Self-efficacy, self-management, and quality of life in people with a stoma.

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Intellectual property and publications

I, William Dewi Goodman, confirm that the work submitted is my own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Study One publication **(Chapter Two):**

Goodman, W., Allsop, M., Downing, A., Munro, J., Taylor, C., Hubbard, G., & Beeken, RJ. (2021). A systematic review and meta-analysis of the effectiveness of self-management interventions in people with a stoma. Journal of Advanced Nursing, 78(3), 722-738. doi:10.1111/jan.15085.

Contributions of all authors to **Study One:**

I (WG) developed the search terms for the review, which were reviewed by other authors (MA, AD, RJB). Another author and I screened the titles and abstracts and reviewed the full texts for eligibility (WG, RJB). I (WG) assessed the quality of all studies, conducted a narrative synthesis of those included and the meta-analysis. All authors made substantial contributions to conception and design, and interpretation of data. I (WG) drafted the manuscript, and all authors were involved in revising it critically for important intellectual content for submission to the Journal of Advanced Nursing.

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Contributions of all authors to **Study Two:**

I (WG) along with several of my coauthors contributed to the conception and design of this study (JM, TC, GH, RJB). A coauthor (JM) formatted the survey and I (WG) along with several coauthors recruited the respondents (JM, TC, GH, RJB). I (WG) developed the analysis plan for this study with contributions from my supervisors (AD, MA, RJB). I (WG) analysed the data. All authors made substantial contributions to the interpretation of data. I (WG) drafted the manuscript, and all authors were involved in revising it critically for important intellectual content for submission to Quality of Life Research.

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I (WG) conceptualised and developed the study methodology, with support from my supervisors (AD, MA, RJB). I (WG) formatted the surveys on Online Surveys and Ethica Data, and recruited all participants with support from various stoma-related charities. I (WG) developed the statistical analysis plan, with contribution from my supervisors (AD, MA, RJB), and performed the data analyses. All authors made substantial contributions to the interpretation of data. I (WG) drafted the manuscript, and all authors were involved in revising it critically for important intellectual content for submission to JMIR.

Conference abstracts

Study Two was accepted as an oral presentation at the European Health Psychology Society annual meeting 2022.

Thesis structure

The thesis has been structured and submitted as an alternative style of doctoral thesis which includes published material. There are a total of four studies included in the thesis. **Studies One** and **Two** have been published in peer-reviewed journals. At the time of submission **Study Three** is under review at Supportive Care in Cancer and **Study Four** has been prepared for submission to peer-reviewed journals. There is an introduction chapter proceeding the manuscripts, and a discussion chapter following the presentation of the studies, to bind the manuscripts into a coherent piece of work. The four studies included in the thesis have been presented exactly as published or submitted, except in minor cases where formatting has been amended to ensure the thesis is a coherent whole (e.g. table numbers, reference formatting). As per the guidance for an alternative style of doctoral thesis, each chapter contains its own list of references. An alternative thesis style was chosen as this approach can maximise the research outputs generated from a PhD. The alternative style of thesis is also aligned with the Graduate Board priorities at the University of Leeds, who encourage all postgraduate research students to publish and disseminate their PhD results.

Dedication

This is for my dad. One of my biggest supporters, who wanted to see me graduate in a ‘floppy hat’.

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Abstract

Following stoma formation surgery quality of life can be impaired. Although this can improve over time, people with a stoma still report quality of life lower than that of people without a stoma years after stoma formation. Self-management interventions have been devised to increase an individual's self-efficacy to self-manage their stoma and thus improve their quality of life. However, we do not know whether all people with a stoma experience quality of life in the same way and how individuals' experiences may differ. We also do not have an understanding of whether quality of life and self-efficacy can fluctuate from day-to-day and what factors influence this. Understanding these gaps in the research may help us to develop more tailored and adaptive self-management interventions in the future. **Study 1** was a systematic review of previous self-management interventions and identified some of the key characteristics of these interventions which were associated with improvements in quality of life, self-management skills and self-efficacy. **Studies 2 and 3** utilised secondary data of individuals with a stoma to identify quality of life derived profiles. Results suggest that people with a stoma are not a homogenous group in regard to their quality of life and the different profiles are associated with certain demographic and clinical characteristics and advice received from healthcare professionals. **Study 4** was an ecological momentary assessment study with repeated surveys 3 times a day over the course of a week. Findings suggest that quality of life and self-efficacy fluctuate within individuals, with quality of life increasing as the day goes on and self-efficacy higher when individuals are at home. The studies in this thesis contribute to a greater understanding of how future self-management interventions might be tailored to enhance an individual's self-efficacy and improve their quality of life. Dynamic and adaptive interventions should be considered to tailor the type of advice and support delivered at the right time for individuals living with a stoma.

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Abbreviations

IBD	Inflammatory Bowel Disease
QOL	Quality of life
NHS	National Health Service
SE	Self-efficacy
RCT	Randomised controlled trials
TIDieR	Template for intervention description and replication
BCTs	Behaviour change techniques
LPA	Latent profile analysis
EMA	Ecological momentary assessment
PPI	Patient and public involvement
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
NR	Not reported
CG	Control group
IG	Intervention group
ns	Non-significant
Stoma-QOL	Stoma Quality of Life Scale
SSES	Stoma Self-Efficacy Scale
SF-36	36-Item Short Form Survey
EORTC QLQ	The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
COH-QOL-O	The City of Hope Quality of Life Ostomy Questionnaire
DDQ-15	Digestive Disorders Questionnaire
SIBDQ	Short Inflammatory Bowel Disease Questionnaire
FACT-C	Functional Assessment of Cancer Therapy – Colorectal
ESCA	Exercise of Self-Care Agency
WHOQOL-BREF-HK	Hong Kong Chinese version of the World Health Organisation Quality of Life Measure – Abbreviated Version
SD	Standard deviation
F	F-test repeated ANOVA
Z	Mann Whitney U test
t	Independent sample t-test
MD	Mean difference

X^2	Chi-squared test
I^2	Percentage of variation across the studies that is due to heterogeneity
MOST	Multiphase optimisation strategy
PA	Physical activity
FAP	Familial adenomatous polyposis
SQoL	Stoma Quality of Life Scale
AIC	Akaike Information Criteria
BIC	Bayesian Information Criteria
ANOVA	Analysis of variance
N	Number of participants
M	Mean
OR	Odds ratio
CI	Confidence interval
CORECT-R	COloRECTal cancer data Repository
ASCN	Association of Stoma Care Nurses
CREMAS	An adapted STROBE Checklist for Reporting EMA Studies
β	Coefficient
ρ	Rho
JITAI	Just-in time adaptive intervention
MoA	Mechanism of Action
EMI	Ecological momentary intervention
MYMOP	Measure Yourself Medical Outcomes Profile

Chapter 1: Introduction

1.1 Stoma overview

A stoma is an artificial opening on the abdomen that has been created to divert the flow of faeces or urine[1]. There are three main types of stomas: colostomy, ileostomy and urostomy. This PhD is focussed on the experiences of people who have one of two bowel stomas; colostomy (an opening to the colon) and ileostomy (an opening to the ileum)[1]. Colostomies are normally formed on the right side of the abdomen and the output is generally expected to be between 1 to 3 times a day and look more like a common stool[2]. On the other hand, ileostomies are generally formed on the left side of the abdomen and operate more frequently at 3 to 6 times day with the output usually of a looser consistency[2]. However, this can vary from person to person.

A stoma can be permanent, where there is not enough bowel left to reconnect to the anus, or temporary, where a stoma can be reversed by a further operation. A reversal can be performed within months, but temporary stomas can remain for years[3]. Stomas are routinely formed in both elective and emergency surgeries which may determine whether the stoma is permanent or temporary, with emergency surgeries usually forming temporary stomas[4].

There are no global estimates for the number of people with a stoma, however, in Europe there are believed to be approximately 700,000 people living with a stoma, with 1 million in the United States and a further million living in China[5-7]. In the United Kingdom there are estimated to be over 200,000 people living with a stoma with around 21,000 stoma formation surgeries performed every year, of which 55 to 64% are believed to be permanent[8, 9]. Colorectal cancer is the foremost reason for stoma formation surgeries with estimates from the UK and Sweden suggesting that between 25 to 32% of people who undergo surgery for rectal cancer will have a stoma formed[10, 11]. Inflammatory bowel disease (IBD) and diverticular disease are the biggest non-cancer reasons for stoma formation[12]. Stomas can also be formed for other reasons such as physical trauma, incontinence and familial adenomatous polyposis[1].

Over the past few decades, people with chronic illnesses have been living longer, due to improvements in living conditions, treatment and prevention[13]. Chronic illnesses can have a long-lasting, negative impact upon a person's life due to ongoing treatment and management of their condition: this can be understood by measuring the impact on an individual's quality of life (QOL). While stomas themselves are not a chronic illness, they are a form of treatment for many chronic illnesses, including colorectal cancer, IBD and diverticular disease, and, in certain circumstances, can be a lifelong form of treatment[1]. Therefore, stomas have been characterised as a form of chronic care[14]. With the rise in annual stoma formation surgeries in the UK increasing by around 7,500 in the last two decades[15, 16] it is imperative that we explore the QOL of this under-researched population.

1.2 Quality of life

1.2.1 Definitions of quality of life

QOL is increasingly viewed as an important indicator of successful treatment and management of health conditions, not only by individuals but also by the UK National Health Service (NHS)[17]. Developing an understanding of peoples’ QOL is seen to be key to evaluating interventions that are designed to improve symptoms, care, and recovery[18]. Indeed, self-reported QOL is progressively used to identify areas of modification for interventions or treatment, or to abandon those with poor outcomes and as such has become a key factor in clinical decision-making[18, 19].

Currently, there is no consensus on a definition for QOL, which can vary within and between disciplines[18]. As such there are several different definitions that could have been used in this thesis. The World Health Organisation broadly defines QOL as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”[20]. Health-related QOL is a subset of QOL focussed on the impact of health conditions on daily functioning, disability and the individual’s ability to live a fulfilling life[21]. A definition of health-related QOL put forward is that it is broadly a state of well-being comprised of 2 components of being able to perform everyday activities and the individuals satisfaction with the control of the disease and effects of the treatment[22]. Another definition suggests that it is the individuals own perception of their physical and mental health over time[23]. While a further definition has suggested that health-related QOL is associated with the effect of a disease or treatment of a condition on an individual and encompasses “physical and occupational function, psychological state, social interaction and somatic sensation”[24]. QOL in terms of an individual’s health can be viewed as a multidimensional construct covering four broad health dimensions of physical (symptoms and treatment side-effects), social (social contact and interactions), mental (well-being and psychological distress) and functional (physical and social functioning)[25]. Without consensus on the definition of health-related QOL, this PhD will consider QOL in broad terms as set out in the definitions above related to health, and which take into account the impact on all aspects of an individual’s daily life.

1.2.2 Quality of life amongst people with a stoma

Following stoma formation surgery QOL can be impaired in people with a stoma. Cross-sectional research amongst those with rectal cancer (N=453) in Sweden has found that compared to those without a stoma, those with a stoma report lower levels of QOL across multiple dimensions including mental health, body image, and physical and emotional functioning[26]. A review of 17 cross-sectional studies comparing QOL in people with and without a stoma from cancer also found that those with a stoma reported higher levels of psychological distress, more impaired social functioning, and greater impairment in sexual function[27]. However, this review did also highlight that the results from the existing literature were not entirely consistent. There was no formal evaluation of the studies included in the review, but all studies were cross-sectional and there was a lot of variation in the time that had elapsed from surgery with anywhere between 1 and more than 10 years post-surgery. A more recent study amongst people with Crohn’s Disease found no difference in overall QOL between those with and without a stoma but did find impaired social role satisfaction in those individuals with a stoma[28].

Longitudinal research amongst individuals with colorectal cancer that have been followed up for 5 years suggests that if differences in QOL are observed, the differences between people with and without a stoma can remain[29, 30]. This research suggests that those with a stoma continue to have higher levels of depression, body image concerns, lower levels of physical and role functioning, and lower overall QOL at follow-up compared with those without a stoma[29, 30]. However, there were no statistically significant differences between those with and without a stoma in other scores on emotional, cognitive, and social functioning scales as well as symptoms around insomnia, nausea and vomiting, and pain[29, 30].

However, there is also research to suggest that there may be individual differences in how people experience their adjustment to having a stoma post-surgery. A cross-sectional study of 391 people with a stoma conducted a retrospective survey of their QOL post-stoma formation surgery[31] found a bimodal distribution in QOL responses, with people either reporting high QOL or very low QOL. However, this study relies on retrospective recall, up to 37 years post-surgery in some cases, which may make their responses less reliable when recalling how they felt at the time. Nonetheless, it is one of the only studies to date to explore potential differences in reported QOL as opposed to considering the participants as a homogenous group in relation to this, and it may suggest that there may be a group of people that require additional support[31]. QOL is a multidimensional construct, yet within this population there has been no research to statistically identify whether there are subpopulations who have different patterns of experience based upon the domains of QOL.

1.2.3 Factors impacting on quality of life

Individual experiences in QOL may be influenced by various factors. Stoma formation surgery, while helping to manage the individual's illness, requires adaptation to a new daily life and can lead to complications that need to be managed[32]. These factors can impact upon the QOL of the individual and be physical (related to the stoma itself or the stoma appliance) or social and psychological in nature. There is also emerging research that suggests that the demographic and clinical characteristics of an individual can be associated with their QOL.

1.2.3.1 Impact of physical factors

Physical factors that impact upon the QOL of a person with a stoma can be split into appliance-related complications (i.e., those associated with using the stoma bag) and stoma-related complications (i.e., those associated with the physical problems caused by the stoma). People with a stoma will have to cope with appliance-related complications including ballooning (when gas is expelled through the colon into the bag causing it to inflate), pancaking (where the motion collects around the stoma and may seep out between the adhesive and the skin), leakages, and odour[33]. A non-systematic review of 30 studies[34] and a systematic review of 14[35] studies found that appliance-related complications were negatively associated with overall QOL. However, the two longitudinal studies identified in the systematic review[35], only considered people with a stoma from colorectal cancer when compared to without a stoma from colorectal cancer which limits generalisability to the wider stoma population[36, 37].

Individuals can suffer a number of complications related to their stoma, with complication rates ranging from 20-70%[38]. These complications can be grouped into early and late complications, with early complications comprising of necrosis, retraction, peristomal skin irritation (from leakages) and peristomal infection[39] and late complications comprising of parastomal hernias, prolapse and stomal stenosis (narrowing of the stoma)[40]. Early complications usually occur during the first 2 months of having a stoma, however, skin irritation caused by leakages can be an ongoing issue. In a cross-sectional study[41] of US veterans peristomal skin irritation was found to be associated with a lower QOL. These findings were further supported in a study of community-dwelling adults that found that those with frequent peristomal skin irritation was associated with lower QOL scores across physical, social and psychological subscales as well as the overall QOL scale[42]. Treatment of some of the complications, including stoma necrosis, retraction and prolapse may necessitate emergency surgery to correct the problem which research has suggested is associated with lower levels of QOL compared with elective surgery[43].

Parastomal hernias are one of the most common complications for people with a stoma, with incidence estimates ranging from 32% at 12 months post-surgery to 58% at 7 years[44]. Parastomal hernias are rated the top stoma-related complication research priority by people with a stoma[45]. They can cause pain, bowel obstructions or present difficulties in managing the stoma appliance increasing the risk of leakages[38]. Cross-sectional studies have found a negative association between the presence of a parastomal hernia and QOL measures in the domains of physical functioning, pain, general health, symptom load, worry and an overall sense of well-being [46, 47].

The current research into the physical factors that impact upon QOL in people with a stoma has mostly been conducted in cross-sectional studies. These studies can only provide us with a sense of their QOL in that one moment, however, many of the stoma complications that occur most often are transitory and the effects of them on QOL may not last. They also cannot help us to determine causality as to whether the complications caused the lower QOL or whether those individuals already had low QOL. Therefore, the QOL that participants report in these studies may bear no relation to past complications that they also report. This is important for us to know in designing effective interventions for individuals to self-manage their stoma. Furthermore, the few longitudinal studies that have been conducted are also limited by providing us with a changing view of QOL months apart when transitory complications (e.g. leakages, pancaking, ballooning) could impact QOL within a much shorter period of days or hours.

1.2.3.2 Impact of social and psychological factors

Alongside the impact of physical factors on QOL, people with a stoma also report additional social and psychological factors that can have a negative impact on their QOL. Sexuality and body image are key components in QOL for people with a stoma[48], post-surgery these can be impacted with some women reporting pain during intercourse and men struggling with erectile dysfunction[49]. A non-systematic review of 30 studies[34] and a systematic review of 17[27] studies have provided evidence that the presence of a stoma can negatively impact the sexuality domain of QOL. More recent non-systematic reviews of the literature have suggested that this association could be linked to the change in the individual’s perception of their body image, as they believe that they are not sexually attractive, with one study reporting that 75% of respondents reported their body image as ‘very low’[50, 51]. Additionally, findings from one of these reviews also suggest that the relationship people with a stoma have with their partner could play a moderating effect if they have a strong bond and their partner is supportive, as they are more likely to return to a sexual relationship quicker[50]. These findings suggest a complicated view of QOL in the domains of sexuality and body image. However, the quality of the studies in these reviews was not assessed and there is a lack of detail provided on the studies themselves which inhibits our ability to appropriately weigh the evidence provided. While the present research has suggested that changing body image perceptions and partner relationships could have an impact on QOL, it also suggests that not every person with a stoma may share the same experience. Therefore, exploring whether there are different subpopulations of people with a stoma based upon their patterns of QOL could allow us to identify the characteristics of the individuals that are more in need of additional support for certain QOL domains.

People with a stoma also report issues with social situations post-surgery[52]. Some people with a stoma have fears of being stigmatised by family and friends and as a result attempt to conceal their stoma from them either by withholding information or withdrawing from social situations and recreational activities altogether[53-55]. High levels of perceived stigma have been found to be negatively associated with ostomy adjustment, which in turn is associated with QOL in people with a stoma[56-58]. Research has also suggested that socialising post-surgery raises additional concerns for individuals related to travel and awareness of the closest toilet facilities[35, 52]. The additional layers of complexity involved in being in social settings outside the home can have a negative influence on QOL[27, 28, 35]. However, the research on the impacts of having a stoma in social situations is based on retrospective interviews or surveys which can introduce recall bias into the data[59]. In order for us to be able to evaluate the true impact of these social situations on QOL in people with a stoma, we need to gather data in the moment.

1.2.3.3 Impact of demographic and clinical characteristics

There is emerging research to suggest that ratings of QOL are associated with demographic and clinical characteristic of people with a stoma. A systematic review of 6 studies investigating demographic characteristics associated with QOL in people with a stoma from colorectal cancer found that amongst the 5 studies that looked at gender all found an association with being female and lower QOL scores[60]. There was some evidence to suggest that age may play a role with 2 of the 5 studies that investigated this link finding an association with being younger and lower QOL scores, although 1 study did find that a sexual function subscale was better in those that were younger[60]. But there was no significant association between QOL and socioeconomic status in the 2 studies that investigated this[60]. However, these findings should be treated with caution as the included studies have small samples, and are only conducted in people with a stoma from colorectal cancer.

Clinical characteristics such as the underlying disease requiring the formation of a stoma have also been suggested as being associated with QOL. A further cross-sectional study (N=102) from the previous systematic review[35] suggests that there is mixed evidence that those who had their stoma formed due to cancer may have poorer QOL in the physical function domain but higher scores in spiritual domain of QOL[61]. Furthermore, those that had a temporary stoma formed were more likely to have greater physical and spiritual domain QOL scores and overall QOL scores, than those who had a permanent stoma[61]. A prospective study (N=408) has also suggested that having an ileostomy rather than a colostomy may also be linked to lower QOL scores, this is suggested to be due to higher rates of leakages and more disturbed sleep compared with people that have colostomies[62].

These findings suggest a complicated relationship between demographic and clinical characteristics and QOL, with some contradictory findings or many other studies finding no statistically significant associations at all[35, 60, 61]. Moreover, while there is a systematic review of the association between QOL and demographic characteristics this is only within those with a stoma from colorectal cancer and there are no reviews that synthesise the studies which report the association between QOL and clinical characteristics. This suggests that more research is needed in this area. Furthermore, although the research has identified that different characteristics may have varying influences on aspects of QOL there has been no research to understand the interaction between various QOL domains and people’s characteristics. While analysis of overall QOL can provide us with an overview of how a person is feeling, we lose specificity to understand where problems may be occurring. Similarly, by analysing the domains of QOL separately we lose an understanding of how they interact.

1.3 Self-management

The majority of interventions seeking to improve QOL for people with a stoma have focused on self-management because this is seen as a key modifiable factor which can influence QOL. Research has suggested that QOL is positively influenced by individuals’ ability to manage their stoma, with a higher level of skills associated with better stoma function and less social and work issues[63-65]. Following stoma formation surgery individuals have to adjust to their stoma which involves a number of self-management behaviours including; learning how to clean it, changing their appliance, coping with complications, and learning what they can eat and what activity they can do[66]. Interventions have therefore been developed to aid individuals prior to or following surgery to help them self-manage their stoma and to avoid complications.

1.3.1 Definition of self-management

There is no consensus on the definition of self-management, it was first termed in the 1960’s to suggest that people are active participants in their own treatment[67]. Since then the definition has been expanded and the term self-management is often used interchangeably alongside other terms such as ‘self-care’, ‘patient education’ and ‘self-regulation’[68]. However, self-management itself is seen as more than simply providing education to patients to increase their knowledge[68]. Furthermore, self-care is thought to be associated with supporting individuals to prevent ill health rather than the management of a condition and self-regulation is concerned with an individual’s ability to control behaviours and emotions[68]. One definition of self-management suggests that it covers 3 specific tasks of medical, behavioural and emotional management of a chronic illness[69]. Another definition proposes that self-management is both complex and dynamic consisting of three dimensions of context (condition specific, the physical and social environment and individual and family factors), process (knowledge and beliefs, self-regulation and social facilitation) and outcomes (proximal, engaging in treatments, activities or health behaviours which lead to distal outcomes of QOL, and health status)[70]. For the purposes of this PhD a broad definition of self-management has been adopted; the ability of the individual to manage their chronic condition (including treatment, symptoms and health behaviour) in an effective way to maintain optimal QOL[71].

1.3.2 Self-management interventions

Self-management interventions are increasingly being utilised in the healthcare system in recent years due to people living longer with chronic illnesses[71]. As the relationship between doctor and patient has transitioned from a more passive role on the part of the individual to one where they are at the centre of their own care, self-management interventions have become increasingly popular[72]. A core part of these interventions is to impart the skills and knowledge for the individual to manage their illness but also to impart confidence in being able to perform the behaviour. It has been suggested that self-efficacy (SE), no matter the chronic condition, is important to the management of the condition and therefore is integral to the success of self-interventions[73, 74]. Self-management interventions have been found to improve QOL at 6 and 12 months in other groups such as: chronic heart failure, chronic obstructive pulmonary disease and diabetes mellitus type 2[75].

Within the UK, clinical stoma nurse specialists are responsible for educating individuals post stoma formation surgery on how to self-manage their stoma[76] there is currently no research to suggest what advice they wish to receive or are receiving as part of their care. However, a pilot survey of 225 people who currently had a stoma, or had one at some point, found that self-management concerns around pouch leakages, pain, odour and skin irritation were considered top research priorities[45]. This suggests that these concerns are not being entirely tackled by the current care model.

In people with a stoma there have been three systematic reviews investigating various aspects of self-management interventions. These self-management interventions are heterogenous, providing content which covers the practical management of the stoma and the appliance; how to cope with stoma complications; how to adjust to everyday life; the impact on family, work, and social life; dietary and lifestyle adjustments; and coping with the psychological implications. Danielsen et al.[77] identified 7 eligible studies and concluded that they had a positive effect on patient outcomes. In terms of psychosocial outcomes, they found that in the 2 studies that measured QOL it was significantly improved post-intervention and SE and adjustment to the stoma were also significantly improved in the 2 studies that measured them. In regard to stoma skills and knowledge they found that these were both improved as well. Health system outcomes were also improved, they found that time until discharge was shortened, and the interventions were more cost effective than control conditions. However, the majority of the studies included within the review were a pre-post design or relied on retrospective data and the quality of the included studies was not assessed. A further review by Phatak et al.[78] identified 7 eligible articles which found mixed results for the effect of the interventions on length of stay in hospital and complications and no effect on readmission rates. The final review by Faury et al.[79] identified 13 eligible studies, of which 5 measured QOL. Significant increases in QOL after the self-management intervention were found in only 3 of the studies. These mixed findings were replicated across other outcomes, including psychosocial and self-management skills, stoma complications, length of hospital stay and readmissions. Taken together, these reviews suggest that the self-management interventions developed for people with a stoma are having mixed effects. However, the quality of the included studies was rated as low or unclear for the 2 reviews that measured this, and all reviews included studies with weak designs including pre-post analyses or retrospective cohorts[77-79]. Furthermore, not all studies measured QOL, self-efficacy or self-management skills, which are important in being able to judge the effectiveness of these types of interventions.

These systematic reviews provide an overview of the effect self-management interventions have on a number of healthcare system and individual-level variables. However, the quality of the included studies is low and there is no requirement on the standard of the methodology included. To understand the effect that the interventions are having on QOL and SE, we need to synthesise the data from randomised controlled trials (RCT) so that we are drawing conclusions from studies utilising the strongest methodology. Furthermore, in order to understand why these interventions have such variable effects, we need to explore the intervention components, including the characteristics of the intervention as outlined in the template for intervention description and replication (TIDieR) checklist[80]. This includes the mode of delivery for the intervention, who conducted the intervention and the intensity of the intervention. There is also an increasing amount of research investigating the role that theory plays in underpinning these interventions and the behaviour change techniques (BCTs) used[81].

1.3.2.1 Theoretical basis for self-management interventions

The previous reviews of self-management interventions have suggested mixed effects on QOL, SE and self-management skills in people with a stoma. In order to enhance these interventions, there is a need to understand the behaviour of the individuals and the behaviour change these interventions are trying to affect. Behaviour change theories can be useful by providing a framework through which specific constructs are proposed to influence behaviour and can suggest which strategies are most effective in bringing about behaviour change[82]. This would suggest that intervention development should have a theoretical underpinning. However, reviews of behaviour change interventions have suggested that between 36% and 95% of interventions do not have a theoretical basis[83-85].

There have been several reviews that have been conducted to investigate whether a theoretical basis to an intervention is associated with improvements. A number of reviews for interventions using the internet for behaviour change, HIV prevention in adolescents, dietary change for cancer prevention, fruit and vegetable intake for children and self-management for stroke survivors have found that those with a theoretical basis are more effective than those without[86-90]. One review of interventions to promote a healthy diet in primary care found mixed results with those with a theoretical underpinning showing positive effects for fruit and vegetable intake but those without having a greater effect in reducing fat intake[91]. There are also reviews that have found no difference between interventions with and without a theoretical underpinning in dietary and physical activity in the general population, limiting gestational weight gain, self-management for young people with Type I Diabetes and the prevention and control of communicable diseases[92-95].

While reviews amongst people with a stoma have considered the effect of self-management interventions on both patient-centred outcomes and health system outcomes, they have not identified whether these interventions have been developed with a theoretical basis[77-79]. The previous reviews that have looked at whether there is a theoretical basis for interventions in other populations have found that those that do could be more effective than those without[86-90]. Therefore, we should seek to determine to what extent interventions for people with a stoma have a theoretical basis and which specific theories they are using.

1.3.2.2 Behaviour change techniques

Self-management interventions are complex with a myriad of interacting components, unfortunately there are consistently issues with reporting these interventions[96]. There have been calls for more precision in how components of self-management interventions are reported[97]. Behaviour change techniques (BCTs) are considered ‘active ingredients’ in interventions that are designed to modify behaviour, which can be used individually or in concert with other BCTs[98]. There have been several attempts to classify BCTs, however, in order to move to a comprehensive system with consensus across experts a Delphi-type exercise was conducted[81]. This consisted of 3 stages: creating a list of distinct BCTs and defining them; having multiple experts use the list to code interventions and comparing the reliability; and finally developing a hierarchical structure. The final taxonomy of BCTs consisted of 93 BCTs across 16 different groupings. **Table 1.1** outlines the groupings and individual BCTs of the BCT Taxonomy (v1). This Taxonomy has recently been updated into the Behaviour Change Technique Ontology which covers 281 BCTs across 20 different groupings[99].

Associated strengths with the development of this taxonomy were that it would aid in intervention development as there would be a comprehensive list of BCTs to draw upon rather than just those the researchers could think of to include[81]. Furthermore, its use combined with systematic reviews and meta-analytic techniques would allow for identification of the most effective BCTs[81]. As such, this taxonomy has been applied in reviews of interventions for other populations. In a systematic review of 48 studies of interventions for people affected by overweight and obesity they found that the BCTs of goal setting and self-monitoring of behaviour were predictive of short- and long-term effects on diet and physical activity, as was increasing the number of BCTs used in the interventions[100]. Furthermore, a systematic review of 19 studies of interventions for people with Type II Diabetes found that 90% of effective interventions included the BCTs of social support, goal setting, feedback on behaviour, and self-monitoring of outcome of behaviour[101]. The effective interventions were also likely to include 3.7 more BCTs on average than those that were not effective.

Table 1.1: The Behaviour Change Techniques Taxonomy (v1). Adapted from Michie et al.[81]

Grouping	**Behaviour change techniques**
Goals and planning	Goal setting (behaviour); problem solving; goal setting (outcome); action planning; review behaviour goal(s); discrepancy between current behaviour and goal; review outcome goal(s); behavioural contract; commitment
Feedback and monitoring	Monitoring of behaviour by others without feedback; feedback on behaviour; self-monitoring of behaviour; self-monitoring of outcome(s) of behaviour; monitoring of outcome(s) of behaviour without feedback; biofeedback; feedback on outcome(s) of behaviour
Social support	Social support (unspecified); social support (practical); social support (emotional)
Shaping knowledge	Instruction on how to perform the behaviour; information about antecedents; re-attribution; behavioural experiments
Natural consequences	Information about health consequences; salience of consequences; information about social and environmental consequences; monitoring of emotional consequences; anticipated regret; information about emotional consequences
Comparison of behaviour	Demonstration of the behaviour; social comparison; information about others' approval
Associations	Prompts/cues; cue signalling reward; reduce prompts/cues; remove access to the reward; remove aversive stimulus; satiation; exposure; associative learning
Repetition and substitution	Behavioural practice/rehearsal; behaviour substitution; habit formation; habit reversal; overcorrection; generalisation of target behaviour; graded tasks
Comparison of outcomes	Credible source; pros and cons; comparative imagining of future outcomes
Reward and threat	Material incentive (behaviour); material reward (behaviour); non-specific reward; social reward; social incentive; non-specific incentive; self-incentive; incentive (outcome); self-reward; reward (outcome); future punishment
Regulation	Pharmacological support; reduce negative emotions; conserving mental resources; paradoxical instructions
Antecedents	Restructuring the physical environment; restructuring the social environment; avoidance/reducing exposure to cues for the behaviour; distraction; adding objects to the environment; body changes
Identity	Identification of self as role model; framing/reframing; incompatible beliefs; valued self-identify; identity associated with changed behaviour
Scheduled consequences	Behaviour cost; punishment; remove reward; reward approximation; rewarding completion; situation-specific reward; reward incompatible behaviour; reward alternative behaviour; reduce reward frequency; remove punishment
Self-belief	Verbal persuasion about capability; mental rehearsal of successful performance; focus on past success; self-talk
Covert learning	Imaginary punishment; imaginary reward; vicarious consequences

These reviews indicate that across multiple different populations identifying the BCTs that are used in effective interventions can be beneficial. By identifying the BCTs they have provided future researchers with a list of key BCTs to include when designing interventions for these populations. However, there are criticisms of this Taxonomy in that it simplifies behavioural interventions when there is substantial variation in people's behaviour[102]. It does not take into account the gap between beliefs and behaviour of the health professional and participant, the beliefs of the health professional and the training they received, or the gaps between the intervention protocol and how it was implemented[102]. There is also a reliance on authors reporting accurately the BCTs that were used within the interventions, which when restricted by word counts may be missed. Despite this, identifying the BCTs that have been used within self-management interventions for people with a stoma could be of benefit to future researchers in the field by providing an initial basis in relation to what might work or not.

1.3.2.3 Self-efficacy and quality of life

There is growing evidence to suggest that an individuals perceived SE in coping with chronic conditions is an essential aspect of effective self-management and is a target for many BCTs[81, 103]. SE is a psychological term that was first defined by Bandura and included as a concept when he outlined Social Cognitive Theory in 1986[104]. This theory suggests that learning occurs within a social context, it takes into account prior behaviour, cognitions, and both the physical and social environment in which an individual finds themselves in. SE relates to an individual's confidence in being able to carry out a certain behaviour successfully, this is based upon an individual's perceived abilities as well as barriers and facilitators within the environment. This concept has been adopted by multiple other health behaviour theories, including the Theory of Planned Behaviour[105], the Transtheoretical Model[106] and the Health Action Process Approach[107]. It has also become a key measure in assessing participants confidence to perform different behaviours to manage health conditions in evaluations of self-management interventions[108]. More recently, SE (beliefs about capabilities) has been identified as one of 26 different mechanisms of action (MoA) which are components of interventions that can change an individual's behaviour[109]. Other MoAs could be used amongst people with a stoma to encourage self-management behaviour, such as self-regulation (behavioural regulation), an individual's ability to control or adapt their behaviour to reach their goals[110]. However, the research amongst people with a stoma has primarily focussed on measuring SE as a MoA, with several systematic reviews of self-management interventions including this as an outcome[77-79].

Bandura reasoned that higher levels of SE corresponded with a greater commitment and motivation which can facilitate changes in health behaviours and can aid individuals in overcoming barriers and adjustment when trying to adopt health behaviours[111, 112]. It has been hypothesised that increasing SE for self-management in individuals with chronic conditions improves health outcomes including QOL[113].

Research in people with a stoma provides support for this hypothesis. A cross-sectional study amongst 75 people with a stoma over the age of 60 explored the correlation between SE to self-manage and QOL and found a strong positive correlation between the two ($r=0.79$)[114]. An additional cross-sectional study of 84 people with a stoma found similar results with SE to self-manage highly correlated with multiple domains of QOL; physical (r=0.49), psychological (r=0.66), and social (r=0.69) and overall QOL (r=0.69)[115]. Furthermore, a cross-sectional study of 96 people with a stoma found that both the stoma SE to self-manage subscale and social SE subscale were correlated with subscales of the Short Form Health Survey 36[116]. The weakest correlations were found with the subscale on limitations due to physical health problems (stoma SE, r=0.23; social SE, r=0.21) conversely the strongest correlations were found for physical functioning (stoma SE, r=0.56; social SE, r=0.49) and general health (stoma SE, r=0.49; social SE, r=0.57). While this research suggests that SE to self-manage could be a key mechanism to include in self-management interventions to ensure that QOL is enhanced, there is a lack of research as to how SE to self-manage could be influenced in people with a stoma. Similarly, our current understanding of QOL in this population, our understanding of the relationship between SE and QOL is provided by small, cross-sectional studies. There is research to suggest in other populations that QOL and SE may not be stable constructs and can change over shorter periods of time, for example over hours or days[117-121]. Therefore, research is also needed to explore the temporal variation of SE in people with a stoma, as if this fluctuates over shorter periods of time then interventions should be designed to support SE within situations that this may be affected.

1.4 Methodological approaches for addressing gaps in the literature

Gaps have been identified within the literature which, if addressed, could provide a greater understanding of SE and QOL amongst people with a stoma. Firstly, the majority of the research into QOL in people with a stoma has treated them as a homogenous group and has not considered that people may have different experiences. One technique that could address this is latent profile analysis (LPA). LPA allows for the identification of subpopulations based upon responses to certain variables such as the domains of QOL. LPA could provide a way to identify similar groups of people based upon the various domain specific QOL scores, and then explore associations with participant characteristics[122]. This technique could provide us with information on how we can better tailor and target interventions to people with a stoma, providing more individualised care which is the aim of the NHS' Long Term Plan from 2019[17, 122]. This plan from the NHS outlined how the health service would enable people to have more control over their own health through the increased use of digital technology and boosting out-of-hospital care. While we could conduct a series of individual regression analyses with each of the separate QOL domains, LPA provides specificity to QOL concerns and the interaction between the different domains.

Furthermore, much of the research in this area to date is either cross-sectional or prospective studies with long follow-up periods. Both of these designs limit our understanding of QOL and SE either to one time point or they do not provide us with an understanding of how these concepts could fluctuate from moment to moment. One way to deal with these limitations is through the use of an intensive longitudinal design utilising an ecological momentary assessment (EMA) approach to data collection[123]. EMA involves the repeated surveying of participants asking them to rate their behaviours, thoughts, attitudes or feelings in the moment that they are responding. If we apply this approach in people with a stoma, we would be able to gain an understanding of potential short-term fluctuations in QOL and SE. EMA could provide us with ecologically valid data on individuals QOL and SE by surveying participants in the moment and eliminating the risk of recall bias[123]. Furthermore, as this approach involves participants completing repeated surveys over a short period of time it would allow observation of how participants QOL and SE can change in various situations[123]. This understanding would allow us to develop more directed interventions that could provide advice on how to enhance QOL and SE in the contexts in which they are lower.

Another method which could be used to address these limitations is by using the day reconstruction method (DRM)[124]. DRM combines aspects of EMA and time-budget measurement by asking participants to reconstruct how they were feeling in the preceding day with techniques designed to reduce recall bias[124]. This method is argued to still provide ecologically valid data while also allowing for more flexibility of when participants can complete the measures[125]. However, research has found that while the DRM can track findings from EMA studies when averaged over time, they are not as accurate at the individual timepoint level and so where feasible EMA is better at collecting situation-specific data[126].

1.5 Patient and public involvement

Traditional methods of research development and conduct of projects involve researchers working alone[127]. However, patient and public involvement (PPI) in research is growing in importance and is seen as a key aspect at all stages in research projects[128]. PPI can inform various aspects including the type of research that is conducted, how it is conducted, and how the research is disseminated and applied in practice[129]. PPI is also able to provide lived experience to enhance the research which goes beyond the ability of the research team to provide [129]. There is a belief that PPI may be beneficial in reducing ‘research waste’, where irrelevant research questions to healthcare professionals and patients are asked, inappropriate study designs are conducted; findings are not published; or select findings are published[130]. Engaging in PPI and with other parties with practical experience with the topic may help to eliminate ‘research waste’[131].

Due to the evidence suggesting the informative benefits of incorporating PPI and the increasing requirement from funders for the involvement of PPI in research, this PhD drew on the expertise of relevant stakeholders within the field[132]. I put together a steering committee for this PhD to advise on various aspects of the included studies. The committee was comprised of 6 individuals: 2 people with a stoma (male and female), 2 stoma care nurses, a representative from a charity which represents people with a stoma (and had a stoma themselves), and a representative from a stoma care company. While the group may not have provided a fully diverse range of views, they provided views on all aspects of the care continuum and the ongoing effects of having a stoma.

1.6 Summary

Research to date has provided us with an overview of the factors, physical, social and psychological as well as demographic and clinical characteristics, that can impact QOL post stoma formation surgery. There has also been some research to suggest that self-management interventions could play a role in improving QOL by enhancing SE. However, there are a number of gaps and limitations with the current research.

Previous reviews have found that self-management interventions have mixed effects on QOL, SE and self-management skills. However, the quality of the studies that have been included in these reviews is low with pre post or non-randomised designs used. There is therefore a need for a review which identifies and synthesises the data from RCTs. Furthermore, due to the complexity of self-management interventions there is a need to identify the characteristics of the interventions which have beneficial effects. This includes the mode of delivery, who conducted the intervention, and the intensity of the intervention; as well as the theoretical underpinning of the interventions and the behaviour change techniques that were used.

We also do not currently know whether people with a stoma are a homogenous group in regards to their QOL. There may be subpopulations of people with a stoma based upon their QOL who may need bespoke interventions. Nor do we know whether there is a difference in the type of advice people would like to receive to help manage their stoma and complications. Understanding these factors could be key to developing more tailored interventions, which is a focus of the NHS ‘Long Term Plan’[17].

However, in order to optimise the chances of success of these interventions there is also a need for a more detailed understanding of the day-to-day experiences of QOL and SE in this population. The current research investigating QOL and SE in this population is mostly cross-sectional, which limits our understanding of its temporal nature. Furthermore, our understanding of self-management amongst people with a stoma primarily comes from interventions to improve self-management and SE in order to improve people’s QOL. It is therefore important to examine peoples’ QOL and SE in their day-to-day lives, independently of interventions, and whether there are certain variables that influence this.

This PhD will attempt to address the gaps and limitations in the current research by employing novel and advanced quantitative methods; LPA and intensive longitudinal methods utilising an EMA approach. This PhD will draw upon existing large datasets to fill the gaps in the research. Through the use of these methods, alongside additional insights from a systematic review and meta-analysis, we can better understand how existing self-management interventions improve QOL, SE and self-management skills; identify those who are likely to have lower QOL; understand what kind of advice they have received and would like to receive; explore the variation of QOL and SE from day-to-day; and investigate whether contextual factors (time of day, company, location and activity) are associated with QOL and SE. Together the results from these studies may help us to develop more tailored, dynamic and effective interventions to help people with a stoma enhance their SE to self-manage and thus increase their QOL.

1.7 Aims and objectives

The overall aim of this PhD is to explore and better understand SE, self-management and QOL in people with a stoma to inform the development of future self-management interventions.

The aim will be addressed by three key objectives:

1. To undertake a systematic review and meta-analysis of self-management interventions in people with a stoma to identify the intervention characteristics associated with improvements in SE, self-management skills and QOL.
2. To use LPA to identify subgroups of individuals with a stoma based upon their self-reported QOL and identify the members of these groups based upon their demographic and clinical characteristics, behavioural factors and advice received and interested in.
3. To use EMA to investigate the day-to-day variability of SE and QOL and assess whether contextual factors (activity, location, company and time of day) are associated with this variability.

The thesis aims to answer these research questions:

1. Who are the individuals that are likely to require support to enhance their SE, improve their self-management and increase their QOL? (Studies 2, 3 and 4)
2. What is needed to support individuals with a stoma to improve their SE, self-management skills, and QOL? (Studies 1, 2 and 3)
3. In what contexts might individuals most need support to enhance their SE and improve their QOL? (Studies 1, 2, 3 and 4)

1.8 Thesis overview

A review of the literature was conducted first to synthesise the evidence from previous self-management interventions. **Chapter 2** outlines a systematic review and meta-analysis of randomised controlled trial self-management interventions for people with a stoma that reported a measure of QOL, SE or self-management skills. The review also built upon previous reviews by investigating associations with improvements in these outcomes with intervention characteristics, behaviour change techniques and whether the intervention was grounded in theory.

Chapters 3 and **4** outline research to identify groups of people with a stoma based upon their self-reported QOL that could benefit from additional support. The two chapters are complementary, utilising data from a large survey conducted amongst people with a stoma (**Chapter 3**) and a subgroup of people with a stoma from a national colorectal cancer survey (**Chapter 4**). These chapters utilise LPA to identify subgroups within the population that have similar patterns of QOL. Previous research has treated this population as homogeneous, whereas here we identify differences in demographic and clinical characteristics between groups as well as different advice and support that is wanted.

Chapter 5 presents the findings of an ecological momentary assessment study designed to provide an understanding of how quality of life and self-efficacy fluctuate over the course of a week. Much of the previous research is cross-sectional or based upon long follow-up periods but has not considered how quality of life and self-efficacy could be influenced by the context in which they are in at the time. The findings from **Chapters 3** and **4** were used to identify individuals that may have lower levels of quality of life based upon their demographic and clinical characteristics to take part in this study.

Finally, **Chapter 6**, considers the findings of the previous chapters in relation to previous research, discusses the strengths and limitations of the studies, and outlines directions for future research.

1.9 References

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Chapter 2: A systematic review and meta-analysis of the effectiveness of self-management interventions in people with a stoma.

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Study 1	
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2.1 Abstract

Aims: Explore the evidence from randomised controlled trials for the effect of self-management interventions on quality of life, self-management skills and self-efficacy, and to explore which intervention characteristics are associated with effectiveness.

Design: Systematic review.

Data sources: A search of the literature was conducted in these databases: MEDLINE (OVID), EMBASE (OVID) and PsychINFO (OVID) from January 2000 to February 2020.

Review methods: Studies were included if participants had a bowel stoma, were over the age of 18 and the design was a randomised controlled trial of a self-management programme. The outcome measures for this review were quality of life, self-management skills and self-efficacy. The Behaviour Change Technique Taxonomy was used to code interventions for underlying components and alongside other intervention characteristics, associations with improvements in outcomes were explored.

Results: The search identified 3141 articles, 16 of which were eligible. A meta-analysis of self-efficacy scores from 5 studies (N=536) found an improvement in those that received the self-management intervention at follow-up with a 12-point mean difference compared to the usual care group. Effects on quality of life and self-management skills were mixed, and meta-analyses of these data were not possible. Across 13 studies an average of 10 behaviour change techniques were used with, credible source (e.g. nurse, doctor, therapist) (n= 13), instruction on how to perform the behaviour (n=13), demonstration of the behaviour (n=12) used most often. The behaviour change technique of self-monitoring was associated with an improvement in quality of life. The involvement of a nurse was associated with higher self-efficacy and self-management skills.

Conclusion: This review suggests that self-management interventions can increase peoples' self-efficacy for managing their stoma.

Impact: A standardised approach to the reporting of interventions and the measures used is needed in future studies to better understand the effect on quality of life and self-management skills.

Keywords: Stoma; self-management; quality of life; self-efficacy; nurses; meta-analysis; systematic review

2.2 Introduction

There are no global estimates for the amount of people with an ostomy but around 1 million people in China, 1 million people in the United States and 700,000 people in Europe are thought to be living with a stoma[1, 2]. It is estimated that colorectal cancer is responsible for the formation of 50% of bowel stomas and Inflammatory Bowel Disease (IBD) is the biggest non-cancer cause[1, 3]. The formation of a stoma can have a profound impact on a patient's life; for example, people with a stoma due to bowel cancer report lower quality of life (QOL) than those without a stoma[4]. Although over 2 years QOL did improve in this group but remained below those that did not have a stoma. Further research has shown that QOL can improve over the course of a year in people with a stoma from other conditions as well as cancer[5, 6].

In a number of chronic conditions, self-management interventions have become an increasingly important tool for providing high-quality care to patients. Self-management interventions support an individual to manage their health condition on a day-to-day basis through providing education and passing on skills through training[7]. The aim of these interventions is to increase self-efficacy, a person's belief in their ability to carry out a certain action, to enhance their self-management skills, and improve their health status[8]. For people with a stoma, self-management interventions are often designed to educate and improve confidence in how to care for their stoma to reduce the chance of developing clinical complications and stoma appliance-related problems[1, 9-12].

2.3 Background

Systematic reviews of self-management interventions for people with a stoma suggest they can increase QOL and self-efficacy, but a positive effect on clinical outcomes (e.g. length of hospital stay and number of complications) has not been supported[13, 14]. A recent systematic review synthesised results from education interventions for people with a stoma from colorectal cancer and identified 13 studies, 5 of which measured QOL[15]. Of these, only 3 demonstrated an improvement in overall QOL, but, in the same review all 6 studies that measured self-management skills (measured by time to proficiency in managing their stoma and a survey scale), self-efficacy or psychosocial outcomes showed an improvement. The mixed findings presented in these reviews could be due to the inclusion of studies with weaker study designs (pre-post). To better establish the efficacy of these interventions, a review of the evidence from randomised controlled trials (RCT) is necessary, with meta-analyses to formally test the effectiveness of these interventions across multiple studies.

In recent years there has been a move towards enhancing our understanding of the underlying characteristics of interventions, especially in the context of healthcare. To improve the reporting of interventions, guidelines and taxonomies have been developed. The Template for Intervention Description and Replication (TIDieR) checklist outlines areas to improve the reporting of interventions but also allows identification of factors that may be important (mode of delivery, provider, intervention duration)[16]. Taxonomies have also been developed to classify pre-established behaviour change techniques (BCTs). The Behaviour Change Technique Taxonomy is one way in which the underlying components of interventions can be explored and has been used extensively in health research[17]. Previous systematic reviews of chronic diseases have found that certain BCTs such as self-monitoring, instruction on how to perform the behaviour, feedback on behaviour and goal-setting are associated with improved outcomes[18, 19]. Identifying these characteristics could help to inform future interventions for this population to improve QOL, self-management skills and self-efficacy. This is particularly important given there have been calls for more feasible and effective interventions to improve patient outcomes for people with a stoma[14].

2.4 The Review

2.4.1 Aims

The primary objective of this systematic review was to explore the effect of RCT self-management interventions on QOL, self-management skills and self-efficacy of people with a bowel stoma and conduct a meta-analysis. The secondary objectives of this review were to identify the characteristics of self-management interventions developed for people with a stoma and explore whether these were associated with improvements in QOL, self-management skills and self-efficacy.

2.4.2 Design

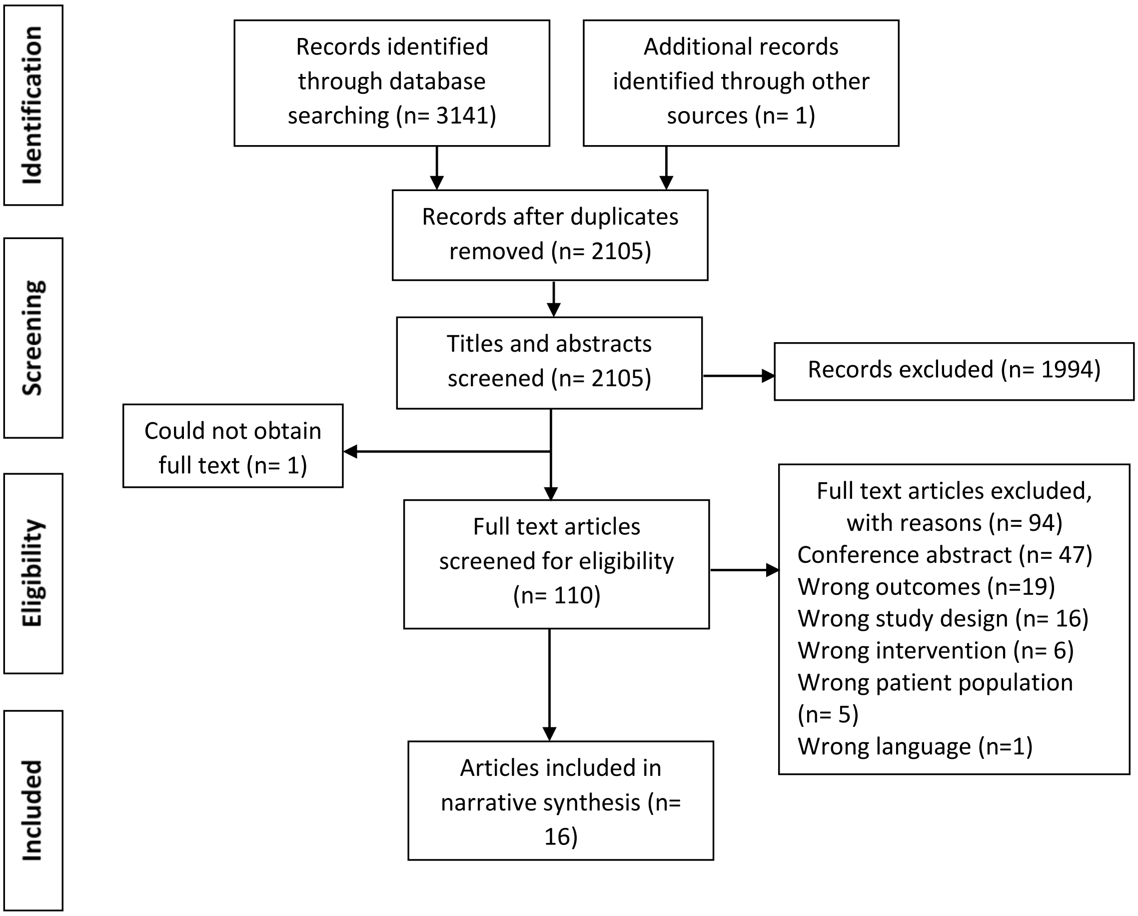
This systematic review was registered with PROSPERO; CRD42020169762. This review was completed to the ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses’ (PRISMA) checklist (**Appendix A.1**).

2.4.3 Search methods

A systematic review of the literature was conducted in these databases: MEDLINE (OVID), EMBASE (OVID) and PsychINFO (OVID) from 1st January 2000 to 13th February 2020. These databases were selected based upon their use in previous reviews of this subject area and they provided the greatest spread of research across medical and psychological related fields. The search strategy for the MEDLINE database can be found in **Appendix A.2**, but the search strategy for all databases combined synonyms for a stoma and self-management interventions, with the outcomes and study design being assessed by the authors. The database search was supplemented by forward and backward searching of key articles to identify any potentially relevant papers missed by the search.

The review was limited to studies published within the last 20 years to ensure their relevancy and was restricted to those published in English language publications. The studies were limited to the inclusion of at least one of three outcomes (QOL, self-management or self-efficacy). The search results were then screened for relevancy by reviewing their titles and abstracts against the inclusion and exclusion criteria independently by two authors. Full texts of the screened articles were then reviewed by the same authors to identify eligible studies. The search results and the screening process can be seen in **Figure 2.1**.

Figure 2.1: PRISMA Flow



Note: ‘Other sources’ refers to forward and backward citation searching.

2.4.4 Search outcomes

Studies were considered eligible if participants had a bowel stoma (either temporary or permanent) and were over the age of 18. Eligible studies were those that described and tested the effect of a self-management intervention. Studies were RCTs and could be pilot or feasibility studies as long as there was a comparison or control group. For this review, self-management interventions were defined as those that actively involve people with a stoma in the form of education (imparting knowledge on consequences and management of their condition) or training (providing skills for daily life, goal-setting and problem solving)[7], with the aim of the interventions being to improve the patient's ability to self-manage their condition, in relation to treatment, symptoms and lifestyle[20]. The key outcomes of the present review are QOL, self-management skills, and/or self-efficacy. The original registration of this review specified the inclusion of pre-post study designs; however, this was later restricted to RCTs to ensure methodological rigour.

2.4.5 Quality appraisal

The risk of bias for RCT studies was assessed using the Cochrane Risk of Bias assessment tool (Cochrane RoB)[21]. The results of each domain will be assessed from "low" to "high" risk of bias and an overall assessment made for each study, based upon the study author's analysis.

2.4.6 Data abstraction

Data from the identified studies was extracted into a form adapted from the Cochrane Public Health Group's Data Extraction and Assessment Template including:

1. General: title, authors, country, year of publication.
2. Methods: duration of study, design.
3. Participants: number, age, diagnostic criteria, baseline characteristics, setting.
4. Intervention characteristics: content, timing, duration, mode of delivery, provider and theoretical underpinning.
5. Outcomes: as specified above.
6. Results: for each outcome of interest.

2.4.7 Synthesis

Meta-analyses were not able to be conducted due to the heterogeneity of variables for QOL and self-management, these results are discussed and compared narratively. A meta-analysis was able to be conducted to combine the results of comparable studies for self-efficacy. Means and standard deviations were extracted for the included studies. The meta-analysis was conducted in Review Manager v5.3 and was run as an inverse variance fixed effects meta-analysis. The level of significance for the Chi-squared test for heterogeneity was set at a more conservative $p<.10$, with a non-significant result indicating no heterogeneity. The I^2 values of percentage of variation across the studies that is due to heterogeneity were judged as: 0-40% low heterogeneity, 30-60% moderate heterogeneity, 50-90% substantial heterogeneity, and 75-100% considerable heterogeneity[22].

The content of the interventions was used to identify the BCTs incorporated, this was done using the BCT Taxonomy (v1) to code the information[17]. This taxonomy contains 93 distinct BCTs (e.g. action planning, monitoring of emotional consequences, social comparison) which are clustered into 16 groups (e.g. goals and planning, social support, reward and threat). A narrative synthesis was conducted which described the interventions characteristics (BCTs, timing, duration, mode of delivery, provider and theoretical underpinning).

Studies which showed an increase in either QOL, self-efficacy or self-management were grouped together and the BCTs used in each of those studies were quantified for each variable. This sought to highlight the most frequently used BCTs in the successful interventions. More formal analyses were not possible due to the heterogeneity of the interventions. Associations were also drawn between the wider intervention characteristics (mode of delivery, duration, theoretical underpinning, provider) and improvements in the outcome variables.

2.5 Results

2.5.1 Study selection

Through searching databases 3141 records were obtained. This resulted in 16 eligible papers for inclusion within the systematic review[23-38]. **Figure 2.1** presents the PRISMA flow diagram of the study. **Table 2.1** outlines the characteristics of the included studies and sample sizes for the studies ranged from 42[23] to 218[33]. **Table 2.2** outlines the characteristics of the interventions and key findings.

Table 2.1: Characteristics of included studies

Author, year	Country	Sample size	Retention rate at follow-up	Male N	Age in years, mean (SD)	Stoma type (n)	Reason for stoma formation
Chaudhri, 2005[23]	UK	CG=21 IG=21	NR	CG=13 IG=11	CG= Median 62 (range 43-82) IG= Median 69 (range 36-79)	CG= Ileostomy (15), colostomy (6) IG= Ileostomy (16), colostomy (5)	Colorectal cancer
Cheung, 2003[24]*	China	63	CG=30 IG=29	CG= 20 IG=20	CG= 56.4 (13.5) IG= 60.1 (10.9)	CG= Colostomy (16), ileostomy (14) IG= colostomy (10), ileostomy (19)	Colorectal cancer
Crawford, 2012[25]*	USA	88	CG= 34 IG= 34	CG= 16 IG= 18	CG= 54.7 (13.1) IG= 59.8 (15.1)	CG= Ileostomy (26), colostomy (8) IG= ileostomy (19), colostomy (15)	NR
Forsmo, 2016[26]	Norway	CG= 61 IG= 61	NR	CG= 41 IG= 34	CG= Median 66 (range 19-89) IG= Median 64 (range 23-88)	CG= Colostomy (30), ileostomy (31) IG= colostomy (35), ileostomy (26)	Colorectal cancer

Khalilzadeh, 2019[27]	Iran	CG= 30 IG= 30	NR	CG= 19 IG= 14	NR	CG= Colostomy (24), ileostomy (6) IG= colostomy (22), ileostomy (8)	CG= Cancer= 26, Other=4 IG= Cancer= 26, Other= 4
Lim, 2019[28]	Singapore	CG= 31 IG= 32	CG= 24 IG= 27	CG= 17 IG=16	CG= 62.3 (13.4) IG= 63.5 (13.3)	CG= Colostomy (15), ileostomy (9) IG= colostomy (11), ileostomy (16)	Cancer
Lo, 2010[29]	Taiwan	CG= 27 IG= 27	NR	CG= 14 IG= 17	CG= 63 (17.6) IG= 57.9 (17.5)	NR	Colon cancer
Lo, 2011[30]	Taiwan	CG= 57 IG= 50	CG= 56 IG= 46	CG= 32 IG= 26	CG= 62 (15.8) IG= 57.9 (17.6)	NR	Colon cancer
Pouresmail, 2019[31]	Iran	CG= 27 IG= 26	CG= 23 IG= 23	CG= 9 IG= 12	CG= 53.8 (9.2) IG= 45.9 (10.4)	CG= Colostomy (16), ileostomy (7) IG= colostomy (18), ileostomy (5)	CG= Cancer= 21, Fistula=0, Polyp=1, Other=1 IG= Cancer= 20, Fistula=1, Polyp=1, Other=1
Seo, 2019[32]	South Korea	CG= 20 IG1= 20 IG2= 20	NR	CG= 15 IG1= 17 IG2= 15	CG= 61 (9.2) IG1= 58 (14.0) IG2= 56 (8.7)	CG= Ileostomy (18), colostomy (2) IG1= ileostomy (18), colostomy (5) IG2= ileostomy (15), colostomy (2)	NR
Sier, 2017[33]	Netherlands	CG= 113 IG= 105	NR	CG= 70 IG=71	CG= 60.8 (13.4) IG= 63.7 (10.5)	CG= Colostomy (61), ileostomy (50) IG= colostomy (66), ileostomy (37)	CG= Malignancy= 82, Ulcerative Colitis=8, Crohn's Disease=4, Diverticulitis=2, Anal diseases=1, Other=15 IG= Malignancy= 90, Ulcerative Colitis=3, Crohn's Disease=3, Diverticulitis=2, Anal diseases=1, Other=6
Su, 2019[34]	China	CG= 64 IG= 60	CG= 57 IG= 50	CG= 32 IG= 35	CG= 59.1 (12.9) IG= 57 (14.7)	CG= Ileostomy (40), colostomy (17) IG= ileostomy (41), colostomy (9)	Rectal cancer

Wang, 2018[35]	China	CG= 106 IG= 106	CG= 103 IG= 100	CG= 67 IG= 62	CG= 59.2 (14.1) IG= 57 (14.9)	CG= Colostomy (82), ileostomy (17), other (4) IG= colostomy (74), ileostomy (18), other (8)	CG= Rectal cancer= 67, colon cancer= 18, bladder cancer= 2, other= 16 IG= Rectal cancer= 65, colon cancer= 11, bladder cancer= 6, other= 18
Wen, 2019[36]	China	CG= 45 IG= 47	NR	CG= 25 IG= 30	52.8 (11.1)	NR	Colorectal cancer
Xu, 2018[37]	China	CG= 28 IG= 20	NR	CG= 19 IG=14	CG= 61.1 (13.6) IG= 60.9 (11.5)	Colostomy	Cancer
Zhang, 2013[38]	China	CG= 60 IG= 61	CG= 51 IG= 52	CG= 36 IG= 31	CG= 55.3 (13.7) IG= 52.9 (13.3)	Colostomy	Rectal Cancer

Note: RCT= Randomised Controlled Trial; NR= Not Reported; CG= Control Group; IG= Intervention Group; *= these studies did not provide a breakdown of the complete sample size into IG and CG but only those that completed follow-up.

Table 2.2: Intervention details and outcome measures

Author, year	**Intervention summary (Content / Duration / Mode of delivery / Provider / Timing)**	**Key outcome findings**
Lo, 2010[29]	**Content:** Multimedia learning education programme focussed on reasons for stoma formation, the anatomy, stoma care and irrigation. **Duration:** 1 session lasting 30-45 mins. **Mode of delivery:** film and pictures, face-to-face. **Provider:** instructor. **Timing:** Postop.	**Self-management** (Attitude of self-care scale and Behaviour of self-care scale): Significant difference in change scores from baseline to follow-up for IG and CG for attitude (27.04 (SD= 7.14) vs 14.56 (SD= 5.96), t=6.97, p<.001) and behaviour (27.04 (SD= 4.02) vs 19.41 (SD= 7.18), t=4.82, p<.001). scores.
Lo, 2011[30]	**Content:** Multimedia education programme had two sections, the first focussed on information about the formation and reasoning behind the formation of a stoma. The second section focussed on stoma care. **Duration:** 1 session lasting 30-45 mins. **Mode of delivery:** 2D anime (style of hand-drawn computer animation), film and pictures to reinforce the information. **Provider:** researcher. **Timing:** Postop	**Self-management** (Attitude of self-care scale and Behaviour of self-care scale): IG scores were significantly higher on attitudes (F= 8.91, p<.001) and behaviours (F= 9.48, p<.001) than CG.
Crawford, 2012 [25]	**Content:** taught hands-on skills through verbal instruction and printed materials. Session 2 for the intervention group was delivered via a DVD teaching a step-by-step approach to stoma appliance care. Complications, diet and practical advice for living with a stoma. **Duration:** 3, 1-hour long sessions both IG and CG. **Mode of delivery:** intervention DVD for 1 session and face-to-face. **Provider:** nurse. **Timing:** Postop	**Self-efficacy** (visual analog scale from 0-100): IG 79.09 (SD= 18.74); CG 78.18 (SD= 19.87); t=-0.20, p=.84. **Self-management** (nurse observation scored pass fail on 4 self-care skills): IG median score 4 (range 2-4); CG median score 4 (range 1-4); t=-0.19, p=.85.
Khalilzadeh Ganjalikhani , 2019 [27]	**Content:** Education on how to care for the stoma and change the appliance (shown through modelling and practice). Information was also provided on complications, how to live with a stoma and stoma appliances. **Duration:** 1, 2-hour long session. **Mode of delivery:** face-to-face and a training booklet. **Provider:** stoma nurse. **Timing:** Postop	**Quality of life** (COH-QOL): Baseline IG 144.8 (SD= 34.07); CG 185.7 (SD= 84.9); t=-2.40, p=.10. Follow-up IG 229.9 (SD= 83.3); CG 202.7 (SD= 38.3); t=1.65, p=.009.
Forsmo, 2016 [26]	**Content:** Education preop included importance of their role in training and information on the surgery, training in stoma care, impact of stoma on relationships and everyday life. Postop were taught how to change stoma appliance, where to buy equipment	**Quality of life** (15D): no statistically significant difference between IG and CG scores from baseline (IG 0.871; CG 0.870) to follow-up (IG

	and told about national stoma association. They also received equipment to take home. **Duration:** Preop education was 1 or 2 sessions at 45-60 mins and daily education postop. **Mode of delivery:** face-to-face. **Provider:** enhanced recovery after surgery nurse and stoma nurse specialist. **Timing:** Preop and postop.	0.812; CG 0.811, p= ns). Test score not reported.
Chaudhri, 2005 [23]	**Content:** education on how to manage a stoma appliance and patient assessed for competence. Immediately prior to surgery they were assessed on competency again. **Duration:** 2 home visits (45 mins each). **Mode of delivery:** conducted prior to surgery face-to-face. **Provider:** colorectal nurse. **Timing:** Preop.	**Self-management** (Time to stoma proficiency (days from surgery to reach proficiency on set criteria)): IG 5.5 days (range 2-10); CG 9 days (range 4-10); p=.0005. Test score not reported.
Zhang, 2013 [38]	**Content: r**einforcing self-care skills, encouragement to attend an ostomy club to hear other experiences, verbal encouragement to increase confidence, providing social support and reducing negative emotions. **Duration:** There were 2 telephone sessions delivered and a third was offered if self-efficacy was still low. **Mode of delivery:** follow-up telephone calls after discharge. **Provider:** enterostomal nurse. **Timing:** Postop	**Self-efficacy** (SSES): Both IG and CG improved over time (F=44.81, p<.001), there was no statistical between group difference (F=1.29, p=.259) and there was an interaction between group and time (F=10.11, p=.002). With higher scores for the IG.
Cheung, 2003[24]	**Content:** progressive muscle relaxation therapy was taught to participants in order to lower the risk of peristomal hernia. Participants were also given an audio-recording to guide them through the therapy at home and a manual with visual illustrations. **Duration:** 2 teaching sessions. They were instructed to carry out the relaxation exercise 2-3 times per week and record the frequency in a log sheet. They were also phoned every 2 weeks. **Mode of delivery:** postop face-to-face, via telephone, audio recording and manual. **Provider:** nurse or therapist. **Timing:** Postop	**Quality of life** (QOL-Colostomy & WHOQOL-BREF-HK): QOL-Colostomy there was a significant increase in scores in both IG and CG over time (F=35.96, p<.001), but there was no between group difference (F=2.63, p=.01). WHOQOL-BREF-HK there was a significant increase in scores over time in both IG and CG (F=97.63, p<.001) and a significant group difference between IG and CG (F= 26.52, p<.001) with IG scores higher.
Seo, 2019[32]	**Content:** Ostomy management reinforcement education allows practice in changing a stoma appliance and receive reinforcement and feedback afterwards. Additional education was provided on self-care, everyday life with an ostomy and how to deal with complications. This knowledge was assessed, and feedback provided with explanations. **Duration:** Control group received one session and intervention groups 1 and 2 received 2 and 3 sessions respectively, 30 mins each. **Mode of delivery:** face-to-face. **Provider:** research team and nurse. **Timing:** Postop	**Self-efficacy** (self-efficacy scale score from 10 to 100 points for 17 items): Higher scores for IG1 and IG2 than the CG (F=8.62, p=.001). But no significant difference between IG1 and IG2. **Self-management** (nurse observation scored from 1 to 4 on 10 self-care items): Higher scores for IG1 and IG2 than the CG (F=49.54, p<.001). But no significant difference between IG1 and IG2.
Sier, 2017[33]	**Content:** Education around the surgery and its consequences; stoma care and practice with appliance and provided a stoma diary. Also evaluated stoma care, discussed experiences and tackled any problems or complications. **Duration:** 1 home visit before surgery and 2 after, 2 hours long each. **Mode of delivery:** face-to-face. **Provider:** Stoma therapist. **Timing:** Preop and postop.	**Quality of life** (Stoma-QoL): IG scores were higher than CG at 1 month (63.4 (SD= 10.5) vs 56.6 (SD= 10.9), p<.001) and at 3 months (65.3 (SD= 10.2) vs 60.5 (SD= 10.8, p=.002). Test score not reported.
Lim, 2019[28]	**Content:** Psychoeducational session preop, encouraging communication and a positive attitude; identifying resources in the community; how to cope with new situations to continue normal life; identifying and reducing fears and uncertainty; assessing needs and empowering self-care. An educational booklet on stoma care was also provided. **Duration:** 1 session preop, 5 telephone calls were also arranged, 1 preop and 4 postop 15 mins each to explore any issues that arise from the educational session and postop and discharge. **Mode of delivery:** face-to-face, telephone and an educational booklet. **Provider:** researcher who is a nurse. **Timing:** Preop and postop.	**Quality of life** (EORTC QLQ-CR29): No difference in IG and CG over time (F=.32, p=.58), there was no statistical between group difference (F=3.41, p=.07) and no statistical interaction between group and time (F=.23, p=.64). **Self-efficacy** (SSES): No statistical difference in IG and CG over time (F=.18, p=.68), there was no statistical between group difference (F=3.28, p=.08) and no statistical interaction between group and time (F=1.74, p=.20). **Self-management** (Time to stoma proficiency (days from surgery to reach proficiency on set criteria)): No statistically significant difference between IG and CG (Z=-1.24, p=.22)
Su, 2019[34]	**Content:** information on what a stoma is, self-care of the stoma, how to manage daily, recording of self-management schemes and information to contact the clinical team. Advice on any problems and complications, emotional support and individuals	**Quality of life** (Stoma-QoL): Both IG and CG improved over time (F=16.90, p<.001), there was a between group difference (F=17.99, p<.001) and an interaction between group and

	were directed to the self-management scheme section of the manual. **Duration:** 4 phone calls lasting 10-20 minutes, and 1 outpatient appointment lasting up to 20 minutes. **Mode of delivery:** Stoma self-management manual, telephone and face-to-face. **Provider:** enterostomal therapist and a wound ostomy continence nurse. **Timing:** Postop	time (F=3.89, p=.022). With higher scores for the IG. **Self-efficacy** (SSES): Both IG and CG improved over time (F=11.32, p<.001), there was a between group difference (F=11.88, p=.001) and an interaction between group and time (F=7.30, p=.001). With higher scores for the IG.
Pouresmail, 2019 [31]	**Content:** Control and intervention group both taught stoma care, how to change the appliance and how to recognise and prevent complications. The intervention group in 2 sessions were able to practice skin care and changing the appliance on a physical simulator and could identify any problems before practicing on their stoma. **Duration:** 4 sessions, 30-45 mins. **Mode of delivery:** face-to-face. **Provider:** Enterostomal therapy nurse. **Timing:** Postop	**Self-efficacy** (SSES): IG scores were significantly higher than the CG from baseline to follow-up (F=13.56, p=.001).
Wen, 2019[36]	**Content:** Group education in self-care skills, how to cope with complications and strategies to implement when at home. Group discussion of problems faced and problem solving, encouraged to explore their current stage of behavioural change, reflect on failures and to share experiences. A stoma self-management manual and links to websites and other services were provided. **Duration:** There were 4 sessions, 1 hour each within the hospital. At baseline, a couple of days before discharge and then at follow-up visits at 1 and 3 months after discharge. **Mode of delivery:** group education and discussion and stoma self-management manual. **Provider:** researcher and an enterostomal therapy nurse. **Timing:** Postop	**Self-efficacy** (self-efficacy scale consisting of 8 items scored from 1 to 5): Both IG and CG improved over time (F=57.63, p<.001), there was a between group difference (F=188.98, p<.001) and an interaction between group and time (F=41.37, p<.001). With higher scores for the IG.
Wang, 2018[35]	**Content:** Taught in hospital how to use a mobile application. This application could be used at home to book appointments with the nurse, upload photos to receive a diagnosis on their stoma and consultations could be provided over the app to receive support. Educational sessions were also conducted over the app teaching stoma care skills, sharing experiences of other people with a stoma, promoting confidence in patient's role in self-care, and tackling negative emotions and fears. **Duration:** weekly smartphone sessions in the first month followed by biweekly sessions over the next 2 months. **Mode of delivery:** face-to-face app training, primarily mobile application. **Provider:** enterostomal therapy nurses. **Timing:** Postop	**Self-efficacy** (SSES): Both IG and CG improved over time (F=682.21, p<.001), there was a between group difference (F=23.16, p<.001) and an interaction between group and time (F=49.58, p<.001). With higher scores for the IG.
Xu, 2018[37]	**Content:** Intervention to improve self-efficacy included direct and alternative experience, verbal persuasion and social and psychological support. **Duration:** There were 4 sessions within the first month, 2 within the second month and 1 within the last month. **Mode of delivery:** face-to-face or over the phone. **Provider:** nurse. **Timing:** Postop	**Quality of life** (EORTC QLQ-C30): Cognitive function IG 61.67 (SD=23.63); CG 36.31 (SD= 29.41); t=3.19, p=.003. Emotional function IG 67.50 (SD= 21.44); CG 47.32 (SD= 26.84); t=2.79, p=.008. Physical function IG 73.33 (SD= 19.10); CG 52.62 (SD= 28.88); t=2.80, p=.008. Role function IG 57.50 (SD= 36.06); CG 36.90 (SD= 28.82); t=2.20, p=.033. Social function IG 70.83 (SD= 24.70); CG 55.39 (SD= 23.59); t=2.20, p=.033. **Self-efficacy** (SSES): IG scores were higher than CG at 1 month (80.25 (SD= 10.74) vs 75.25 (SD= 6.16), t=2.04, p=.047) and at 3 months (91.15 (SD= 10.71) vs 62.43 (SD= 12.63, t=8.26, p<.001).

Note: IG= Intervention Group; CG= Control Group; ns= non-significant; Stoma-QOL= Stoma Quality of Life Scale; SSES= Stoma Self-Efficacy Scale; SF-36= 36-Item Short Form Survey; EORTC QLQ= The European Organization for Research and Treatment of Cancer Quality of life Questionnaire; COH-QOL-O= The City of Hope Quality of Life Ostomy Questionnaire; DDQ-15= Digestive Disorders Questionnaire; SIBDQ= Short Inflammatory Bowel Disease Questionnaire; FACT-C= Functional Assessment of Cancer Therapy – Colorectal; ESCA= Exercise of Self-Care Agency; WHOQOL-BREF-HK= Hong Kong Chinese version of the World Health

Organisation Quality of Life Measure-Abbreviated Version; SD= Standard Deviation; F=F-test repeated ANOVA; Z=Mann Whitney U test; t=independent sample t-test.

2.5.2 Quality of life

Seven studies measured QOL[24, 26-28, 33, 34, 37]. One study used a generic quality of life scale; the WHO Quality of Life Scale[24]. One study used an overall health-related quality of life scale; 15D[26]. Six studies used disease/stoma-specific measures of quality of life; the Stoma-Quality of Life Questionnaire[33, 34], the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Cancer30[37], the City of Hope-Quality of Life-Ostomy Questionnaire[27], the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Colorectal29[28], and the Quality of Life-Colostomy Scale[24].

Due to the use of different scales to measure QOL a meta-analysis was not considered appropriate. The study that measured generic QOL reported significantly greater improvements in QOL in the intervention group when compared to the usual care group[24], whereas the study that measured overall health-related QOL did not report significant differences between the two groups in regards to QoL[26]. Of the six studies that used stoma and disease-specific QOL questionnaires, four reported greater improvements in scores in the intervention group when compared to the usual care group[27, 33, 34, 37]. The other two studies found no difference in between the intervention and control group[24, 28].

2.5.3 Self-management skills

Six studies reported on self-management skills[23, 25, 28-30, 32]. Two studies measured self-management through the time to stoma proficiency[23, 28], two studies used scales of self-care attitudes and behaviours[29, 30], and two studies used nurse observation of participants in their ability to manage their stoma with grading on scales for completion of self-management behaviours[25, 32].

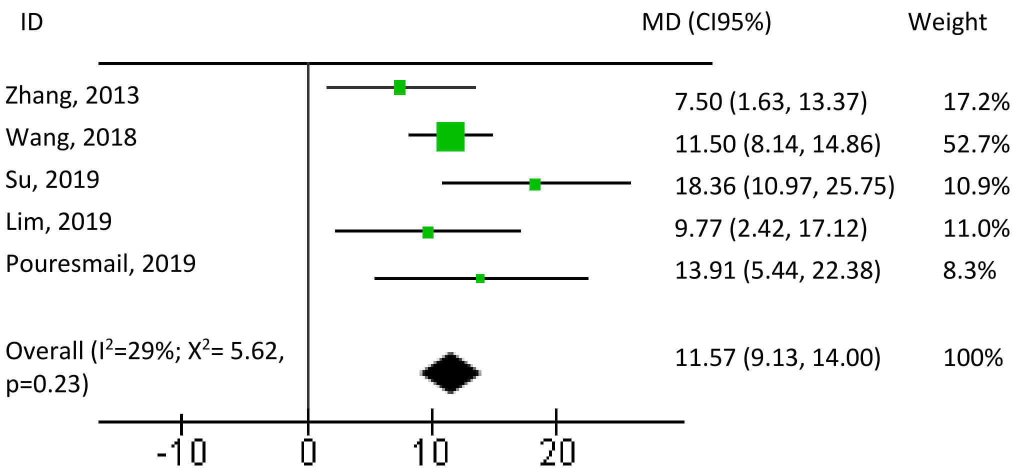
Two studies measured time to stoma proficiency, with one finding that the intervention significantly decreased time to stoma proficiency compared to the usual care group[23] whereas the other study found no significant difference between the control and intervention group[28]. Two studies used self-report measures of self-management, they both found that the interventions group reported significant improvements over the usual care group[29, 30]. Two studies had direct nurse observation of participants, one study found significant higher scores in stoma management ability in participants in the intervention group compared to the control[32] but the other study found no significant differences between the two groups[25].

2.5.4 Self-efficacy

Nine studies measured self-efficacy[25, 28, 31, 32, 34-38]. Six studies used the Stoma Self-Efficacy Scale[28, 31, 34, 35, 37, 38], and three studies developed their own self-efficacy scales[25, 32, 36].

Five studies all used the same measure of self-efficacy (stoma self-efficacy scale), had similar lengths of follow-up periods (45 – 90 days) and broadly similar content and providers for the interventions making them appropriate for a meta-analysis to be conducted[28, 31, 34, 35, 38], one study which used the same measure had a different follow-up period and therefore was not included[37]. The results of the meta-analysis can be seen in **Figure 2.2**. Participants who received a self-management intervention reported higher self-efficacy compared to participants who received usual routine care (MD=11.57; 95%CI 9.13, 14.00) at follow-up and there were low levels of heterogeneity (I^2=29%). Of those 5 studies there were 536 participants between them. The four studies that could not be included in the meta-analysis, three reported significantly higher self-efficacy scores compared to the control group[32, 36, 37] and one did not report any significant differences compared with the control group[25].

Figure 2.2: Meta-analysis of self-management interventions on self-efficacy



Note: MD= Mean Difference; X^2= Chi-squared test; I^2= percentage of variation across the studies that is due to heterogeneity; the meta-analysis was run as an inverse variance fixed effects meta-analysis.

2.5.5 Intervention characteristics

Only 13 interventions provided sufficient detail to be able to be coded for BCTs[23-28, 31-36, 38]. The studies used an average of 10 BCTs (range 6-22). Credible source (n= 13), instruction on how to perform the behaviour (n=13), demonstration of the behaviour (n=12), behavioural practice/rehearsal (n=12), information about health consequences (n=11) and monitoring of behaviour by others without feedback (n=9) were the most described BCTs in the interventions. The other BCTs described are covered in **Appendix A.3**.

Twelve of the interventions were conducted post-operatively[24, 25, 27, 29-32, 34-38], two of the interventions were conducted pre-operatively[23] and two of them covered both the preop and postop period[26, 28, 33]. Thirteen of the interventions involved a healthcare professional in the delivery[23-28, 31, 33-38], with the other three delivered by the research team or an instructor[29, 30, 32]. Five of the interventions were delivered face-to-face[23, 26, 31-33] and one each were delivered via telephone and a mobile application[35, 38]. The other nine interventions used various combinations of face-to-face, telephone, manuals and other multimedia to deliver the interventions[24, 25, 27-30, 34, 36, 37]. The duration of the interventions varied from only one session[25, 27, 29, 30], to 2-3 sessions[23, 24, 26, 32, 33, 38], to 4 or more sessions[28, 31, 34-37].

Across the studies only five reported some level of theoretical underpinning[28, 34-36, 38], four cited Bandura's Social Learning Theory[28, 34, 35, 38], with the other using the Transtheoretical Model[36]. Across the studies the description of how the theory was used was fairly consistent. All five studies reported how the theory was used to select/develop the interventions but only one study mentioned how the theory was used to tailor the intervention to participants[36]. All five studies measured theory relevant constructs pre and post intervention. An average of 15 BCTs (range 9-22) were identified in these five studies, compared to an average of 7 (range 6-9) for those studies with no theoretical underpinning.

2.5.6 Associations with intervention characteristics

The BCTs of credible source, instruction on how to perform the behaviour, demonstration of the behaviour, behavioural practice/rehearsal, information about health consequences, and monitoring of behaviour by others without feedback were all associated with improvements in QOL, self-efficacy and self-management. For all the number of studies which showed an improvement in one of the key outcomes and the BCTs used in those interventions see **Appendix A.4**. There was no association between the number of BCTs used in a study and improvement in any of the outcome variables.

Those studies that measured QOL and found an improvement[24, 27, 33, 34, 37] were more likely to have face-to-face interactions post-op than those that found no improvement[26, 28]. Furthermore, the studies that found an improvement in at least one QOL scale measured reported encouraging the BCT of self-monitoring of behaviour more than compared to those that did not find any difference in QOL[24, 27, 33, 34].

Those studies that measured self-efficacy and were not included within the meta-analysis and reported significantly improved self-efficacy in the intervention group included in-person training with a nurse or a longer period of time (24 hours) with a digital intervention[32, 36, 37]. Whereas, the study by Crawford et al.[25] that did not report any significant difference between the intervention and control group provided a light-touch intervention with a 1-hour session of in-person nurse training replaced with a DVD.

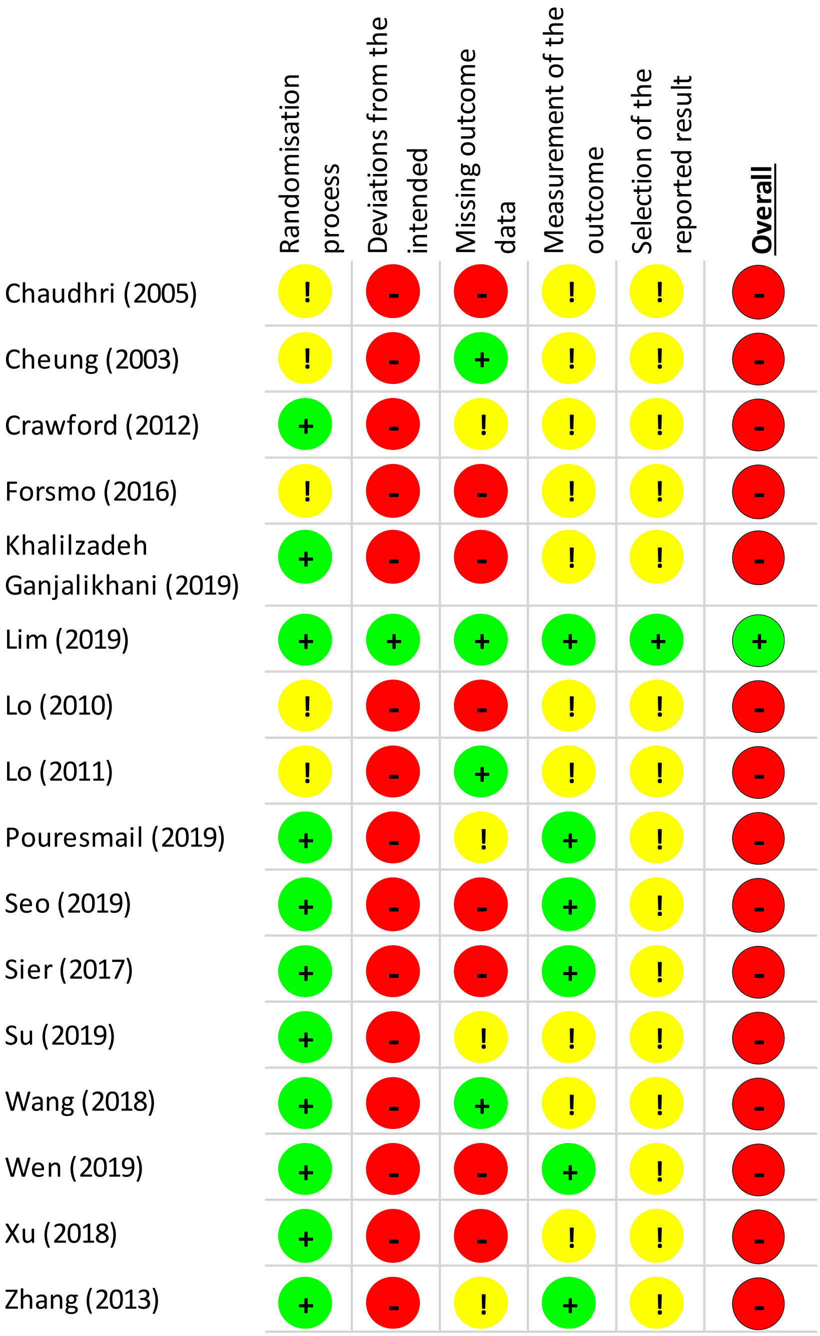
Of the four studies that measured stoma self-management more objectively with time to proficiency and through nurse-rated management scores, there were differences in the intervention content. The two studies that found decreased time to stoma proficiency or higher nurse-rated management scores tested interventions that focussed more on how to manage the stoma, with direct involvement of the nurse, providing feedback and encouragement[23, 32]. The two studies where there was no difference in time to stoma proficiency or nurse-rated management scores tested interventions that did not have the direct involvement of the nurse in teaching stoma self-management, with this either provided through a booklet[28] or a DVD[25].

There was no association that could be drawn between the studies that had a theoretical underpinning[28, 34-36, 38] and those that did not on any of the outcome variables[23-27, 29-33, 37]. There was also no association based upon the level of expertise of the nurse (enterostomal nurse vs a nurse with no specialisation).

2.5.7 Risk of Bias in included studies

Figure 2.3 outlines the risk of bias in the included RCTs. The quality of the included studies was low with only one RCT being deemed to be at low risk of bias[28]. The rest of the RCTs were deemed to be at high risk of bias[23-27, 29-38], due to ‘Deviations from the intended interventions’.

Figure 2.3: Risk of bias classification for included studies



	Randomisation process	Deviations from the intended	Missing outcome data	Measurement of the outcome	Selection of the reported result	**Overall**
Chaudhri (2005)	!	-	-	!	!	-
Cheung (2003)	!	-	+	!	!	-
Crawford (2012)	+	-	!	!	!	-
Forsmo (2016)	!	-	-	!	!	-
Khalilzadeh Ganjalikhani (2019)	+	-	-	!	!	-
Lim (2019)	+	+	+	+	+	+
Lo (2010)	!	-	-	!	!	-
Lo (2011)	!	-	+	!	!	-
Pouresmail (2019)	+	-	!	+	!	-
Seo (2019)	+	-	-	+	!	-
Sier (2017)	+	-	-	+	!	-
Su (2019)	+	-	!	!	!	-
Wang (2018)	+	-	+	!	!	-
Wen (2019)	+	-	-	+	!	-
Xu (2018)	+	-	-	!	!	-
Zhang (2013)	+	-	!	+	!	-

Note: Green circles indicate low bias, yellow circles indicate some concerns and red circles indicate high bias.

2.6 Discussion

This is the first systematic review to synthesise the international evidence from RCTS of self-management interventions for people with a stoma, and meta-analyse the effects on self-efficacy. The meta-analysis demonstrated a mean difference in self-efficacy scores of 12 (95%CI 9.13, 14.00) post-intervention (45-90 days), between the intervention and control groups with higher scores in the intervention group. There was also some evidence to suggest self-management interventions have a broadly positive effect on self-reported self-management skills. However, the findings were more mixed for QOL and objective measures of self-management skills, such as time to stoma proficiency and observation of stoma ability. This review is also the first to identify the intervention characteristics, including BCTs, used in self-management interventions of people with a stoma and look at the associations with positive outcomes. Across the interventions an average of 10 BCTs were used, however, the number of BCTs used was not associated with an improvement in any of the outcomes. Furthermore, the direct involvement of a nurse in teaching stoma care management was associated with improved self-efficacy and self-management skills and contact post-operatively and self-monitoring were associated with higher QOL.

The results from the present review in regards to QOL, self-efficacy and self-report self-management are in line with those of Faury et al.[15] and Danielsen et al.[13]. In both previous reviews a majority of the studies that measured the same outcomes showed an increase in scores. However, there is a difference between the self-report and objective measures of self-management. In this present review the findings from the objective measures were mixed which is different from the previous reviews. This could suggest that the self-management interventions may not be imparting effective self-management practices. Furthermore, although this review was able to conduct a meta-analysis showing there was 12-point mean difference between the intervention and control groups at follow-up, favouring the intervention, there is no research currently to suggest that this is a clinically meaningful difference for individuals.

Across interventions that saw improved outcomes compared to those that did not, the number of BCTs used was broadly similar to reviews of other conditions[39, 40]. However, we are unable to determine which of the BCTs that are used are influencing the outcomes. A number of the most coded BCTs are likely to occur due to the nature of the information and support that needs to be provided to the patient to manage their stoma and the fact that, at least within the UK, this is routinely delivered by a stoma care nurse in hospital post-surgery[41]. Previous cross-sectional research has suggested that social support can be beneficial in helping people with a stoma to adjust, whether this is from medical staff[42] or through family and community support[43-45]. However, the BCT social support was only identified in 4 studies in this review with 3 of the studies showing an improvement in outcomes, which suggests that it may be under-utilised as a tool to support people with a stoma within the identified interventions. This may highlight that the nature of these interventions is medicalised and focussed on ensuring the participant can manage their stoma while potentially ignoring the social consequences of the stoma. The majority of studies reported an overall score of QOL, exploring constituent subscales of these measures might provide a more nuanced view of the impact of these interventions on the QOL of the participants.

Furthermore, this review suggests that the involvement of a nurse in delivering the intervention appears to be related to improvements in self-efficacy and self-management skills. The importance of nurses has been highlighted in a previous review in relation to effectiveness in care and chronic disease management and health promotion[46]. However, what is not known in the present review is whether there is continuity of care for individuals during the intervention. Borwell[47] has emphasised the importance of continuity of care for people with a stoma, therefore, future research should seek to provide greater clarity on this aspect by ensuring that the interventions are described in detail.

This review identified that the majority of studies did not have a theoretical underpinning. Previous reviews of other diseases have found that interventions with a theoretical underpinning result in better health and psychological outcomes for patients[48, 49]. Nevertheless, in this review there was no association between better outcomes and a theory-based intervention. However, this should be treated with caution as it could be that the appropriate theory was not being used for this population. For example, the integration of nursing theories into self-management intervention development, especially when these interventions are majority delivered by nurses, might be of benefit to future research. Furthermore, theory-based interventions could have had a meaningful impact upon the outcomes but none of the utilised measures had any research suggesting what a clinically meaningful difference would be.

2.6.1 Limitations

This review has some limitations. Firstly, as has been highlighted in previous reviews, coding of the BCTs is dependent upon the accuracy and quantity of the detail that authors go into when describing the intervention[39, 50], which restricts the ability to adequately code every intervention for BCTs. The heterogeneity also meant that meta-analyses could not be conducted for QOL and self-management measures. Furthermore, due to the complexity of self-management interventions, it is difficult to identify which components are contributing to the success of the interventions. Only associations can be drawn between components and improved outcomes, with additional research needed to unpick this. Also, this review limited included papers to those in English language publications, therefore, research conducted in other languages could have been missed. The search strategy for the present review did not include 2 large academic databases, CINAHL and PubMed, however, a thorough forward and backward citation search of key papers did not elicit any additional papers that would be included in the final review. Finally, this review did not assess the reliability of the measures used as it was beyond the scope of the objectives, however, future reviews should consider this in order to aid in the interpretability of the results.

2.6.2 Conclusions

Although this is the first review to identify the BCTs and other characteristics used within self-management interventions for this population we are unable to assess the effectiveness of these components. Future research is required to determine which components are the most effective in increasing QOL, self-efficacy and self-management skills. One possible approach to testing multiple combinations of the intervention characteristics to ascertain their efficacy is the multiphase optimisation strategy (MOST) methodology[51]. Furthermore, we do not know whether there needs to be different BCTs used when delivering the intervention in different environments (e.g. hospital or home), different countries with varying healthcare systems or with different populations of people with a stoma (e.g. temporary vs permanent, IBD or cancer, bowel stomas or urostomies).

In conclusion, evidence from RCTs suggests self-management interventions for people with a stoma appear to be an effective way to improve outcomes for this group, particularly self-efficacy. This review also provides an important first step in determining the effective components of self-management interventions for people with a stoma. Future self-management interventions for this patient group should consider the direct involvement of a nurse in the delivery of the intervention and consider incorporating social support. Further research, utilising the MOST methodology, is needed to determine effective intervention characteristics to ensure successful patient self-management.

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Conflict of interests

No conflict of interest has been declared by the authors.

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Chapter 3: Quality of life profiles and their association with clinical and demographic characteristics and physical activity in people with a stoma: A latent profile analysis

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3.1 Abstract

Purpose: Quality of life can be negatively impacted by the formation of a stoma and is influenced by a number of factors. Research to date treats people with a stoma as a homogenous group based on their quality of life. We attempted to identify subgroups based upon self-reported quality of life and explored variables associated with group membership.

Methods: Secondary analysis of a cross-sectional sample of 1419 people with a stoma. Participants completed validated questionnaires for quality of life, physical activity and clinical and demographic characteristics. Latent profile analysis was used to identify the optimal number of subgroups (profiles) and multinomial regression modelling was conducted to identify variables associated with profile membership.

Results: The analysis revealed 4 distinct profiles of people with a stoma: 'consistently good quality of life' (N=891 (62.8%)), 'some quality of life concerns' (N=184 (13.0%), 'low quality of life' (N=181 (12.8%)) and 'financial concerns' (N=163 (11.5%)). Modelling revealed that people with a recent stoma (formed <2 years previously), who have a hernia and are less physically active were more likely to belong to the 'low quality of life' profile. Furthermore, those aged 16-55 were more likely to have financial concerns.

Conclusion: This study was the first to identify latent profiles within this population and assess whether certain variables are associated with membership. Future research should build upon this to identify additional variables associated with these profiles, which can help to provide the basis for targeting and tailoring future interventions to specific sub-groups of people with a stoma.

Keywords: quality of life, stoma, hernia, physical activity

3.2 Background

A bowel stoma is an artificial opening on the abdomen that has been created to divert the flow of faeces[1]. There are no current global estimates for the number of people living with a stoma, however, available estimates from the USA and China suggest there are about 1 million people with a stoma in each country and around 700,000 people with a stoma in Europe[2, 3]. Colorectal cancer is thought to be the foremost cause for creation of a stoma with data from the UK and Sweden suggesting that 25%-32% of patients who undergo surgery will have a stoma formed[4, 5]. Stomas can also be formed due to inflammatory bowel disease (IBD), diverticular disease, physical trauma and incontinence[1]. Quality of life (QOL) can be impaired in patients post stoma formation surgery. Research amongst Swedish rectal cancer patients found that those without a stoma had higher levels of QOL compared to those with a stoma[6]. However, a study of Crohn's Disease patients with and without a stoma found no difference in overall QOL but did find lower social role satisfaction in those with a stoma[7]. Additional research has also indicated that this difference in QOL between those with and without a stoma can remain for over 2 to 5 years[8, 9].

QOL in people with a stoma can be impacted by a number of different stoma-related problems[10], which are captured by stoma-specific QOL measures such as the Stoma Quality of Life Scale that cover work and social issues, body image concerns, issues with the stoma and financial matters[11]. These problems may be influenced by demographic and clinical factors such as age, gender and time since treatment. Clinical characteristics including presence of a hernia, cancer being the underlying disease, and having an ileostomy compared to having a colostomy can also be associated with lower levels of QOL[12-15]. Additionally, there is a growing body of evidence to suggest that behaviours such as being physically active can have an important effect on QOL in colorectal cancer survivors and people with IBD[16, 17].

The current research into QOL amongst people with a stoma has looked at the variables that are associated with QOL, however, there has been no investigation as to whether there are distinct subgroups of people with a stoma who report specific patterns of QOL. Latent profile analysis (LPA) takes a person-oriented approach by identifying subpopulations within the sample based upon responses to certain variables[18]. This method lends itself to the multidimensional nature of QOL by allowing us to identify whether there are distinct groups of people with similar patterns of QOL responses. This can allow for identification of those who are most in need of intervention or may need intervention in different areas, which is in line with the recent development of a person-centred approach to healthcare[19, 20]. This method has been used previously to identify areas for future development of behaviour change interventions for diet[21], sexual health[22] and alcohol and drug problems[23] and also interventions for patients with hypertension[24] and for older adults[25]. For example, a study by Choi et al.[25] identified 4 distinct profiles (physical disability type, emotional disability type, crisis type and stable type) based upon health-related QOL scores amongst older adults (over 65 years). They found that membership of people in the ‘emotional disability’ profile, who were characterised by low scores on the anxiety and depression subscale but higher scores on the other subscales, was associated with lower scores on happiness, depression and cognitive decline scales and belonging to a one-person household compared to the ‘stable’ profile. They concluded that this profile would benefit from an intervention aimed at mental health assistance. Therefore, using latent profile analysis within a sample of people with a stoma may help us to identify how to better tailor interventions.

The primary purpose of this study was to identify distinct subpopulations of individuals with a stoma based upon their self-reported QOL. We also assessed whether membership of these groups was associated with demographic and clinical characteristics and physical activity (PA). To our knowledge no previous research has conducted this type of analysis within this population, consequently no hypotheses were formed due to the exploratory nature of the study.

3.3 Methods

3.3.1 Study design

The present study was a secondary analysis of data from a cross-sectional, observational survey conducted between 26 April and 16 May 2018. This was an exploratory survey investigating the relationship between support garments and stoma-related QOL. Ethical approval for the original study was obtained from the University of the Highlands and Islands Research and Ethics Committee (Ref: OLETHSHE903), and approval to use this data for the present study was obtained from the lead investigator of the original study, GH. See **Appendix B.1** for a full list of the variables within the original dataset.

3.3.2 Participants

A sample of 1528 participants was obtained using a convenience sampling method. The total number of people contacted is not known. Participants were asked to complete the survey if they currently had, or had ever had, at least one type of stoma (ileostomy, colostomy or urostomy), were at least 16 years old and could answer questions in English. For the present study, the focus was on people with a bowel stoma, therefore, those with a urostomy or who did not select any stoma were removed leaving a final sample of 1419. The sample size was determined to be appropriate for this study based on a rule of thumb established in previous latent profile analysis studies. A Monte Carlo simulation study looked at a number of different sample sizes and concluded that a sample size of 500 would be sufficient to identify the optimal number of profiles[26].

3.3.3 Procedure

The survey was hosted on the Online Surveys website. The link to the survey was distributed via social media (Twitter and Facebook) and through an email sent to customers of Vanilla Blush, a UK-based stoma and hernia support garment supplier. Participants were directed to a page that gave them information on the survey and its aims and were asked to consent by ticking a box.

For the present study members of our stakeholder group were approached to consult on the cut-offs that were used for the variables of age, number of abdominal surgeries and time with a stoma. Two people with a stoma, a charity representative and two stoma nurse specialists were members of a stakeholder group formed to provide advice and feedback on a body of research related to people with a stoma. All contact with members of the stakeholder group was via email or teleconference.

3.3.4 Measures

3.3.4.1 Demographic and clinical characteristics

Sex was originally measured as ‘Female’, ‘Male’ and ‘Other’, but due to the small number of ‘Other’ (N=3) these were set to missing and a dichotomous variable was created (Male, Female). Age was measured as age range (8-point scale [16-25 to 86+]). For the purpose of this study this ordinal variable was dichotomised into aged 55 or younger and aged 56+. This was based on a review of the distribution of the data and feedback on the appropriateness of the cut-off from the stakeholder group. The reasoning given from the stakeholder group was that those who were below the age of 55 were more likely to have IBD and those older were more likely to have cancer.

The presence of a hernia or bulge was measured by 3 questions; if they had ever had a medically diagnosed parastomal or incisional hernia and whether they had a bulge around their stoma. These were combined and dichotomised into either ‘No’ hernia or bulge or ‘Yes’ hernia or bulge. The reason for stoma formation was selected from IBD, Cancer, Physical Trauma or Other. Some of the other reasons that were outlined by participants included diverticulitis, familial adenomatous polyposis (FAP) and Hirschsprung’s disease. Participants selected their type of stoma between ileostomy and colostomy. The number of abdominal surgeries (4-point scale [1 to 4 or more surgeries]) and the range of time with a stoma (7-point scale [0-6 months to more than 4 years]) were both measured as ordinal variables. For the purpose of this study these variables were dichotomised into: abdominal surgeries 1 or 2+, and time with a stoma ≤2 years or >2 years. These decisions were also based on a review of the distribution of the data and feedback on the appropriateness of the cut-offs from the stakeholder group. The reasoning given by the stakeholder group for these cut-offs was that for abdominal surgeries it was felt that those having multiple surgeries would have a different experience than those that only required 1 surgery and for the time with a stoma at 2 years would be sufficient to capture those that were learning to manage their stoma.

3.3.4.2 Physical activity

PA was measured using an adapted single-item tool[27]. Respondents rated on a scale how many days in the past week they had done 30 minutes or more PA that raised their breathing rate, this was measured from “0 days” to “7 days”.

3.3.4.3 Quality of life

QOL was measured by the Stoma Quality of Life Scale (SQoL)[11]. The SQoL contains 19 items over 5 subscales: Work/Social Function, Sexuality and Body Image, Stoma Function, Financial Concerns and Skin Irritation; these are measured on a 5-point Likert scale from “Never” to “Always”. The results for each subscale are then transformed into a 0-100 scale based upon the algorithm in Baxter et al.[11]. The reliability of the overall scale is rated as good (α=.89).

3.3.5 Statistical analysis

Statistical analyses were conducted using IBM SPSS v26 and Latent GOLD v5.1. Descriptive statistics were run on all variables included.

Within the data, 2.3% (898 of 37415) of values were missing but 26.4% (375 of 1419) of cases had a single missing data point. The variables with the most missing data points were two items on the sexuality and body image subscale (‘My sexual partner is bothered by my stoma’, N=191 [13.5%]; ‘I enjoy sexual activity’, N=190 [13.4%]) and the single item on the financial concerns subscale (‘I have financial concerns regarding my stoma supplies’, N=137 [9.7%]). Little’s MCAR test was run to determine whether the data was missing completely at random or not. The MCAR test was significant (χ^2[1108]=1505.9, p<.001) therefore, the data was not missing completely at random. To account for this the LPA was run using the maximum likelihood method which uses all data available.

A three-step approach was taken to conducting the LPA. The first step identified the appropriate number of profiles based upon responses to the SQoL subscales. Initially a single profile was run with this increasing to 5 (the number of subscales of SQoL). The models were then compared across multiple indicators of model fit: Akaike Information Criteria (AIC), Bayesian Information Criteria (BIC) and entropy. For AIC and BIC a lower number indicates better model fit whereas for entropy a number closer to 1.00 indicates better latent profile separation. However, as there is no gold standard for model fit statistics for LPA, the models were also evaluated based upon their interpretability, and models with groups of 5% of the sample or smaller were rejected. The second step involved assigning participants to a profile based upon their probability scores. A one-way analysis of variance (ANOVA) test was conducted to determine whether there were differences in the QoL subscales mean scores across the profiles. Post-hoc Bonferroni tests were run to assess mean differences between each profile. The final step involved running a multinomial regression to assess whether there was a difference in profile membership based upon demographics, clinical characteristics and PA. This was run with the maximum likelihood method to account for potential bias in classification errors and non-random missing data[28]. Overall differences across profiles on each variable were assessed by running Omnibus Wald tests, with Wald X^2 pairwise comparison tests being run to test for differences for each variable between profiles, the Bonferroni correction for multiple analyses was applied.

3.4 Results

3.4.1 Descriptive Statistics

Table 3.1 provides an overview of the demographic and clinical characteristics of the sample alongside the mean scores for QOL. The sample of 1419 ostomates was predominantly female (79.1%), had an ileostomy (67.4%) and had their stoma formed because of IBD (55.3%). Just under half of the sample reported having a hernia or bulge (48.3%) and the mean reported number of days of PA per week was 2.6 (SD=2.3). For the SQoL subscales (range 0 [low QOL] – 100 [high QOL]) financial concerns had the highest mean score of 81.3(SD 28.5) and skin irritation had the lowest mean score of 47.2 (SD 27.9).

Table 3.1: Descriptive statistics for the sample (N=1419)

Demographic and clinical characteristics		
Sex (N, %)		
	Female	1122 (79.1)
	Male	289 (20.4)
	Missing	8 (0.6)
Age (N, %)		
	16-55	961 (67.7)
	56+	451 (32.2)
	Missing	1 (0.1)
Stoma (N, %)		
	Ileostomy	956 (67.4)
	Colostomy	444 (31.3)
	Missing	19 (1.3)
Reason for stoma formation (N, %)		

	IBD	785 (55.3)
	Cancer	328 (23.1)
	Physical Trauma	103 (7.3)
	Other	188 (13.2)
	Missing	15 (1.1)
Hernia or bulge (N, %)		
	No	727 (51.2)
	Yes	685 (48.3)
	Missing	7 (0.5)
Time with stoma (N, %)		
	0-24 months	479 (33.8)
	More than 2 years	926 (65.3)
	Missing	14 (1.0)
Number of abdominal surgeries (N, %)		
	1	335 (23.6)
	2 or more	304 (21.4)
	Missing	18 (1.3)
Stoma Quality of Life Subscales		
	Work and Social Function (M, SD)	63.6 (23.0)
	Missing (N, %)	57 (4.0)
	Sexuality/Body Image (M, SD)	61.5 (19.3)
	Missing (N, %)	198 (14.0)
	Stoma Function (M, SD)	52.8 (20.6)
	Missing (N, %)	16 (1.1)
	Financial Concerns (M, SD)	81.3 (28.5)
	Missing (N, %)	137 (9.7)
	Skin Irritation (M, SD)	47.2 (27.9)
	Missing (N, %)	13 (0.9)
Physical Activity		
	No. days per week (M, SD)	2.6 (2.3)
	Missing (N, %)	5 (0.4)

Note: N = number of participants; M = mean; SD = standard deviation; IBD= Inflammatory Bowel Disease.

3.4.2 Latent profile analysis

The model fit statistics for the five LPA models are outlined in **Table 3.2**. AIC and BIC decreased with the addition of each additional latent profile. Entropy decreased initially with the addition of a latent profile but began to increase from the four latent profile model. The five-profile model had a profile with only 4.8% of the sample in and so was rejected. Based upon these statistics and the interpretability of the model a four-profile model was selected.

Table 3.3 presents the estimated mean SQoL scores from the 4-profile model and **Figure 3.1** plots this. One-way ANOVA tests indicate there were significant differences between the profiles for all the SQoL subscales and the post-hoc Bonferroni tests indicate which profiles were different to each other. Profile 1 (N=891, 62.8%) was characterised by a high score on financial concerns but also higher than average QOL scores across all subscales and so was labelled ‘consistently good quality of life'. Profile 2 (N=184, 13.0%) was characterised by moderate QoL concerns across all subscales and was labelled 'some quality of life concerns'. Profile 3 (N=181, 12.8%) was characterised by low QOL scores across all the subscales and was labelled 'low quality of life'. Profile 4 (N=163, 11.5%) was characterised by its low score on financial concerns but high scores on work/social function and sexuality/body image and was labelled 'financial concerns'.

Table 3.2: Model fit statistics

Number of profiles	AIC	BIC	Entropy	Smallest profile %
1	61156.1	61208.7	1.00	NA
2	55916.7	56027.1	0.90	38.7
3	55160.1	55328.4	0.84	18.0
4	54186.3	54412.4	0.88	11.5
5	53196.6	53480.5	0.89	4.8

Note: AIC= Akaike Information Criteria; BIC= Bayesian Information Criteria.

Table 3.3: Final class count and proportions, and quality of life scores for each profile

	Profile 1 – Consistently good quality of life N=891 (62.8%)	Profile 2 – Some quality of life concerns N=184 (13.0%)	Profile 3 – Low quality of life N=181 (12.8%)	Profile 4 – Financial concerns N=163 (11.5%)	P value	Bonferroni post-hoc test
Posterior probabilities Mean (SD)	0.96 (0.11)	0.97 (0.06)	0.89 (0.15)	0.94 (0.11)	-	-
	Quality of life scores: Mean (SD)					
Work/Social Function	🟩 68.4 (21.7)	🟥 63.0 (19.8)	🟥 35.3 (15.0)	🟩 70.6 (15.9)	<.001	1 > 2,3; 2 > 3; 2 < 4, 3 < 4
Sexuality/Body Image	🟩 63.5 (19.0)	🟩 64.1 (17.4)	🟥 42.4 (12.8)	🟩 68.9 (15.9)	<.001	1 > 3; 1 < 4; 2 > 3; 3 < 4
Stoma Function	🟩 56.6 (20.1)	🟥 52.4 (17.8)	🟥 30.0 (14.1)	🟩 58.1 (15.4)	<.001	1 > 2,3; 2 > 3; 2 < 4; 3 < 4
Financial Concerns	🟩 100.0 (<0.1)	🟥 75.0 (<0.1)	🟥 36.5 (22.6)	🟥 35.6 (20.2)	<.001	1 > 2,3,4; 2 > 3,4
Skin Irritation	🟩 50.7 (28.2)	🟥 46.2 (25.1)	🟥 28.5 (23.1)	🟩 50.5 (26.0)	<.001	1 > 3; 2 > 3; 3 < 4

Note: Bonferroni post-hoc tests difference at p<.05 between each class on each subscale (1= Consistently good quality of life, 2= Some quality of life concerns, 3= Low quality of life, 4= Financial concerns) e.g. for Work/Social Function "1 > 2,3" means that profile 1 has a mean score that is larger than profiles 2 and 3 and this is statistically significant at p<.05; N= Number of participants; SD= standard deviation; highlighted green= above the quality of life subscale mean; highlighted red= below the quality of life subscale mean.

Figure 3.1: Quality of life subscales for the latent profile classes

Table 3.4: Characteristics of each latent profile

	Profile 1 – Consistently good quality of life (N=891)	Profile 2 – Some quality of life concerns (N=184)	Profile 3 – Low quality of life (N=181)	Profile 4 – Financial concerns (N=163)	Wald Omnibus p value
	N (%)				
Reason for stoma formation		[3]	[2]		0.006
IBD	475 (53.3)	118 (64.1)	88 (48.6)	104 (63.8)	
Cancer	232 (26.0)	33 (17.9)	32 (17.7)	31 (19.0)	
Physical trauma	65 (7.3)	14 (7.6)	14 (7.7)	10 (6.1)	
Other	111 (12.5)	16 (8.7)	45 (24.9)	16 (9.8)	
Stoma					0.096
Ileostomy	599 (67.2)	126 (68.5)	115 (63.5)	116 (71.2)	
Colostomy	281 (31.5)	54 (29.3)	63 (34.8)	46 (28.2)	
Time with stoma					0.078
2 years or less	294 (33.0)	67 (36.4)	71 (39.2)	47 (28.8)	
More than 2 years	589 (66.1)	114 (62.0)	110 (60.8)	113 (69.3)	
Number of abdominal surgeries					0.16
1	221 (24.8)	40 (21.7)	30 (16.6)	44 (27.0)	
2+	657 (73.7)	144 (78.3)	150 (82.9)	115 (70.6)	
Sex					0.41

Female	697 (78.2)	144 (78.3)	154 (85.1)	127 (77.9)	
Male	191 (21.4)	37 (20.1)	27 (14.9)	34 (20.9)	
Age	^{2}	^{1}			0.006
16-55	568 (63.7)	144 (78.3)	127 (70.2)	122 (74.8)	
56+	322 (36.1)	40 (21.7)	54 (29.8)	41 (25.2)	
Hernia	^{3}	^{3}	^{1,2,4}	^{3}	<.001
No	479 (53.8)	110 (59.8)	54 (29.8)	84 (51.5)	
Yes	407 (45.7)	74 (40.2)	125 (69.1)	79 (48.5)	
	Mean (SD)				
Physical activity (days)	2.7 (2.3)^{3}	2.9 (2.3)^{3}	1.9 (2.1)^{1,2,4}	2.9 (2.3)^{3}	0.001

Note: Superscript numbers relate to Wald X^2 pairwise comparison tests at $p<.05$ between each class and the class number indicated (1= Consistently good quality of life, 2= Some quality of life concerns, 3= Low quality of life, 4= Financial concerns); IBD= Inflammatory Bowel Disease; percentages might not add up to 100% due to missing data.

3.4.3 Association with latent profile membership

Table 3.4 outlines the clinical and demographic characteristics and PA of the membership of each profile. This table also shows Omnibus Wald tests which indicated that there were overall differences between profiles on the reason for the stoma formation, age of the individual, the presence of a hernia or bulge and the PA of the individual ($p<.05$). Wald X^2 pairwise comparison tests identify that Profile 3 ('Low quality of life') is different from the other 3 profiles with a greater proportion of people having a hernia or bulge in this profile than the other 3. Furthermore, individuals classified into profile 3 were on average spending 1 less day being physically active than those in the other profiles.

Table 3.5 outlines the results of the multinomial regression investigating the association between these characteristics and membership of a specific profile, with Profile 1 being used as the reference category within the analysis. Individuals classified into profile 2 ('Some quality of life concerns') and profile 4 ('Financial concerns') were younger compared to profile 1. Those in profile 2 were more likely to have a colostomy (OR=1.64, 95%CI=1.08; 2.49) and were less likely to have their stoma formed because of 'cancer' (OR=0.57, 95%CI=0.35; 0.93) or 'other' reasons (e.g. Diverticulitis, FAP and Hirschsprung's Disease) (OR=0.52, 95%CI=0.28; 0.98).

Those classified into profile 3 ('Low quality of life') were less likely to have had their stoma for longer than 2 years (OR= 0.65, 95%CI=0.43; 0.96) and to spend more days being physically active (OR=0.85, 95%CI=0.78; 0.94) but were more likely have a hernia or bulge (OR=3.32, 95%CI=2.17; 5.07).

Table 3.5: Variables associated with profile membership

	Profile 2 – Some quality of life concerns	Profile 3 – Low quality of life	Profile 4 – Financial concerns
	Odds Ratio (95% CI)		
Reason for stoma formation (reference: IBD)			
Cancer	**0.57 (0.35; 0.93)**	0.76 (0.41; 1.41)	0.60 (0.34; 1.08)
Physical trauma	0.86 (0.44; 1.68)	0.87 (0.42; 1.78)	0.67 (0.31; 1.48)
Other	**0.52 (0.28; 0.98)**	**1.86 (1.10; 3.15)**	0.57 (0.27; 1.18)
Stoma (reference: Ileostomy)			
Colostomy	**1.64 (1.08; 2.49)**	1.20 (0.72; 2.00)	1.40 (0.83; 2.35)
Time with stoma (reference: 2 years or less)			
More than 2 years	0.81 (0.56; 1.16)	**0.65 (0.43; 0.96)**	1.22 (0.80; 1.85)
Number of abdominal surgeries (reference: 1)			
2+	1.27 (0.83; 1.93)	1.37 (0.85; 2.22)	0.78 (0.53; 1.16)
Sex (reference: Female)			
Male	1.02 (0.66; 1.56)	0.64 (0.38; 1.08)	0.96 (0.62; 1.50)
Age (reference: 16-55)			
56+	**0.56 (0.37; 0.85)**	0.66 (0.42; 1.02)	**0.64 (0.42; 0.98)**
Hernia (reference: No)			
Yes	0.93 (0.65; 1.33)	**3.32 (2.17; 5.07)**	1.26 (0.87; 1.81)
Per day increase in physical activity	1.04 (0.97; 1.12)	**0.85 (0.78; 0.94)**	1.07 (0.99; 1.15)

Note: Profile 1 'Consistently good quality of life' is the reference category; CI= Confidence Interval; IBD= Inflammatory Bowel Disease.

3.5 Discussion

This study is the first to identify that people with a stoma are heterogenous in how they report their QoL. Four distinct profiles were identified, with 'consistently good quality of life' being the most common, and 'some quality of life concerns', 'low quality of life' and 'financial concerns' being of roughly equal size. The results of this study suggest that members of all profiles could benefit from additional support around social and work situations, body image concerns and how to deal with stoma function issues and skin irritation. However, a more intensive intervention may be required for those who have recently had a stoma, have a hernia or have had their stoma formed for 'other' reasons (e.g. diverticulitis, FAP and Hirschsprung's Disease) as these individuals were more likely to belong to the 'low quality of life' profile according to our regression analyses. Furthermore, those who were less physically active were also more likely to belong to this profile, which could be a consequence of their clinical characteristics but could suggest that they may benefit from an intervention encouraging PA. To the best of our knowledge this is the first study to identify the QoL profiles of people with a stoma and to explore the factors associated with membership of these profiles. These findings provide us with a basis on which to tailor interventions to those most in need.

The results of the regression indicate that age may play a role in financial concerns. Those who are older and possibly retired may feel more secure in their financial position, compared to those who are younger and who therefore may have more concerns about the impact of their stoma on their working/financial situation. Previous qualitative work has highlighted that some people with a stoma have concerns about their working situation, and some do not return to work post-surgery[29]. This might explain why younger individuals are more likely to belong to profiles 2 ‘some quality of life concerns’ and 4 ‘financial concerns’ and might therefore benefit from more support and information on returning to work and managing financial difficulties. However, this may also be dependent on geographical location, as countries may have different levels of generosity of social security for older people and even within countries different health authorities may provide varying levels of support for people with a stoma.

This study identified one profile that had consistently lower QOL scores across all areas. The ’low quality of life’ profile accounted for 12.8% of the sample and included individuals who were more likely to have a recent stoma and the stoma formed for ‘other’ reasons. This is in line with previous research; a small (n=49) prospective study of patients with a stoma found that QOL improved over time with younger patients[30]. Two cross-sectional studies have found an association between QOL and self-efficacy in people with a stoma[31, 32], which could suggest that as their confidence in managing their stoma improves so would their QOL. However, research is needed with prospective cohorts to determine whether, as people progress with their stoma, they transition from the ‘low quality of life’ profile to one with improved QOL. There is also currently little research on QOL in people with a stoma beyond those that have had a stoma formed due to cancer or IBD. Further research is needed in other disease areas to unpick the finding that those with a stoma formed for ‘other’ reasons are more likely to be in the ‘low quality of life’ profile. Available services to support people with a stoma post-surgery may currently be more relevant to those with IBD and cancer than to those from less common diseases.

Individuals classified into profile 3 ‘low quality of life’ were also more likely to have a hernia or bulge and were less physically active. These findings are in line with previous cross-sectional research which suggests that the presence of a hernia or bulge is associated with lower QOL scores[6, 33, 34]. Further cross-sectional research also suggests that the presence of a bulge or hernia is associated with lower levels of PA[6]. However, these relationships need to be modelled over time to determine causality. Interventions that target these issues could improve QOL within this profile. For example, the Hernia Active Living Trial[35], which is recruiting people with a stoma and a hernia or bulge, is seeking to improve QOL and physical fitness through strengthening the abdominal wall to reduce hernia progression.

There may be additional factors associated with membership of the profiles that were not measured. For example, complications with the stoma or other health issues may have been associated with the 'low quality of life' profile[2, 36, 37]. Interestingly, we did not find an association between membership of this profile and the type of stoma. Previous research has suggested that 22-35% of people with an ileostomy report a daytime leakage compared to 12-20% of people with a colostomy with similar results reported for night-time leakages (ileostomy 21-33% vs colostomy 3-15%), which could contribute to lower QOL[14]. Furthermore, variables such as health services use, health outcomes and engagement with offered interventions or support would be useful to know to understand the level of support required. Additional research is required to assess whether other factors may be associated with membership of the profiles to develop a more comprehensive view on interventions that could benefit this group. Research will also need to consider how future interventions will be utilised by health professionals to target those individuals in need within health services.

Strengths of this study are the large sample size and the focus on a person-centred approach by using LPA to identify profiles of QOL responses. The LPA approach has produced profiles that provide suggestions for future tailored interventions. Further exploratory cross-sectional studies are needed to confirm and expand upon the findings of this study. However, cross-sectional studies can only examine associations. Further research that can take a longitudinal perspective and explore the dynamic interaction of QOL over the course of an individual's life is needed, using latent transition analysis, for example. Furthermore, future research could strengthen the identification of the profiles by partitioning samples into training and validation sets to run profile identification and then validate the findings.

There are limitations with the present study. Firstly, the sample may not be representative of the wider stoma population as the majority of the sample had their stoma formed because of IBD when cancer is the most common reason for stoma formation[4]. This could be due to the method of recruitment as social media and the mailing list of a support garment supplier were used, which may have biased the sample towards younger age groups who are more likely to have had IBD. As this study was a secondary analysis of previously collected data, the sampling methods used, and the variables collected were not optimised for the aims of the present study. For example, certain variables were not ideal (e.g. age range instead of age, which reduces the precision of the variable;

single-item of PA instead of time spent over a week; and the Stoma QOL Scale which requires further validation) and other variables such as BMI, which is associated with higher rates of stoma complications[38] were not available. Variables that were used within the analysis may also overlap, such as age and reason for stoma formation, however, tests for multicollinearity indicated only moderate overlap. Also, although we identified different profiles based upon reported QOL we do not know whether the differences between profiles, although statistically significant, are clinically meaningful. Future research should consider employing the Delphi technique to help identify what the minimum clinically meaningful difference would be on these scales.

In conclusion, this is the first study to identify latent profiles within a sample of people with a stoma and highlights that the sample is heterogenous in how they report QOL. Furthermore, it suggests that different groups may benefit from different interventions or support. For example, those who have a recent stoma, a hernia, are less physically active or have had their stoma formed for ‘other’ reasons may benefit from more intensive support as they are more likely to have inhibited QOL. Additionally, those who are younger may benefit from additional support around financial issues and advice on returning to work. Future research is required to explore the consistency of these profiles across more representative samples and to expand the range of variables associated with profile membership. Further work in this area will improve the development and tailoring of interventions to enhance QOL for people living with a stoma.

Declarations

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Conflict of interests

The authors report no conflict of interests.

Availability of data and material

This was secondary data analysis.

Ethics approval

Ethical approval for the original study was obtained from the University of the Highlands and Islands Research and Ethics Committee (Ref: OLETHSHE903).

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Chapter 4: Understanding the associations between receipt of, and interest in, advice from a healthcare professional and quality of life in individuals with a stoma from colorectal cancer: A latent profile analysis.

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Study 3	
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4.1 Abstract

Purpose: To explore whether profiles derived from self-reported quality of life were associated with receipt of, and interest in, advice from a healthcare professional in people with a stoma.

Methods: Secondary analysis of cross-sectional national survey data from England of 4487 people with a stoma from colorectal cancer. The survey assessed quality of life using various scales, receipt and interest in various forms of advice, and physical activity. A three-step latent profile analysis was conducted to determine the optimum number of profiles. Multinomial regression explored factors associated with profile membership. A series of logistic regression models examined whether profile membership was associated with interest in advice.

Results: Five profiles were identified; 'consistently good quality of life', 'functional issues', 'functional and financial issues', 'low quality of life' and 'supported but struggling'. Individuals in the 'functional and financial issues' and 'low quality of life' profiles were more likely to have received financial advice compared to the 'consistently good quality of life' profile. When compared to the 'consistently good quality of life' profile, all other profiles were more likely to report wanting advice across a range of areas, with the strongest associations in the 'low quality of life' profile.

Conclusion: Findings indicate that people with a stoma are not a homogenous group in terms of quality of life. Participants in profiles with quality of life concerns report wanting more advice across various categories but findings suggest there is scope to explore how this can be tailored or adapted to specific groups.

Key words

Quality of life; advice; stoma; colorectal cancer; physical activity

4.2 Introduction

A stoma is an artificial opening on the abdomen that has been created to divert the flow of faeces or urine[1]. Recent estimates suggest over 175,000 people in the UK live with a stoma, with 13,500 stoma formation surgeries conducted annually[2]. Colorectal cancer is the foremost reason for creation of a bowel stoma[3], with those that have a stoma formed due to cancer having impaired quality of life (QOL) compared to those without a stoma[4]. A systematic review found that stoma complications, a changing body and changes to usual activities can negatively impact QOL, which can be further influenced by demographic and clinical characteristics such as age, gender and the time since cancer treatment[5]. Although QOL improves over time research suggests that it is still lower for those with compared to those without a stoma[4]. QOL is increasingly viewed as a key measure to evaluate patients’ recovery from treatment[6] and is incorporated into the NHS long-term strategy to improve patient care and encourage patient self-management[7]. Therefore, an understanding of how QOL varies across people with a stoma will aid in developing interventions to improve this because it means that specific groups in greatest need can be targeted by healthcare professionals to improve QOL.

The receipt of advice from healthcare professionals is a common approach to empower patients with the ability to self-manage their condition, adopt healthier behaviours and thus improve their QOL. Behavioural factors such as physical activity can be associated with higher levels of QOL in people with colorectal cancer and smoking has been associated with lower levels of QOL[8, 9]. A large study of colorectal cancer survivors (n=15254) looking at recall of physical activity advice found that receipt of advice from a healthcare professional was associated with reporting meeting physical activity guidelines[10]. A study of research priorities for people with a stoma found that communication with healthcare professionals about living with a stoma was ranked as one of their top priorities[11]. Research has also found that 42% of people living with a stoma had not received physical activity advice and 30% had not received dietary advice but 90% of these individuals wanted to receive this advice[12]. Furthermore, a previous study of people with a stoma from colorectal cancer concluded that ostomy nurses should provide advice to patients in order to help them adjust to specific challenges they may face such as stoma complications[13]. However, not all patients have the same needs, and understanding how to direct and adapt advice could support the delivery of more personalised care in line with the NHS long-term strategy[7].

QOL is a multidimensional construct that can help to capture an individual’s view on their experience of health and allows for the evaluation of interventions designed to improve this[14, 15]. Latent profile analysis (LPA) allows for the identification of subgroups of a sample by exploring whether there are patterns of responses to certain variables which allows for the exploration of group membership with other variables[16]. A previous exploratory LPA study found that people with a stoma can be divided into 4 distinct groups based upon their self-reported QOL[17]. Those in the 'low quality of life' profile were more likely to have hernia or bulge, have a newer stoma, and were less likely to be physically active whereas those in the 'some quality of life concerns' and 'financial concerns' profiles were more likely to be younger compared to the 'consistently good quality of life' profile. However, the advice and support that patients needed had to be inferred from their profile rather than having participant-reported data on the advice they would like to receive.

The present study utilises population-based data from a survey of colorectal cancer survivors collected in 2013 in England[18]. The primary objective of this study is to use LPA to identify groups of patients, based upon their self-reported QOL, and explore the associations between group membership and advice they received or would like to receive.

4.3 Methods

4.3.1 Study design

This study is a secondary analysis of a cross-sectional, national survey of colorectal cancer patients. The data were accessed using the COloRECTal cancer data Repository (CORECT-R). The CORECT-R resource, and analyses based upon the data within it, has received approval from the Southwest-Central Bristol research ethics committee (18/SW/0134).

4.3.2 Procedure and participants

Participants that had received a diagnosis of colorectal cancer in 2010 and 2011 and who were still alive as of January 2013 were sent a postal survey with 2 follow-up reminders. Eligible individuals were identified by the National Cancer Registration and Analysis Service and the survey was administered by the National Health Service (NHS) England. A total of 21,802 people responded to the survey; this study is focussed on the 4,487 who self-reported that a stoma was present when completing the survey.

4.3.3 Measures

4.3.3.1 Demographic and clinical characteristics

Sex was measured using a single question and recorded as male or female. Age was from their time of diagnosis. An area-based measure of socioeconomic status was derived using the Indices of Multiple Deprivation[19]. Individuals were assigned to a quintile ranging from 1 (least deprived) to 5 (most deprived) based upon their postcode at diagnosis. Respondents were asked whether they had certain long-standing health problems (e.g. angina, high blood pressure, etc) which were summed to provide the number of comorbid conditions each individual had, with the maximum being 17. Time since initial treatment was assessed by asking participants whether they were still receiving their initial treatment, were less than 3 months since treatment, between 3 and 12 months, between 1 and 5 years or more than 5 years since treatment.

4.3.3.2 Behavioural measures

Physical activity was measured by a single item asking how many days in the past week they had been physically active for 30 minutes or more that had raised their heartbeat. Smoking status was recorded as non-smoker, ex-smoker or smoker.

4.3.3.3 Receipt of and interest in advice

Participants were asked whether they had received advice from healthcare professionals across several different categories. They were also asked whether it would have been helpful to have more advice on each of these aspects. These questions came from the Cancer Patient Experience Survey[20] and were important for this study in that they map to key QOL domains. For the purposes of this study, the advice questions were condensed into diet and exercise, any financial information, information for family and friends, physical aspects of living with and beyond cancer and psychological aspects of living with and beyond cancer. **Appendix C.1** outlines how these categories were condensed.

4.3.3.4 Quality of life

Several measures of QOL were used in the survey. Participants completed the EQ-5D-5L but the VAS was not included in the questionnaire[21]. The domains of Self-care (e.g. ‘I have no problems washing or dressing myself’), Usual Activities (e.g. ‘I have no problems doing my usual activities’) and Pain and Discomfort domain (e.g. ‘I have no pain or discomfort’) were used in the present study. Participants completed only the Additional Concerns subscale from the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) scale in order to obtain participants’ views on specific concerns related to colorectal cancer[22](e.g. ‘I like the appearance of my body’). The survey also included the Social Difficulties Inventory[23], which consists of three subscales. The Money Matters subscale (e.g. ‘Have you had any financial difficulties’) and the Self and Others subscale (e.g. ‘Have you had any difficulty communicating with those closest to you (e.g. partner, children, parents)’) were used in the present study.

The subscales/domains that were used within the present study were selected to allow for comparison with the only previous LPA study within this population[17]. Information on which subscales were selected to be comparable with those of the previous study can be found in **Appendix C.2**.

4.3.4 Statistical analysis

Data were analysed using Stata v16.0 and Latent GOLD v6.0.

All variables were summarised descriptively. For the EQ-5D-5L, the domain means were used in the analysis[21]. The domains use a Likert scale with 5 options (ranging from no problems to severe problems). Research suggests that Likert responses can be used as continuous measures as long as there are at least 5 levels[24, 25]. The FACT-C Additional Concerns subscale score was calculated following the guidance for the scale[22]. The scores range from 0-28. The Social Difficulties Inventory subscales were calculated according to the guidance[23]. The range for the Self and Others subscale was 0-15 and for Money Matters it was 0-13.

The variables with the most missing data were those related to interest in receiving more advice, with missing data at 16.5% for these variables. This was a multi-response question; hence all variables had the same missing data if the question was missed. To account for the missing data in the analysis the maximum likelihood method was used which uses all available data.

The three-step approach to LPA was used for this study. The first step involved identifying the optimum number of profiles. A series of models were run with 1 to 6 (the number of subscales included in the analysis) profiles. These models were assessed on several model fit statistics: Akaike Information Criteria (AIC) and Bayesian Information Criteria (BIC) and entropy. For AIC and BIC, a smaller number indicates a better fit and for entropy a number closer to 1 indicates a better separation between profiles. The size of the smallest profile was also taken into consideration, and if this was below 5% of the sample then this model was not considered. Once the optimum model was selected, participants were assigned to their profile based upon probability scores.

A one-way analysis of variance (ANOVA) analysis was conducted to test whether there was an overall difference in the subscales across each profile and post-hoc Bonferroni tests were conducted to test for differences in the subscale scores between profiles. A multinomial regression analysis was conducted to explore whether demographic and clinical characteristics, behavioural measures and receipt of advice were associated with profile membership. Overall differences between the profiles were assessed with the Wald Omnibus tests and associations between profiles were assessed with Wald χ^2 pairwise comparison tests, with the Bonferroni correction applied for multiple tests. Finally, a series of logistic regressions were conducted exploring whether profile membership was associated with interest in receiving advice, controlling for clinical and demographic characteristics and whether they had previously received advice.

4.4 Results

4.4.1 Descriptive statistics

Table 4.1 provides an overview of the descriptive statistics of the sample. The sample of 4487 ostomates from colorectal cancer were predominantly male (60.4%), were between 1 and 5 years from their initial treatment (75.2%), and were physically active for an average of 2.1 days a week (SD=2.4). The majority of participants did not receive advice on any of the reported areas, although 48.6% of participants did report receiving advice on free prescriptions. Participants were most interested in receiving advice on the physical (28.5%) and psychological (24.3%) effects of treatment.

Table 4.1: Descriptive statistics for the sample (N=4,487)

Variable		N (%)
Sex		
	Female	1589 (35.4)
	Male	2712 (60.4)
	Missing	186 (4.2)
Age Mean (SD)		71.2 (10.9)
	Missing	229 (5.1)
Deprivation quintile		
	1 – least deprived	917 (20.4)
	2	1071 (23.9)
	3	1017 (22.7)
	4	846 (18.9)
	5 – most deprived	636 (14.2)
	Missing	0
Number of comorbidities Mean (SD)		1.7 (1.5)
	Missing	261 (5.8)
Time since cancer treatment		
	Still having treatment	185 (4.1)
	Less than 3 months since treatment	77 (1.7)
	Between 3 and 12 months since treatment	680 (15.2)
	Between 1 and 5 years since treatment	3374 (75.2)
	More than 5 years since treatment	53 (1.2)
	Missing	195 (4.4)
Days in a week physically active Mean (SD)		2.1 (2.4)
	Missing	157 (3.5)
Smoking status		
	Non-smoker	2231 (49.7)
	Ex-smoker	1776 (39.6)
	Smoker	393 (8.8)
	Missing	87 (1.9)
Advice received diet, lifestyle and physical activity		
	Yes	2211 (49.3)
	No	2033 (45.3)
	Missing	243 (5.4)

Advice received Financial information		
	Yes	2429 (54.1)
	No	1815 (40.5)
	Missing	243 (5.4)
Advice received Information for family and friends		
	Yes	757 (16.9)
	No	3487 (77.7)
	Missing	243 (5.4)
Advice received Physical effects of treatment		
	Yes	1091 (24.3)
	No	3153 (70.3)
	Missing	243 (5.4)
Advice received Psychological effects of treatment		
	Yes	709 (15.8)
	No	3535 (78.8)
	Missing	243 (5.4)
Interest in advice diet, lifestyle and physical activity		
	Yes	1025 (22.8)
	No	2722 (60.7)
	Missing	740 (16.5)
Interest in advice Financial information		
	Yes	982 (21.9)
	No	2765 (61.6)
	Missing	740 (16.5)
Interest in advice Information for family and friends		
	Yes	564 (12.6)
	No	3183 (70.9)
	Missing	740 (16.5)
Interest in advice Physical effects of treatment		
	Yes	1278 (28.5)
	No	2469 (55.0)
	Missing	740 (16.5)
Interest in advice Psychological effects of treatment		
	Yes	1090 (24.3)
	No	2657 (59.2)
	Missing	740 (16.5)
Usual activities Mean (SD) range 1-5		3.8 (1.2)
	Missing	61 (1.4)
Self-care Mean (SD) range 1-5		4.5 (0.9)
	Missing	34 (0.8)
Self and others Mean (SD) range 0-15		12.9 (2.6)
	Missing	486 (10.8)
FACT-C Mean (SD) range 0-28		16.3 (6.2)
	Missing	0
Money matters Mean (SD) range 0-13		11.9 (2.2)
	Missing	542 (12.1)
Pain and discomfort Mean (SD) range 1-5		4.2 (0.9)
	Missing	59 (1.3)

Note: N= number of participants; SD= standard deviation.

4.4.2 Latent profile analysis

Based upon the model fit statistics and review of the overall make-up of the profiles the 5-profile model was selected as the optimum model. Model fit statistics for all models conducted can be found in **Appendix C.3**. **Table 4.2** presents the average scores of the QoL subscales across each of the profiles and **Figure 4.1** graphically represents the standardised QoL scores for all the profiles.

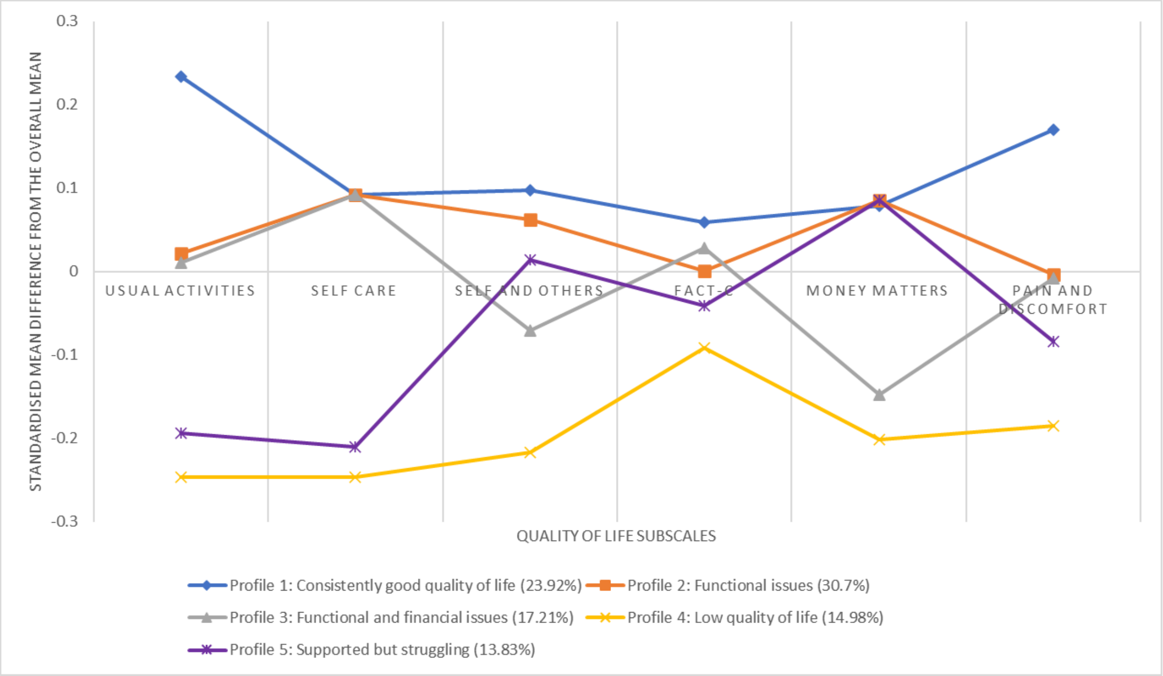
Profile 1 is characterised by higher-than-average scores across all QoL subscales, therefore, this was labelled as the 'Consistently good quality of life' profile. Profile 2 was characterised as having generally higher-than-average scores on the Usual Activities, Self-Care, Self and Others and Money Matters subscales but lower-than-average scores on the FACT-C and Pain and Discomfort subscales, therefore, this was labelled as 'Functional issues'. Profile 3 was characterised by similar scores to profile 2 but with additional problems around Money Matters and this was labelled as 'Functional and financial issues'. Profile 4 was characterised by lower-than-average scores across all subscales and so was labelled the 'Low quality of life' profile. Profile 5 had similarly low scores to profile 4 on the Usual Activities, Self-Care and FACT-C subscales but high scores on the Self and Others and Money Matters subscales and so this was labelled 'Supported but struggling'.

Table 4.2: Final profile frequencies and quality of life scores for each subscale

	Profile 1 – Consistently good quality of life N= 1074 (23.9%)	Profile 2 – Functional issues N= 1406 (30.7%)	Profile 3 – Functional and financial issues N= 731 (17.2%)	Profile 4 – Low quality of life N= 655 (15.9%)	Profile 5 – Supported but struggling N= 621 (13.8%)	Bonferroni post-hoc test
Posterior probabilities Mean (SD)	0.95 (0.11)	0.99 (0.02)	0.98 (0.07)	0.96 (0.11)	0.95 (0.11)	
Quality of life scores: Mean (SD)						
Usual activities	5.0 (0)	3.9 (0.9)	3.9 (0.9)	2.6 (1.0)	2.9 (1.1)	1>2,3,4,5; 2>4,5; 3>4,5; 4<5
Self-care	5.0 (0)	5.0 (0)	5.0 (0)	3.3 (0.9)	3.5 (0.7)	1>4,5; 2>4,5; 3>4,5; 4<5
Self and others	14.4 (1.0)	13.9 (1.4)	11.8 (2.8)	9.7 (3.6)	13.2 (1.9)	1>2,3,4,5; 2>3,4,5; 3>4; 3<5; 4<5
FACT-C	18.0 (6.6)	16.2 (6.4)	17.1 (4.9)	13.7 (5.7)	15.2 (5.8)	1>2,3,4,5; 2>4,5; 2<3; 3>4,5; 4<5
Money matters	12.9 (0.3)	13.0 (0)	9.9 (2.6)	9.3 (3.0)	13.0 (0)	1>3,4; 2>3,4; 3>4; 3<5; 4<5
Pain and Discomfort	5.0 (0)	4.12 (0.7)	4.1 (0.8)	3.2 (0.9)	3.8 (0.9)	1>2,3,4,5; 2>4,5; 3>4,5; 4<5

Note: N= number of participants; SD= standard deviation; post-hoc Bonferroni tests indicate significant differences (p<.05) between the profiles; boxes highlighted in green indicate scores above the overall mean and those in red indicate scores below the overall mean.

Figure 4.1: Representation of each of the profiles across the subscales



4.4.3 Association with latent profile membership and interest in advice

Table 4.3: Descriptive statistics across the profiles

Variable	Profile 1 – Consistently good quality of life N= 1074 (23.9%)	Profile 2 – Functional issues N= 1406 (30.7%)	Profile 3 – Functional and financial issues N= 731 (17.2%)	Profile 4 – Low quality of life N= 655 (15.0%)	Profile 5 – Supported but struggling N= 621 (13.8%)	WALD Omnibus p value
	N (%)					
Sex		^{4}		^{2}		<.001
Female	396 (36.9)	548 (39.0)	228 (31.2)	206 (31.5)	211 (34.0)	
Male	628 (58.5)	796 (56.6)	484 (66.2)	421 (64.3)	383 (61.7)	
Deprivation quintile	^{4}	^{4}	^{4}	$^{1, 2, 3}$		<.001
1 – least deprived	260 (24.2)	314 (22.3)	145 (19.8)	98 (15.0)	100 (16.1)	
2	276 (25.7)	346 (24.6)	195 (26.7)	127 (19.4)	127 (20.5)	
3	237 (22.1)	330 (23.5)	153 (20.9)	138 (21.1)	159 (25.6)	
4	177 (16.5)	256 (18.2)	138 (18.9)	141 (21.5)	134 (21.6)	
5 – most deprived	124 (11.6)	160 (11.4)	100 (13.7)	151 (23.1)	101 (16.3)	
Time since diagnosis	$^{4, 5}$			^{1}	^{1}	<.001
Still having treatment	25 (2.3)	59 (4.2)	28 (3.8)	41 (6.3)	32 (5.2)	
< 3 months	14 (1.3)	21 (1.5)	18 (2.5)	15 (2.3)	9 (1.5)	
3 to 12 months	133 (12.4)	202 43(14.4)	151 (20.7)	100 (15.3)	94 (15.1)	
1 to 5 years	861 (80.2)	1056 (75.1)	515 (70.5)	477 (72.8)	465 (74.9)	
> 5 years	10 (0.9)	21 (1.5)	7 (1.0)	7 (1.1)	8 (1.3)	

Smoking status	^{4}			^{1}		0.004
Non-smoker	592 (55.1)	728 (51.8)	360 (49.3)	278 (42.4)	273 (44.0)	
Ex-smoker	394 (36.7)	547 (38.9)	287 (39.3)	276 (42.1)	272 (43.8)	
Smoker	65 (6.1)	103 (7.3)	77 (10.5)	90 (13.7)	58 (9.3)	
Advice received diet, lifestyle and physical activity						0.14
Yes	510 (47.5)	683 (48.6)	403 (55.1)	322 (49.2)	293 (47.2)	
No	500 (46.6)	639 (45.5)	303 (41.5)	304 (46.4)	287 (46.2)	
Advice received Financial information	$^{3, 4}$	$^{3, 4}$	$^{1, 2}$	$^{1, 2}$		<.001
Yes	499 (46.5)	683 (48.6)	493 (67.4)	420 (64.1)	334 (53.8)	
No	511 (47.6)	639 (45.5)	213 (29.1)	206 (31.5)	246 (39.6)	
Advice received Information for family and friends						0.28
Yes	145 (13.5)	202 (14.4)	155 (21.2)	138 (21.1)	117 (18.8)	
No	865 (80.5)	1120 (79.7)	551 (75.4)	488 (74.5)	463 (74.6)	
Advice received Physical effects of treatment						0.61
Yes	228 (21.2)	317 (22.6)	226 (30.9)	173 (26.4)	147 (23.7)	
No	782 (72.8)	1005 (71.5)	480 (65.7)	453 (69.2)	433 (69.7)	
Advice received Psychological effects of treatment						0.63
Yes	146 (13.6)	194 (13.8)	149 (20.4)	117 (17.9)	103 (16.6)	
No	864 (80.5)	1128 (80.2)	557 (76.2)	509 (77.7)	477 (76.8)	
Interest in advice diet, lifestyle and physical activity						
Yes	151 (14.1)	288 (20.5)	244 (33.4)	213 (32.5)	129 (20.8)	
No	722 (67.2)	857 (61.0)	417 (57.1)	358 (54.7)	368 (59.3)	
Interest in advice Financial information						
Yes	115 (10.7)	165 (11.7)	316 (43.2)	288 (44.0)	98 (15.8)	
No	758 (70.6)	980 (69.7)	345 (47.2)	283 (43.2)	399 (64.3)	
Interest in advice Information						

for family and friends						
Yes	50 (4.7)	107 (7.6)	136 (18.6)	189 (28.9)	82 (13.2)	
No	823 (76.6)	1038 (73.8)	525 (71.8)	382 (58.3)	415 (66.8)	
Interest in advice Physical effects of treatment						
Yes	182 (17.0)	353 (25.1)	293 (40.1)	300 (45.8)	150 (24.2)	
No	691 (64.3)	792 (56.3)	368 (50.3)	271 (41.4)	347 (55.9)	
Interest in advice Psychological effects of treatment						
Yes	127 (11.8)	279 (19.8)	275 (37.6)	280 (42.8)	129 (20.7)	
No	746 (69.5)	866 (61.6)	386 (52.8)	291 (44.4)	368 (59.3)	
	Mean (SE)					
Comorbidities	1.2 (0.04)$^{2, 3, 4, 5}$	1.7 (0.04)$^{1, 4, 5}$	1.4 (0.1)$^{1, 4}$	2.4 (0.1)$^{1, 2, 3, 5}$	2.4 (0.1)$^{1, 2, 4}$	<.001
Age	72.1 (0.3)$^{3, 4, 5}$	73.5 (0.3)$^{3, 4, 5}$	63.7 (0.4)$^{1, 2, 4, 5}$	68.2 (0.5)$^{1, 2, 3, 5}$	76.5 (0.4)$^{1, 2, 3, 4}$	<.001
Physical activity	2.9 (0.1)$^{2, 3, 4, 5}$	2.1 (0.1)$^{1, 4, 5}$	2.4 (0.1)$^{1, 4, 5}$	1.3 (0.1)$^{1, 2, 3}$	1.0 (0.1)$^{1, 2, 3}$	<.001

Note: Superscript numbers relate to Wald X^2 pairwise comparison tests at $p < .05$ between each class and the class number indicated (1 = Consistently good quality of life, 2 = Functional issues, 3 = Functional and financial issues, 4 = Low quality of life, 5 = Supported but struggling); results for the Wald X^2 and Omnibus tests are only available for variables included in the LPA model, therefore, this would not include interest in advice variables; percentages might not add up to 100% due to missing data.

Table 4.3 outlines the descriptive statistics across all the profiles and the Wald Omnibus and χ^2 tests for differences between profiles. **Table 4.4** outlines the results from the multinomial regression with profile 1 'Consistently good quality of life' used as the reference group. Individuals that were classified into profiles 2-5 were more likely to have more comorbidities, be closer to when their treatment occurred and be less physically active compared to those in profile 1. Those that were members of profile 3 and 4 were more likely to be younger than those in profile 1 but those in profile 5 were more likely to be older. Those classified into profiles 4 and 5 were also more likely to be smokers and live in a more deprived area than those in profile 1. Those in profiles 3, 4 and 5 were more likely to be male than those in profile 1.

Across profiles 3 and 4 individuals were more likely to have received financial advice compared to profile 1. But there were no other significant differences observed across the other receipt of advice variables.

Table 4.4: Variables associated with profile membership

	Profile 2 – Functional issues	Profile 3 – Functional and financial issues	Profile 4 – Low quality of life	Profile 5 – Supported but struggling
Odds ratio (95%CI)				
Sex (reference: female)				
Male	1.0 (0.8; 1.2)	**1.4 (1.1; 1.8)**	**1.5 (1.2; 1.9)**	**1.4 (1.1; 1.8)**
Age	1.0 (1.0; 1.0)	**0.9 (0.9; 0.9)**	**0.9 (0.9; 1.0)**	**1.0 (1.0; 1.1)**
Deprivation quintile	1.0 (0.9; 1.1)	1.0 (1.0; 1.1)	**1.2 (1.1; 1.3)**	**1.2 (1.1; 1.3)**
Number of comorbidities	**1.3 (1.2; 1.4)**	**1.4 (1.2; 1.5)**	**1.8 (1.7; 2.0)**	**1.6 (1.4; 1.7)**
Time since treatment	**0.8 (0.7; 0.9)**	**0.8 (0.7; 0.9)**	**0.8 (0.7; 0.9)**	**0.7 (0.6; 0.9)**
Days in a week physically active	**0.9 (0.9; 0.9)**	**0.9 (0.9; 1.0)**	**0.8 (0.7; 0.8)**	**0.7 (0.7; 0.8)**
Smoking status (reference: non-smoker)				
Ex-smoker	1.1 (0.9;1.3)	1.2 (1.0; 1.5)	1.2 (0.9; 1.5)	**1.3 (1.1; 1.7)**
Smoker	1.2 (0.9; 1.7)	1.4 (1.0; 2.1)	**2.1 (1.4; 3.0)**	**2.0 (1.3; 3.0)**
Advice received Diet, lifestyle and physical activity (reference: no)				
Yes	1.1 (0.9; 1.4)	1.0 (0.8; 1.2)	0.8 (0.7; 1.1)	1.0 (0.8; 1.3)
Advice received Financial information (reference: no)				
Yes	1.0 (0.9; 1.2)	**1.7 (1.3; 2.1)**	**1.7 (1.3; 2.1)**	1.2 (1.0; 1.6)
Advice received Information for family and friends (reference: no)				
Yes	1.0 (0.8; 1.3)	1.2 (0.9; 1.6)	1.4 (1.0; 1.9)	1.2 (0.9; 1.7)
Advice received Physical effects of treatment (reference: no)				
Yes	1.2 (0.9; 1.5)	1.2 (0.9; 1.3)	1.1 (0.8; 1.5)	1.2 (0.9; 1.6)
Advice received Psychological effects of treatment (reference: no)				
Yes	0.9 (0.7; 1.2)	1.0 (0.7; 1.4)	0.9 (0.6; 1.3)	1.2 (0.8; 1.7)

Note: bold values indicate statistical significance at p<.05; Profile 1 'Consistently good quality of life' is used as the reference category; CI= confidence interval.

Table 4.5 outlines the results of the logistic regression models exploring interest in receiving advice, with 'not interested' as the reference category. These results indicate that having already received advice was associated with less interest in wanting further advice, except for financial information where there was no significant difference. There were also significant results for profile membership being associated with interest in receiving further advice across all advice categories apart from financial information for the 'Functional issues' profile. Across all regressions there were consistent findings that membership of profiles 2, 3, 4 and 5 compared to profile 1 were more likely to be interested in receiving further advice.

However, the strongest relationships were observed for the ‘low quality of life’ profile across all models, where being a member of this profile was associated with being interested in diet and physical activity advice (OR=2.6, 95%CI: 2.0; 3.5), financial information (OR=5.4, 95%CI: 4.0; 7.3), information for family and friends (OR=7.0, 95%CI: 4.7; 10.4), physical effects of living with and beyond cancer (OR=4.2, 95%CI: 3.2; 5.5), and psychological effects of living with and beyond cancer (OR=5.2, 95%CI: 3.8; 6.9) compared with profile 1.

Table 4.5: Logistic regression model results exploring interest in receiving advice

	Interest in diet, lifestyle and physical activity advice	Interest in financial information	Interest in advice for family and friends	Interest in advice on the physical effects of treatment	Interest in advice on the psychological effects of treatment
Odds ratio (95%CI)					
Sex (reference: female)					
Male	0.9 (0.8; 1.1)	1.1 (0.9; 1.3)	1.1 (0.9; 1.4)	**0.8 (0.7; 1.0)**	**0.7 (0.6; 0.9)**
Age	**1.0 (1.0; 1.0)**	**1.0 (1.0; 1.0)**	**1.0 (1.0; 1.0)**	**1.0 (1.0; 1.0)**	**1.0 (1.0; 1.0)**
Deprivation quintile	1.0 (0.9; 1.1)	**1.1 (1.1; 1.2)**	1.0 (0.9; 1.0)	1.0 (0.9; 1.1)	1.0 (0.9; 1.1)
Number of comorbidities	**1.1 (1.0; 1.1)**	**1.1 (1.0; 1.2)**	**1.2 (1.1; 1.3)**	**1.1 (1.0; 1.1)**	**1.1 (1.1; 1.2)**
Time since treatment	1.0 (0.9; 1.2)	0.9 (0.8; 1.0)	1.0 (0.9; 1.1)	1.0 (0.9; 1.1)	1.1 (1.0; 1.2)
Days in a week physically active	1.0 (1.0; 1.0)	1.0 (1.0; 1.1)	1.0 (0.9; 1.0)	1.0 (1.0; 1.0)	1.0 (1.0; 1.0)
Smoking status (reference: non-smoker)					
Ex-smoker	0.9 (0.8; 1.1)	0.9 (0.8; 1.1)	1.0 (0.8; 1.3)	0.9 (0.7; 1.0)	0.8 (0.7; 1.0)
Smoker	1.0 (0.8; 1.3)	1.3 (1.0; 1.8)	1.2 (0.9; 1.7)	1.0 (0.8; 1.3)	0.9 (0.7; 1.2)
Advice received Diet, lifestyle and physical activity (reference: no)					
Yes	**0.5 (0.4; 0.6)**				
Advice received Financial information (reference: no)					
Yes		0.9 (0.8; 1.1)			
Advice received Information for family and friends (reference: no)					
Yes			**0.5 (0.4; 0.7)**		
Advice received Physical effects of treatment (reference: no)					
Yes				**0.3 (0.2; 0.4)**	
Advice received Psychological effects of					

treatment (reference: no)					
Yes					**0.4 (0.3; 0.5)**
Profiles					
2 – Functional Issues	**1.8 (1.4; 2.3)**	1.2 (0.9; 1.6)	**1.9 (1.3; 2.7)**	**1.8 (1.4; 2.3)**	**2.0 (1.6; 2.6)**
3 – Functional and financial issues	**2.6 (2.0; 3.4)**	**4.6 (3.5; 6.1)**	**3.9 (2.6; 5.8)**	**2.8 (2.2; 3.6)**	**3.7 (2.8; 4.9)**
4 – Low quality of life	**2.6 (2.0; 3.5)**	**5.4 (4.0; 7.3)**	**7.0 (4.7; 10.4)**	**4.2 (3.2; 5.5)**	**5.2 (3.8; 6.9)**
5 – Supported but struggling	**2.0 (1.5; 2.7)**	**1.8 (1.3; 2.5)**	**3.5 (2.3; 5.4)**	**1.7 (1.1; 4.9)**	**2.5 (1.8; 3.4)**

Note: bold values indicate statistical significance at $p<.05$; Profile 1 'Consistently good quality of life' is used as the reference category; CI= confidence interval.

4.5 Discussion

This study identified 5 distinct profiles of people with a stoma from colorectal cancer based upon their self-reported QOL. 'Functional issues' was the largest profile followed by 'consistently good quality of life', 'functional and financial issues', 'low quality of life' and 'supported but struggling'. Members of the 'functional and financial issues' and 'low quality of life' profiles were more likely to have received advice on financial matters compared to profile 1, 'consistently good quality of life'. There were no other differences between the profiles on the advice received. When compared with profile 1, all other profiles were more likely to be interested in receiving advice across all categories. These findings also compliment and confirm some of the findings from the previous LPA study and suggest further avenues for future research and tailoring of interventions[17].

The findings from the present study suggest there is no significant association between receipt of advice and profile membership beyond the receipt of financial information to the 'low quality of life' and 'functional and financial issues' profiles. This could suggest that health professionals are taking a blanket approach to the advice they provide to patients and not the tailored approach that is recommended and outlined in the NHS long-term strategy[7]. The Association for Stoma Care Nurses (ASCN) guidelines from 2021 indicate a number of areas in which advice and support should be offered to patients but there is no information provided on how to tailor this[26]. Research has suggested that patients can suffer from information overload which can prevent them from taking in information[27], therefore it is imperative that patients are not overburdened with possible unnecessary information which they are not interested in receiving.

This study has also identified that those from the profiles with the most QOL concerns, 'low quality of life', 'supported but struggling', and 'functional and financial issues' had the strongest associations with wanting more information for family, friends or carers. This could be due to them relying more on their support. A review of research into living with a stoma suggests that those that perceive they have greater social support from their family and friends have less difficulty in adjusting to a stoma than those who perceive they have little social support[28]. Therefore, ensuring that family and friends are included when advice is provided by healthcare professionals to patients may have a beneficial impact on the QOL of the patient.

Members across all profiles were less physically active than those in the ‘consistently good quality of life’ profile. Whilst this is in line with the previous LPA study for the ‘low quality of life’ profile[17] it may suggest that colorectal cancer survivors with a stoma have more functional issues than the wider stoma population. Lower levels of physical activity could also be related to being more likely to have comorbid conditions, or due to them being more likely to be closer to their initial treatment with side effects from certain cancer treatments associated with lower levels of physical activity[29, 30]. However, to determine causality a prospective study would be needed. Furthermore, being a smoker was associated with being a member of the ‘low quality of life’ profile, which previous research suggests is related to lower levels of QOL[9]. Around half of the respondents reported receiving advice on their health behaviour but close to a quarter of people reported being interested in receiving advice on this, therefore, a tailored approach of offering health behaviour advice dependent on individuals’ lifestyle and clinical characteristics may provide more positive outcomes.

This study supports the findings of existing LPA research in this population[17]. The previous LPA study identified 2 profiles with financial concerns similar to those identified by the present study, ‘functional and financial issues’ and ‘low quality of life’. The members of these profiles across both studies were likely to be younger[17] which is in line with other research that suggests that the QOL of younger individuals could be more impacted than older individuals[31, 32]. Therefore, it may be that there needs to be more comprehensive advice provided to younger individuals around financial issues. However, this study also identified those from profile 5, ‘supported but struggling’, as wanting more financial advice despite reporting no financial concerns. This could be explained by their reported concerns in carrying out usual activities and self-care and they may be pre-empting a change in their circumstances and want additional financial advice now.

A strength of this study is the large sample size, with the broad range of variables available which amplify our understanding from the previous LPA study amongst this population[17]. Furthermore, we can assess clinically meaningful differences between the profiles across some subscales. For example, for both the FACT-C additional concerns subscale and the subscales for the Social Difficulties Inventory a change in scores of 2-3 points indicates a clinically meaningful difference[33, 34]. Therefore, apart from the ‘consistently good quality of life’ and ‘functional issues’ profiles, all profiles are different from each other in a clinically significant way. Future studies targeting interventions tailored to each profile could use this approach to look for clinically meaningful improvements in QOL as participants may move between profiles in response to interventions.

There are some limitations associated with this study. Firstly, the measures assessing QOL were generic and were not able to take into account the unique concerns of people with a stoma which would better allow us to identify the physical and mental issues associated with having a stoma and aid in tailoring interventions. This also impacts on the comparability with the previous LPA study which used stoma-related QOL measures[17]. Finally, although these results provide information on the type of advice patients would like to receive which can help in tailoring interventions, this data was collected several years ago and may not be indicative of current stoma care. National guidelines outlined in 2021[26] have indicated areas for additional support to be offered to patients to facilitate their adjustment to their stoma similar to those outlined in this paper. However, consideration needs to be given to the personalisation of this support to patients which this paper offers advice on.

In conclusion, this study has identified 5 profiles based upon QOL of colorectal cancer survivors with a stoma. The results suggest that people with QOL concerns are not receiving adequate levels of advice across different areas relevant to their well-being, and this is particularly prominent for those who are in the ‘low quality of life’ profile. To improve care for this group of patients, ASCN guidelines on support for patients need to consider how to best to tailor advice to those patients that need it, and how to deliver this advice in a meaningful way.

Statements and Declarations

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Competing interests

The authors have no relevant financial or non-financial interests to disclose.

Ethics approval

The CORECT-R resource, and analyses based upon the data within it, has received approval from the Southwest-Central Bristol research ethics committee (18/SW/0134).

Consent to participate

Informed consent was obtained from all individual participants included in the study.

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Chapter 5: Quality of life and self-efficacy amongst people with a stoma: A longitudinal study using ecological momentary assessment

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5.1 Abstract

Background: When a stoma is formed people with a stoma have to adjust to managing this on a daily basis. There are a number of factors which can impact upon their self-efficacy to self-manage and their quality of life including complications with their stoma, body image concerns, stigma, and the changes to their daily routine. Ecological momentary assessment studies in other populations have suggested that these constructs may vary over short periods of time and could be influenced by contextual factors. We, however, do not currently understand how context-specific factors such as what an individual is doing, who they are with or where they are could impact upon quality of life and self-efficacy in people with a stoma.

Objectives: This study aimed to understand whether quality of life and self-efficacy fluctuated over time and whether contextual factors (e.g., activity, location, or company) and time of day were associated with quality of life and self-efficacy over the course of a week.

Methods: A smartphone-based ecological momentary assessment study was conducted over a 7-day period with measurements taken 3 times a day (morning, afternoon and evening). Measures included demographic and clinical characteristics of age, gender and time with a stoma, and self-reported self-efficacy and quality of life in the moment rated from 0-100 (with 100 being the best). Multilevel modelling was conducted due to the clustering of responses within individuals, with models run for both self-efficacy and quality of life.

Results: Null multilevel models indicated that both self-efficacy and quality of life varied over time, with around 35% of total variance explained by within-person variability which suggests there are intra- individual fluctuations over time. Results indicated that for the self-efficacy model, when people were reporting from home, they had higher levels of self-efficacy than outside the home. This was the opposite for the quality of life model with higher reported levels of quality of life outside the home and also increasing levels of quality of life throughout the day.

Conclusions: These findings indicate that among people with a stoma, self-efficacy and quality of life do vary from moment to moment. Furthermore, contextual factors such as location and time of day are associated with self-efficacy and quality of life. There is a need to explore how future self-management interventions could enhance self-efficacy to self-manage outside of the home environment, with the potential for more dynamic and tailored interventions.

5.2 Introduction

A stoma is an artificial opening on the abdomen created to divert the flow of faeces or urine; this paper focuses on the two bowel stomas, ileostomies and colostomies[1]. There are no global estimates for the number of people with a stoma although estimates for the US and China suggest there are around 1 million people with a stoma in each, with 700,000 in the EU[2, 3]. A stoma is primarily formed due to bowel cancer but can also be formed due to inflammatory bowel disease (IBD), physical trauma and other reasons (e.g. Hirschsprung's disease, familial adenomatous polyposis and diverticular disease)[1, 4]. Research suggests that people with a stoma formed due to bowel cancer can have impaired quality of life (QOL) and although this can improve over time it remains below that of those without a stoma[5-7].

Self-management of a stoma can involve changes to an individual’s daily routine, complications and psychological impacts such as body image concerns and dealing with stigma[8]. A systematic review of 14 studies of people with a stoma (N=1752) found that these changes caused by stoma formation can have a negative impact on their QOL[9]. Previous research using latent profile analysis within this population has found that groups with QOL concerns are more likely to have a hernia, be younger and have had their stoma for a shorter amount of time compared to those in the ‘consistently good quality of life’ group[10].

In people with a stoma, self-management interventions have been utilised to improve QOL, by increasing their self-efficacy (SE), their confidence in being able to manage their stoma[11, 12]. A meta-analysis of 5 self-management interventions for people with a stoma that measured SE found a 12-point mean (scale range from 22-110) difference in scores between intervention and control groups at follow-up[13]. Research has begun to suggest that individuals’ attitudes, beliefs and affective states could vary depending on the time they are measured and the circumstances in which they are measured[14]. Within other populations there is emerging research to suggest that both QOL and SE may not be the stable constructs we have treated them as in traditional self-management interventions. Ecological momentary assessment (EMA) studies have found that QOL and SE may fluctuate over shorter periods of time (e.g. over the course of a day) and could be influenced by contextual factors such as location[15-19]. Within the current stoma research, the day-to-day fluctuations in QOL and SE are not understood, nor are contextual factors such as where a person is, what they are doing or who they are with.

EMA is a methodology in which participants are repeatedly surveyed to provide a snapshot of their thoughts and feelings at the moment that they responded[20]. This method reduces issues around recall bias and can provide data on how variables fluctuate from one point in time to another[21].

Furthermore, cross-sectional and longitudinal studies, which are the basis for much of the research within this population, are focussed upon the associations of inter-individual (between-person) factors whereas EMA can examine both inter and intra-individual (within-person) factors which can vary over time and setting[22]. Using EMA within this population presents an opportunity to better understand in what circumstances both QOL and SE vary and thus inform enhancements to future self-management interventions, as within-person changes have not been considered in interventions to date.

Therefore, the primary aims of this study were to assess whether quality of life and self-efficacy fluctuate over time and what variability is attributable to within and between-person variances. Furthermore, we assessed whether contextual factors (activity, company, location) and time of day were associated with QOL and SE over a week.

5.3 Methods

5.3.1 Design and participants

This study involved gathering intensive longitudinal data across 7 days. Participants were recruited via social media (X (formerly Twitter) and Facebook), as well as emails sent to members of relevant charities and support groups and adverts placed in newsletters. Participants were eligible to take part if they had a bowel stoma (colostomy or ileostomy), were over the age of 18 and lived in the UK. Participants were required to have a smartphone, to which they were willing to download a mobile application (app) and have access to their smartphone at various points throughout the day. Ethical approval for this study was provided by the University of Leeds Medicine and Health Ethics Committee (reference number MREC 20-043). This study has been reported in line with an adapted STROBE Checklist for Reporting EMA Studies (CREMAS)[23].

5.3.2 Procedures

Prior to ethics being obtained, the components of this study were discussed with a steering group comprised of relevant patients, nurses, and charity and industry representatives. These individuals provided feedback on the timing of the surveys, the number of surveys triggered, as well as the wording of the measures to ensure clarity for participants.

Recruitment for this study began as the UK was emerging from COVID-19 lockdowns starting on 19th April 2021 and concluding on 5th March 2022. For this study the app, Avicenna Research (formerly Ethica Data)[24] was used to gather data throughout the 7-day period. This app was selected due to its compliance with data protection regulations, its use in previous research studies which demonstrates its feasibility for supporting research studies and its suitability for hosting EMA studies.

It also had the ability to function remotely with no face-to-face interaction between participants and the researchers required for its operation.

At baseline, participants were sent a link to a survey to complete demographic and clinical characteristic measures. After this was completed, they were then sent step-by-step instructions on how to download and register for the Avicenna Research app (formerly Ethica Data app). Surveys were programmed to be sent to participants at 9am, 1pm and 7pm to provide a view of participants' quality of life over the course of the day. These surveys started triggering the day after participants had registered for the study. Participants had a 2-hour window in which to complete the surveys, to allow flexibility around their schedules. Participants were encouraged to report any issues they had with the app to the research team promptly so that these could be resolved.

After the 7 days was completed, participants completing 80% or more of the timed surveys were sent a £10 Amazon gift voucher as compensation, which they were informed of during enrolment to the study.

5.3.3 Measures

The full baseline and timed surveys can be accessed in **Appendix D.1** and **D.2**.

5.3.3.1 Demographic and clinical characteristics

Participants were asked for their age in years (as a continuous variable), their gender identity (male, female or other), and the type of stoma participants had (ileostomy, colostomy, or don't know). Participants were also asked the reason for the formation of their stoma ('Cancer', 'Crohn's Disease', 'Ulcerative Colitis', 'Diverticulitis' and 'Other'). Participants could specify in the 'Other' category the reason for their stoma formation. The length of time a participant had their stoma was provided in either months or years, for this study all responses were converted to months. Participants were asked whether they had any long-standing health conditions (angina, high blood pressure, liver disease etc), they could also select 'other' and specify the condition. All selected conditions were summed, and a number of comorbidities variable was derived.

5.3.3.2 Context

Survey responses were scheduled to trigger at 3 points during the day, to assess whether the time of day in which the responses were answered accounted for the variance. A 'Time of Day' variable was created with 'Morning', 'Afternoon', and 'Evening' as the 3 levels and 'Morning' as the reference. Each time participants answered the timed surveys they were initially asked 3 questions to gather information on the context in which they were answering the survey. These questions were: 'What is your current location?', 'What are you doing?' and 'Who are you with?'. Each of the questions had multiple response options with the additional option of providing their response by selecting 'Other'.

5.3.3.3 Self-efficacy

Self-efficacy was assessed with a single measure on a scale from 0 to 100 (i.e., 'At this moment RIGHT NOW how confident do you feel that you can do the different tasks and activities needed to manage your stoma right now? 0 (not at all confident) – 100 (totally confident).'). This measure was adapted from a previous ecological momentary assessment study in another population to make it relevant for people with a stoma[25].

5.3.3.4 Quality of life

QOL was assessed with a single measure on a scale from 0 to 100 (i.e., 'We would like to know your overall satisfaction with your life in general RIGHT NOW. This scale is numbered from 0 to 100 where 100 means totally satisfied and 0 means totally unsatisfied.'). This was taken from the Stoma Quality of Life Scale[26], with this single measure identified as being able to detect changes in QOL over shorter periods.

5.3.4 Statistical analyses

All statistical analysis was conducted in SPSS v28.0. Descriptive statistics were run on the demographic and clinical characteristics. For gender, no participant selected 'other', therefore this option was not included. Any participants that selected 'don't know' for type of stoma were changed to missing. For the reason for stoma formation, 'Crohn's Disease' and 'Ulcerative Colitis' were combined into an 'Inflammatory Bowel Disease' category and due to the low numbers of people reporting 'Diverticulitis' this was combined with the 'Other' category. For each of the context questions, variables were dichotomised based upon the distribution of the data and whether they would provide a meaningful interpretation. This included location ('At home' or 'Not at home'), activity ('Relaxing' or 'An activity that required more cognitive or physical exertion') and company ('Alone' or 'With someone else').

Multilevel models were conducted due to the clustering of responses within individuals. The models are able to account for both the within and between-person variation. Initial null (no predictor) multilevel models were run to determine the amount of within and between-person variance for both QOL and SE.

Two further multilevel models were conducted with SE and QOL as the dependent variables. Contextual variables (activity, location, company, time of day) were included as fixed effects in the model. Observation time-point was controlled for within the analysis as a fixed effect to account for any effects due to this. Important covariates, based upon previous research, were included within the model: age, time with stoma, and number of comorbidities[9, 10]. Intra-individual variables, such as SE scores, Location, Activity and Company were person-mean centred to test for within-person associations and then the person-mean was centred by the grand mean to test for the association between-person. QOL was not included within the SE model as the relationship between the two is not bidirectional. Within-person variables of Location, Activity and Company and within-person SE, for the QOL model, as well as time of day and observation time-point were included as random effects to test whether these effects varied across people. Statistical significance was assessed at 0.05. Analyses were conducted with full information maximum likelihood estimations to account for missing data.

5.4 Results

5.4.1 Descriptive statistics

A total of 62 people completed the EMA protocol, and **Figure 5.1** outlines the flow of the participants through each stage of the study. From initial contact with the research team to completion of baseline measures 83.7% were eligible or remained interested in taking part in the study. From initial interest to the completion of the EMA protocol, this dropped to 59.6%. However, from completion of baseline to completion of the EMA protocol 71.3% of participants remained. From a total of 1302 possible data points (62 participants x 21 time points), participants completed 1057 (81.2%), which is an average of just over 17 data points completed per person. This was almost equal across time of day with a range of 81-83 missing data points for the morning, afternoon and evening.

Figure 5.1: Flow of participants through the study

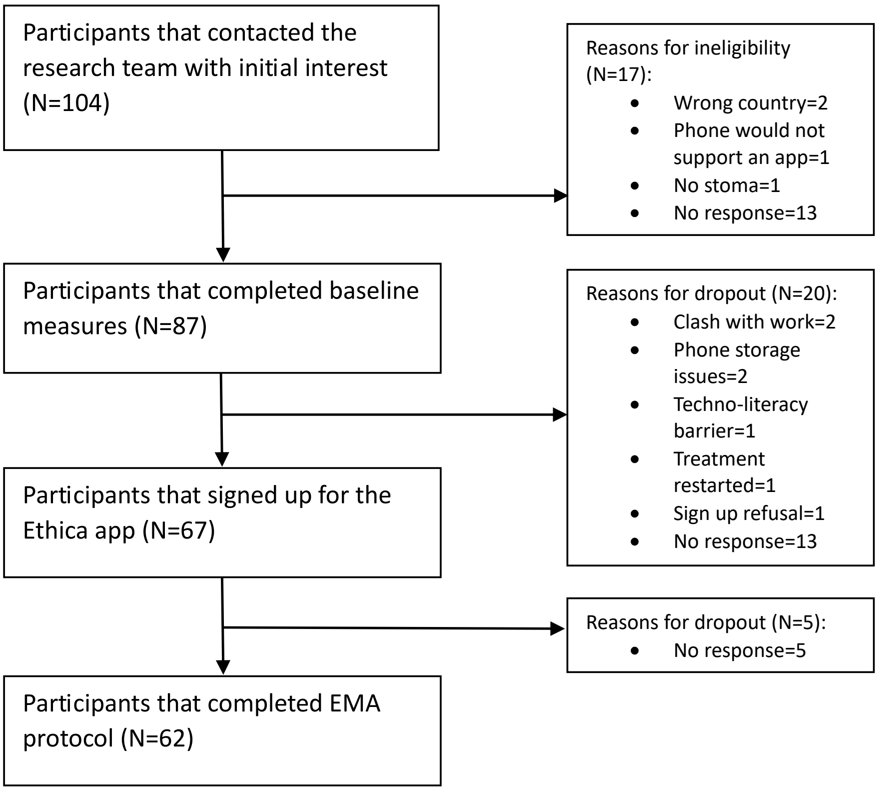

Table 5.1 provides an overview of the demographic and clinical characteristics for the sample. The sample of 62 people with a stoma consisted of majority females (69.4%), those with IBD as the reason for their stoma formation (53.2%) and those with an ileostomy (77.4%). The average age of participants was 51.4 (SD=13.9) with a range from 19 to 77, and participants had their stoma for on average just under 10 years with a range of 3 months to 61 years. A majority of participants had at least 1 comorbid condition (N=36, 58.1%), with the most common reported conditions being Asthma (N=11), high blood pressure (N=10), and back problems (N=7).

Table 5.1: Descriptive statistics for the participants

Demographic and clinical characteristics (N=62)		
Gender (N, %)		
	Female	43 (69.4)
	Male	19 (30.6)
	Missing	0 (0)
Age Mean (SD)		51.4 (13.9)
	Missing (N, %)	0 (0)
Stoma (N, %)		
	Ileostomy	48 (77.4)
	Colostomy	14 (22.6)
	Missing	0 (0)
Reason for stoma formation (N, %)		
	IBD	33 (53.2)

	Cancer	20 (32.3)
	Other	9 (14.5)
	Missing	0 (0)
Time with stoma (Months) Mean (SD)		100.4 (146.2)
	Missing	0 (0)
Number of comorbidities (N, %)		
	None	26 (41.9)
	1	15 (24.2)
	2 or more	21 (33.9)
	Missing	0 (0)

Note: N= number of participants; SD= standard deviation.

5.4.2 Null multilevel models

No predictor models for QOL and SE indicated that the intraclass correlations for these were 0.64 and 0.65, respectively, indicating a moderate amount of stability over time. Therefore, there is still around 35% of within-person variability which suggests there are intra- individual fluctuations over time.

5.4.3 Quality of life and self-efficacy multilevel models

Table 5.2 shows the results of the multilevel models for SE and QOL. For the SE model, only the fixed effect of within-person Location was statistically significant, it suggests that when individuals are outside the home, they tend to report lower SE scores (β=-3.8, 95%CI=-6.4; -1.3). The random effects of Location suggest that associations vary significantly from person to person (β=61.5, 95%CI=35.8; 105.6).

For the QOL model, there were statistically significant associations with the time of day the assessment was reported, with QOL scores increasing throughout the day (Afternoon: β=2.0, 95%CI=0.8; 3.2, Evening: β=3.9, 95%CI=2.6; 5.2). There were also significant associations with the location QOL was reported, with higher scores when outside the home (β=2.3, 95%CI=0.04; 4.6). Furthermore, people with a stoma who have a higher average score of SE over the week also report statistically significant higher QOL scores at each assessment point (β=0.7, 95%CI=0.5; 0.9). Similarly, for the within-person scores of SE, those individuals who report a higher SE score at a given time point also tend to report higher QOL scores (β=0.5, 95%CI=0.3; 0.6). The random effect of within-person SE indicates that despite finding a fixed relationship between SE and QOL, patterns differed significantly between individuals (β=0.1, 95%CI=0.04; 0.2).

Table 5.2: Multilevel model estimates for contextual effects on QOL and SE scores

Variables	Self-Efficacy		Quality of Life	
Fixed Effects	β	95%CI	β	95%CI
Intercept	**89.5**	**76.9; 102.1**	**64.3**	**53.4; 75.1**
Within-person Activity	-0.4	-1.5; 0.7	-1.0	-2.4; 0.4
Between-person Activity	-13.3	-32.8; 6.1	13.7	-3.2; 30.6
Within-person Company	-0.6	-2.3; 1.1	-1.2	-2.8; 0.5
Between-person Company	1.3	-11.3; 14.0	-0.7	-11.6; 10.1
Within-person Location	**-3.8**	**-6.4; -1.3**	**2.3**	**0.04; 4.6**
Between-person Location	5.3	-16.9; 27.6	12.0	-7.1; 31.1
Time of day (reference: Morning)				
Afternoon	-0.4	-1.4; 0.6	**2.0**	**0.7; 3.4**
Evening	0.9	-0.2; 1.9	**3.8**	**2.3; 5.4**
Within-person Self-Efficacy			**0.4**	**0.3; 0.6**
Between-person Self-Efficacy			**0.7**	**0.5; 0.9**
Age (years)	0.01	-0.2; 0.3	**0.3**	**0.1; 0.5**
Time with stoma (months)	0.003	-0.02; 0.03	**-0.03**	**-0.05; -0.01**
Number of comorbidities	0.004	-2.3; 2.4	-1.6	-3.7; 0.4
Observation time point	-0.5	-3.0; 2.0	1.4	-2.4; 5.2
Random Effects (variances)				
Residual	**50.0**	**44.4; 56.3**	**64.6**	**57.2; 73.1**
ρ	**0.2**	**0.1; 0.3**	**0.3**	**0.2; 0.3**
Intercept	**119.2**	**79.0; 179.7**	**75.9**	**47.2; 121.9**
Within-person Activity	0.1	5.1×10^{-49}; 5.5×10^{45}	4.0	0.4; 44.6
Within-person Company	13.2	2.6; 66.6	6.2	0.9; 45.2
Within-person Location	**61.5**	**35.8; 105.6**	**33.6**	**14.2; 79.6**
Time of day (reference: Morning)				
Afternoon			7.6	2.2; 25.6
Evening			**12.6**	**4.8; 33.5**
Within-person Self-Efficacy			**0.1**	**0.04; 0.2**
Observation time point	**42.6**	**18.3; 99.4**	**149.2**	**90.7; 245.5**

Note: bold findings indicate p<.05; β=coefficient; CI=confidence interval; ρ= Rho; within and between-person Self-Efficacy were not included in the Self-Efficacy model and the random effect of time of day was not included in the Self-Efficacy model due to convergence issues; significant random effects indicate substantial variation in the scores across individuals.

5.5 Discussion

This study is the first exploration of the within and between person variances enabled by EMA methodology in people with a stoma. We were able to identify that both QOL and SE are not stable constructs for this population and their scores fluctuated within individuals over the measurement period. For SE, individuals felt more confident in being able to manage their stoma when they are within the home environment, although there is also substantial variability in those scores. For QOL, individuals were more likely to report higher scores as the day progressed with scores on average 2 points higher in the afternoon and 4 points higher in the evening and also higher scores were associated with reporting QOL outside of the home. Also, both within and between person SE scores were associated with QOL indicating that higher confidence in being able to manage their stoma is associated with greater QOL scores at any given time.

This study found that QOL scores over the week were associated with contextual factors. The time of day that participants were submitting reports was associated with QOL, with lower scores in the morning and scores improving as the day went on. Previous research amongst people with a stoma has suggested that sleep disturbances could impact upon their QOL due to having to wake, possibly multiple times, during the night to change their stoma bag[27]. This could have had an impact on their QOL scores in the morning which have then improved into the afternoon and evening. Future research should consider including a sleep quality questionnaire in an EMA study to see whether this association with QOL is influenced by time of day. Furthermore, in this present study the location a person was when reporting their QOL scores was also statistically significant. The findings suggest that being outside of the house may be associated with higher QOL scores which aligns with a previous review of EMA studies in healthy subjects that found greater well-being when participants were in a natural environment[28]. However, given the timing of the current study, the lifting of COVID-19 lockdown restrictions may have had an effect on QOL with people able to move more freely outside again[29].

This study also found an association between both within and between person SE and QOL. This suggests that people who are on average more confident in managing their stoma and also individuals with greater confidence within the moment are more likely to report higher QOL scores. These findings are consistent with previous research in this population that found a positive correlation between SE and QOL scores[30]. However, the findings from this present study also suggest that not only do we need to increase SE amongst people with a stoma but that we also need to ensure that people with a stoma are confident in a variety of different contexts.

This is further reinforced in the SE model from this study in which we found that the location people were reporting from was associated with SE. For example, when people were at home, they reported greater confidence in being able to manage their stoma than when they were outside of the home. This may be because people with a stoma are in an environment in which they are familiar and have access to all the resources and facilities they need to manage their stoma. Previous research has also highlighted that travel is a considerable source of worry for people with a stoma[9]. Just-in-time adaptive interventions (JITAIs) are an approach to interventions whereby advice and support is offered in the moment based upon responses to certain measures or based upon contextual factors (e.g. location)[31, 32]. Therefore, future research should consider using JITAIs to look at improving

SE for individuals when they are outside the house and offering practical solutions to help them feel confident in managing their stoma in environments that are not familiar to them. Furthermore, random effects findings suggest there was substantial variability for the location variable and SE, for the QOL model, suggesting that participants do not all experience similar associations, therefore JITAIs could provide more tailored and adaptive interventions for participants.

This study had several strengths. Firstly, multiple avenues were used for recruitment, and we did not solely rely on social media which may have given us a biased sample towards younger and more educated samples[33]. Furthermore, the data suggested that compliance with the surveys was high with only 19% missing data points. Systematic reviews of EMA studies have found mean compliance rates ranging from 71% to 86% therefore the present study is on the higher side of the average[28, 34-36]. Furthermore, the design of the study facilitated data collection from participants in the moment potentially reducing errors arising from retrospective recall[21].

However, there were limitations to the present study. Firstly, given the timing of when this study was conducted it is possible that associations could be linked to the gradual lifting of COVID-19 lockdown restrictions which began in early 2021 and continued into mid-2021[29]. This study also required participants to have a smartphone and some digital-literacy to download and install apps, which may have made some groups such as older individuals ineligible to take part. However, smartphone use and digital-literacy are growing in older populations[37]. Despite this, as our recruitment techniques were primarily facilitated through use of the internet, we may have recruited a younger sample, which may not be representative of the wider stoma population[33]. Therefore, further EMA studies are needed in the future with a larger, more diverse sample of people with a stoma. Finally, due to wanting to ensure that additional burdens were not placed upon participants, single measures of QOL and SE were used in this study. These measures provide a general overview of the constructs but would not provide granular detail of differences in the dimensions of these measures that have been observed in previous research[10]. Furthermore, these measures did not have defined clinically significant differences, therefore further EMA studies are needed with measures that have defined clinical significant differences to understand whether the statistically significant results have clinically relevant findings[38].

In conclusion, this first investigation into the variability of QOL and SE identified fluctuating scores over a week in a population of individuals with a stoma. The findings suggest that future interventions could seek to bolster SE for self-management in people with a stoma at different times throughout the day to enhance their QOL. Differential associations between SE and QOL in certain contexts suggests tailored interventions may be needed, with some individuals likely to particularly benefit from interventions designed to boost self-efficacy, and support self-management, outside of the home environment. Additional studies using EMA methodology in people with a stoma are needed to further explore the associations found in larger, more representative samples, and to test the potential for JITAI's to improve self-management and in turn, QOL, for this population.

5.6 References

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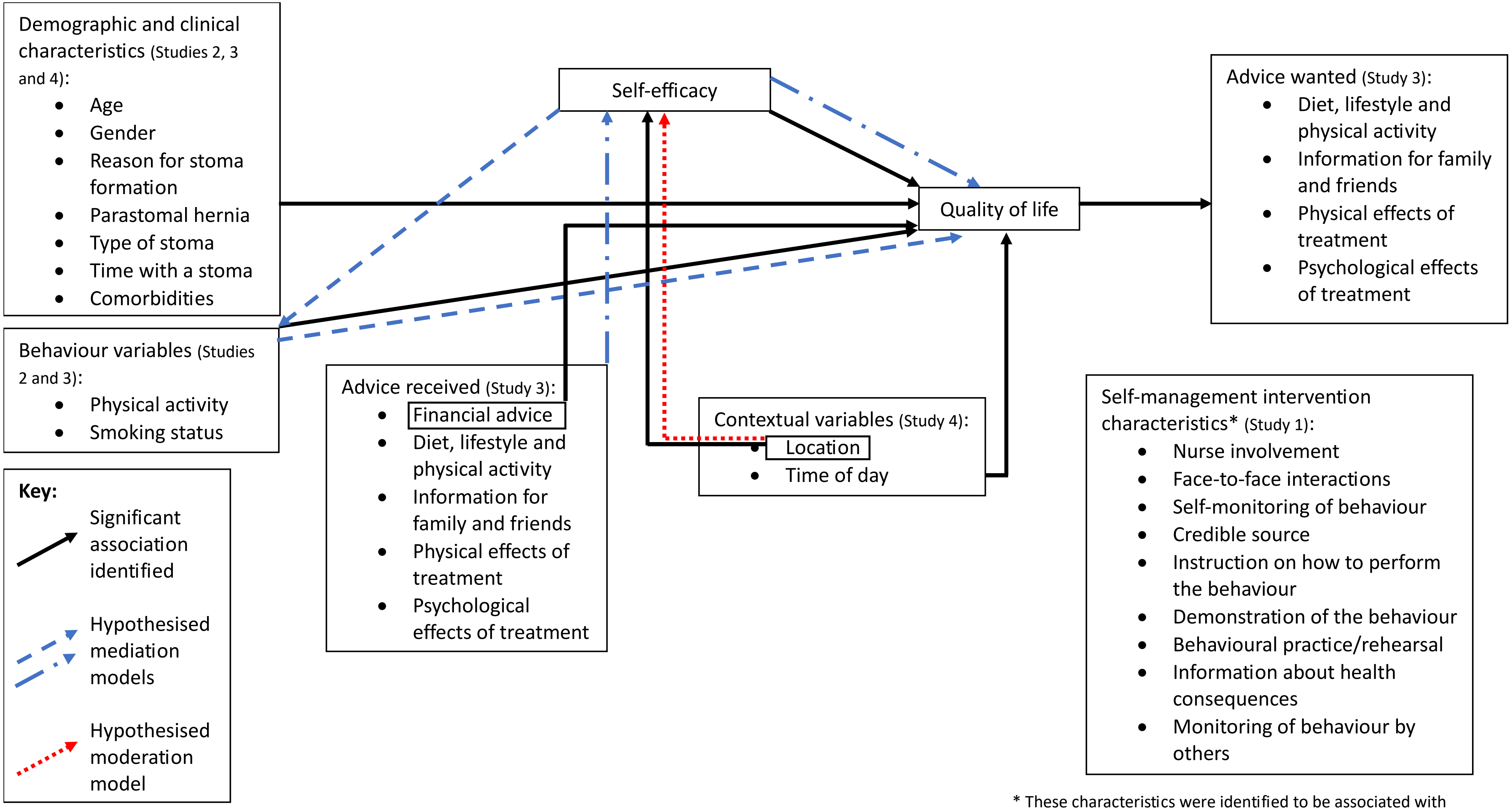
Chapter 6: Discussion

6.1 Summary of findings and contribution to existing literature

The overall aim of this thesis was to explore and better understand self-management, self-efficacy (SE) and quality of life (QOL) in people with a stoma. The results from my systematic review and meta-analysis, indicated that self-management interventions may improve SE for this population, but the evidence was mixed for an impact on QOL and self-management skills. The use of self-monitoring as a behaviour change technique (BCT) appeared to be associated with improvements in QOL whereas the involvement of a nurse face-to-face was associated with improvements in SE and self-management skills. Findings from the secondary data analyses conducted in my second and third studies highlighted that people with a stoma do not have the same QOL profiles. People who are younger, have a parastomal hernia, have more comorbidities, have a recent stoma and are less physically active are more at risk of experiencing low QOL across several domains and were more likely to want support. Results from my ecological momentary assessment study suggested that although SE to self-manage a stoma is associated with QOL, both QOL and SE also fluctuate over time in different ways. SE was higher when individuals were at home whereas QOL was higher when individuals were outside the home and higher QOL was also reported later in the day compared to the morning. Overall, I have identified key characteristics of self-management interventions, those individuals that may require additional support and when this support should be offered.

The findings from these studies are outlined in **Figure 6.1**, along with hypothesised relationships. These are discussed in further detail below in relation to the research questions outlined in Chapter 1 and with reference to previous research.

Figure 6.1: Actual and hypothesised associations between the variables in this thesis



* These characteristics were identified to be associated with improvements in QOL and SE in the systematic review. Arrows have not been drawn as no formal analyses were conducted.

6.1.1 Who are the individuals that are likely to require support to enhance their SE, improve their self-management and increase their QOL?

The studies in this thesis identified the demographic and clinical characteristics of the individuals with a stoma that may require more support, the advice these individuals have already received and how physically active they are. Within Studies 2 and 3 I found differences in demographic and clinical characteristics based upon the membership of the QOL profiles. Study 2 findings indicated that those who were younger were more likely to have financial concerns and those with a parastomal hernia were more likely to belong to the 'low quality of life' profile. Previous research suggests that working-age individuals are more concerned about returning to work and the presence of a parastomal hernia can have negative effects on QOL[1-4]. Findings from Study 4 provide further support as those who were older reported higher QOL scores over the course of a week. Additional findings from Study 3 indicated that being male and from a more deprived background were associated with membership of the 'low quality of life' profile, which contradicts previous cross-sectional research and a systematic review suggesting females are more likely to have decreased QOL due to problems with sleep, body image and depression and which found no significant association between socioeconomic status and QOL[5, 6]. However, these findings come from small cross-sectional studies and the findings from the review are based upon 6 studies of which only 2 investigated the association with socioeconomic status.

The reason for stoma formation being for 'Other' reasons (e.g. physical trauma, Diverticulitis or Hirschsprung's Disease) was also associated with belonging to the 'low quality of life' profile in Study 2. Close to 25% of this profile had their stoma for 'Other' reasons compared with around 10% in the other profiles, however, most research is focused on individuals with a stoma formed due to cancer or IBD, therefore, future research needs to consider those with a stoma for other reasons.

Findings from Study 3 also suggested that the 'low quality of life' and 'functional and financial issues' groups were more likely to receive financial advice from healthcare professionals. However, there were no other statistically significant differences observed in the receipt of any other advice across the other profiles. Whereas, previous cross-sectional research exploring lifestyle advice provided by GPs found that individuals who had a poorer self-rating of health were more likely to receive advice[7]. These findings suggest that advice, apart from financial advice, may not be tailored to those who may benefit from it.

Behavioural factors such as physical activity (PA) were associated with profile membership in both Studies 2 and 3. Individuals with lower levels of PA were more likely to belong to the 'low quality of life' profiles. However, there is a paucity of research investigating the association between PA and patient-reported outcomes in people with a stoma. Cross-sectional survey studies of PA in people with a stoma have found that 84% do not meet government guidelines for PA but a greater proportion of those who are physically active since their surgery report their QOL as being ‘much better’ compared with those who have done no PA[8, 9].

While further research needs to be conducted to confirm these findings, the results from this thesis suggest that more tailored, personalised care should be offered towards those with certain demographic and clinical characteristics to help improve QOL. This is in line with the Comprehensive Model for Personalised Care outlined by the NHS to support their Long-Term Plan, which suggests that those with long-term conditions should receive more personalised, increasingly complex care to help them self-manage[10, 11]. This model also suggests that care should be targeted to those who require it, and the findings from this thesis suggest that those who are younger, from a lower socioeconomic status, have a stoma formed for ‘Other’ reasons and have more comorbidities or a parastomal hernia, would benefit most. Furthermore, those with the most QOL concerns are likely to have lower levels of PA so incorporating PA recommendations within self-management interventions may help people with a stoma to improve their QOL.

6.1.2 What is needed to support individuals with a stoma to improve their SE, self-management skills, and QOL?

This thesis also considered what factors may be important to support individuals including the provision of advice, nurse involvement, theory and BCTs and enhancing SE. The findings from this thesis suggest that there may be an association between PA and QOL and SE and QOL. Previous research suggests that people with a stoma face barriers to being physically active including fear of the bag coming loose and leakages occurring, developing a parastomal hernia or causing pain[8, 9]. There has not been any research that has investigated whether increasing SE to self-manage is associated with increased PA. We know from Study 1 that previous self-management interventions tested in RCTs have not included PA information, advice, or support. A previous cross-sectional survey of 425 people with a stoma that found 42% and 30% had not received PA or dietary advice but 90% of these wanted to receive this[12]. Furthermore, the findings from Study 3 identified an interest in receiving lifestyle and PA advice across all the profiles experiencing concerns compared with the ‘consistently good quality of life’ profile. I hypothesise that if we were to enhance individuals’ SE in managing their stoma this could reduce their anxiety about being physically active and lead to higher QOL. There have been 2 pilot and feasibility interventions to increase SE to be physically active in people with a stoma, which found that these interventions were acceptable by the participants[13, 14]. Therefore, there is a clear demand from people with a stoma for providing

PA advice and this appears to be acceptable but there is a need for RCT research to provide data on the effectiveness of this advice.

Alongside wanting lifestyle and PA advice, findings from Study 3 indicate that people want more support in adjusting to the physical and psychological changes associated with treatment across all profiles with QOL concerns. People with a stoma must adjust to a number of physical changes which can lead to psychological issues. The current Association of Stoma Care Nurses (ASCN) guidance focuses heavily on stoma-related complications, however, this does not cover changes to day-to-day lives which may impact on the fluctuations in SE and QOL that we found in Study 4[15]. Previous qualitative research has indicated substantial changes to people's everyday lives including changing bowel habits, dietary adjustments, confidence in leaving the home and clothing they can wear[16]. A review has also suggested that stigma, fear of disclosure of having a stoma and feelings of resentment towards the stoma are psychological factors that arise after surgery[17]. Within Study 1 I identified self-management interventions that sought to address these psychological factors and problems that might arise in day-to-day life; however, these aspects are not covered by ASCN guidance[15]. This suggests that ASCN guidance could be expanded to address these everyday challenges, or additional interventions put in place to support adjustment to a stoma.

Furthermore, provision of support for family and friends was also indicated as lacking in Study 3. Social support is a key BCT that has been found to be beneficial in other self-management interventions in diabetes and stroke populations, although it was not identified in Study 1[18, 19]. A systematic review exploring studies (N=6) of how the formation of a stoma can impact upon spouses found that spouses wanted to be involved in stoma education particularly around the adjustment to having a stoma, as they found that a stoma also had an impact on the spouses social and sexual life[20]. The authors concluded that healthcare professionals should provide education to family and friends so that they all can support people with a stoma in their self-management.

The ASCN guidance outlines the key role that nurses play in providing this support and education to people with a stoma, to help them manage their condition within the UK[15]. In Study 1, I identified that nurse involvement in self-management interventions was associated with improvements in both SE and self-management skills. A review of 30 Cochrane systematic reviews of self-management interventions for people with chronic disease found that 23 reviews reported that nurses were responsible for delivering a proportion of the included interventions[21]. However, they were unable to conclude whether the presence of the nurse was associated with improvements in the outcomes due to issues with inconsistent reporting of the profession and qualifications of the healthcare professional. Similarly, in Study 1 I was not able to determine the level of expertise of the nurse (e.g.

stoma care nurse), and whether this was associated with greater improvements in SE and self-management skills. Further research is needed to understand whether a specialised healthcare professional is required, as this will have implications for the implementation and cost effectiveness of interventions.

In addition to who provides this information, consideration needs to be given to the development of these interventions using theory and incorporating BCTs. When looking at the use of behaviour change theory and improvements in the outcomes within Study 1, no association was found. Previous reviews in other populations identified inconsistent findings on the role of theory-based self-management interventions, which could suggest that theory is not necessarily a key factor in developing an effective intervention[18, 22-29]. However, as only 5 studies in Study 1 mentioned a theoretical underpinning we cannot suggest this is conclusive evidence for theory not exerting an influence on outcomes. Additionally, consideration needs to be given as to how theories have been implemented in these interventions, which I did not look at in Study 1[30]. An investigation into two systematic reviews of PA and healthy eating interventions has found that 90% of interventions did not adequately outline how the constructs of the theory they were using were targeted by the BCTs in the intervention description[22]. Furthermore, another systematic review of online self-management interventions for people with diabetes found that the BCTs used were not always consistent with the underlying theory[31]. Therefore, we cannot conclusively suggest that a theoretical basis is not necessary in intervention development.

Within Study 1 I identified a range of BCTs that were used in the self-management interventions. The number of BCTs used did not appear to be associated with improvements in any of the outcomes, which is consistent with some previous research in other populations[32] but is contradictory with reviews in other populations that did find an association[33, 34]. This could suggest that BCTs should be selected based upon an understanding of the determinants of the behaviour that is wanting to be changed and not how many BCTs can be incorporated into the intervention.

SE (beliefs about capabilities) is a ‘Mechanism of Action’ (MoA) through which BCTs can affect behaviour and is thus considered a key component of self-management interventions[35-37]. Research synthesising links between BCTs and MoAs has identified links between 7 BCTs and SE including: graded tasks, verbal persuasion about capability, focus on past success, demonstration of the behaviour, problem-solving, behavioural practice/rehearsal, and reducing negative emotions[36]; with the ‘Theory and Techniques Tool’ also suggesting that the BCTs of self-talk and instruction on how to perform behaviour are also linked to this MoA[38]. This supports the findings from Study 1 which identified the BCTs of instruction on how to perform the behaviour, demonstration of the behaviour and behavioural practice/rehearsal in most of the interventions. A Cochrane review of self-management interventions led by nurses found that providing education on how to perform the behaviour without a demonstration can limit the effectiveness of the intervention[21]. The BCT of self-monitoring of behaviour was also associated with improvement in QOL in Study 1. This BCT has been found to be key in previous reviews of interventions designed to improve PA and healthy eating in people with Diabetes[33, 34]. This suggests that researchers need to consider the BCTs that they are using in future self-management interventions.

Moreover, research has found that SE is associated with QOL, with a cross-sectional study amongst people with a stoma finding a positive correlation between the two[39]. This is supported by findings from Study 4 which found that both within and between-person SE were associated with QOL which also suggests that the variation of SE scores within-people is also associated with QOL. These findings suggest that not only do we need to increase SE overall, but we need to ensure it remains high moment to moment. Therefore, SE could be a mediating factor between received advice and support and QOL. Within Study 1 I found that self-management interventions were effective at increasing individuals' SE to self-manage their stoma. Additionally, Studies 1 and 3 found that self-management interventions had some effect on increasing QOL and receipt of advice on financial issues was associated with being a member of the 'low quality of life' and 'functional and financial issues' profiles. Previous research in patients that had undergone surgical aortic valve replacement surgery found a mediating relationship of SE between social support and QOL[40]. Therefore, future research should consider conducting a mediation analysis to understand how the receipt of advice and support can influence QOL and whether this is explained by SE.

Based upon the findings in this thesis, an ideal intervention needs to include several factors in future self-management interventions. Advice on lifestyle and PA, how to adjust to having a stoma, and support for family and friends, should be incorporated, and there may need to be some level of nurse involvement with respect to how the intervention is delivered. SE appears to be a key target for self-management interventions seeking to enhance QOL. While further research needs to be conducted around the effective BCTs to use, those of instruction on how to perform the behaviour, demonstration of the behaviour and behavioural practice/rehearsal appear to have an evidence base linking them to SE as a MoA and my systematic review also suggests that self-monitoring of behaviour is important for enhancing QOL.

6.1.3 In what contexts might individuals most need support to enhance their SE and improve their QOL?

Finally, I sought to understand the context in which individuals may need support and the findings from this thesis suggest that location, time of day and the length of time an individual has had their stoma should be considered. The results from my EMA study suggest that SE is higher when participants are at home. To investigate this relationship further I have suggested, in **Figure 6.1**, that future research may want to consider that location may be a moderating factor. Location could influence the strength of the relationship between SE and QOL or even change its direction[41]. The results from Study 4 also suggested that when people were outside of the house, they reported higher QOL scores. This has been found in a previous systematic review of ecological momentary assessment (EMA) studies where higher well-being was associated with being in a more natural environment[42]. However, I was unable to explore this association with the natural environment within Study 4 as 65% of the responses were recorded within the home environment. There is also a possibility that this association between QOL and location could be related to the loosening of lockdown restrictions in the UK which was occurring at the time that the study started recruitment[43].

Additionally, the findings from Study 4 suggest that QOL is influenced by the time of day an individual reports their scores, with greater QOL later in the day. A previous scoping review of ecological momentary interventions (EMIs) to support individuals with mental health problems found that some interventions tailored support, such as an intervention providing cognitive behavioural therapy for people with depression which provided recommendations based upon contextual factors like location and time of day data[44]. The findings in this thesis suggest that QOL and SE could be influenced by momentary factors and self-management interventions may need to be dynamic. Understanding this relationship in greater detail will allow us to tailor interventions to support individuals when they need it most[45].

In addition to the momentary context that an individual finds themselves in, the findings from Studies 2 and 3 suggest that the length of time they have had their stoma may influence when support should be received. For example, having a stoma formed within the last 2 years was associated with being a member of a profile with lower QOL scores. However, within Study 2 there were 2 profiles with QOL concerns which had no association with length of time with a stoma, which could suggest that there are areas in which those with a stoma longer than 2 years may also require additional support. Study 1 identified that stoma self-management interventions were primarily conducted around the time of stoma formation surgery so we are unable to suggest whether these interventions would be effective for people who have had a stoma for years. Therefore, although the time since stoma formation is an important indicator of when support is needed further research is required in those who have had their stoma for longer to understand how this should be delivered.

Overall, these findings suggest that those with a more recent stoma may require more support than those that have had one for longer, although there are also areas in which longer-term support may be of benefit. Furthermore, as findings suggest that SE and QOL can fluctuate within a day and could be influenced by the location of the individual and the time of day, interventions may benefit from being more dynamic. Interventions that can respond in the moment to people's needs possibly based upon the characteristics of the individual, self-reporting of their SE and QOL, sensor-based location data, and the time, should be considered.

6.2 Strengths and limitations

Although the findings outlined in this thesis provide us with a greater understanding of SE, self-management and QOL in people with a stoma, these must be considered in the context of the strengths and limitations of the methodologies used to address the gaps identified in the literature.

6.2.1 Survey designs

Studies 2 and 3 within this thesis used cross-sectional study designs. The strengths of these designs are that they are relatively inexpensive for the amount of data gathered, indeed both samples had roughly 1500 and 4500 participants respectively[46]. Within Study 4 an EMA approach was used, which collected intensive longitudinal data over the course of a week. This methodology has a number of strengths, as it requires participants to answer questions as to how they are feeling at that moment in time eliminating the possibility of recall bias[47], improving the accuracy of the data. Furthermore, because participants are repeatedly surveyed over the course of a week it allowed exploration of the temporal relationship of QOL and SE[47].

However, there are several limitations with these designs. Firstly, the cross-sectional studies 2 and 3 are unable to determine cause and effect due to there being only one time point, this also means the temporal sequencing of the outcomes and exposure cannot be determined[46]. In Studies 2, 3 and 4 there is a possibility of self-report bias, participants may have overreported their QOL and SE to make it seem like they were coping better with their stoma than they were[48]. There may therefore be a difference between the value obtained and the true value the participant holds. In Study 4, an EMA approach requires greater involvement by the participant, with surveys conducted multiple times a day for several days and they can be notified at inconvenient times[49]. This burden on the participants can increase the likelihood of dropout, noncompliance with the EMA protocol or false reporting of results[50].

6.2.2 Secondary analysis

Studies 2 and 3 were secondary analysis of previously collected cross-sectional data. A strength of these datasets is that they can often be larger and are more cost-efficient than conducting the original study[51]. Both studies align with existing definitions of 'big data' studies in health research that include those with more than 1000 participants[52]. It has been suggested that 'big data' studies can be used to enhance healthcare; including by increasing earlier diagnosis and improving the effectiveness of treatments, identifying risk factors for diseases; improving patient safety by making more informed decisions for their healthcare; and improving the prediction of patient outcomes[53]. The findings from both Studies 2 and 3 have informed suggestions in this thesis for how future interventions could target individuals and what advice they want to receive.

However, there are limitations with these datasets. For example, the measures that are chosen to collect from the patients may not align with our research questions, or they may have inherent weaknesses associated with them. Within Study 2 a measure of parastomal hernias was collected as this is a common complication that people with a stoma are likely to face[54]. However, there were no questions that asked about other complications such as leakages, pancaking, prolapse or skin irritation[55-57]. While these complications may be transitory compared with parastomal hernias they do also have a negative impact upon QOL[58-62]. Similarly, Study 3 gathered data on the comorbidities of the individuals, which previous research amongst those living beyond cancer has found to be associated with poorer QOL[63]. However, there were no measures which asked about stoma-related complications. Therefore, across both studies, we may be missing insights into how stoma-related complications may be associated with the QOL profiles.

6.2.3 Recruitment strategies

Within this thesis, various recruitment strategies were used. As secondary data, the strategies utilised by Studies 2 and 3 were not within my control, but each has its strengths and limitations. Studies 2 and 4 utilised social media (X (formerly Twitter) and Facebook) as a recruitment method. While these provide access to a broad cross-section of society the individuals that use them are more likely to be younger than the general population[64]. Study 2 also recruited from the database of a UK-based supplier of stoma support garments, which could have provided us with a sample skewed to those that were more physically active as support garments are suggested to be worn during PA[15]. Participants in Study 3 were recruited by a survey being sent to all colorectal cancer patients in England from 2010 and 2011 who were still alive 12 to 36 months after diagnosis, with

21,802 out of 34,467 (63.3%) returning the survey[65]. This provided a large dataset, but the sample may be biased by the large proportion that did not return the survey[46]. As we know individuals that are older, have more health problems and are from more deprived backgrounds are less likely to respond[66, 67].

For Study 4 I also recruited through stoma support groups and charities (Colostomy UK and Ileostomy and Internal Pouch Association). The study was advertised through newsletters, WhatsApp groups, emails and websites. Previous research has found that by utilising disease-specific charities and groups, recruitment is more effective than through national registers of patients, who are more likely to decline[68]. Therefore, Study 4 utilised some of the more successful recruitment strategies and although recruitment through the NHS may have provided access to other less accessible groups, this was not deemed feasible with the COVID-19 pandemic at the time[69].

A small incentive was used to encourage participation in Study 4. These are used in most EMA studies due to the burden involved, however, the incentive was kept small as a previous study identified that when the incentive was seen as too generous participants began to treat the study like a job, leading them to change their behaviour and take the study too seriously[50, 70]. There are also ethical concerns with the use of incentives in health research exerting influence over the participants[71].

6.2.4 Sample representativeness

In Studies 2 and 4 participants were recruited mainly through use of the internet, either by emails to a customer database (Study 2), posts on Twitter and Facebook (Studies 2 and 4), posts in stoma support forums (Study 4) or emails from charities (Study 4). Research has suggested that these online methods of recruitment are more efficient than offline methods but that efficiency can be reduced over time which is why multiple online methods of recruitment were adopted[72]. But it may have unintentionally excluded individuals that do not have regular access to the internet, including older people or people from lower socioeconomic backgrounds[73, 74]. These are also individuals that are more likely to report health issues and are in need of more support[75, 76]. However, this may not have been an issue as within the UK where participants were recruited there is widespread and increasing internet use in all age groups including those above the age of 75 with regular internet usage increasing from 29% in 2013 to 54% in 2020[77]. There is broad access to the internet in the UK with 96% of households in 2020 having internet access, although those from a lower socioeconomic background are less likely to have internet access (14%) and those from that background and over the age of 75 are even less likely to have internet access (30%)[78, 79]. Therefore, recruitment through online methods may explain the younger mean age of 51.4 years in

Study 4 and more than 60% of the sample in Study 2 being under the age of 55, when data suggests over 70% of people with a stoma are over the age of 60[80].

In Studies 2 and 4 females represented the majority of the sample; roughly 80% and 70% respectively. Whereas in Study 3 males accounted for 60% of the sample and in Study 1 most studies included in the systematic review had a majority of male participants, although this could be due to colorectal cancer rates being higher in males and most studies (N=11) included in Study 1 were conducted in cancer populations[81]. In the wider stoma population, there is estimated to be an even distribution of people with a stoma between males and females[82]. Furthermore, in Studies 2 and 4 approximately 55% of the sample had their stoma formed due to IBD, with those with cancer making up a smaller proportion of the samples. [81, 83]This is at odds with the wider stoma population where cancer is the foremost reason for stoma formation[84]. A potential explanation for this could be related to age, as those with colorectal cancer are likely to be older with the highest incidence rates in the 85 to 89 age group in the UK and as discussed, this group may have not been captured through online methods of recruitment[81]. Additionally, those with colorectal cancer may have ongoing treatment related to their cancer and so may be experiencing side effects such as fatigue from chemotherapy[83]. Differences in the sample characteristics in the studies included in this thesis and those of the wider stoma population suggest that these findings should be treated with caution until further research can be conducted.

Within this thesis there was no investigation into the association that ethnicity may have with QOL or SE. While there is no breakdown of people with a stoma based upon their ethnicity within the UK, previous research has indicated that those from Asian backgrounds are more likely to have lower levels of QOL than those from non-Asian backgrounds[85]. Furthermore, there may be cultural differences in how individuals may manage their stoma, with those from practicing Muslim backgrounds having to wash and change their stoma bag 5 times a day before prayers[86]. This could impact upon an individual's QOL due to the additional amount of work required to manage their stoma. While Studies 2 and 3 did not measure ethnicity and so there could have been no formal analysis of this, a measure could have been included within Study 4. While this may not have been included within the formal multilevel analyses, due to the predictors being selected based upon the findings of the previous research in this thesis, it would have been a useful variable to provide the reader with more understanding of the sample as a whole. Future research should consider how ethnicity could be associated with QOL and SE and how this should be tackled in future self-management interventions.

6.2.5 Quality of life measures and definitions

Across the studies in this thesis there have been various measures of QOL that have been used. Within Study 1 we found that self-management interventions used global measures of QOL, health-related measures and disease-specific measures. Within Study 2 the Stoma Quality of Life Scale was used[87], whereas in Study 3 various measures were used including the EQ-5D[88], the FACT-C[89] and the Social Difficulties Inventory[90]. For Study 4 an adapted version of the overall measure of QOL from the Stoma Quality of Life Scale was used[87]. The FACT-C and the Social Difficulties Inventory were the only measures for which there are identified levels for clinically important differences in the scores[91, 92]. While this is a strength of Study 3, it also indicates a limitation of the other studies that do not have research to indicate whether the statistically significant differences are clinically meaningful. With the increasing importance of QOL in health research there is a need to demonstrate that the improvements that interventions produce demonstrate a clinically important difference to patients, healthcare professionals and policy makers[93].

Furthermore, a systematic review of self-management interventions in improving QOL for patients with chronic conditions found that these interventions were better at improving disease specific QOL than global QOL[94]. As different illnesses impact upon different bodily functions they may then result in different physical and emotional problems that can only be identified by disease-specific measures of QOL[95]. Therefore, while it is a strength that we have identified clinically meaningful differences within Study 3 on the FACT-C and Social Difficulties Inventory, further work needs to be conducted to identify what a clinically meaningful difference would be for a stoma-specific measure of QOL.

Moreover, as has already been mentioned, various measures of QOL were used within this thesis which could restrict the conclusions we can draw across the studies due to the different domains that are covered across these measures. For Studies 2 and 3 there was an attempt to keep the domains used within the analyses as consistent as possible despite the different measures used by matching the domains as outlined in Appendix C.2. However, this was not possible to do with Study 4 due to the need to keep the EMA protocol brief to reduce missing data and so a single, overall measure of QOL was used. However, future research should consider attempting to look at measuring the domains of QOL in EMA studies to understand where QOL concerns may be arising in different contexts.

Within this thesis a broad definition of QOL was taken to cover the multidimensional aspects of QOL as they pertain to the health of an individual[96]. However, while this definition covered aspects of health that would be comparable across a variety of different diseases it may have inadvertently disregarded areas of concern that are more specific to people with a stoma. In particular sexuality and body image concerns can arise through the formation of a stoma and measures of QOL in people with a stoma will include items on these aspects[1, 87]. Furthermore, measures of stoma-specific QOL are also likely to include items related to the function of the stoma[87]. Therefore, while the definition used within this thesis is broad in the sense that it captures health-related QOL that is relevant across a multitude of different diseases, more stoma-specific statements could have been included within the definition to make it more applicable to the sample.

6.2.6 Self-efficacy measures

Within this thesis only one measure of SE was developed for use within Study 4. In this study a single overall measure of SE to self-manage a stoma was used. Ideally this would have broken down into constituent behaviours of self-management such as learning how to clean their stoma, changing their appliance, coping with complications, and learning what they can eat and what activity they can do[97]. However, due to the requirements for the EMA protocol to be brief and as this was the first study utilising this approach in this population, a single measure was deemed more appropriate at this stage. However, future studies should consider measures of SE linked to the specific behaviours of stoma self-management due to the distinct nature of these behaviours. This would provide us with a greater understanding of where individuals confidence may be lacking and whether certain behaviours require different support in different contexts.

Furthermore, this thesis focussed solely on SE as a MoA to understand how people with a stoma self-manage their stoma. This is because it is one of the most commonly measured MoA within this field of research, with several previous reviews synthesising data on SE from self-management interventions[98-100]. However, SE is not the only MoA that could influence self-management behaviour in people with a stoma, focus could also have been given to others such as self-regulation (behavioural regulation)[101]. Self-regulation is an individual’s ability to monitor and adapt their behaviour based upon internal or external feedback to achieve their goals[101]. This MoA has been used in previous behaviour change interventions aiming to increase self-regulation through action planning, goal-setting, or encouraging participants to self-monitor their behaviour[101]. A measure of self-regulation could have been included within Study 4, however, the choice of variables was driven by those investigated within previous studies to enable comparisons. However, future studies should consider including additional MoAs as to provide a more complete understanding.

6.2.7 Behaviour Change Technique Taxonomy

In Study 1 the BCT Taxonomy was used to identify the BCTs in the self-management interventions. Strengths of this taxonomy have been discussed previously, including that it provides a comprehensive list of BCTs for researchers to draw upon when designing interventions, it allows for more faithful replication of successful interventions and it allows for easy identification of BCTs for systematic reviews to conduct analyses to classify the most effective in interventions[102]. This is an important point as Study 1 relied on the accuracy of the description of the intervention by the authors, who could miss important BCTs from the intervention description due to a lack of understanding of the breadth of techniques[103]. This has been raised in a number of previous systematic reviews that have sought to understand the effectiveness of BCTs in interventions[18, 19]. Therefore, researchers should be encouraged to use resources such as the BCT Taxonomy, or the updated BCT Ontology, to help standardise reporting of BCTs, aid in replication of interventions and to help identify effective active ingredients[102, 104].

However, there has also been some criticism of this taxonomy and its use within health psychology. For example, it has been argued that within health psychology there is substantial person variability, while some individuals respond to interventions to promote healthy behaviours others continue smoking, not exercising, or eating unhealthily[105]. The BCT Taxonomy has been proposed as a solution by identifying and systematising the active and effective ingredients in interventions to ensure that future interventions are effective[102]. However, it’s argued that coding intervention protocols with the BCT Taxonomy does not help in bridging the gap between people’s beliefs and their behaviour[105]. Furthermore, Ogden[105] has suggested that there are also gaps between the health professionals (or whoever is delivering the interventions) beliefs and behaviour with the individual, gaps between the health professional’s beliefs and the training they receive to deliver the intervention and gaps between the protocol and how the protocol is implemented, which need to be considered. While the BCT Taxonomy can help in replication of studies, the coding of protocols may not necessarily help us in understanding the effectiveness of interventions for changing individuals’ behaviour and addressing the person variability[105].

6.2.8 Patient and public involvement

Previous research has outlined the beneficial impact of the integration of patient and public involvement (PPI) into health research by providing the patient perspective[106]. Indeed, within this thesis firsthand knowledge of people with a stoma amongst the stakeholders has been invaluable in adapting the studies and making them more relevant to the patient’s perspective. A stakeholder group was formed at the start of the PhD to advise on various aspects of the research. The group consisted of 2 people with a stoma, 2 stoma care nurses, a charity representative (who also had a stoma themselves), and an industry representative (who had a nursing background). Over the course of the PhD, I met with the full group once, and with members of the group individually multiple times and sought feedback over email at various points.

During the full group meeting in the 13th month of my PhD, PPI representatives provided feedback on the surveys that were developed for Study 4 suggesting combining bulge and hernia questions and adding a ‘don’t know’ option to the type of stoma. They also advised on changes to the EMA protocol, reducing the number of days it was run from 10 to 7 and the number of surveys per day from 5 to 3. They reasoned that it would reduce the amount of missing data and would not discourage participation in the study but would still provide me with enough data points to conduct the planned analysis. They also provided ideas on where to advertise the study to recruit participants, including certain Facebook groups and charities like Ileostomy and Internal Pouch Association and Colostomy UK.

For Study 2, members of the stakeholder group were contacted in the 18th and 19th months of my PhD to provide feedback on the profile names that were chosen and to suggest alternatives if they felt these were not appropriate. They were also asked about dichotomising variables and provided their insights into where the split should be for age, number of abdominal surgeries and time with a stoma. For Study 3, data was obtained from the UK Colorectal Cancer Intelligence Hub which has their own PPI group to ensure the Hub is used to advance the interests that are deemed to be of most importance to patients and the public. This group provided feedback on my initial application form in the 19th month of my PhD to request the data and I presented my findings to them once the study was completed in the 38th month of my PhD.

However, there are also limitations in this thesis associated with the PPI. For example, there is a difference between seeking advice from PPI members and working collaboratively with them in setting the priorities and selecting the study designs of the research. Additionally, there is a recent push in research to include patients in the drafting of manuscripts in order for them to provide their insights in the discussion[107]. By gate-keeping the aspects that they were involved in I could have focussed on topics not considered important to them and missed out on valuable insights that they could have had into the findings of the research. Therefore, it is important that in future research, especially the development of a new self-management intervention, PPI is embedded at every stage of the research process including authorship[107].

Furthermore, although we were able to gather a group of stakeholders with a range of experience from various sectors there was a lack of diversity amongst the demographics of the group. The whole group was of a white ethnic background, highly educated and there was 1 man. This presents us with a skewed view of the issues that are facing this population. This is not uncommon in PPI, with previous research highlighting that those who tend to undertake these positions are from professional backgrounds with skills in using technical language and expressing views in formal meetings which may exclude those from other backgrounds[108, 109]. Future research should attempt to recruit a more diverse group and possibly split out the patients from the nurses and other stakeholders to allow more space for patient perspectives to be heard. Moreover, qualitative research into encouraging diversity in PPI suggests a more person-centred approach by acknowledging people's individual circumstances, through payments for involvement, flexibility to the aspects they are involved in and building trust with a single, stable individual[110].

6.3 Implications of findings

6.3.1 Future research

Based upon the findings from this thesis and the strengths and limitations of the methodologies used there are several avenues for future research to take including: improving the assessment of QOL in this population, use of a prospective cohort design, development of a more tailored and dynamic self-management intervention based upon the development or application of a dynamic behaviour change theory and the use of emerging artificial intelligence technology.

6.3.1.1 Quality of life measure

As QOL is a key measure for patients in evaluating the effects of interventions then a suitable measure needs to be available[111, 112]. A systematic review of 40 studies that developed or validated patient-reported outcome measures in people with a stoma found that of the studies that validated QOL measures, the development of the measure, and the content validity were rated inadequate on the COSMIN taxonomy[113]. This was stated to be in relation to the lack of inclusion of both health experts and patients in the development of the measures, who are key in ensuring the appropriate focus on the constructs. They concluded that there is a need for greater validation of the current measures rather than the development of new ones. However, any future development or validation of QOL measures needs to embed PPI at the centre of this work to ensure that the measures remain patient focussed[114].

Furthermore, alongside further validation work, a consensus needs to be formed as to what represents a clinically meaningful difference for the stoma-specific QOL measures. There are methods that can be used to identify a clinically meaningful difference such as the anchor-based approach, distribution-based methods or the Delphi method[93]. Anchor-based approaches require the use of an external measure in which a change can be reliably observed[115]. These can be either objective, such as healthcare use, or subjective such as patient self-report of worsening symptoms. This method has the benefit of being linked to the patient's perspective, but different values could be obtained depending on the anchor that is used and there is a possibility that the value falls within the measure's natural random variation[116, 117]. Distribution-based methods look at the variation of the scores, this can be done by looking at the standard error of measurement, standard deviation or the effect size of the scores, each of which has different thresholds associated with detecting minimal changes[93]. Due to the varying thresholds, there are likely to be different values depending on the method that is used[116]. There are also questions as to whether identifying the minimal score below which change is likely due to measurement error is actually identifying clinical significance[118]. The Delphi technique is an opinion-based method where a group reach a consensus following the application of either of the previous two approaches[93]. Prior to the panel meeting, participants are sent a survey and asked to record their views which are then distributed to the other participants when the panel is convened. While there may be a substantial divergence of initial views an iterative process tends to result in a convergence of views[119]. This process has become a popular method to determine minimal clinically important differences[93].

While validating existing measures of stoma-specific QOL is important, there is also an increasing focus on empowering patients in their own healthcare which can be extended to how they rate their own QOL[120]. The Measure Yourself Medical Outcomes Profile (MYMOP) is a QOL measure that allows the participant to decide which symptoms they consider to be important to them[121]. This measure is conducted within a consultation or with a researcher at the start of an intervention where participants are encouraged to think about the symptoms that are important to them, these are then rescored at follow-up. Research validating this measure with the SF-36 amongst 265 patients of general and complementary practitioners found that the measure was valid with a significant correlation in the change scores of both measures[122].

This measure provides participants with control over how they report their QOL and may be appropriate to use within self-management interventions when they and the research team are trying to observe the effect the intervention can have on their priorities. However, there are limitations with the measure as it may be less appropriate to use with other study designs that were used within this thesis such as cross-sectional and EMA studies. Furthermore, as the measure limits participants to reporting one or two symptoms it may narrow our view of the impact of stoma self-management as there are a multitude of problems that people with a stoma can face such as leakages, pain, skin irritation, pancaking, or a parastomal hernia[55-57]. There are also arguments as to whether this measure should be used in conjunction with a more established stoma-specific measure as it does not provide us with an understanding of the social and work or sexuality and body image dimensions of QOL[87]. The development and use of QOL measures with greater clinical utility will allow future observational and intervention studies to make stronger suggestions based upon the outcomes of the studies.

6.3.1.2 Prospective cohort

Within the NHS in the past 20 years, hard copies of patient notes have been replaced with electronic health records[123]. The digitisation of health records can not only improve the healthcare of patients but can allow researchers to evaluate what is currently offered to suggest improvements[124]. Although it is currently not feasible to use these for people with a stoma as each individual NHS Trust keeps their own system of records and there are no codes to quickly identify patients with a stoma from electronic health records. There is currently no national database of people with a stoma in the UK. A national strategy is required to establish either a database of people with a stoma or to allow identification of them from electronic health records, to better facilitate evaluation of current health system practices and easier identification of people for future interventions[53, 124].

However, while the increasing use of electronic health records in our healthcare system is an encouraging prospect and has tangible benefits linked to quality improvement within the system, these generally do not include measures of QOL[123]. The NHS ‘Long Term Plan’[10] has outlined the need for increased self-management of conditions and empowering the patient with the skills to cope with complications themselves. Therefore, while electronic health records will be of benefit, allowing us to judge the effectiveness of care within the health system[123], they will lack the understanding of how participants self-management skills support them in day-to-day life as the measurement of SE and QOL are not part of routine care. Consequently, there is a need for routine assessment of patients outside of the healthcare context so we can appropriately evaluate how they are coping with their stoma.

Prospective cohort studies are an observational design whereby participants with a certain characteristic are repeatedly sampled over time[125]. They have a number of benefits such as providing a temporal understanding between exposure variables and outcomes, also if the outcomes are rare then this design may be an efficient way of investigating the association between exposure and outcome[125]. However, they are expensive to conduct due to the large number of participants recruited and the level of data management required, follow-ups can also continue for years[125]. They are also susceptible to missing data with large dropouts over time which can introduce bias into the findings[126].

Within people with a stoma, prospective cohort studies have either had small sample sizes (n=100)[127], follow-ups of only up to 2 years[127-130] and the majority are focussed on the incidence of stoma complications[127, 129, 130]. For example, a current prospective cohort study within the UK is the CIPHER study which is investigating surgical techniques and the incidence of parastomal hernias over 2 years following surgery[131]. While these prospective cohort studies have provided a useful insight into how complications can develop over long periods of time there have been no studies which have sought to understand the development of the relationship between SE in stoma management and QOL. As has been outlined in Figure 6.1, SE may act as a mediator in relationships between QOL and various forms of advice that have been received from healthcare professionals. Furthermore, there may be behavioural factors such as PA which may act as mediators between the relationship of SE and QOL. Therefore, a prospective cohort with a behavioural and psychosocial focus is needed to allow us to see the temporal sequencing of the variables to investigate these relationships.

Additionally, while we have identified that people with a stoma are not a homogenous group in terms of their QOL, we do not know whether the membership of these groups is stable over time. A prospective cohort study would allow for latent transition analysis to be conducted allowing us to see what QOL profiles there are and whether at different time points these remain or there are new profiles[132]. We would also be able to analyse the individuals that change groups over time and what factors predict this change, allowing us to develop more tailored interventions to enhance QOL[132].

6.3.1.3 Self-management interventions

The studies within this thesis have identified how QOL and SE are not stable constructs and how QOL does not apply uniformly across the population. The studies have helped to identify who may require additional support, what that support should be, how it should be delivered, and when that support may be most needed. Considering these findings, they suggest that self-management interventions need to be more dynamic and tailored to an individual's needs. This corresponds with the NHS' long-term plan to encourage patients to increasingly self-manage their conditions[10]. A qualitative study exploring views of healthcare professionals on the provision of dietary advice to people with a stoma found that they considered that learning through experience was the best approach for dietary self-management[133]. However, they also acknowledged that some patients prefer a more guided approach to dietary self-management[133]. Therefore, tailored programmes may be more beneficial to supporting people with a stoma. This is supported by a review of Cochrane reviews of self-management interventions led by nurses that found that tailored interventions were more effective than non-tailored interventions[21].

The findings suggest that there are a group of individuals who could benefit from a more intensive intervention: those who have a recent stoma, have more comorbidities or a parastomal hernia, are less physically active, and are younger. However, there are also other groups with different QOL concerns that could benefit from further support in specific areas. The findings also suggest that QOL and SE could fluctuate from moment to moment based upon the context the individual finds themselves in. Therefore, this suggests that a future self-management intervention needs to be more adaptive than current interventions identified in Study 1 which provide support primarily around the time of stoma formation. In 2005 the term EMI was coined as an extension of the EMA approach, whereby feedback and support are provided in the moment based upon responses to certain questions or contextual factors[45]. With the development of smartphones in recent years EMIs have also adapted; Just-In-Time Adaptive Interventions (JITAIs) are a subset of EMIs whereby advice and support are adapted and tailored over time to take into account an individual's changing psychological and contextual state with provision at the time they are most receptive[44, 134]. A systematic review of 19 papers covering 14 JITAIs for increasing PA found that JITAIs were acceptable to the participants but there were mixed effects on behaviour, although no studies were powered to detect changes[135]. They conclude that further JITAI research is needed as it is in its early stages and there needs to be a focus on theory-driven JITAI interventions.

Within Study 4 of this thesis, I also conducted qualitative work which looked at the feasibility and acceptability of the EMA approach to participants. While this is the first study to utilise this methodology within this population the findings demonstrate that this methodology is appropriate to use within this sample and can produce a dataset with missing data on the higher side of the average compliance rate for EMA studies (my study: 81.2%; average compliance: 71% to 86%)[42, 136-138]. Participants reported that the study was "easy" and "straightforward" and the time to complete the surveys was not intrusive. The participants suggested improvements that could be made such as offering larger incentives, conducting the study over a longer period and providing more opportunities for participants to explain their responses. While this is an emerging area of research, especially within this population, this suggests that research utilising an EMA protocol is acceptable to this population and therefore they may be open to EMIs such as JITAIs. Additionally, the suggested improvements form a basis from which a future self-management JITAI could be developed. Further information on the demographics of the interviewed participants and what they outlined in the interviews can be found in **Appendix E.1** and **E.2**.

6.3.1.4 Dynamic behaviour change theory

The research in this thesis suggests that self-management interventions may need to be more dynamic and therefore so too does the theory that these are based upon. Many of the current health behaviour theories that are used to develop interventions (e.g. Theory of Planned Behaviour, the Health Belief Model, and Social Cognitive Theory) assume that psychological processes remain consistent over time and they do not take into account contextual or environmental influences, however, I have demonstrated in Study 4 that these have a role in the variation of QOL and SE[139, 140]. They also assume that there is a homogenous group that experiences similar psychological processes, which I have also demonstrated is not the case for QOL in people with a stoma in Studies 2 and 3[141]. EMA studies can allow us to explore the temporal nature of human behaviour and psychological processes over time and therefore there needs to be an appropriate theoretical framework on which to build upon future interventions. A large systematic review of EMA studies (N=633) investigating health behaviour (PA, diet, sexual health, smoking and alcohol) found that very few studies sought to develop and validate a dynamic theory[139]. Therefore, there is a need for future research to consider the development or adaptation of theories to account for the variation of behaviour and psychological processes across time and contexts.

6.3.1.5 Artificial intelligence

Artificial intelligence is the use of computers to mimic the human mind and its decision making and analytical processes[142]. Machine learning is a subset of artificial intelligence whereby a set of algorithms learn from inputted data and can analyse this to make predictions or classifications based upon the data[143, 144]. Machine learning is increasingly used within healthcare to identify the optimal treatment protocol for patients, whether patients will develop a certain disease, or by analysing radiology images for lesions[145].

Additionally, these methods have increasingly been applied to research. The Human Behaviour Change Project had researchers annotate 512 reports of RCTs for smoking cessation interventions for 70 pieces of information[146]. This information was then used to train machine learning algorithms to automatically extract this information, the accuracy of the extracted information was then compared between the algorithms and the researchers. They found that there were comparable levels of accuracy across certain pieces of information but that the algorithm performed poorer overall. They concluded that this was due to the presentation of information within reports and that there needed to be greater standardisation in research articles to enable the algorithm to be more successful[146]. A further study utilising machine learning within healthcare had clinicians predict cancer patients QOL at 6- and 12-months post diagnosis, with and without the use of machine learning predictions[147]. They found that when machine learning was integrated into the clinical decision-making process then clinician's predictions of patients QOL were substantially more accurate.

While the use of machine learning is still in its infancy in health research there are avenues for future applications of this technology. For example, the research in this thesis has demonstrated how people with a stoma are not a homogenous group in relation to their QOL scores and there are demographic and clinical characteristic differences between these groups. Machine learning could help predict the individuals that are likely to need additional support and suggest the appropriate protocol for providing this either to the healthcare professional or directly to the individual themselves.

6.3.2 Implications for practice

Within the UK stoma care pathway, nurses are responsible for patient care prior to elective surgery and provide a basis in stoma management immediately following surgery, with guidance set out by the ASCN[15]. The research outlined within this thesis has highlighted the potential importance of healthcare professionals, particularly nurses, involvement in the provision of advice and care to patients following stoma formation surgery. Therefore, there is a need to maintain this relationship moving forward.

Based upon the findings from this thesis, people with a stoma want to receive more advice and support in areas beyond what is currently outlined in ASCN guidance[15], including in lifestyle and PA, financial information, psychological and physical effects of treatment and information for their family and friends. However, we know that many of these topics have been raised in effective self-management interventions that were identified in Study 1. Therefore, consideration should be given to amending ASCN guidelines to expand advice and support provided to patients beyond how to deal with stoma complications and general management of the stoma appliance[15].

However, there are two issues that need to be addressed prior to this. Firstly, healthcare professionals need to feel confident in being able to raise these topics and provide this advice to individuals. A qualitative study of 21 healthcare professionals who work with people with a stoma found that the mixed research findings on dietary advice lowered their confidence in providing advice[133]. This suggests that additional training for healthcare professionals may be beneficial in providing them with the confidence to provide advice and support to patients. Secondly, while previous effective interventions have been conducted, they have yet to be incorporated into official guidance, which could suggest further work needs to be conducted on the implementation of these interventions into standard practice. Furthermore, there is also a need to consider the demands upon nurses’ time which can negatively impact on patient care[148], so other organisations could be considered to provide additional support to patients. There is already precedence for stoma nurses directing patients to third parties, as this already happens with regard to stoma care appliances from stoma industry partners (e.g. stoma bags and support garments)[149]. Also, within Study 1 aspects of certain interventions involved providing information on how to access local or national support groups and associations and one study involved group education with other people with a stoma. Therefore, ASCN guidelines should outline how stoma care nurses could build relationships with local stoma support groups and national charities and associations that could offer supplementary advice and support.

While Study 1 identified that most studies involved the use of healthcare professionals there was only one study which used an element of group education with peers and no studies explored the use of peer experts in the interventions. Peer experts are an increasingly used resource to support patients with chronic conditions, as they have firsthand knowledge of how to adjust to their condition[150]. They have been found to be useful in previous self-management interventions in other patient populations with chronic illnesses, for example, arthritis, diabetes, mental health and multiple sclerosis[151-155]. A cross-sectional study amongst people with a stoma concluded that peer support could improve QOL in people with a stoma from IBD, with a review concluding similarly for people with a stoma from colorectal cancer[156, 157].

Peer experts could also provide a way to provide longer-term support to people with a stoma and reduce the burden on nurses’ time. The interventions included within the systematic review in this thesis were all conducted around the time of stoma formation surgery. While these provided support in developing skills for post-surgery self-management there was no intervention for ongoing support in the long-term which we have identified in Studies 2 and 3 could be useful for people. This may be due to the majority of those interventions identified in Study 1 requiring the involvement of nurses, and the continuation of care in the long term would not be feasible. Previous research has explored the skills healthcare professionals need to develop to provide effective self-management to patients[158]. This research identified that beyond providing further training and education to healthcare professionals, they need an awareness of community support resources to which they can direct patients to as well as developing collaborative care with patients and carers. By understanding the needs of the patients and their families and with a greater knowledge of support beyond the healthcare setting, the healthcare professional can refer patients to support groups or forums that can provide ongoing support. Many of these groups are peer-led and could relieve some of the burden upon the healthcare professional[159].

Another option is the use of digital technologies to supplement self-management support as Study 1 did identify an intervention which utilised digital technology[160] and another has been identified since the review was conducted[161]. Furthermore, as has already been discussed, JITAIs could also be useful digital interventions to provide dynamic support. Digital technologies are being increasingly used within the healthcare setting as a supplemental tool to nurse involvement[162]. There are relatively few studies that have used digital technologies in people with a stoma but the two I have identified have found that they can help support SE to self-manage their condition, while also being acceptable to participants[160, 161]. A commentary on stoma nurse adaptations to COVID-19 within the UK found that digital technologies were at the centre of this, with information moving online, virtual consultations and direction to support group webinars[163]. The authors commented that this had led to a more efficient service for patients and fewer complaints. Digital technologies offer an acceptable and scalable solution to pressures on the healthcare system but would still require some expert input as digital literacy does not necessarily translate to health literacy[164].

6.4 Conclusions

In conclusion, this thesis has contributed novel, published findings to develop the evidence base that have deepened our understanding of QOL and SE in people with a stoma and how they self-manage their condition. Together the findings from the research across this thesis can inform the development of future self-management interventions for people with a stoma. Current self-management interventions in this population treat people with a stoma as a homogenous group, whereas I have found that there are distinct groups of people with varying levels of QOL across various subscales. Furthermore, QOL and SE are not stable constructs and fluctuate over the course of a week based on contextual factors (time of day and location). I have also found that both within- and between-person SE is closely associated with QOL and that we need to consider how we can enhance both in-the-moment and overall SE in people with a stoma. These findings suggest that we need to consider more adaptive and tailored interventions for people with a stoma which consider the range of experiences and needs of this group.

6.5 References

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Appendix A: Study 1 supplementary materials

Appendix A.1: PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	30
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	31
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	32-33
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	33
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	33
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	34-35
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	33-34
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix A.2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	33
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	34-35
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	33
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	35
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	35
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	35

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	35
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	35
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	35-39
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	42-43
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	36-39
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	42
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	44-45
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	45-47
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	47
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	46-48
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	49

Appendix A.2: Search strategy for MEDLINE (OVID)

MEDLINE Search Strategy January 1st 2000 to 13th February 2020:

---

1 Ostomy/
2 Ileostomy/
3 Colostomy/
4 Duodenostomy/
5 Jejunostomy/
6 Enterostomy/
7 "colostom*".ab,ti.
8 "ileostom*".ab,ti.
9 "ostom*".ab,ti.
10 "enterostom*".ab,ti.
11 "duodenostom*".ab,ti.
12 "jejunostom*".ab,ti.
13 "stoma patient* ".ab,ti.
14 Health Education/
15 Self Care/ or Self-Management/
16 Patient Education as Topic/
17 Health Promotion/
18 Behavior Therapy/
19 Teaching/
20 education/ or mentoring/ or teaching/
21 Health Behavior/ or Behavior/
22 Life Style/
23 social support/ or psychosocial support systems/
24 "health education".ab,ti.
25 self-management.ab,ti.
26 "therapeutic education".ab,ti.
27 "stoma education".ab,ti.
28 self-care.ab,ti.
29 "self care".ab,ti.
30 empowerment.ab,ti.
31 "patient education".ab,ti.
32 teaching.ab,ti.
33 education.ab,ti.
34 life-style.ab,ti.
35 lifestyle.ab,ti.
36 "life style".ab,ti.
37 psychosocial.ab,ti.
38 "action plan".ab,ti.
39 "management plan".ab,ti.
40 "treatment plan".ab,ti.
41 "individuali?ed plan".ab,ti.
42 self efficacy/
43 self-efficacy.ab,ti.
44 "self efficacy".ab,ti.
45 "behaviour*".ab,ti.

46 "behavior*".ab,ti.
47 "behaviour* therap* ".ab,ti.
48 "behavior* therap* ".ab,ti.
49 "health behaviour".ab,ti.
50 "health behavior".ab,ti.
51 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50
52 "f?ecal diversion".ab,ti.
53 stoma.ab,ti.
54 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 52 or 53 (89953)
55 51 and 54
56 limit 55 to (english language and yr="2000 -Current")

Appendix A.3: Behaviour change techniques coded from the interventions

BCT Coded	Chaudhri, 2005	Cheung, 2003	Crawford, 2012	Forsmo, 2016	Khalilzadeh Ganjalikhani, 2019	Lim, 2019	Pouresmail, 2019	Seo, 2019	Sier, 2017	Su, 2019	Wang, 2018	Wen, 2019	Zhang, 2013	Total
Credible source	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	13
Instruction on how to perform the behavior	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	13
Demonstration of the behavior	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥		12
Behavioral practice/rehearsal	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥		12
Information about health consequences			🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	11
Monitoring of behavior by others without feedback	🟥	🟥	🟥		🟥	🟥		🟥		🟥	🟥		🟥	9
Avoidance/reducing exposure to cues for the behavior			🟥	🟥	🟥			🟥	🟥	🟥	🟥			7
Self-monitoring of behaviour	🟥	🟥				🟥	🟥		🟥	🟥		🟥		7
Feedback on behaviour	🟥					🟥		🟥		🟥	🟥		🟥	6
Verbal persuasion about capability				🟥		🟥		🟥			🟥		🟥	5
Social support (emotional)						🟥				🟥		🟥	🟥	4
Reduce negative emotions						🟥					🟥		🟥	3
Social comparison											🟥	🟥	🟥	3
Problem solving						🟥				🟥		🟥		3
Social support (practical)						🟥				🟥		🟥		3
Information about social and environmental consequences						🟥			🟥					2
Graded tasks						🟥					🟥			2
Goal setting (behavior)						🟥						🟥		2
Social support (unspecified)											🟥			1
Habit formation		🟥												1
Action planning												🟥		1
Review behavior goal(s)												🟥		1
Self-monitoring of outcome(s) of behaviour										🟥				1
Discrepancy between current behaviour and goal												🟥		1
Commitment												🟥		1
Identification of self as role model												🟥		1
Framing/reframing												🟥		1
Incompatible beliefs												🟥		1
Valued self-identify												🟥		1
Mental rehearsal of successful performance												🟥		1
Imaginary punishment												🟥		1
Imaginary reward												🟥		1

Total	7	7	7	7	7	16	6	9	8	13	13	22	9	

Appendix A.4: Number of studies per improved study outcome which used a BCT

BCT Coded	Improved Quality of life (n=4)		Improved self-efficacy (n=6)		Improved self-management (n=2)		Combined average percentage
	n	%	n	%	n	%	%
Credible source	4	100	6	100	2	100	100
Instruction on how to perform the behavior	4	100	6	100	2	100	100
Demonstration of the behavior	4	100	5	83	2	100	92
Behavioral practice/rehearsal	4	100	5	83	2	100	92
Information about health consequences	3	75	6	100	1	50	83
Monitoring of behavior by others without feedback	3	75	4	67	2	100	75
Avoidance/reducing exposure to cues for the behavior	3	75	3	50	1	50	58
Self-monitoring of behaviour	3	75	3	50	1	50	58
Feedback on behaviour	1	25	4	67	2	100	58
Verbal persuasion about capability	0	0	3	50	1	50	33
Social support (emotional)	1	25	3	50	0	0	33
Reduce negative emotions	0	0	2	33	0	0	17
Social comparison	0	0	3	50	0	0	25
Problem solving	1	25	2	33	0	0	25
Social support (practical)	1	25	2	33	0	0	25
Information about social and environmental consequences	1	25	0	0	0	0	8
Graded tasks	0	0	1	17	0	0	8
Goal setting (behavior)	0	0	1	17	0	0	8
Social support (unspecified)	0	0	1	17	0	0	8
Habit formation	1	25	0	0	0	0	8
Action planning	0	0	1	17	0	0	8
Review behavior goal(s)	0	0	1	17	0	0	8
Self-monitoring of outcome(s) of behaviour	1	25	1	17	0	0	17

Discrepancy between current behaviour and goal	0	0	1	17	0	0	8
Commitment	0	0	1	17	0	0	8
Identification of self as role model	0	0	1	17	0	0	8
Framing/reframing	0	0	1	17	0	0	8
Incompatible beliefs	0	0	1	17	0	0	8
Valued self-identify	0	0	1	17	0	0	8
Mental rehearsal of successful performance	0	0	1	17	0	0	8
Imaginary punishment	0	0	1	17	0	0	8
Imaginary reward	0	0	1	17	0	0	8

Appendix B: Study 2 supplementary materials

Appendix B.1: Full variable list

Why did you have your stoma(s) formed?

If you selected Other, please specify:

COLOSTOMY Please select what type(s) of stoma you have (Please tick all that apply).

ILEOSTOMY Please select what type(s) of stoma you have (Please tick all that apply).

UROSTOMY Please select what type(s) of stoma you have (Please tick all that apply).

UNSURE Please select what type(s) of stoma you have (Please tick all that apply).

How long have you been living with a stoma?

How many abdominal surgeries have you had in your lifetime? (please include stoma surgery, and all non-stoma related surgery)

OPEN What types of abdominal surgery have you had? (including stoma surgery, and any non-stoma related surgery) (Please select ALL that apply)

LAPARASCOPIC What types of abdominal surgery have you had? (including stoma surgery, and any non-stoma related surgery) (Please select ALL that apply)

UNSURE What types of abdominal surgery have you had? (including stoma surgery, and any non-stoma related surgery) (Please select ALL that apply)

What age were you when you had your stoma?

Do you currently live in the UK?

If NO, please select which country you currently live in:

What is your sex?

What age are you?

Have you ever been told by a nurse or doctor that you've had/have a parastomal hernia?

Do you have/have you ever had a bulge around the stoma, making one side stick out a bit more?

Have you ever been told by a nurse or doctor that you've had/have an incisional hernia?

Has anyone discussed the different types of support garments with you?

STOMA NURSE If Yes, who discussed these with you? (Please select ALL that apply)

OTHER NURSE If Yes, who discussed these with you? (Please select ALL that apply)

MY GP If Yes, who discussed these with you? (Please select ALL that apply)

MY SURGEON If Yes, who discussed these with you? (Please select ALL that apply)

OTHER PERSON WITH STOMA If Yes, who discussed these with you? (Please select ALL that apply)

FAMILY MEMBER If Yes, who discussed these with you? (Please select ALL that apply)

SUPPLIER If Yes, who discussed these with you? (Please select ALL that apply)

SUPPORT GROUP If Yes, who discussed these with you? (Please select ALL that apply)

CHARITY If Yes, who discussed these with you? (Please select ALL that apply)

OTHER If Yes, who discussed these with you? (Please select ALL that apply)

If you selected Other, please specify:

Do you currently own any kind of support garment for your stoma? (including support belts/support underwear such as vests, pants, and girdles)

If you selected No, can you suggest a reason (didn't know about them? not interested?)

How many support BELTS do you currently own?

How many days have you worn your support BELT in the past month? (Leave blank if you do not own any)

How many support UNDERWEAR garments do you currently own (e.g. vests, pants, girdles)?

How many days have you worn your support UNDERWEAR in the previous month (including vests, pants, knickers, girdles)? (Leave blank if you do not own any)

How many support garments (belt or underwear) have you had on NHS prescription in the past year?

DIDN'T KNOW If you don't use your support garment(s) please select as many of the following reasons that may apply:

EXPENSIVE If you don't use your support garment(s) please select as many of the following reasons that may apply:

UNCOMFORTABLE If you don't use your support garment(s) please select as many of the following reasons that may apply:

NO BENEFIT If you don't use your support garment(s) please select as many of the following reasons that may apply:

VELCRO NOISY If you don't use your support garment(s) please select as many of the following reasons that may apply:

OTHER If you don't use your support garment(s) please select as many of the following reasons that may apply:

If you selected Other, please specify:

Rate your overall satisfaction with your life in general right now on a scale of 0 to 100. With 0 being totally unsatisfied and 100 being totally satisfied. Enter that number in the box below.

Rate your overall satisfaction with your life in general during the last month on a scale of 0 to 100, with 0 being totally unsatisfied and 100 being totally satisfied. Enter that number in the box below.

I am able to participate in hobbies that I enjoy

I am able to go out with friends

My stoma interferes with my ability to work or attend college/university/school

I worry about travelling because of my stoma

I enjoy sexual activity

I feel attractive

My sexual partner is bothered by my stoma

It bothers me if others are aware I have a stoma

I worry about lack of privacy when I need to empty my pouch

I feel comfortable in my clothing

I am satisfied with the foods I eat

I have financial concerns regarding my stoma supplies

I have problems with odour

I am able to share my feelings and concerns about my stoma with a family member or friend

I am embarrassed by gas (noises or rapid filling of bag)

I worry my stoma appliance will leak

I am bothered by skin irritation around the stoma

Social situations make me feel anxious

I perform the same household and family duties

It was difficult to hide the stoma appliance under clothing

I was self-conscious about the appearance of the stoma appliance

The stoma appliance limited the choice of clothes that I could wear

The stoma appliance was obvious to other people

The colour of the stoma appliance was discreet

It was difficult to hide the stoma appliance because of ballooning

The stoma appliance was comfortable to wear

I was not concerned about skin irritation under the stoma appliance (for example, feelings of burning, itching, pinching or pain)

It was uncomfortable to remove the stoma appliance from my body

I often forgot that I was wearing the stoma appliance

The stoma appliance was comfortable as it fitted well to my body movements

The stoma appliance disrupted my sleep during the night

In the past week on how many days have you done a TOTAL of 30 minutes or more of physical activity, which was enough to raise your breathing rate. This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places,

How confident are you that you can do gentle exercises to strengthen your abdominal muscles (range of motion, using weights, etc.)? - Not at all confident........................Totally confident

How confident are you that you can do aerobic exercise such as walking, swimming, or bicycling? - Not at all confident........................Totally confident

How confident are you that you can exercise without it causing problems with your stoma? - Not at all confident........................Totally confident

How confident are you exercising WITHOUT your support garment? - Not at all confident........................Totally confident

How confident are you exercising WITH your support garment? - Not at all confident........................Totally confident

Please tell us anything you would like to add about your stoma, and your experience with support garments and/or belts.

Appendix C: Study 3 supplementary materials

Appendix C.1: Original and condensed categories of advice

Original advice categories	Condensed advice categories
Diet and lifestyle (including smoking)	Diet and exercise
Physical activity and exercise	
Financial help or benefits	Any financial information
Free prescriptions	
Returning to or staying in work	
Information/advice for family/friends or carers	Information for family and friends
Physical aspects of living with and beyond cancer	Physical aspects of living with and beyond cancer
Psychological aspects of living with and beyond cancer	Psychological aspects of living with and beyond cancer

Appendix C.2: Quality of life subscales used in present study and comparison with those of the previous study

Subscales/domains used in present study	Subscales used in previous study (Goodman et al., 2022)
EQ-5D-5L – Self-Care and Usual Activities	Work/Social Function subscale (e.g. 'My stoma interferes with my ability to work or attend school').
Social Difficulties Inventory – Self and Others subscale	Sexuality/Body Image subscale (e.g. 'I am able to share my feelings and concerns about my ostomy with a family member or friend').
FACT-C – Additional Concerns subscale	Stoma Function subscale (e.g. 'It bothers me if others are aware I have a stoma').
EQ-5D-5L – Pain and Discomfort	Skin Irritation subscale (e.g. 'I am bothered by skin irritation around the stoma').
Social Difficulties Inventory – Money Matters subscale	Financial Issues subscale (e.g. 'I have financial concerns regarding my ostomy supplies').

Appendix C.3: Model fit statistics for the latent profile analysis models

Number of profiles	AIC	BIC	Entropy	Smallest profile %
1	102574.1	102651.0	1.00	NA
2	69555.4	69715.6	0.96	37.7%
3	55114.8	55358.3	0.95	20.5%
4	46265.5	46592.3	0.94	15.8%
5	39354.3	39764.5	0.95	13.8%
6	42840.6	43334.1	0.94	2.2%

Note: AIC= Akaike Information Criteria; BIC= Bayesian Information Criteria.

Appendix D: Study 4 supplementary materials

Appendix D.1: Baseline questionnaire

You are being invited to participate in a research study titled 'Understanding day-to-day well-being and self-management practices in people with a stoma'. This study is being done by William Goodman from the University of Leeds.
The purpose of this research study is to understand how individuals manage their stomas day-to-day, and how their well-being and confidence changes throughout the day. This survey will take you approximately 8 minutes to complete. Your participation in this study is entirely voluntary and you can withdraw at any time without providing a reason.
We believe there are no known risks associated with this research study; however, as with any online related activity the risk of a breach is always possible. To the best of our ability your participation in this study will remain confidential, and only anonymised data will be published. We will minimise any risks by keeping your personal information entirely confidential in a password protected folder on University of Leeds servers. This will be deleted once the research is completed. Further information is available via the University of Leeds Privacy Notice. For further information on this study please refer to the Information Sheet emailed to you.

What is your study ID?

What type of stoma do you have?

Ileostomy

Colostomy

Don’t know

How long have you been living with a stoma?

Years:

Months:

What was the reason for the formation of your stoma?

Cancer

Crohn’s disease

Ulcerative colitis

Diverticulitis

Physical trauma

Other please specify:

What is your gender?

Male

Female

Other

Prefer not to say

Does your gender identity match your sex as registered at birth?

Yes

No

Prefer not to say

What is your age? Please specify in years

What is your marital status?

Married/living with partner

Single

Divorced

Widowed

Other

You only need to answer one of the two following questions.

What is your height in cm?

What is your height in ft/in?

You only need to answer one of the two following questions.

What is your weight in kg?

What is your weight in st/lbs?

What is your smoking status?

Current smoker

Ex-smoker

Never smoked

How many abdominal surgeries have you had (including your stoma surgery)?

Do you currently have a parastomal hernia or a bulge around your stoma, making one side stick out more?

Yes

No

Don’t know

Have you had a parastomal hernia or a bulge in the past?

Yes

No

Don’t know

Do you have a long-standing health condition?

Yes

No

Which, if any, of the following conditions do you have?

Alzheimer’s disease or dementia

Angina

Arthritis

Asthma or other chronic chest problem

Blindness or visual impairment

Deafness or hearing impairment

Diabetes

Epilepsy

Heart condition

High blood pressure

Kidney disease

Learning difficulty

Liver disease

Long term back problems

Long standing mental health problem

Long standing neurological problem

Do not have a long standing condition

Another long-standing condition (please specify)

Thank you for completing the questions. Someone will be in touch with the next steps.

Appendix D.2: Repeated EMA questionnaire

Are you happy to continue taking part in this research?

- Yes
- No

What is your current location?

- At home (choose if working from home)
- At work
- Travelling
- Out shopping
- At a friend or family member’s house
- Out for recreation
- In a healthcare setting (GP surgery/Hospital)
- Other please specify

What are you doing?

- Working
- Commuting
- Exercising
- Shopping
- Relaxing
- Socialising
- Housework/Chores
- Other please specify

Who are you with?

- Family/Partner
- Friends
- Colleagues
- Alone
- Other please specify

We would like to know your overall satisfaction with your life in general RIGHT NOW. This scale is numbered from 0 to 100 where 100 means totally satisfied and 0 means totally unsatisfied. Drag the dial on the scale to indicate how your well-being is RIGHT NOW.

At this moment RIGHT NOW how confident do you feel that you can do the different tasks and activities needed to manage your stoma right now? 0 (not at all confident) - 100 (totally confident). Drag the dial on the scale to indicate how confident you feel RIGHT NOW.

Over the past 2 hours which of the following stoma management practices have you conducted?

Changed/emptied stoma appliance

Cleaned skin around stoma

Wore a support garment (vest, underwear or belt)

Performed exercises to strengthen your core muscles

Used deodorant to reduce odour

Dietary management

Other (please specify)

Over the past 2 hours which of the following resources/facilities/support, if any, have you had to access to manage your stoma?

Toilet facilities

Ostomy supplies

Support from partner/friend

Other (please specify)

Have needed resources/facilities but could not access them

Did not need access to resources/facilities

Appendix E: Discussion supplementary materials

Appendix E.1: Demographic and clinical characteristics of interviewed participants (N=20)

Variable	**N (%)**
Gender	
Male	6 (30)
Female	14 (70)
Missing	0
Disease	
Cancer	6 (30)
IBD	10 (50)
Diverticulitis	2 (10)
Other	2 (10)
Missing	0
Type of stoma	
Ileostomy	14 (70)
Colostomy	6 (30)
Missing	0
Age	
55 or below	10 (50)
Above 55	10 (50)
Missing	0
Time with stoma	
2 years or less	6 (30)
More than 2 years	14 (70)
Missing	0
Parastomal hernia	
Yes	6 (30)
No	11 (55)
Missing	3 (15)
Number of abdominal surgeries	
1	5 (25)
More than 1	14 (70)
Missing	1 (5)

Appendix E.2: Overview of themes generated from analysis of participant interviews

From analysis of the interview transcripts (n=20), three themes were generated: feedback on EMA protocol, improvements to the study, and benefits of taking part.

Feedback on EMA protocol

The majority of participants that were interviewed reported that the Ethica app was "*easy*" and "*straightforward*" to download, signup to, and navigate and complete surveys. The use of a mobile application had benefits as participants reported the reminders to complete the surveys as being useful: "*if I'd not had the reminders on my phone I never would have remembered*". **ID60 Female, 60yrs, Cancer.**

The amount of time taken to complete the surveys was mentioned as a positive: "*it certainly only took a few minutes each time so it wasn't particularly intrusive*". **ID60 Female, 60yrs, Cancer.** However, there were reports that the time at which the surveys needed to be completed did not always align with what participants' schedules allowed: "*I wasn't then able to answer the survey on a couple of occasions because of work.*" **ID15 Female, 27yrs, IBD.** This was not always due to the time that the surveys were scheduled but the situation the participants found themselves in: "*I was out to a dinner party which started at 7 o'clock that night, so I couldn't complete the survey until 7 o'clock, I couldn't really do it in front of other people because it would have been very antisocial… But those were the occasions when you know… I would have given the lowest marks for my wellbeing at those times because I was a little bit anxious relating to the stoma.*" **ID74 Male, 76yrs, IBD.**

Improvements to the study

Participants suggested improvements that could be made to the study. Firstly, while the participants acknowledged that they took part in this study for altruistic reasons they proposed that an increase in the amount of compensation for taking part may encourage others to do so as well: "*Personally I would just do it, because I just, I think doing research is so important… if I'm thinking about getting other people to do it… maybe just yeah offering people something like Amazon vouchers, I would say a bigger value*". **ID62 Female, 36yrs, Other.**

While participants found the brevity of the surveys beneficial for not intruding on their day-to-day activities, others wanted to provide additional elaboration on their feelings at the moment around their QOL and SE: "*I felt it was quite difficult to express the reasons behind some of the rankings that I gave and the time.*" **ID25 Male, 48yrs, Cancer.**

The study period was set at a week, in consultation with our steering group, to minimise missing data. However, participants reported that they would have been willing to complete the study over a longer period, as they indicated that a week did not adequately provide an overview of their life with a stoma: "*I do wonder whether, just thinking about my own experience, whether a week is definitely representative. Maybe it would be useful to do, I don't know maybe 2 weeks over a month.*" **ID60 Female, 60yrs, Cancer.**

Benefits of taking part

While being interviewed for their feedback on taking part in the study participants reported benefits they felt. Firstly, taking part encouraged them to reflect on their feelings related to their health and stoma: “*It was quite interesting to note, you know, how my health and wellbeing moved on the scale… and notice the difference between, sort of, mornings and afternoons and evenings*”. **ID88 Female, 53yrs, IBD.** Furthermore, participants also reported feeling a sense of altruism by taking part in research that could help people in the future: “*I just thought if I could help doing a study of how people might feel when they have it or if they need it, it just might help others. And might help people understand what needs are required really when you go through this kind of thing I guess.*” **ID99 Female, 43yrs, IBD.**