 1,600 NHS hospital and specialist care centres.
- Foundation Trusts-new type of NHS hospital-currently 92 available in England.

Emergency vehicles-

- Provided by NHS Ambulance Services Trusts-13 Ambulance Trusts in England.
- The Scottish, Welsh and Northern Ireland ambulance services provide cover for those countries.

NHS Care Trusts-

- Providing care in both health and social care fields-mainly based in England-none in Scotland (no plans to introduce them).

NHS Mental Health Services Trusts- Provide mental health care in England- overseen by PCTs.

Other agencies- Under umbrella of NHS e.g. The National Institute for Health and Clinical Excellence (NICE).

Appendix 2: History of palliative care and hospices in the UK: Key developments:^{22,23,29,30}

In the UK

- ▶ 1905 St Joseph's Hospice: Opened by Sisters of Charity. East End of London (caring for the sick, poor and marginalised).³⁰
- ▶ 1960's onwards saw the development of modern hospice care –(holistic approach to caring).
- ▶ 1967 first modern hospice founded: St Christopher's Hospice in London by Dame Cicely Saunders-pioneer of hospice movement.
- ▶ Religious Nature: Many hospices have a Christian Foundation. Largely developed by charities.
- ▶ 1969 St Christopher's pioneered concept of community-based hospice/palliative care-day care.
- ▶ 1975- First purpose built day care facility was built by St Luke's Hospice Sheffield.²⁹
- ▶ 1977- First hospital-based palliative care team was founded by St Thomas' Hospital London.
- ▶ 1982- Children's hospices started-founding of Helen House in Oxford 1982.
- ▶ Macmillan Cancer Support (Formerly Macmillan Relief) and Marie Curie Cancer Care- also played a major role in developing palliative care-(through funding of services, education and research).

Appendix 3: Brief description of Palliative Care Settings in the UK

Setting	Brief Description
Care at Home (Community) ^{22,23}	<ul style="list-style-type: none"> ▸ Palliative care support available for families and carers in the community (in most districts in Britain). ▸ Hospice at Home service available (service variation across country). ▸ 24 nursing hour care also available. ▸ Home care support teams (composition of team can vary).
Care in an In-patient Unit (Hospice) ^{22,23}	<ul style="list-style-type: none"> ▸ Patients usually admitted to hospices for controlling symptoms, and managing complex issues that cannot be managed adequately elsewhere. ▸ Team comprises of health professionals that are specialists in palliative care. ▸ Average stay at hospice is 10-14 days
Day Hospices ^{22,23}	<ul style="list-style-type: none"> ▸ Day therapy- available in day hospices allows patients to remain at home, and visit the day hospice for therapy as and when required. ▸ A place where patients can meet other people in the same situation.
Hospital Based Services ^{22,23}	<ul style="list-style-type: none"> ▸ These are palliative care services that work within a hospital setting and work alongside other health and social care professionals. ▸ Also known as Hospital Palliative Care Team, Macmillan Support Team or Symptom Control Team.
Bereavement Services ^{17,31}	<ul style="list-style-type: none"> ▸ Bereavement support available in all settings (community, hospices, day hospices, hospitals). Prior to 2004, there was little contribution by UK health services for this kind of support. ▸ Mainly delivered by voluntary organisations and self-help networks. Cruse Bereavement Care is a UK charity that specialises in bereavement support. ▸ Support offered by meeting the patient but can also be offered over the phone by paid staff and volunteers.
Prisons and secure hospitals ¹	<ul style="list-style-type: none"> ▸ Some prisons are able to offer palliative care and end of life care to prisoners ▸ Under the Mental Health Act (secure hospitals)- prisoners should be treated with dignity and respect and offered palliative and end of life care if required.

- Hostels for homeless¹**
- › Palliative and end of life care provision for the homeless in UK is under review.
 - › Many homeless people are often not registered with a GP, it can be very difficult to identify them and refer them for appropriate care.

Acknowledgements

We would like to thank the following organisations and individuals for their expert help and advice throughout the duration of this project.

National Council for Palliative Care Ms Lucy Sutton (Director of Policy Development), and Ms Ann Eve (Minimum Data Sets Project Manager).

Help the Hospices Ms Melanie Hodson (UK Information Manager), and Ms Jo Blackburn (Director of Practice Development).

Professor Lloyd Williams Academic Palliative and Supportive Care Studies Group (APSCSG) (The University of Liverpool).

Dr David Oliver Consultant in Palliative Medicine (Wisdom Hospice, Rochester, Kent).

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Appendix 5: ISRCTN Trial Registration

ISRCTN25758268 - A feasibility study of Sheffield Profile for Ass...

<http://www.controlled-trials.com/isrctn/pf/25758268>

[Print]

[Close]

A feasibility study of Sheffield Profile for Assessment and Referral for Care (SPARC): a holistic needs assessment questionnaire

ISRCTN	ISRCTN25758268
ClinicalTrials.gov identifier	
Public title	A feasibility study of Sheffield Profile for Assessment and Referral for Care (SPARC): a holistic needs assessment questionnaire
Scientific title	A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)
Acronym	SPARC
Serial number at source	NA
Study hypothesis	<p>The Academic Unit of Supportive Care is undertaking a research study about holistic needs assessment. We are carrying out a study with patients referred for supportive or palliative care, to learn if using the SPARC questionnaire improves their care.</p> <p>The study aims are:</p> <ol style="list-style-type: none"> 1. To determine the effect of holistic needs assessment on health related quality of life and self identified concerns in patients referred for supportive and palliative care 2. To determine the effect of holistic needs assessment on interventions, consultations and referrals within supportive and palliative care 3. To measure the difference at baseline assessment between patients identified as cancer survivors, those living with a long term condition and those receiving end of life care, in terms of their concerns, quality of life and need for supportive or palliative care 4. We hope to learn if using SPARC makes a difference in quality of life, and in referrals for help; whether it makes a difference how early on it is used, and whether the experience is different for different groups of patients
Lay summary	http://cancerhelp.cancerresearchuk.org/trials/a-study-testing-questionnaire-work-out-care-needs-people-using-supportive-or-palliative-care-service-sheffield-sparc-feasibility
Ethics approval	Bradford Research Ethics Committee, REC Approval Reference Number 10/H1302/88 approval pending as of 05/05/2011
Study design	Randomised waiting list controlled trial
Countries of recruitment	United Kingdom
Disease/condition /study domain	All patients (cancer and non cancer) referred to the service
Participants - inclusion criteria	<ol style="list-style-type: none"> 1. Any diagnosis (cancer and non-cancer) 2. Any referral to the service 3. Patients 18 years old or above 4. Patients able to give informed consent
Participants - exclusion criteria	<ol style="list-style-type: none"> 1. Incapable of giving informed consent 2. Incapable of completing SPARC even with the help of a relative or informal carer 3. Under 18 years old
Anticipated start date	01/01/2010
Anticipated end date	30/07/2012
Status of trial	Completed
Patient information material	Not available in web format, please use the contact details below to request a patient information sheet.
Target number of participants	Follow up data from n=128 patients (n=500 patients required taking account of attrition)

Interventions	<ol style="list-style-type: none"> 1. The study will be carried out with in-patients, out-patients and in community settings, to assess whether using the SPARC tool makes a difference to symptoms and concerns, quality of life, needs identified, and being referred for help. 2. SPARC is a multidimensional screening tool which gives a profile of needs to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of disease 3. SPARC is intended for use by primary care, hospital teams or other services to improve patient management, either by current professional carers or by referral to a specialist team 4. It covers: <ol style="list-style-type: none"> 4.1. Physical and psychological symptoms 4.2. Spiritual issues 4.3. Activities/independence 4.4. Family, social and treatment issues 5. Its aim is to identify patients who could benefit from additional supportive or palliative care 6. We will use SPARC in addition to the usual care that people receive 7. Some patients will complete the questionnaire straightaway, others will receive it after a period of two weeks 8. For everyone, care will continue as normal 9. The responses given on the SPARC questionnaire will be followed up by one of the usual care team to ensure that needs identified are addressed 10. Participants will fill in three short research questionnaires as part of the study, repeated after two weeks, four weeks and six weeks 11. Once people have opted to participate in the study, they will be allocated either to the group receiving SPARC straight away, or to the group which receives it after two weeks (randomly decided) 12. A small group of participants will be invited to take part in interviews
Primary outcome measure(s)	<ol style="list-style-type: none"> 1. The difference in score between the patient Measure Yourself Concerns and Wellbeing (MYCAW) on the patient self-scoring visual analogue scale at baseline and the two-week follow up 2. Assuming the changes in the score (baseline to week 2) are normally distributed, a t-test will be carried out to test the null hypothesis that the difference between the intervention and control groups in the mean score on the first symptom nominated on the scale at baseline and two weeks is zero 3. To detect a medium difference between two independent sample means requires a minimum of 64 individuals in each group with scores at baseline and two weeks (Cohen, 1992). Therefore, a total of 128 patients will have to be recruited. 4. In order collect both baseline and follow-up data from 128 patients, 500 patients will be recruited to the study, assuming that approximately one quarter will be able to participate at the two-week follow-up. 5. The calculation for the sample size has taken account of the attrition to be expected in this population overall, although with varied survival rates, we can also expect to recruit sufficient numbers of patients able to give useable follow-up data. The statistical analysis will therefore be predominantly descriptive, with correlations drawn between specific demographic and medical variables with SPARC scores.
Secondary outcome measure(s)	<ol style="list-style-type: none"> 1. The change in scores in the EQ-5D at the two time points 2. Changes in the enablement scores (PEI) at the two time points 3. Comparisons will be made between the intervention group and the waiting list control 4. Outcomes in patients entering the service in different ways, as inpatients where input is requested, as inpatients on the Palliative Care Unit, and as outpatients, will be explored 5. The pattern of actions taken and referrals made as a result of the SPARC screening tool will be examined, by analysis of the clinical record 6. Comparisons will be made regarding MYCAW patient nominated concerns, EQ-5D, and the PEI at baseline between patient groups (long term conditions, cancer survivors, and people needing end of life care)
Sources of funding	<ol style="list-style-type: none"> 1. Macmillan Cancer Support (UK) 2. Sheffield Teaching Hospitals NHS Foundation Trust (UK)
Trial website	
Publications	
Contact name	Dr Bill Noble
Address	Macmillan Senior Lecturer in Palliative Medicine Sykes House Little Common Lane
City/town	Sheffield

Zip/Postcode	S11 9NE
Country	United Kingdom
Tel	+44 (0)114 262 0174 (ext 28)
Email	n.ahmed@sheffield.ac.uk
<hr/>	
Sponsor	University of Sheffield (UK)
Address	c/o Mr Nisar Ahmed 10-12 Brunswick Street The University of Sheffield
City/town	Sheffield
Zip/Postcode	S11 9NE
Country	United Kingdom
<hr/>	
Date applied	04/05/2011
Last edited	31/01/2012
Date ISRCTN assigned	05/07/2011

Appendix 6: Funding Letter 1 (Pilot RCT)

UK Office
89 Albert Embankment
London SE1 7UQ
Tel 020 7840 7840
Fax 020 7840 7841

**WE ARE
MACMILLAN.
CANCER SUPPORT**

Dr. Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House
Little Common Lane
Sheffield
S11 9NE

17 December 2009

Dear Bill,

Confirmation of funding for MaCPaCC study 'A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service'

I am pleased to confirm that Macmillan Cancer Support has agreed to fund £150,030 to the MaCPaCC study 'A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service'. The study will start on 1st January 2010 and will end on the 30th June 2012.

The study has been independently reviewed by academic and service user reviewers. In addition, the study has been approved by the Commissioning Group, which comprises of research, service and healthcare expertise within Macmillan.

I look forward to receiving the findings from the research in due course.

With best wishes,



Dr David Wright
Research Manager

CancerLine 0808 808 2020 www.macmillan.org.uk

Macmillan Cancer Support, registered charity number 261017, Scotland (SC039907) and the Isle of Man (604). A company limited by guarantee Registered in England and Wales (2400969), and the Isle of Man (4694F). Registered office: 89 Albert Embankment, London SE1 7UQ.

Appendix 7: Funding Letter 2 (Process evaluation)

Macmillan Cancer Support
89 Albert Embankment
London SE1 7UQ
tel 020 7840 2497
fax 020 7840 7841
smcclelland@macmillan.org.uk

**WE ARE
MACMILLAN.
CANCER SUPPORT**

Dr Bill Noble,
Department of Oncology
The Medical School
Beech Hill road
Sheffield
S10 2RX

6th December, 2012

Dear Dr Noble,

Re: Process evaluation of the SPARC feasibility trial

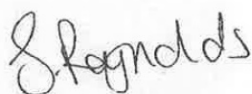
Thank you for sending us your proposal for the above mentioned feasibility study.

I am pleased to confirm that Macmillan Cancer Support will fund the above mentioned research project. The research will commence on 10th December 2012 and run until 10th December 2013 at a total cost of £42,961. This amount will be made as a single grant allocation to the University of Sheffield, and an invoice must be sent not later than 31st December, 2012.

Macmillan will prepare a contract to cover the details of the award.

I look forward on working with you on this on this initiative.

Yours sincerely



Julia Reynolds
Research and Evaluation Manager.

Cc Siobhan McClelland, Head of Evidence.

Questions about living with cancer? Call free on Macmillan 0808 808 00 00 or visit www.macmillan.org.uk
Macmillan Cancer Support, registered charity in England and Wales (261017), Scotland (SC039907) and the Isle of Man (604). A company limited by guarantee. Registered company in England and Wales (2400969) and the Isle of Man (4594F). Registered office: 89 Albert Embankment, London SE1 7UQ.

Appendix 8: Trial insurance letter

UNIVERSITY OF SHEFFIELD

DEPARTMENT OF FINANCE

To Dr Bill Noble **Date** 28-Oct-10
Department Academic Unit of Supportive Care

Certificate of Insurances (non clinical trial)

Trial Number NCT10/04
Department Academic Unit of Supportive Care
Title of Trial A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)
Name of Investigators as stated
Commencement Date Jan-10

The University has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of the above research project/study



Colin Rose MA ACII
Risk2Value Ltd, Insurance Adviser to the University of Sheffield

NCT

Appendix 9: Guidance for medical and nursing staff

Guidance for medical & nursing staff to screen potential patients for the SPARC study

The Academic Unit of Supportive Care is conducting a research study on a holistic needs assessment questionnaire, The Sheffield Profile and Assessment and Referral for Care (SPARC) throughout Sheffield.

This study has gained all the appropriate ethical and research governance approvals.

We aim to carry out a study with in-patients, out-patients, day care and home care patients referred for supportive or palliative care, to see if using an holistic needs assessment questionnaire, SPARC improves care. We are seeking your help to recruit patients for this study.

We would be grateful if you could help us recruit patients for this study that fulfil the inclusion / exclusion criteria (below). Please ask suitable patients if they are willing to be approached by a researcher. You may wish to give patients the letter of invitation and the patient information sheet informing them about the study.

If they agree, please contact a member of the research team (contact details below) who will then discuss the study with the patient in more detail and leave a study pack if appropriate.

Inclusion criteria

1. Any diagnosis (cancer and non-cancer).
2. Any referral to the service.
3. Patients 18 years old or above.
4. Patients able to give informed consent.

Exclusion criteria

1. Patients incapable of giving informed consent.
2. Patients incapable of completing SPARC even with the help of a relative or informal carer.
3. Patients under 18 years old.

You can inform members of the research team about which patients have agreed to participate, by contacting:

**Mr Nisar Ahmed Mobile Number: 07889 825378, or
Dr Michelle Winslow Mobile Number: 07920 056861.**

THANK YOU FOR ALL YOUR HELP

Version 1 (21.10.10) RG/Ethics Number
SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 10: Questionnaire booklet (MYCAW, EQ-5D, PEI)



Academic Unit of Supportive Care

Sykes House
Little Common Lane
Sheffield
S11 9NE
Tel: 0114 262 0174 ext 28

Dr Bill Noble
*Macmillan Senior
Lecturer in Palliative Medicine*
email: m.winslow@sheffield.ac.uk
email: n.ahmed@sheffield.ac.uk

Questionnaire

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Thank you for agreeing to help us with our research. Please complete the study questionnaire booklet. Further questionnaires will be sent to you after two weeks, four weeks and six weeks.

Could you please -

1. Complete the questionnaires for yourself, or you can complete them with the help of a family member, friend or carer.
2. Return the questionnaires in the enclosed pre-paid (freepost) envelope.

Thank you for your help

A Feasibility Study of SPARC- REC Reference Number 10/H1302/88

Measure Yourself Concerns and Wellbeing (MYCAW)

First form

Full name..... Date of birth

Date first completed

Please write down one or two concerns or problems that bother you most.

Concern or problem 1

Concern or problem 2

Please turn over

Please circle a number to show how severe each concern or problem is now:

This should be YOUR opinion, no-one else's!

Concern or problem 1:

0	1	2	3	4	5	6
Not bothering me at all						bothers me greatly

Concern or problem 2:

0	1	2	3	4	5	6
Not bothering me at all						bothers me greatly

Wellbeing:

How would you rate your general feeling of wellbeing now? (How do you feel in yourself?)

0	1	2	3	4	5	6
As good as it could be						As bad as it could be



Health Questionnaire *English version for the UK (validated for Ireland)*

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

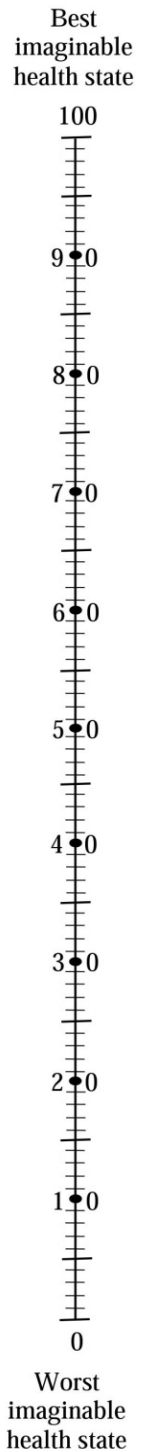
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Please turn over

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state
today**



The Patient Enablement Instrument

Thinking about the last time you saw a doctor or nurse from palliative care, do you feel you are:

	Much better	Better	Same or less	Not applicable
able to cope with life?				
able to understand your illness?				
able to cope with your illness?				
able to keep yourself healthy?				

	Much more	More	Same or less	Not applicable
confident about your health?				
able to help yourself?				

Please turn over

A Feasibility Study of SPARC- REC Reference Number 10/H1302/88

Thank you for completing this form.

Please return in the stamped addressed envelope (freepost) to:

**Mr Nisar Ahmed/Dr Bill Noble
Trent Palliative Care Centre
Freepost SF 1605
Sheffield S11 8TE**

Appendix 11: Honorary contract

Sheffield Teaching Hospitals

NHS Foundation Trust

Ref: HC

Date: 7 March 2013

Mr Nisar Ahmed
████████████████████
Sheffield
██████████

Dear Mr Ahmed

Human Resources Department
Clocktower
Northern General Hospital
Sheffield
S5 7AU

Please ask for: Kay Barker
Telephone: (0114) 2269492
E mail kay.barker@sth.nhs.uk

HONORARY CONTRACT

I am instructed by Sheffield Teaching Hospitals NHS Foundation Trust to offer you a Honorary Contract appointment as a Data Gatherer in the Oncology Department, under the supervision of Dr Bill Noble at the Royal Hallamshire Hospital / Northern General Hospital/ Weston Park Hospital, commencing on the 1st December 2012 to the 31 January 2014.

This Honorary Contract is not a contract of employment and confers no employment rights or entitlements except the rights of access to patients, notes and hospital premises within the remit of the Sheffield Teaching Hospitals NHS Foundation Trust. It is subject to you maintaining the strictest confidentiality of information with which you may come into contact during the course of your appointment, maintaining acceptable standards of conduct and that you make yourself familiar with the relevant policies and procedures of the Trust and specifically in relation to Health and Safety and Fire. Failure to abide by these provisions will result in this authorisation being withdrawn.

As a contract holder of Sheffield Teaching Hospitals NHS Foundation Trust you must comply with all reporting requirements, systems and duties of action put in place by the Trust to deliver research governance.

Attending an occupational health appointment with the Trust may be a requirement of the clearing process. This appointment enables the Occupational Health Department to ensure that any health risks posed to you, patients and employees of the Trust are reviewed and addressed accordingly. This contract is conditional on you attending this appointment if requested to do so by the Occupational Health Department.

This honorary contract is subject to a confidential annual review to assess all aspects of your work and progress.

The Sheffield Teaching Hospitals NHS Foundation Trust accept no responsibility for the damage to or loss of personal property, with the exception of small valuables handed to their officials for safe custody. You are, therefore, recommended to take out an insurance policy to cover your personal property.

Notwithstanding the above, you will be treated in accordance with Trust employees, for the purpose of employment insurance (and for no other purposes) during the proper performance of your duties, provided that at all times you exercise all reasonable skills and judgment and always act in good faith.

It is compulsory for you to wear an identification badge at all times while on Trust premises. Your supervisor will need to complete and authorise the required identity badge application form and email this from their Trust email account to idbadgerequests@sth.nhs.uk. On receipt of this form you will be need to make an ID badge appointment with the HR Department (0114-3052503). At this appointment you will be required to provide suitable photographic identification (e.g. Passport/Driving Licence) before you will be given your ID badge.

If you agree to accept the appointment offered in the foregoing letter on the terms specified therein, please sign the form of acceptance at the foot of this page and return it to the Human Resources Department as soon as possible. The second signed copy of this letter is to be retained for your future reference.

Yours sincerely

K Sarke

**Recruitment Assistant
On Behalf of Sheffield Teaching Hospitals NHS Foundation Trust**

-----Please do Not Detach-----

Ref: HC

I hereby accept the offer of the appointment as mentioned in the foregoing letter, subject to the conditions referred to therein.

Signed

Ahed

Date

15.4.13

This offer, and acceptance of it, shall together constitute a contract between the parties.

cc Dr Bill Noble



National Research Ethics Service

Bradford Research Ethics Committee

Yorkshire & Humber REC Office
Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 305 0128

09 December 2010

Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
University of Sheffield
Academic Unit of Supportive Care
Sykes House, Little Common Lane
Sheffield
S119NE

Dear Dr Noble

Study Title: A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)

REC reference number: 10/H1302/88

Thank you for your letter of 2 December 2010 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
*The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England*

does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		02 November 2010
Covering Letter		02 December 2010
Summary/Synopsis	1	21 October 2010
Response to Request for Further Information		
Participant Information Sheet: Personal consultee	2	23 November 2010
Letter of invitation to participant	1	21 October 2010
Opt in form interviews with patients	1	21 October 2010
Letter from funder		17 December 2009
Consultee Declaration form	2	23 November 2010
Participant Information Sheet	2	23 November 2010
Investigator CV		21 October 2010
Participant Consent Form	1	21 October 2010
Participant Consent Form: Consent form for interviews	1	21 October 2010
Protocol	3	23 November 2010
Personal consultee agreement form	1	02 November 2010
Evidence of insurance or indemnity		28 October 2010
Referees or other scientific critique report		
Referees or other scientific critique report		27 October 2009

Letter from Statistician		27 October 2010
REC application	2	27 October 2010
Questionnaire: Measure Yourself Concerns and Wellbeing		
Questionnaire: Patient Enablement Instrument		
Questionnaire: SPARC	1	01 July 2005
Interview Schedules/Topic Guides	1	21 October 2010
Questionnaire: EQ-5D		
Reminder letter to patients	1	21 October 2010
Guidance for medical and nursing staff	1	21 October 2010
Personal consultee information sheet	1	02 November 2010
Response to reviewers' comments		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

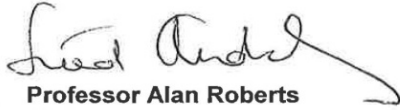
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1302/88

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



Professor Alan Roberts
Chair
OBE, TD, DL, MPhil, PhD, DSc, LLD, DTech

Email: Sinead.audsley@leedspft.nhs.uk

Enclosures: "After ethical review – guidance for researchers",

Copy to: *Simon Heller, Sheffield Teaching Hospitals NHS Foundation Trust*

Appendix 13: REC approval letter following amendments (NHS Sites)



National Research Ethics Service

Bradford Research Ethics Committee

Yorkshire & Humber REC Office
Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Tel: 0113 305 0128

14 January 2011

Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
University of Sheffield
Academic Unit of Supportive Care
Sykes House, Little Common Lane
Sheffield
S11 9NE

Dear Dr Noble

Study title: A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)
REC reference: 10/H1302/88
Amendment number: 1
Amendment date: 16 December 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Amended REC form		
Participant Consent Form: Consultee Declaration form	3	14 December 2010
Participant Consent Form: Patient Consent for Interview	2	14 December 2010
Participant Consent Form	2	14 December 2010
Participant Information Sheet: Personal Consultee Information Sheet	3	14 December 2010
Participant Information Sheet	3	14 December 2010

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Notice of Substantial Amendment (non-CTIMPs)	16 December 2010
Covering Letter	16 December 2010

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

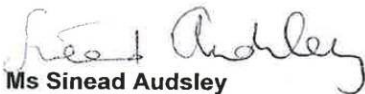
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H1302/88:	Please quote this number on all correspondence
---------------------	---

Yours sincerely



**Ms Sinead Audsley
Committee Co-ordinator**

E-mail: Sinead.audsley@leedspft.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Simon Heller, Sheffield Teaching Hospitals Foundation Trust

Bradford Research Ethics Committee

Attendance at Sub-Committee of the REC meeting by correspondence

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Sharif Al-Ghazal	Consultant Plastic Surgeon	Expert
Professor Alan Roberts	Chair	Expert

Appendix 14: REC approval letter (Non-NHS Sites SLH)



National Research Ethics Service

Bradford Research Ethics Committee

Yorkshire & Humber REC Office
Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 305 0128

14 February 2011

Dr Bill Noble
Academic Unit of Supportive Care
Sykes House, Little Common Lane
Sheffield
S119NE

Dear Dr Noble

Study title: A feasibility study of an holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)
REC reference number: 10/H1302/88
SSA reference number: 11/YH/0016

The REC gave a favourable ethical opinion to this study on 30th January 2011.

Notification(s) have been received from local assessor(s), following site-specific assessment. On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research Site	Principal Investigator / Local Collaborator
St. Luke's Hospice Little Common Lane Abbey Lane Sheffield S119NE	Dr Bill Noble

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H1302/88

Please quote this number on all correspondence

Yours sincerely

This Research Ethics Committee is an advisory committee to the Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Appendix 15: Edited reminder letter



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House, Little Common Lane
Sheffield, S11 9NE
Tel: 0114 262 0174
Email: bill.noble@sheffield.ac.uk

Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

April 2012

Dear

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Thank you for being willing to consider participating in our research study.

It maybe that you have already completed the questionnaires and this letter has crossed in the post. If so thank you and we apologise for this reminder letter.

We enclose a further freepost envelope- please use this to return the questionnaires.

With many thanks for your assistance.

Yours sincerely,

Mr Nisar Ahmed/ Dr Michelle Winslow/ Dr Bill Noble

I would prefer not to complete the questionnaires- please do not send further ones

SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 16: Trust R&D approval letter

Ref: STH15896/AL

Sheffield Teaching Hospitals 
NHS Foundation Trust

8th February 2010

Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
University of Sheffield
Academic Unit of Supportive Care
Sykes House
Little Common lane
Sheffield
S11 9NE

Dear Dr Noble

Authorisation of Project

STH ref: STH15896
Study title: A feasibility study of a holistic needs assessment questionnaire in a supportive and palliative care service using the Sheffield Profile for Assessment and Referral for Care (SPARC)

Chief Investigator: Dr Bill Noble, University of Sheffield
Principal Investigator: Dr Bill Noble, University of Sheffield

Sponsor: Sheffield teaching Hospitals
Funder: Macmillan Cancer Support

The Research Department has received the required documentation for the study as listed below:

- | | |
|--|---|
| 1. Sponsorship IMP studies (non-commercial) | Not applicable |
| Sponsorship responsibilities between institutions | Not applicable |
| Responsibilities of investigators | Not applicable |
| Monitoring Arrangements | Not applicable |
| 2. STH registration document: completed and signed | REC application form
B Noble 27 Oct 10 |
| 3. Evidence of favourable scientific review | Macmillan Cancer Support
D Wright 17 Dec 09 |
| 4. Protocol – final version | Version 3 23 Nov10 |
| 5. Participant Information sheet | |
| Personal Consultee Information Sheet | Version 3 14 Dec 10 |
| Information sheet | Version 3 14 Dec 10 |
| 6. Consent form | |
| Consent form | Version 2 14 Dec 10 |
| Consent form for interview | Version 2 14 Dec 10 |
| Consultee declaration form | Version 3 14 Dec 10 |
| 7. Signed letters of indemnity | University of Sheffield
C Rose 28 Oct 10 |
| 8. ARSAC / IRMER certificate | Not applicable |
| 9. Evidence of hosting approval from STH directorate | STH Finance Form
D Bax 04 Feb 11 |
| 10. Evidence of approval from STH Data Protection Officer | STH Finance Form
P Wilson 03 Feb10 |
| 11. Letter of approval from REC | Bradford REC
10/H1302/88
09 Dec 10
14 Jan 10 |



Chairman: David Stone OBE • Chief Executive: Andrew Cash OBE

smoke-free
hospitals

Ref: STH15896/AL

12. Proof of locality approval	STH R&D 03 Feb 11
13. Clinical Trial Authorisation from MHRA	Not applicable
14. Honorary Contract	Not applicable
15. Associated documents	
Guidance for medical and nursing staff	Version 1 21 Oct 10
Letter of Invitation	Version 1 21 Oct 10
Opt in form for interviews with patients	Version 1 21 Oct 10
Interview schedule	Version 1 21 Oct 10
Reminder letter to patients	Version 1 21 Oct 10
Summary of study for professionals	Version 1 21 Oct 10
Questionnaire - MYCAW	
Questionnaire - Patient Enablement Instrument	
Questionnaire - SPARC	
Questionnaire - EQ-5D	
16. Signed financial agreement/contract	STH Finance Form E Fraser 03 Feb 11

The project has been reviewed by the Research Department and authorised by the Director of R&D on behalf of STH NHS Foundation Trust to begin.

Yours sincerely



Professor S Heller
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust
Telephone +44 (0) 114 2265934
Fax +44 (0) 114 2265937

Appendix 17: SPARC study timescale: Revised to show phases 1 and 2

Activity	2010												2011												2012												2013	
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	Jan	Feb
	a	e	a	a	a	u	u	u	e	c	o	e	a	e	a	a	a	u	u	u	e	c	o	e	a	e	a	a	a	u	u	u	e	c	o	e		
Literature Review																																						
Study design and protocol writing																																						
Research Governance and Ethics																																						
Service user consultation																																						
Familiarisation with the service and introducing staff/centres to study																																						
Data Collection (15 months)																																						
Interim Report																																						
Analysis																																						
Report writing																																						
Dissemination																																						

PHASE 1 COMPLETION OF OUTCOME EVALUATION

START OF PHASE 2 PROCESS EVALUATION

A no cost extension was approved by Macmillan Cancer Support. In the end recruitment period was 22 months. A final report was submitted on 31st January 2013.

Appendix 18: Case note review data collection Proforma

Case Note Review Data Collection Proforma

Date of note review.....

Name of researcher...

Patient Unique Identifier			
ID nos			
Study arm			
consent dated			
consent received			
baseline dated			
baseline received			
eight week point (date)			
date of death			
died during study period (period is 8 weeks from baseline received)			
number of hospital admissions 12mths baseline received			
number of hospital admissions during study from baseline received			
number of outpatient visits 12mths prior baseline received			
number of outpatient visits during study from baseline received			
days in hosp 12mths prior baseline received			
days in hosp during study from baseline received			
setting recruited from			
date of birth			
gender			
Ethnicity			
White - British		Chinese or other ethnic background – Chinese	
White - Irish		Asian – other background	
White – other background		Mixed – White and Black Caribbean	
Black or Black British - Caribbean		Mixed – White and Black African	
Black or Black British – African		Mixed – White and Asian	
Black – other background		Mixed – other background	
Asian or Asian British - Indian		Other ethnic background (state)	
Asian or Asian British - Pakistani		Information Withheld/not reported	
Asian or Asian British – Bangladesh			
Partnership Status			
Married/Civil Partnership/Single/Divorced/Widowed/Co-habiting			
living arrangements			
patient lives alone			
occupation			
religion			
primary diagnosis			
second diagnosis			

third diagnosis	
fourth diagnosis	
National Diagnosis Code	
diagnosis date	
diagnosis date (mean)	
year of diagnosis	
date of first referral	
year of first referral	
age on registration	
location before service	
location referred to	
service requested	
referral source	
summary of main concerns on first referral	
primary reason for referral	
additional reasons for referral	
urgency of referral	
care received upon referral Was the care received at recruitment (date of receipt of completed baseline questionnaires)- for: 1. EOLC cancer, 2. EOLC non-cancer, 3. Cancer Survivor, 4. Long-term condition	
SPARC filed in notes?	
Reference to SPARC?	
Any actions: Log with all dates and times	Symptoms, diagnostics tests, clinical interventions, medication changes, involvement of other disciplines, medical and nursing plan

Appendix 19: STH NHS Foundation Trust (Key facts and figures)

Reference: Information taken directly from the Annual Report, Sheffield Teaching Hospitals (STH): Description about the Sheffield Palliative Care Service (context and settings) (Palliative Care Annual Report Summary STH 2011/12).

<p>Overview Sheffield Teaching Hospitals (STH) Description about the Sheffield Palliative Care Service (context and settings)</p>
<ul style="list-style-type: none"> ▪ Provision of specialist supportive and palliative care service to patients (irrespective of diagnosis), their families and carers in order to improve symptom control and quality of life. ▪ Settings and sites: Royal Hallamshire Hospital (RHH), Weston Park Hospital (WPH) & Northern General Hospital (NGH). Comprising: palliative care inpatient unit, acute hospital, hospital support team, consultant led outpatient clinics, intensive home nursing service (providing basic end of life care). ▪ 2300 patients treated per year. ▪ Partnership work with other health professionals/community specialist palliative care services, provision of home care packages. ▪ 24/7 service on call rota palliative medicine cover (alongside colleagues in Chesterfield), available to patients in all care settings in the area. ▪ Organisation's total income: £3.1 million, 100% NHS for palliative care. ▪ Out of hours availability: Yes.
<p>Inpatient activity</p>
<ul style="list-style-type: none"> ▪ NGH (MPCU): 302 admissions/year. ▪ Admitted directly from home: 37.4%. ▪ National average for inpatient palliative care admissions ending in death in 2010-11: 55.5% (National Council for Palliative Care Minimum Data Set Figures, Nov 2011). ▪ Mean bed occupancy (MPCU): 91.4% vs national average: 77.3%.
<p>Hospital Support Team Activity</p>
<ul style="list-style-type: none"> ▪ Episodes of Hospital Support across the service: 2,253/year. ▪ Central campus vs Northern campus: proportionally younger caseload. ▪ Northern campus vs Central campus: higher proportion of non-cancer referrals (higher than average percentage at NGH, a reflection of open access and flexible service provision). ▪ National average for non-cancer referrals to hospital support teams in 2010-11:21.2%. ▪ National average for hospital support episodes ending in death in 2010-11: 33.4% with 55.6% ending in discharge home.
<p>Outpatient activity</p>
<ul style="list-style-type: none"> ▪ Outpatient consultations: 883/year. ▪ Nationally average numbers of attenders per clinic: 2.3 in 2010-11.
<p>Therapy Report</p>
<ul style="list-style-type: none"> ▪ Occupational Therapy and Physiotherapy staff: provision of a wide range of support and interventions (MPCU), with active role in discharge planning.
<p>Bereavement Service</p>
<ul style="list-style-type: none"> ▪ Telephone calls main form of bereavement support offered by nursing staff and volunteers.
<p>End of life care pathway: (EOLCP) Facilitator</p>
<ul style="list-style-type: none"> ▪ EOLCP Facilitator: role is to help further embed the EOLC Pathway into practice (by more direct clinical input). ▪ Responsible for Nursing/Medical EOLC education and training at Central and NGH Campus, also Community Nursing. ▪ Champions on wards throughout the Trust.
<p>Cavendish Cancer Care at MPCU</p>
<ul style="list-style-type: none"> ▪ Provision of supportive care and complementary therapies at bedside. ▪ 125 people referred for therapy MPCU, NGH (1st April 2011-31st March 2012),114 patients, and 11 carers. ▪ Of the 114 patients referred, 72 (63%): female and 42 (37%): male. ▪ Age range: 29 to 98. Median age: 69. ▪ Non-malignant diagnosis (8/114) made up 7% of the total.
<p>Oral history and photography service (at MPCU)</p>
<ul style="list-style-type: none"> ▪ Opportunity for patients to produce their own audio life story recordings and photographs with specialist support.
<p>Staffing at MPCU (NGH)</p>
<ul style="list-style-type: none"> ▪ Consultant medical staff (n=6), SpRs (n=7), F2s & GP registrars (n=6), Clinical Nurse Specialists (CNSs) (n=9), Social Worker (n=1), Occupational Therapist (n=1), Physiotherapist (n=1), Pharmacy Team (n=6), Administrative team (n=4), MPCU Nursing Staff (n=3), Staff Nurses (n=26), Support Workers (n=9), Housekeeping (n=3), Oral History Project (n=2), Specialised Medicine Governance Team (n=4).

Appendix 20: SLH The Sheffield Hospice (Key facts and figures)

Reference: Information taken directly from SLH Corporate Brochure 2011/2012 and the Minimum Data Set for 2011/2012 St. Luke's The Sheffield Hospice: Description about the Sheffield Palliative Care Service (context and settings).

Key facts
<ul style="list-style-type: none"> ▪ Opened in October 1971. ▪ Independent charity. ▪ Provides support in three settings namely; a 20 bed inpatient unit, the Therapies and Rehabilitation Centre (day care patients), and in the community via a team of 10 specialist palliative care community nurses who provide support to patients in their own homes, or to those in nursing homes/care homes. ▪ 1,400 patients cared for per year, supports > 5,000 people (patients, families and carers). ▪ Cares for adults regardless of age, culture, religion or ethnic background with life limiting illnesses irrespective of diagnosis (cancer and non-cancer). ▪ Service is free. ▪ Provides specialist supportive and palliative care support to patients attending to their holistic needs, and extends support to their families and carers. ▪ Provides ongoing bereavement support (to families and carers). ▪ Clinical staff breakdown: Clinical Nurse Specialists: n=10, 1.8 wte Consultants, 1 GP ass. spec.
In Patient Unit
<ul style="list-style-type: none"> ▪ 20 bed, service provision 24/, 365 days/year specialist inpatient intensive care. ▪ Approximately 50% patients discharged home/year. ▪ 2011-2012: 327 patients cared for in the inpatient unit. ▪ Total patients referred: 294 ▪ Age, gender and diagnosis: 25-64 years: n=73, 65-74 years: n=81, 75-84 years: n=89, 85 years and over: n=51. Male: 141, Female: 153, Cancer/malignant diagnosis: 272, other diagnosis: 22. ▪ Ethnicity: White British 276, White Irish: 2, Other White: 5, Pakistani: 1, Other Asian: 3, Black Caribbean: 4, Black African 1, Not Stated: 2. ▪ Location after before admission: Patient's own home (including relative's or carer's home): 224, Care Home: 5, Hospital (Acute): 98. Location After end of stay: Died: 201, Patient's own home (including relative's or carer's home): 95, Care Home: 10, Hospital (Acute): 16. ▪ Average length of stay: All Patients: 20.5 days, Cancer Patients: 20.3 days, Non-Cancer Patients: 23.1 days.
Therapies and rehabilitation Centre (Day Care)
<ul style="list-style-type: none"> ▪ Provision of specialist therapies, treatments and advice tailored to meet individual holistic needs for patients (both inpatient and in community). ▪ Programmes are usually for a set period, patients attend centre once a week. ▪ Number of GP referrals is on the increase, average attendance 18 patients/day-every week day. ▪ Supports and helps approximately 350 patients to live independently in home/community. ▪ 2011-2012: 3,242 day-patient visits to the centre. ▪ Total patients referred: 374, 19 re-referrals. ▪ Age, gender and diagnosis: 25-64 years: n=91, 65-74 years: n=112, 75-84 years: n=111, 85 years and over: n=60. Male: 164, Female: 210, Cancer/malignant diagnosis: 338, other diagnosis: 36. ▪ Ethnicity: White British 363, White Irish: 3, Other White: 2, Indian: 1, Other Asian: 2, Black Caribbean: 2, Black African 1. ▪ Number of deaths: 277, continuing patients: 116. ▪ Average length of stay (defined as average duration in days from date of first attendance to death or discharge): 139.
Community Care
<ul style="list-style-type: none"> ▪ 10 St. Luke's Community Specialist Palliative Care Nurses (Community Team) working alongside GPs, district nurses, hospital consultants, specialist hospital nurses and other health professionals to provide tailored programmes of care to patients in their own homes/in community. ▪ Also provide palliative care education/learning to care/nursing homes. ▪ 10 Community nurses care for around 400 patients in community at any one time point. ▪ Can act as a single point of contact, can arrange intensive home nursing if needed via district nurse and Sheffield's city-wide intensive home nursing service. ▪ 2011-2012 4,108 patient visits made in total. ▪ Total patients referred: 1241 ▪ Age, gender and diagnosis: 19-24: 1, 25-64 years: n=301, 65-74 years: n=356, 75-84 years: n=357, 85 years and over: n=226. Male: 638, Female: 603, Cancer/malignant diagnosis: 1088, other diagnosis: 153. ▪ Ethnicity: White British 1175, White Irish: 10, Other White: 12, Other Mixed: 2, Indian: 3, Pakistani: 11, Bangladeshi: 2, Other Asian: 10, Black Caribbean: 9, Black African: 5, Chinese: 2. ▪ Deaths: 546, Discharges: 712, Continuing Patients: 200. ▪ Patients died: Patient's own home (including relative's or carer's home): 280, Care Home: 107, Hospital/Specialist Palliative Care Unit: 76, Acute Hospital: 83.

<ul style="list-style-type: none"> ▪ Average (mean) length of period of home care (defined as average time in days from first visit to death/discharge): All Patients: 55.6.
<p>Bereavement Support</p>
<ul style="list-style-type: none"> ▪ Provision of bereavement Service (by community nurses). ▪ Hospice has its own hospitality service. ▪ Total Service Users: 559. ▪ Age, gender and diagnosis of users: 16-18 years: n=2, 19-24: 5, 25-64 years: n=211, 65-74 years: n=102, 75-84 years: n=44, 85 years and over: n=5, Not Recorded: 190. Male: 144, Female: 415, Diagnosis of deceased relative/friend of service user, Cancer/malignant diagnosis: 510, Other Diagnosis: 49, Total: 559. ▪ Service Users Ethnicity: White British 379, White Irish: 1, Other White: 2, Indian: 1, Bangladeshi: 1, Not Stated: 175. ▪ Service Users Discharged: 396, Number of Continuing Users: 169. ▪ Average (mean) length of period of support (defined as average duration in days from date of first contact to date of last contact before discharge): 102.
<p>Palliative Care Education</p>
<ul style="list-style-type: none"> ▪ Commitment to palliative care education and training. ▪ Hospice staff provide training and education to medical, nursing students and speciality doctors. ▪ 2011-2012: 70 medical students were on placements, and 17 training doctors.
<p>Caring for carers and loved ones</p>
<ul style="list-style-type: none"> ▪ Provision of care to loved ones, families, and carers. ▪ 2011-2012: 2,135 contacts made with bereaved families and carers.
<p>Volunteers</p>
<ul style="list-style-type: none"> ▪ Play an important role. ▪ 400 of them, ages 16-78 assist with service delivery and with fundraising activities. ▪ Many different roles: St.Luke's shops, as patient companions, assist with fundraising events, and assist with patient transport.
<p>Financial challenges</p>
<ul style="list-style-type: none"> ▪ Cost to run St.Luke's Hospice/hour: £750 for 365 days/year. ▪ Only 1/3rd funding from NHS. ▪ Significant financial challenges due to recession. ▪ Requirement to raise > £4million/year to continue to deliver essential services, savings of > £1 million already made.
<p>Where the money came from 2011-2012</p>
<ul style="list-style-type: none"> ▪ Total £6.872 million. ▪ Fundraising: 66%. ▪ Primary Care Trust (NHS): 34%.
<p>Breakdown of fundraising income (£4.060 million)</p>
<ul style="list-style-type: none"> ▪ Charity shops: 37%. ▪ Community, corporate, events, trusts, in memory, regular giving: 34%. ▪ Legacies: 22%. ▪ Lottery: 14%.
<p>Where the money went to</p>
<ul style="list-style-type: none"> ▪ Direct patient care and services: 74%. ▪ Other costs: 26% (e.g. pay for nurses, HR services, communications, costs associated with fundraising).

Appendix 21: Patient invitation letter



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House, Little Common Lane
Sheffield, S11 9NE
Tel: 0114 2357619
Email: bill.noble@sheffield.ac.uk

Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai

September 2012

Dear Patient

A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

We are a team of researchers based at The Academic Unit of Supportive Care at the University of Sheffield. We would like to invite you to take part in a research study.

The Sheffield Profile for Assessment and Referral for Care (SPARC) questionnaire is designed to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of disease.

We hope to learn if using SPARC makes a difference to your quality of life, and in referrals for help, and whether the experience is different between groups of patients.

Please read the patient information sheet enclosed with this letter. Participating in the study is completely voluntary and you will receive the same care whether or not you chose to participate.

If you would like any more information about the study or about taking part in it, please do not hesitate to phone Mr Nisar Ahmed or Dr Michelle Winslow on 0114 2357619

If you wish to participate please sign the consent form and return the completed consent form and questionnaire in the pre-paid envelope.

Thank you for your help.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Nisar Ahmed'.

Mr Nisar Ahmed/ Dr Michelle Winslow/ Dr Bill Noble

Appendix 22: Patient information sheet



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House, Little Common Lane
Sheffield, S11 9NE
Tel: 0114 262 0174
Email: n.ahmed@sheffield.ac.uk

Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Invitation to participate in the study

You are being invited to take part in a research study undertaken by a team of researchers based at the University of Sheffield. Before you decide, it is important for you to understand why the research is being done, and what it will involve. Please take the time to read the following information carefully, and discuss it with others, if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Studies suggest that patients have needs that are not being fully met at the moment. We want to find out if patient care improves if the SPARC questionnaire is used in addition to the usual support services.

SPARC (Sheffield Profile for Assessment and Referral for Care) is a questionnaire for assessing patients' needs. There are 9 sections, each asking about a different aspect of your health: 46 questions altogether.

Why have you chosen me?

You have been chosen because you have been referred to a supportive or palliative care service and may be interested in taking part in this research. We are asking all in-patients, out-patients, day care and home care patients referred for supportive or palliative care, if they would like to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be able to keep this information sheet and will be asked to sign a consent form. You are free to withdraw at anytime without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your future medical care.

You can obtain general advice about participating in research studies from INVOLVE; this is a national advisory group which supports greater public involvement in NHS,

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public health and social care research (INVOLVE is funded by the National Institute for Health Research). INVOLVE information can be accessed via their website (<http://www.invo.org.uk/index.asp>) or by telephone contact 02380 651088.

What does taking part involve?

We will ask everyone to fill in the SPARC questionnaire. The questions are about you, your health and how you are feeling.

All patients will receive SPARC at some point in the study: half the patients will be chosen at random to complete it straight away; the others will complete it after two weeks.

We will ask you to fill in three short research questionnaires at the start of the study and then again two, four and six weeks later. The three research questionnaires are:

- Measure Yourself Concerns and Wellbeing (MYCAW), which asks you to nominate and score two important concerns;
- EQ-5D: a questionnaire which provides an overall estimation of health-related quality of life; and
- the Patient Enablement Instrument (PEI) which asks how helpful your recent consultation was.

A small number of patients will be invited to participate in interviews. As part of the study, we would also like to look at information in your clinical records.

If you decide to take part a member of the research team will give you the information sheet and questionnaires to complete. Assistance is available should you need it.

What are the possible risks and disadvantages of taking part?

Completing the questionnaires will take up some of your time. Occasionally, people may feel upset by being reminded of illness or difficulties. Specialist help and support are available should you feel any part of the study has upset or affected you in any way.

What are the possible benefits of taking part?

This study will contribute to identifying the best methods for identifying patients' needs. We hope to learn if using SPARC makes a difference in quality of life, and in referrals for help, and whether the experience is different for different groups of patients.

Will my taking part in the study be kept confidential?

Information from SPARC will be given to the doctors and nurses in the supportive and palliative care team.

Information from the research questionnaires (MYCAW, EQ-5D and PEI), your clinical records and from any interview will be kept strictly confidential and it will be securely stored. All research data about you collected in this study will be treated in accordance with the "EU Directive on the protection of individuals with regard to the processing of personal data" and UK regulations.

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What will happen to the results of the research study?

The research team will use the information you give to help to improve care for patients. The results will be written into a report, along with information from other parts of the study (available to all participants). This report will be presented to the organisation that has funded the research and discussed with the service itself. The results of the study may be published in international medical journals and presented at scientific meetings. The information may be used in the education of other health professionals and contribute to postgraduate studies. You will not be identified in any way.

Who is organising and funding the research?

The research is funded by Macmillan Cancer Support, and organised through the Academic Unit of Supportive Care, The University of Sheffield.

Who has reviewed the study?

This study has been reviewed by colleagues at the University of Sheffield, a panel convened by Macmillan Cancer Support, a research ethics committee (Bradford Research Ethics Committee), and representatives of the North Trent Cancer Network Consumer Research Panel (NTCRN CRP). The NTCRN CRP are a group of patients and carers who represent the interests of people with cancer under the auspices of the NHS.

What if I am harmed or I am unhappy about any aspect of the study?

As there are no specific risks associated with this study it is highly unlikely that you will be harmed. However, if you have any concerns or complaints about any aspect of the study please contact, in the first instance, the Principal Investigator on the study:

Dr Bill Noble, Academic Unit of Supportive Care, The University of Sheffield,
Telephone: 0114 2620174.

If you remain unhappy and wish to complain formally, you can go through the NHS Complaints Procedure by contacting Professor Chris Welsh, Medical Director, Sheffield Teaching Hospitals NHS Foundation Trust, 8 Beech Hill Road, Sheffield, S10 2SB. Telephone: 0114 271 2178.

Who can I contact for further information?

If you would like further information about this study, you can contact Dr Bill Noble, Mr Nisar Ahmed, or Dr Michelle Winslow, on (0114) 262 0174.

Thank you for taking the time to read the information sheet.

Appendix 23: Patient consent form and EQ5D (thermometer)



Professor A P Weetman, Dean
 Division of Clinical Sciences (South)
 Professor Sam H Ahmedzai
 Head of Academic Unit of Supportive Care

Dr Bill Noble
 Macmillan Senior Lecturer in Palliative Medicine
 Academic Unit of Supportive Care
 University of Sheffield
 Sykes House, Little Common Lane
 Sheffield, S11 9NE
 Tel: 0114 262 0174
 Email: n.ahmed@sheffield.ac.uk

A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Principal Investigator: Dr Bill Noble

Patient ID Number: _____

Please initial
 box

1. I confirm that I have read and understand the patient information sheet (**Version 3, 14.12.10**) for the above named study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of any of my medical notes, and data collected during the study, may be looked at by responsible individuals from the evaluation team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above named study.

Name **Date** **Signature**

Address

Telephone Number

For Office Use:		
Name of Person receiving consent (if different from researcher)	Date	Signature
_____	_____	_____
Name of Researcher	Date	Signature
_____	_____	_____

Thank you- please could you return the consent form and questionnaire in the free-post envelope.



Health Questionnaire

English version for the UK (validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

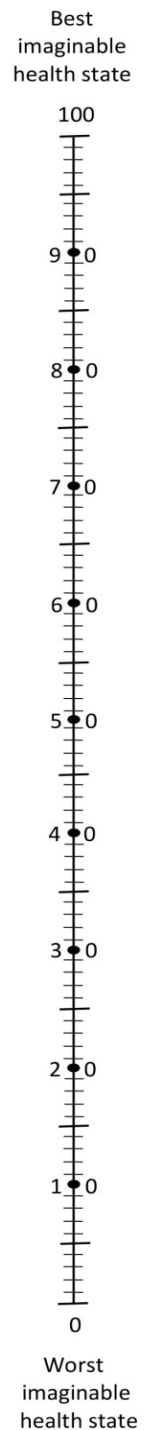
Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state
today**



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Thank you for completing this form

Appendix 24: Semi-structured interview schedule for patients

Semi-structured interviews with patients

Outline interview **Aide-mémoire** for sub group of patients agreeing to take part in qualitative interview.

This is a semi-structured interview, where participants can respond to open questions with their comments and concerns. Prompts are often unnecessary, but are sometimes useful to help move the conversation forward.

Introduction: check participation understood

willing to participate and consent signed-audio-recorded

understands can end interview at any time

confidentiality explored- what will happen to the information

1. How did you find completing the SPARC questionnaire?
Prompts- (easy?, difficult?, what you were expecting?).
2. What did you think about the SPARC questions?
Prompts- (suitable for you? inappropriate? too personal/sensitive?, missed important things?).
3. Has anything changed because of filling in the SPARC questionnaire?
Prompts- (for the better or for the worse?).
4. Do you think that completing the SPARC questionnaire resulted in any actions being taken?
Prompts- (about your treatment?, about any care?, for your family?)
5. Do you have any other comments to make about SPARC?
Prompts- (about treatment?, care?, about your doctors and nurses?)

Thank you for taking the time to take part in this interview.

Explain what will happen to the information given

Version 1 (21.10.10) RG/Ethics Number
SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 25: Patient invitation letter for semi-structured interview



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House, Little Common Lane
Sheffield, S11 9NE
Tel: 0114 262 0174
Email: bill.noble@sheffield.ac.uk

Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

Date:

Dear

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Thank you for taking part in the above named study. We would like to invite you to take part in a short interview about your experience of completing *SPARC (a holistic needs assessment tool) and about taking part in this study.

Interviews will take around 20-30 minutes and take place at a location which is convenient to you.

If you would like any more information about taking part in the interview, please do not hesitate to phone Mr Nisar Ahmed or Dr Michelle Winslow on 0114 262 0174 (extension 28).

If you wish to participate please complete the enclosed form, sign the consent form and return these in the pre-paid envelope.

Thank you for your help.

Yours faithfully,

Mr Nisar Ahmed/ Dr Michelle Winslow/ Dr Bill Noble

***SPARC: Sheffield Profile for Assessment and Referral for Care**

Appendix 26: Patient opt-in form for semi-structured interview



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
Academic Unit of Supportive Care
University of Sheffield
Sykes House, Little Common Lane
Sheffield, S11 9NE
Tel: 0114 262 0174
Email: bill.noble@sheffield.ac.uk

Professor A P Weetman, Dean

Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

I would be willing to be contacted by a researcher about taking part in an interview for the above named study.

Name.....

Address.....

.....

.....

Signed.....

Date.....

Phone number.....

Email address.....

A good time to contact me is.....

Please return in the freepost envelope provided. Thank you.

Version 1 (21.10.10) RG/Ethics Number 10/H1302/88
SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 27: Patient consent form for semi-structured interview



Dr Bill Noble
 Macmillan Senior Lecturer in Palliative Medicine
 Academic Unit of Supportive Care
 University of Sheffield
 Sykes House, Little Common Lane
 Sheffield, S11 9NE
 Tel: 0114 262 0174
 Email: bill.noble@sheffield.ac.uk

Professor A P Weetman,
 Dean
 Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
 Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Principal Investigator: Dr Bill Noble

Name of Researcher:

Patient ID Number:

1. I confirm that I have read and understand the patient information sheet (**Version 3, 14.12.10**) for the above named study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of any of my medical notes, and data collected during the study, may be looked at by responsible individuals from the evaluation team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I give permission for the interview with a researcher to be audio-recorded.
5. I understand that quotes from my interview may be used within written reports or publications and that any quotes would be completely anonymous and could not be linked to me in any way.
6. I agree to take part in the above named study

Please initial box

Name of Patient

Date

Signature

Address Telephone

Number

Name of Person receiving consent (if different from researcher)

Date

Signature

Appendix 28: Coded interview transcript example (Patient)

Key: I: Interviewer, and P: Patient

Interview Transcript: Patient Semi-Structured Interview

Patient ID: BM001

Date of Interview: 16.5.11

Interviewer's name: Nisar Ahmed

Location of interview: Patient's home

Length of interview: 7.27 minutes

Thanked participant for taking part in study and for agreeing to do an interview (off-tape).

I: The first questionnaire you did was about 6 weeks ago. You probably remember that one?

P: Yeah, yeah

I: It's got different issues like your physical issues, psychological etc.

P: Yeah

I: Ok and the questions I've got really are, how did you find completing that questionnaire? (SPARC shown), did you think?, what do you think about it?, do you think?, it was difficult?, easy or?...

P: Ehh,

I: I let you it, you can have a look at it

P: For me it were quite easy to answer

Comment [N1]: 1

I: Right

P: I didn't really have to think about it

Comment [N2]: 1

I: Right

P: Because it was fairly straight forward

Comment [N3]: 1

I: Right ok

P: I think there were only a couple where i had to stop and hesitate, and think em

Comment [N4]: 2

I: Right

P: Most of them were just yeah, yeah straight forward

Comment [N5]: 1

I: Great, and i mean is it, what were you expecting?, were you expecting anything different or, i mean, were any sort of questions inappropriate you think or sensitive?

P: Ehh,

I: Cus it covers

P: Religious and spiritual issues are a bit, i didn't know where that came into it really but, i suppose it's for people that have got an illness that's sort of far more intense than mine.

Comment [N6]: 5

I: Right

P: Maybe they can't be cured

Comment [N7]: 5

I: Yeah, that's right, and what the idea is that it's an holistic

P: For me it were right, just (laughter)

Comment [N8]: 1

I: Right yeah. Sometimes what happens is during consultations all the issues aren't discussed so this is giving an opportunity for patients to put down you know any other problems they might have.

P: Yeah

I: The idea is that this would then, ehh result in the health professional doing something about that issue, referring them on to someone for better support.

P: Yeah, it's a good idea, but to be fair i have answered other questionnaires that have been a lot more personal than this.

Comment [N9]: 9

Comment [N10]: 5

I: Really?

P: I don't really find this personal

Comment [N11]: 5

I: Ok

P: In comparison with other things i have done

Comment [N12]: 5

Key: I: Interviewer, and P: Patient

I: Right ok

P: Cus i did another study on my bowels

I: Ok

P: And obviously there was a lot of really personal (inaudible)

I: Right sure

P: So i didn't me personally

I: Yeah

P: Find it

I: Is that in Sheffield too?

P: Yeah it was Hallamshire

I: Hallamshire

I: Right ok

P: It was in relation to my hysterectomy they wanted to see, whether i would have bowel trouble afterwards.

I: Right ok

P: I have

I: And how are you feeling in general now, are you feeling the same as before you started the study?

P: Ehh, i'm not having a too bad day today

I: Right

P: I'm in a lot of pain

I: Right, ok, do you think anything's changed because of completing that questionnaire?, ehh, i don't know if you have actually seen anyone since or during the study?, have you not met up you know with Dr N or..?

P: No, No

Comment [N13]: 8

I: And i think they are trying to arrange an outpatient for you i think at the moment with B, Dr BN.

P: Oh brilliant

I: Ehh, but i think you've seen various outpatients departments haven't you?

P: Yeah, i have seen Mr C

Comment [N14]: 8

I: Right ok

P: But i wasn't there long he basically said there is nothing he could do and he's now passed me back to Dr J...., and i think Dr J.... is gonna pass me down to Nottingham.

Comment [N15]: 8

I: Right, Nottingham, is that a different Department?

P: Apparently there is a specialist down there

I: Right ok

P: I don't know until see Dr J, i think my appointment's next month 6th

I: 6th of month yeah, like i said i think in between they are trying to see you again at the Macmillan Unit, have you been into the Macmillan Unit before?

P: I have been under obviously Dr N before

I: Right ok, right, so obviously what the idea anyone scoring 3 on various issues we give it back to the health professional and they take any appropriate action but it seems as though you've not had an appointment in between have you?

P: No if i can get that out of it then that's fantastic to actually know that someone's listening, or cus the way that i was feeling before this landed on my door step was that i was just stuck.

Comment [N16]: 9

Comment [N17]: 13

I: Right

P: I had no where to go

Comment [N18]: 13

I: Yeah

P: And so, this for me was brilliant, it was someone's actually listening to me.

Comment [N19]: 9

Key: I: Interviewer, and P: Patient

I: Yeah, i mean this is exactly the idea was, i mean i fed that back to Dr N who is trying to make an appointment for you pretty soon now, because a lot of the issues you were scoring quite highly, so that's the ultimate aim of what we are doing to see after 8 weeks, does actually anything happen?, and if does happen.

P: Yeah and ...

I: Does it help improve? you know

P: Yeah

I: Your quality of life

P: Yeah it's a good idea, really is, cus like i said it just felt like i had been forgotten and it was just like i'm gonna be like this forever.

Comment [N20]: 9, 13

I: Yeah

P: And you know i'm only near 35, i don't want to be like this forever

Comment [N21]: 13

I: That's right yeah

P: I have sort of come to terms with the fact that i'm not gonna be how i was

Comment [N22]: 8

I: Right

P: But i need some sort of life i'm stuck in here 24/7

Comment [N23]: 13

I: Right

P: It's not good

I: No it's not, do you get any nurses, or community nurses coming in or?

P: No nothing at all

Comment [N24]: 8

I: Nothing at all, right ok

P: So it's just, (laughing), i got me mum to clean up, i can't do anything, i can struggle on but i pay for it afterwards.

I: Right, yeah

P: So its just not worth it

I: Have you had these problems for a long time now or just started?

P: It started of Gynaecological then like i said it's just pelvic pain and bowel issues

I: Right

P: Ehh all in all ehh about 4 years

Comment [N25]: 8

I: Right ok

P: So but i have got a son as well

I: Oh right

P: And hes had to go through with it bless him, he's 17 now he's not young, but he still needs his mum.

I: Yeah (laughing) right so obviously the next question is do you think completing SPARC resulted in any actions being taken?, ehh i put that back to you.

P: As i just explained that, i mean that, that is that has made it worthwhile

Comment [N26]: 9

I: That, really?

P: Yeah definitely

Comment [N27]: 9

I: Right good, do you have any sort of other comments you would like to make about that particular questionnaire or your general experience of taking part in the study?

P: No like I say i think it's a really good idea err, especially like you say if it does get followed up, cus a lot of questionnaires i have done in the past which i presume this one was, you fill it out and that's it, its used for research and there's nothing that sort of comes from it.

Comment [N28]: 9

Comment [N29]: 13

I: Mmmm..and nothing happens?

P: So err for there to be a follow up

Comment [N30]: 13

I: Yeah

P: And people to get help that need help, obviously, then yeah it's a really, really good idea

Comment [N31]: 9, 13

Key: I: Interviewer, and P: Patient

I: Right, ok so i think that brings me to the last, well that was the last question (laughing). I will switch that, if i can turn that off.

End of interview

Appendix 29: Patient thematic framework/charting example

FINAL PATIENT THEMATIC CHARTING 20.11.14

THEME 1: EASE OF SPARC COMPLETION	
PATIENT ID	
	<p>1) Quite easy/fairly straightforward/no problems completing <i>How patients found completing the SPARC questionnaire: easy, straightforward/no problems completing, answered truthfully/dishonestly.</i></p>
	<p>2) Quite difficult/difficult <i>How patients found completing the SPARC questionnaire: Quite difficult/difficult, hard to fill in.</i></p>
BM001	<p>QUITE EASY: Quite easy to answer, didn't really have to think about it, FAIRLY STRAIGHTFORWARD: fairly straightforward, most of them straight forward (1)</p>
BM002	<p>NO PROBLEM COMPLETING: Don't have a problem with completing forms at all (5)</p>
BM009	<p>QUITE EASY: Quite easy (11)</p>
BM021	<p>QUITE EASY: Quite easy to fill in anyway, NO TROUBLE: no trouble with them whatsoever, PUT DOWN TRUTH: what we've done is put down truth, SCORING: it is just gauging what number, you know, to put it on? (13)</p>
BM028	<p>NO PROBLEM: Not a problem, QUITE EASY: find it quite easy, NO TROUBLE: caused me no trouble, OK: it's okay (17), FORM EASY TO FOLLOW: form is easy enough to follow (18)</p>
BM033	<p>INTELLECTUALLY STRAIGHTFORWARD, EASY: An intellectually straightforward exercise so it's easy in that sense (19)</p>
MA001	<p>QUITE EASY: Quite easy (23) if I had been really bad I would have said that would be down there, ARE FINE: think they are fine (24)</p>
MA006	<p>ANSWERED TRUTHFULLY: Answered them truthfully (26)</p>
MA012	<p>WAS ALRIGHT/MAKES YOU FACE UP TO THINGS: Was alright but mainly it makes you face up to what's happening (28)</p>
MA015	<p>EASY/ALRIGHT: Yes (easy), I thought it was alright (38)</p>
MA024	<p>NO PROBLEM/PRETTY STRAIGHTFORWARD: Don't have a problem with them, pretty straightforward (42)</p>
MA025	<p>NOT DIFFICULT: Not difficult, I just filled it in (46)</p>
MA026	<p>EASY STRAIGHTFORWARD: Easy, yeah (straightforward) (49)</p>
MA029	<p>QUITE EASY/QUITE SIMPLE: Quite easy, quite simple (52)</p>
MA033	<p>ONE OF THE BETTER QUESTIONNAIRES: As questionnaires go it's one of the better</p>
	<p>VERY EMOTIONALLY HARD/MAKES YOU FACE UP TO THINGS: Very emotionally hard makes you focus on the things that you are concerned about - can't do whatever it is you are finding problematic, TASK OF COMPLETION NOT DIFFICULT, BUT EMOTIONALLY DIFFICULT: Two different levels to that so is it difficult? - No, as a task?, it's difficult emotionally - Yes (19), FACING UP TO LOSS OF INDEPENDENCE: I never thought about that I'm going to lose my independence, what they are saying now?, if you are already frightened (20)</p>
	<p>NOT PHASED BY IT: I wasn't phased by it, DIDN'T TROUBLE ME: It didn't trouble me, OPTION TO PUT AWAY AND NOT COMPLETE: If I found my mind wandering I used to put it in a drawer and close it (42)</p>
	<p>SOMETIMES DIFFICULT: Sometimes bit hard to fill in the questions, how do you feel?, I don't know?, DIFFICULT TO SCORE QUESTIONS: shall I put three or shall I put two cos you are thinking do I really feel like this or that is very much?, quite a bit? (52)</p>

	<p>ones (56)</p>
MA039	<p>EASY/STRAIGHTFORWARD/SIMPLE: Easy, straightforward, simple (59), FED UP OF DOING QUESTIONNAIRES: got fed up because done that many in hospital (60), HAVE TO ANSWER TRUTHFULLY HOW YOU FEEL ON THE DAY: no good answering dishonestly have to answer them how you feel on the day (67)</p>
MA046	<p>NO ISSUES WITH IT: Didn't have any issues with it (69)</p>
MA047	<p>QUITE EASY: Quite easy, answered them as best I could (72)</p>
MA057	<p>ALRIGHT/IT FLOWS: Alright it just flows really doesn't it? (75)</p>
MA058	<p>SIMPLE: Simple, MULTIPLE CHOICE VS. OPTION TO WRITE AN ANSWER: when it's sort of multiple choice just occasionally you think it's possibly better to be able to write an answer, VERY GOOD: these are very good yes (80)</p>
MA060	<p>PRETTY STRAIGHTFORWARD: Pretty straightforward, NO PROBLEMS: no problems whatsoever (83)</p>
MA061	<p>QUITE SIMPLE: Quite simple, GENERALLY ALRIGHT: generally they were alright (86)</p>
MA064	<p>NOT DIFFICULT: Not, difficult no, no (88)</p>
MA065	<p>NO PROBLEM COMPLETING: No problem completing none at all, ANSWERED TRUTHFULLY: everything on it was true at the time (91)</p>
MA070	<p>FAIRLY STRAIGHTFORWARD APART FROM ONE/TWO QUESTIONS: Fairly straightforward there were one or two questions like what do I really put there? (98)</p>
MA071	<p>VERY EASY: Very easy (102)</p>
MA090	<p>NOT A PROBLEM: Not a problem to me at all (104)</p>
MA091	<p>QUITE EASY: Quite easy if you didn't think about it (106)</p>
MA093	<p>DIDN'T STARTLE ME: It didn't startle me in any way (109)</p>
MA098	<p>EASY: Find it easy, A NURSE WITH KNOWLEDGE OF WHAT'S GOING ON: maybe because I'm a nurse, I have the knowledge of what is going on, NO PROBLEM: don't find any problem filling the form, VERY STRAIGHT QUESTIONS: very straight questions, SEEKING PEOPLES' OPINION: they just want to get the people's opinion about their illness (111), IT'S CONFIDENTIAL: it's confidential, ANSWERED TRUTHFULLY: so I try all my possible best to tell you the truth, the whole truth and nothing but the truth (112)</p>
MA100	<p>PERFECTLY STRAIGHTFORWARD: Perfectly straightforward, QUICK TO COMPLETE: only took about a minute to complete, TICK BOXES VERY STRAIGHTFORWARD: was a case of tick, tick, tick, scribble that's it, tick the boxes it was very, very straightforward, far more straightforward than I anticipated (114)</p>
MA102	<p>A LITTLE DIFFICULT TO ASSESS: Found it a little difficult to assess, purely because of my own situation, nothing else (116)</p>
THEME 2: SUITABILITY, RELEVANCE AND SENSITIVITY OF SPARC QUESTIONS	
PATIENT ID	
	<p>3) Suitable/appropriate/relevant <i>What patients thought about the questions: questions were suitable/appropriate/relevant.</i></p>
	<p>4) Not relevant/not applicable <i>Felt questions on SPARC/SPARC questionnaire not relevant/not applicable.</i></p>
	<p>5) Inappropriate/too personal/sensitive <i>What patients thought about the questions: questions were inappropriate/too personal/sensitive/invasive/offensive/upsetting/bothering</i></p>
BM001	<p>RELIGIOUS AND SPIRITUAL ISSUES: Religious and spiritual issues are a bit, didn't know where that came into it really but,</p>

Appendix 30: Semi-structured interview schedule for health care professionals

Semi-structured interviews with health care professionals

This is a semi-structured interview, where participants can respond to open questions with their comments and concerns. Prompts are often unnecessary, but are sometimes useful to help move the conversation forward.

Introduction: check participation understood

- ***Willing to participate and consent signed-audio-recorded***
 - ***Understands can end interview at any time***
 - ***Confidentiality explored- what will happen to the information***
1. **Please could you tell me about your current method of assessing patients/families holistic needs?**
(Prompts: what tools are you aware of (use/not use), value/usefulness of these tools, benefits/barriers to use).
 2. **Are you aware of what SPARC is used for?**
(Prompts: were you aware of it before, during or after the study? any expectations?, extent to which extent expectation/s met?)
 3. **Please tell us about your experience of using SPARC.**
(Prompts: how did it go with your last patient?)
 4. **Did you find it overall useful/unhelpful for patients to have completed SPARC?**
(Prompts: was it worth it?)
 5. **How were SPARC results feedback or discussed with patients?**
(Prompts: by telephone, letter, face to face, other?)
 6. **What feedback about using SPARC have you received from patients, and their families or carers?**
(Prompts: have they mentioned it?)
 7. **In what way did using SPARC result in any actions being taken?**
(Prompts: would it have happened anyway?)
 8. **Were there any barriers to the relief of distress highlighted by SPARC?**
(Prompts: is time a problem? too much information?, resources?)
 9. **In what way has SPARC been useful?**
(Prompts: have any patients benefited? Does it help you in your work?)
 10. **Is there anything about SPARC that is unhelpful?**
(Prompts: is it upsetting for patients, difficult to understand?)
 11. **Do you have any other comments about using SPARC?**
(Prompts: any at all?)

Thank you for taking the time to take part in this interview.

Explain what will happen to the information given

Appendix 31: HCP invitation letter for semi-structured interview



Dr Bill Noble
Macmillan Senior Lecturer in Palliative Medicine
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University of Sheffield
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Tel: 0114 262 0174
Email: bill.noble@sheffield.ac.uk

Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

insert name
insert address

Date:

Dear [insert name]

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.
REC Reference Number 10/H1302/88

We would like to invite you to participate in the above research study that has been funded by Macmillan Cancer Support. The Academic Unit of Supportive Care (The University of Sheffield) is undertaking a research study about holistic needs assessment. The study has received a favourable ethics opinion from Bradford Research Ethics Committee and we have made a successful research governance application.

The Sheffield Profile for Assessment and Referral for Care (SPARC) questionnaire is designed to identify supportive or palliative care needs, regardless of diagnosis or stage of disease.

We hope to learn if using SPARC makes a difference to patients' quality of life, and in referrals for help, and whether the experience is different between groups of patients.

You have been chosen because you are working in the supportive or palliative care service and will have cared for a patient/s that has participated in this study. The information gathered will give us a better understanding of assessing patients' needs.

We are inviting you to take part in a semi-structured interview about holistic assessment of supportive and palliative care needs and about your experience of using SPARC. Please read the information sheet enclosed with this letter. Participating in this study is completely voluntary.

If you decide to take part, you will be offered a convenient time at which one of our experienced qualitative interviewers will visit you or telephone you to ask you about your views on holistic assessment of supportive and palliative care needs and your experiences of using SPARC. Interviews will take place at a location which is convenient to you. The interview will take approximately 30 minutes. The interviews will be audio-taped and stored in an anonymised fashion.

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If you would like to participate please complete the enclosed opt in form, sign the consent form and return these in the pre-paid envelope.

If you would like any more information about the study or about taking part in it, please do not hesitate to phone Dr Bill Noble, Mr Nisar Ahmed or Dr Michelle Winslow on 0114 262 0174.

Thank you for your help.

Kind Regards,

A handwritten signature in black ink that reads "Bill Noble". The signature is written in a cursive style with a large initial 'B'.

Dr Bill Noble/ Mr Nisar Ahmed/ Dr Michelle Winslow

Appendix 32: HCP information sheet for semi-structured interview



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Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Invitation to participate in the study

You are being invited to take part in a research study undertaken by a team of researchers based at the University of Sheffield. Before you decide, it is important for you to understand why the research is being done, and what it will involve. Please take the time to read the following information carefully, and discuss it with others, if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Studies suggest that patients have needs that are not being fully met at the moment. We want to find out if patient care improves if the SPARC (Sheffield Profile for Assessment and Referral for Care) questionnaire is used in addition to the usual support services.

SPARC is a questionnaire for assessing patients' needs. There are 9 sections, each asking about a different aspect of patient's health: 46 questions altogether. We have asked all in-patients, out-patients, day care and home care patients referred for supportive or palliative care, if they would like to take part.

We have asked everyone to fill in the SPARC questionnaire. The questions are about patient's health and how they are feeling. All patients received SPARC at some point in the study: half the patients were chosen at random to complete it straight away; the others completed it after two weeks. Completed SPARC forms were then sent to the health professional/team caring for the patient for action. Patients filled in three short research questionnaires at the start of the study and then again two, four and six weeks later.

The three research questionnaires are:

- Measure Yourself Concerns and Wellbeing (MYCAW), which asks patient's to nominate and score two important concerns;
- EQ-5D: a questionnaire which provides an overall estimation of health-related quality of life; and

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- the Patient Enablement Instrument (PEI) asks how helpful their recent consultation was.

A small number of patients were invited to participate in interviews. As part of the study, we also looked at information in patients clinical records. We are now at stage where we wish to examine the views of health care professionals about their experience of using SPARC.

Why have you chosen me?

You have been chosen because you are working in the supportive or palliative care service and will have cared for a patient/s that has participated in this study. The information gathered will give us a better understanding of assessing patients' needs.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be able to keep this information sheet and will be asked to sign a consent form. You are free to withdraw at anytime without giving a reason.

You can obtain general advice about participating in research studies from INVOLVE; this is a national advisory group which supports greater public involvement in NHS, public health and social care research (INVOLVE is funded by the National Institute for Health Research). INVOLVE information can be accessed via their website (<http://www.invo.org.uk/index.asp>) or by telephone contact 02380 651088.

What does taking part involve?

If you decide to take part a member of the research team will give you the information sheet and invite you to take part in a semi-structured interview. Whether you decide to take part or not is entirely up to you. If you decide to take part, you will be offered a convenient time at which one of our experienced qualitative interviewers will visit you or telephone you to ask you about your views on holistic assessment of supportive and palliative care needs and your experience of using SPARC. The interview will take approximately 30 minutes. The interviews will be audio-taped and stored in an anonymised fashion. The transcripts of the interviews will be stored in accordance with the Data Protection Act, again in anonymised form. We will analyse the transcripts to help us gain a better understanding of the views of health care professionals about the use of SPARC. We may use anonymised quotes from your interview in subsequent publications arising from this work, but these quotes will not be traceable back to you in any way. The data (audio-recordings and transcripts) will be stored for up to 15 years in secure storage at the University of Sheffield.

What are the possible risks and disadvantages of taking part?

There are no specific risks associated with taking part in this study but you may suffer some inconvenience in terms of the time taken to be interviewed.

What are the possible benefits of taking part?

This study will contribute to identifying the best methods for identifying patients' needs.

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We hope to learn if using SPARC makes a difference in quality of life, and in referrals for help, and whether the experience is different for different groups of patients.

Will my taking part in the study be kept confidential?

All research data about you collected in this study will be treated in accordance with the “EU Directive on the protection of individuals with regard to the processing of personal data” and UK regulations. All information that is collected about you during the course of the research will be kept strictly confidential. Everyone who takes part in the study will be assigned a study number, and all of the data relating to each person will be held on a database and will only be linked to that study number, and not to your name and address so that you cannot be recognised. All transcripts and recordings will only be labelled with a code number and will be stored securely in a locked room in the University, which is only accessible to the research team. The records will be kept for 15 years after the finish of the study and then destroyed. Access to any information stored on computers will be protected with passwords and restricted to the researchers working on the study.

What will happen to the results of the research study?

The research team will use the information you give to help to improve care for patients. The results will be written into a report, along with information from other parts of the study (available to all participants). This report will be presented to the organisation that has funded the research and discussed with the service itself. The results of the study may be published in international medical journals and presented at scientific meetings. The information may be used in the education of other health professionals and contribute to postgraduate studies. You will not be identified in any way.

Who is organising and funding the research?

The research is funded by Macmillan Cancer Support, and organised through the Academic Unit of Supportive Care, The University of Sheffield.

Who has reviewed the study?

This study has been reviewed by colleagues at the University of Sheffield, a panel convened by Macmillan Cancer Support, a research ethics committee (Bradford Research Ethics Committee), and representatives of the North Trent Cancer Network Consumer Research Panel (NTCRN CRP). The NTCRN CRP are a group of patients and carers who represent the interests of people with cancer under the auspices of the NHS.

What if I am harmed or I am unhappy about any aspect of the study?

As there are no specific risks associated with this study it is highly unlikely that you will be harmed. However, if you have any concerns or complaints about any aspect of the study please contact, in the first instance, the Principal Investigator on the study:

Dr Bill Noble, Academic Unit of Supportive Care, The University of Sheffield,
Telephone: 0114 2620174.

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If you remain unhappy and wish to complain formally, you can go through the NHS Complaints Procedure by contacting Professor Chris Welsh, Medical Director, Sheffield Teaching Hospitals NHS Foundation Trust, 8 Beech Hill Road, Sheffield, S10 2SB. Telephone: 0114 271 2178.

Who can I contact for further information?

If you would like further information about this study, you can contact Dr Bill Noble, Mr Nisar Ahmed, or Dr Michelle Winslow, on (0114) 262 0174.

Please keep this information leaflet for future reference.

Thank you for reading this, and for taking an interest in this research study.

Appendix 33: HCP opt-in form for semi-structured interview



Dr Bill Noble
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Professor A P Weetman, Dean
Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

I would be willing to be contacted by a researcher about taking part in an interview for the above named study.

Name.....

Address.....

.....

.....

Occupation.....

Signed.....

Date.....

Phone number.....

Email address.....

A good time to contact me is.....

Please return in the freepost envelope provided. Thank you.

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SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 34: HCP consent form for semi-structured interview



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Professor A P Weetman, Dean
 Division of Clinical Sciences (South)

Professor Sam H Ahmedzai
 Head of Academic Unit of Supportive Care

Short Title: A Feasibility Study of SPARC: a holistic needs assessment questionnaire.

Principal Investigator: Dr Bill Noble

Name of Researcher: _____

Participant ID Number: _____

Please initial
 box

1. I confirm that I have read and understand the health care professional information sheet (**Version 1, September 2011**) for the above named study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.
3. I give permission for the interview with a researcher to be audio-recorded.
4. I understand that quotes from my interview may be used within written reports or publications and that any quotes would be completely anonymous and could not be linked to me in any way.
5. I understand that data collected during the study may be looked at by named members on the research study team at the University of Sheffield and also by persons from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research.
6. I agree to take part in the above named study.

Name of Participant	Date	Signature
_____	_____	_____

Address	Occupation	Telephone Number
_____	_____	_____

Name of Person receiving consent (if different from researcher)	Date	Signature
_____	_____	_____

Name of Researcher	Date	Signature
_____	_____	_____

When completed 1 for participant, 1 for researcher site file

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SPARC: Sheffield Profile for Assessment and Referral for Care

Appendix 35: Coded interview transcript example (HCP)

Key: I: Interviewer, and HCP: Health Care Professional

HCP ID number: 1

Occupation: Clinical Specialist Palliative Care Nurse

Interviewer's name: Nisar Ahmed

Date: 7.12.11

Location: Sykes House

Length of interview: 12.20 minutes

I: I think that should pick up yes it is picking up now. So right the first question is please could you tell me about your current method of assessing patients and or families holistic needs?

HCP: Right current method, is err, it's verbal we don't use an assessment tool

Comment [N1]: 1

I: Right okay

Comment [N2]: 2

HCP: You know like SPARC

Comment [N3]: 2

I: Yes you don't...

HCP: No, no, so when we go and visit patients we go into erm, we get a referral form and, and on the referral it, it gives us an indication of why the referrer has referred you know it might be the they are referred for pain control, symptom management is that.

Comment [N4]: 1

I: That's fine yes

HCP: Err psychological

I: Right

HCP: Concerns..., but obviously when we go out and do an assessment we do, you know a holistic needs assessment. So the focus of our questions will be very much on the whole person. So the physical needs, the erm psychological concerns, what their understanding of their diagnosis and prognosis. Err, any social concerns, social support around them, spiritual concerns, worries and concerns even now or in the future, so it's a verbal assessment.

Comment [N5]: 1

I: Okay

HCP: And but is we I guess what we do is we you know it's patient focussed, so it's what they see as their main concerns really.

Comment [N6]: 1

I: Right okay so it's not actually a tool, but you have got a list of sort of questions or things that you proforma (yeah, yeah). Right, okay. Err are you aware of what SPARC is used for?

HCP: SPARC is.....

I: That's the tool here....

HCP: Yes. It's a again that's a holistic needs assessment isn't it?

Comment [N7]: 3

I: It is yeah

HCP: And it's, my understanding of it of the aim of it originally is to for it to get used in the initial assessment to help identify what the patient's concerns are. And then whether in our assessment, whether we are picking up those concerns and if you know sometimes patients may find it easier to put in writing what their concerns are, and then it gives us a guide to then address.

Comment [N8]: 3

I: That's correct

HCP: Patients needs yes

Comment [N9]: 3

I: Were you aware of it before, during the study or?

HCP: I was aware of it before the study

Comment [N10]: 3

I: Before the study and did you have any expectations on what it might be used for or?

HCP: I guess the expectations on what it might be used for is to you know we have had quite a lot of discussion about this, about using it. When we go first visit a patient, to help determine what their concerns and problems, and needs are. Err to help as a basis for helping err the direction of our care of them really. And then we have also had discussions about, because obviously at times we do discharge patients if their problems resolve and they stabilise, we discharge them and we've had discussions about whether it's possible may also be a very useful tool to give at the point where we

Comment [N11]: 3

Key: I: Interviewer, and HCP: Health Care Professional

are thinking of discharging to see whether that's, you know whether if we think we've addressed concerns whether the SPARC tool reflects that.

Comment [N12]: 12

I: Yeah that's fine. Err, could you tell me about your experience of using SPARC. Erm how did it go with your last patient?, do you must have some of these SPARC forms that have been sent back to you?

HCP: I've some sent back but not very many and erm actually the two latest ones that have come back, have been patients that I have previously discharged (ok). So erm obviously on reading them there is a couple of areas where I'm thinking I'm going to actually to give them a ring to see if they are okay because it's highlighted a couple of areas. Although one of them was a problem with pain which err I think sometimes its, people, you know you have dealt with the problem but there may still be some degree of pain that they have adjusted to live with if you like.

Comment [N13]: 7

Comment [N14]: 6

Comment [N15]: 7

I: That's right sure, did you find it useful, overall useful or unhelpful for patients to have completed SPARC?

HCP: Erm again, that's actually really difficult questions to answer at the moment because I've not had many back, and I think I've only had about, I think I've only seen about four returned on my desk.

Comment [N16]: 8

I: Of the few you have had what would you say, was it worth it?, basically was the question?

HCP: Yes I think so. It was worth it (yes, yeah)

Comment [N17]: 8

I: How are SPARC results fed back or discussed with patients, did you get a chance to discuss?, I mean by telephone, letter, face to face?

HCP: Err just repeat that...

I: How were the SPARC results?, I mean you said that some of them err you had discharged err, how were they fed back with patients or did you get a chance to discuss any of the issues with the patients?

HCP: Err the one that I'm still involved in with yes I've had chance to discuss the issues with the patients (right). So err, and you know that was helpful.

Comment [N18]: 8

I: Was that face to face, or?

HCP: That was face to face following another visit. A couple I've you know they you know the forms have reappeared back on my desk, it's a matter of me, I think I'm going to phone them to discuss it (right). So I mean it's quite possible that there may be some patients that I've put their names forward for to have the SPARC tool that I've then referred to the day therapy center so, It's quite possible.

Comment [N19]: 5

Comment [N20]: 6

Comment [N21]: 7

I: Okay that why?

HCP: That's probably why I've not seen them back again, you know since the forms have been returned.

Comment [N22]: 7

I: Yes sure err, what feedback about using SPARC have your received from patients and their families?, have you had anything back from them or?

HCP: I think initially I mean I've had a few patients that said they have received this in the post, of the initial request in the post and I've had patients that have said do I have to go? err, do I have to go somewhere to be interviewed?

Comment [N23]: 5

I: Oh I see right

HCP: Because I don't feel I can do that

Comment [N24]: 5

I: Yes sure

HCP: So I've had those sort of comments

Comment [N25]: 5

I: Right, but not specifically about having completed it and then have you had any?

HCP: They have questioned and I have said err, I've explained about the reasons you know verbally explained to them to back up the reasons why it's been sent out to them. And hopefully it's going to be a, an assessment tool that we are going to be using more widely in the future, perhaps to help, help our

Key: I: Interviewer, and HCP: Health Care Professional

assessment of their concerns and needs. And I think once it's been I think sometimes when they get something through the post and it's, just in letter form they are not too sure about it.

Comment [N26]: 5

I: Of course yes we have had a few...

HCP: The word research you know and they think oh, when it's maybe explained verbally they have seem a bit more comfortable about completing it.

Comment [N27]: 5

I: Yes-but you have not actually heard from someone who's actually done the thing and you know have they?...

HCP: They haven't really spoken a great deal about it. No afterwards

Comment [N28]: 5

I: Fine. In what way did you using SPARC result in any actions being taken?, do you think they would have been taken anyway I think you mentioned one of your discharge patients, is any anything basically happened since you have had the three or four that you have mentioned?

HCP: Err at the moment no. Not really. Erm the because as I say they've been, I've discharged them so I've not as yet. You know when we discharge people we usually leave it for them to....

Comment [N29]: 7

I: Contact you?

HCP: Contact us if they feel they need us

Comment [N30]: 7

I: Okay

HCP: So the fact that I've got SPARC tools back which you know there have been a couple of questions that they have answered and it's made me think oh maybe I need to be giving them a ring.

Comment [N31]: 6

I: Right okay

HCP: And I've only received them fairly recently

Comment [N32]: 5, 7

I: Right okay sure

HCP: I do feel I want to make contact with them to say sure they are okay

Comment [N33]: 6

I: That's great right, were there any barriers to the relief of distress highlighted by SPARC for example is time a problem?, is there too much information on there?, do you have resource implications?, for example someone's identified a problem and there's, is there any barrier to relief of that distress?

HCP: Well hopefully not, I mean I think when patients identify I think if they identify err, sexual problems for instance (yeah), we I think that's very useful thing about the SPARC tool because I think patients aren't always very comfortable about talking about that (yeah sure). And err, and there's been I think you know other colleagues have said you know the SPARC tool, the return of the SPARC tool has identified concerns that maybe they haven't expressed verbally, so that's very, very useful. Err, and I think it the fact that they've written that on the form hopefully will help enable them to maybe you know feel more comfortable about discussing it and bringing up concerns. Its how we then address it you know.

Comment [N34]: 10

Comment [N35]: 8

I: That's correct

HCP: Because err, obviously we need to have the resources to be able to erm respond if you know and err, it you know, you, I guess referring patients on to a psychotherapy services if needed. Erm which they have resource issues and I don't know how quick response is. We used to have a psychotherapist that err, was also a sex therapist and err used to do couples counselling with patients. And their loved ones you know but err I don't know whether we've not got the resources so.

Comment [N36]: 11

I: Do you think that would be a barrier then for?...

HCP: Possibly well it wouldn't be, be a barrier to referring but you would {?}, I guess we're are not sure how quickly if there's is very specialised.

I: Ok

HCP: Yes

I: Ok err, last three questions in what way has SPARC been useful?, and some of these might be repetition, but do you think patients have benefited any way and has it helped you in your work?

Key: I: Interviewer, and HCP: Health Care Professional

HCP: Err, I don't at the moment because I've not had that many returned I don't know if patients have benefited, I hope they will benefit from it, I hope that if we do use it there will be great benefit from it you know, so seeing it as a working tool that we are giving about and then in a more direct way following it up. Comment [N37]: 8

I: Ok Comment [N38]: 14

HCP: So I'm quite hopeful about the use of it. Don't know if that's answered the question. Comment [N39]: 14

I: That's absolutely fine, err, is there anything about SPARC that's you know not helpful?, do you think it, it's upsetting for patients or difficult to understand?

HCP: I think it's quite clear to understand. Erm I would hope that they wouldn't find it upsetting, because I think it's quite nicely laid out and the questions are sensitive and quite direct so. Comment [N40]: 10

I: Finally do you have any other comments to make about using SPARC if any other comments you might have?

HCP: Err, I don't think so, so not above and over what said but it would be good to see it used in as part of perhaps as part of our role as I say as an initial assessment. Comment [N41]: 12

I: An early holistic?

HCP: Yes an early holistic assessment tool. And then also perhaps at point of discharge (right), to see if you know how the two forms differ and, and if we have addressed.... Comment [N42]: 12

I: All their needs?

HCP: All their needs Comment [N43]: 12

I: Yeah sure

HCP: So....

I: Right okay that's fine thank you very much for taking part

HCP: Is that it? (laughing)

END OF INTERVIEW

Appendix 36: HCP thematic framework/charting example

FINAL HCP THEMATIC CHARTING

THEME 1: CURRENT METHOD OF ASSESSING PATIENTS/FAMILIES HOLISTIC NEEDS		
HCP ID	1) Description of current method of assessing patients/families holistic needs <i>A description of the current method of assessing patients/families holistic needs</i>	2) Tools used <i>Any tools used when assessing patients' needs (value/usefulness, benefits/ barriers)</i>
HCP 1	VERBAL: Verbal assessment. PATIENT FOCUSED: patient focussed. MAIN CONCERNS: main concerns. GUIDED BY REFERRAL FORM (REASONS FOR REFERRAL): referral form indication why (patient) referred. HNA: do a HNA. WHOLE PERSON FOCUS: focus on whole person. PHYSICAL: physical needs. PSYCHOLOGICAL: psychological concerns. UNDERSTANDING DIAGNOSIS, PROGNOSIS: understanding their diagnosis and prognosis. SOCIAL CONCERNS/SUPPORT: any social concerns. social support. SPIRITUAL: spiritual concerns. CURRENT/FUTURE WORRIES/CONCERNS: worries and concerns now or in the future (1)	DON'T USE ASSESSMENT TOOL: Don't use an assessment tool like SPARC (1)
HCP 2	SYSTEMATIC APPROACH TO SYSTEMS: Take a very systematic approach (to the systems). PHYSICAL: assessing physical needs. PSYCHOLOGICAL: psychological needs. SOCIAL AND SPIRITUAL: social and spiritual needs. MORE MEDICAL MODEL OF CARE/PHYSICAL NEEDS DOMINATE: physical needs (a tendency to dominate) more medical kind of focus in terms of systems). PATIENT-LED: focus on issues patient raised (as being problematic). PROFESSIONAL AGENDA AS A STRUCTURE: kind of a professional agenda as a structure (5)	NOT A SET THING: Not sort of a set thing. WHAT I'M COMFORTABLE WITH: but what I'm comfortable with having done the same way for a long time (5)
HCP 3	AIDE MEMOIRE (FROM HNA DOCUMENT/Framework USED BY MAGUIRE AND FAULKNER): Aide memoire (patient-led), taken from HNA document (AR's document). COVER ALL BASES: cover all the bases, start off saying (like Maguire and Faulkner) START WITH VERY OPEN QUESTION: "can you tell me about what's been going on?", very open question (HEAR PATIENT'S STORY: tell their story). FOCUS ON SOMETHING KEY COMING UP: if something key comes up (an issue), might focus on that. SOME DEGREE OF STRUCTURE: some degree of structure, covers: PHYSICAL: physical domains (specific questions). PSYCHOLOGICAL AND SPIRITUAL: psychological and spiritual (open question). EXPLAIN ROLES: explain my role. ASK WHAT'S HAPPENED: tell me about what's happened (TO BEGINNING OF DIAGNOSIS: back to the beginning of diagnosis). IMPACT OF ILLNESS: how it's impacting... (9) QUESTIONS ABOUT FUTURE: how they see the future. LEADING INTO QUITE HEAVY STUFF EARLY ON: can lead into quite heavy stuff quite early on. AIDE MEMOIRE USED AT END TO MAKE SURE COVERED ALL ASPECTS: use aide memoire at the end to go back to make sure covered other things, that haven't been structured (10)	AIDE MEMOIRE (FROM HNA DOCUMENT/Framework USED BY MAGUIRE AND FAULKNER): Aide memoire taken from HNA document (referring to Alison Richardson's document) (9). formulated from framework used by Maguire and Faulkner. (model for their assessment process), formulate GP and District Nursing Letters: a heading: patients' current understanding of diagnosis and prognosis, advanced statements, issues about DNAR, preference for end of life care, life goals, picking those things, going over all the domains. SPARC: SPARC is really good (10)
HCP 4	PROTOCOL (DEVELOPED BY TEAM MEMBERS): Protocol (two members of the team put together). USE REFERRAL FORM: part of our assessment (referral form). SUB-SECTIONS: sub-sections, address with each patient whether it's SPIRITUAL: spiritual. PSYCHOLOGICAL: psychological. PHYSICAL AND EMOTIONAL: physical and emotional. USE ADMISSIONS FORMAT: use format we have got for our admissions. ADDRESSES ALL ISSUES (FOUR THINGS MENTIONED): addresses all the issues of those four things. NOT STRUCTURED: not structured on info-flex. FAIRLY STRUCTURED: fairly structured (16)	PROTOCOL (DEVELOPED BY TEAM MEMBERS): Protocol (two members of the team put together). USE REFERRAL FORM: part of our assessment (referral form). sub-sections, address with each patient whether it's spiritual, psychological, physical and emotional. USE ADMISSIONS FORMAT: use format we have got for our admissions. addresses all the issues of those four things, not structured on info-flex, fairly structured. NO OTHER TOOLS USED: no (other tools used), that's the only thing (16)
HCP 5	A BRIEF OUTLINE (DEVELOPED BY TEAM MEMBERS)/ALL THINGS NEEDED TO COVER ON ASSESSMENT: A brief outline (put together by a member of the team/senior members) of all the things that you needed to cover with assessing patients. USED AS A GUIDE: used as guide. COVER ALL ASPECTS: cover all aspects. PHYSICAL: physical. PSYCHOLOGICAL: psychological. SOCIAL: social. SPIRITUAL: spiritual (22)	A BRIEF OUTLINE (DEVELOPED BY TEAM MEMBERS): A brief outline (when first started, put together by a member of the team/senior members) of all the things that you needed to cover with assessing patients, used as guide, cover all aspects of what's there. physical, psychological, social, spiritual (22)
HCP 6	DEPENDS ON PATIENT (PERSON-CENTRED): Person-centred, depends on the patient (ON	DEPENDS ON PATIENT (PERSON-CENTRED): Person-centred, depends on the

	MENTAL CAPACITY: on their mental capacity). SPARC AND DEMENTIA PATIENTS: e.g. dementia patients; you can't work with SPARC. NEED FULL MENTAL CAPACITY: ability to answer the questions (full mental capacity). USE SPARC: ASSESS MENTAL CAPACITY: in SPARC I will go through that process. PHYSICAL: on their physical needs. END-STAGE DEMENTIA: if haven't got mental capacity (end stage dementia). COMMUNICATION WITH STAFF: it will be communication with staff. FAMILY AND VISUAL ASSESSMENT OF PATIENT: family and visual assessment of patient. ELDERLY/FRAIL TOO MUCH TO ASK: elderly frail: sometimes too much to ask them. PRIORITISE WHAT'S IMPORTANT: prioritise what's important. ASSESS APPROPRIATENESS IN NURSING HOME PATIENTS/THOSE IMMINENTLY DYING: if in nursing home: sometimes imminently dying, some things aren't always appropriate (25)	patient (on their mental capacity), e.g. dementia patients; you can't work with SPARC, ability to answer the questions (full mental capacity). SPARC: in SPARC I will go through that process, on their physical needs, if haven't got mental capacity (end stage dementia): it will be communication with staff, family and visual assessment of patient, elderly frail: sometimes too much to ask them, prioritise what's important. If in nursing home: sometimes imminently dying, some things aren't always appropriate (25)
HCP 7	INTRODUCING A NEW MODEL/TEMPLATE: HNA (DEVELOPED FROM HNA DOCUMENT): Introducing (in new year) a model of using a HNA. COVER ALL ASPECTS: try and cover all aspects of the patient's care. SEXUALITY/SPIRITUALITY OFTEN OVERLOOKED: things like sexuality or spirituality, which tend to sometimes be a little bit overlooked. USE HNA DOCUMENT/TEMPLATE/MODEL: it's a document (HNA) published a while ago (30), template copied from the other model. HEADINGS: headings about PSYCHOLOGICAL: psychological assessment and SEXUALITY AND BODY IMAGE: sexuality and body image. END OF LIFE ISSUES: end of life issues. FAMILY AND SOCIAL: and all the family and social. COVER ALL ASPECTS NOT NECESSARILY ON FIRST ASSESSMENT: try and cover all this area, maybe not on the first assessment (33)	INTRODUCING A NEW MODEL/TEMPLATE: HNA (DEVELOPED FROM HNA DOCUMENT): Introducing (in new year) a model of using a HNA, try and cover all aspects of the patient's care, things like sexuality or spirituality, which tend to sometimes be a little bit overlooked, it's a document (HNA) published a while ago (30), template copied from the other model, headings about psychological assessment and sexuality and body image, end of life issues, and all the family and social, try and cover all this area, maybe not on the first assessment (33)
HCP 8	MAIN PART OF ASSESSMENT: FIRST VISIT: Biggest part of assessment: usually first visit. FOLLOW HNA FRAMEWORK (DOCUMENT): follow the HNA framework (document). OCCASIONALLY USE SYMPTOM MANAGEMENT TOOLS: symptom management tools (sometimes use). LES score for... neuropathic pain or, use a basic pain tool, NO OTHER GENERAL ASSESSMENT TOOLS: but no other general assessment tools. EXPLAIN ROLES: start explaining my role. OBTAIN ASSESSMENT CONSENT: getting consent to do assessment. CONSENT TO SHARE INFORMATION: to share information. ASSESSMENT SUMMARY (IN CERTAIN FORMAT): when writing up the assessment (certain format). PRIMARY DIAGNOSIS AND REFERRAL BACKGROUND: primary diagnosis and background to what's brought the person to this point. PATIENT-LED, PATIENT'S STORY: get their story, often don't have a lot of information, helps to understand where patients coming from, helps to put them at ease a little bit (patient-led) (35)	FOLLOW HNA FRAMEWORK (DOCUMENT): Follow the HNA framework (usually first visit). OCCASIONALLY USE SYMPTOM MANAGEMENT TOOLS: symptom management tools, sometimes use. LES score for... neuropathic pain or, a basic pain tool, NO OTHER GENERAL ASSESSMENT TOOLS: but no other general assessment tools (35)
HCP 9	NO DEFINITIVE METHOD: Current methods, assessing patients holistically is not definitive. NO PARTICULAR MODEL/TOOL: it's not a particular model, tool that we've used. COVERS ALL ASPECTS: covers every aspect of the patient. ASSESSMENT DOCUMENT: an assessment, document. OBTAIN PATIENT CONSENT (ASSESSMENT AND SHARING OF INFORMATION): ensuring patient gives consent, for passing on of information. DIAGNOSIS AND PHYSICAL: looking at diagnosis and physical needs. PSYCHOLOGICAL: psychological elements. SOCIAL: and social circumstances. MODEL BEEN BROUGHT UP WITH: model been brought up with. MORE RECENTLY PROFORMA: more recently, got a proforma, some (colleagues) definitely work to. SPLIT UP DIFFERENT SYMPTOM ISSUES: split up different symptom issues. PAIN: pain. DYSPNOEA: SYMPTOMS LISTED: dyspnoea all those things are listed. DETAILED DOCUMENT: detailed document. PSYCHOLOGICAL (NOT USING ANY CONSTRUCTED SCALE): then psychological assessment not using any constructed scale. PATIENT CONCERNS/ANXIETIES/FEARS: asking patient about their concerns, their anxieties, fears. SOCIAL CIRCUMSTANCES: then socially picking up on their circumstances and issues associated with that (38)	NO DEFINITIVE METHOD: Current methods, assessing patients holistically is not definitive. NO PARTICULAR MODEL/TOOL: it's not a particular model, tool that we've used, covers every aspect of the patient. ASSESSMENT DOCUMENT: an assessment, document, ensuring patient gives consent, for passing on of information, looking at diagnosis and physical needs, psychological elements, and social circumstances, model been brought up. MORE RECENTLY PROFORMA: more recently, got a proforma, some (colleagues) definitely work to (38)