

**Facilitating Diary Keeping and Participation in Valued  
Activities with Individuals Who Have Had a Stroke: A  
Randomised Controlled Trial**

Thesis submitted for the Degree of Doctor of Clinical Psychology

University of Sheffield

Department of Psychology

By

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## **Declaration**

The work contained in this thesis has not been submitted for any other degree or to any other institution.

## Structure and Word Count

This thesis has been prepared in accordance with following guidance:

Literature Review: Clinical Psychology Review

Research Report: Rehabilitation Psychology

	Excluding References	Including References
Literature Review	7 216	1 468
Research Report	8 288	1 688
Total without appendices	15 504	18 660
Total with appendices	-	26 822

## Abstract

### Literature Review:

The literature review evaluates the evidence for approaches designed to facilitate patient involvement in goal setting within stroke and brain injury rehabilitation. Patient involvement in healthcare decision-making follows guidance for patient-centred practice and is believed to promote adherence to interventions and improved outcomes. The review identifies a range of approaches designed to improve patient involvement in goal setting for neurological rehabilitation and evaluates the evidence provided for them. Qualitative studies of participant perspectives are examined to identify barriers and facilitators for involving patients with acquired brain injury in rehabilitation goal setting.

### Research Report:

The study aimed to investigate the use of implementation intentions to facilitate diary-keeping and participation in valued activities after discharge from community stroke rehabilitation. Using a randomised procedure, participants ( $N=29$ ) were allocated to either a Diary Plan intervention group or a No Diary Plan control group. Whilst all participants were required to complete a diary which incorporated implementation intentions for valued activities, only the Diary Plan participants formed an implementation intention for completing the diary. Between-group analyses showed no effects for the implementation intention on diary completion. Single-group analyses found that formation of implementation intentions for valued activities was associated with higher post-intervention activity levels. Due to the small sample size, cautious interpretation of these results is advocated. Methodological limitations and suggestions for future research in the development of self-management interventions in stroke rehabilitation are discussed.

## **Acknowledgements**

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## Contents

Title page	i
Declaration	ii
Structure and word count	iii
Thesis Abstract	iv
Acknowledgements	v
<b>Section 1. Literature Review</b>	
Abstract	2
1 Introduction	
1.1 Patient involvement in goal setting for stroke and brain injury rehabilitation	3
1.2 Previous reviews of goal setting in rehabilitation	4
2 Method	9
2.1 Aims and Search strategy	10
2.1 Data Collection and analysis	11
3 Results and Discussion	11
3.1 Sampling	12
3.2 Overview of approaches to facilitate patient involvement in goal setting	16
3.2.1 General patient centred approaches	16
3.2.2 Approaches based on models of self-regulation brain injury recovery	18
3.3 Evaluation of the approaches	20
3.4 Summary and methodological considerations	24
4 Barriers and facilitators to patient involvement in goal setting	25
5 Conclusions and future directions	31
References for literature Review	32

## Section 2. Research Report

Abstract	43
Introduction	44
Study Aims and Hypotheses	50
Method	52
Results	57
Discussion	65
Conclusions	73
References for Research Report	74
Appendices	84

# **Section 1: Literature Review**

## **Facilitating Patient Involvement in Setting Goals for Stroke and Brain Injury Rehabilitation: A Review of Approaches**

## **Abstract**

Facilitating patient involvement in healthcare decision-making follows NHS practice guidelines and is believed to improve outcomes and motivation for interventions. Involving patients with acquired brain injury in rehabilitation goal setting may be particularly challenging due to the presence of cognitive and communication difficulties. This review examines evaluations of approaches designed to facilitate patient involvement in goal setting within the context of stroke and brain injury rehabilitation. A range of approaches were identified and described within two broad categories i) general patient-centred approaches and ii) approaches based on models of self-regulation and brain injury recovery. Evidence for these approaches is evaluated and discussed in relation to methodological issues. Qualitative studies of participant perspectives are examined to identify key barriers and facilitators for involving patients with acquired brain injuries in rehabilitation goal setting.

## **1 Introduction**

Patient-centred care has emerged as an important principle for improving healthcare in national guidelines over the last 10 years (Department of Health NHS Plan, 2000; National Service Framework (NSF) for Older People, 2001). Involvement of 'patients in healthcare consultations and goal setting is seen as a central dimension of 'patient-centredness' (Leplege, Gzil & Cammelli et., 2007; Sumision & Law, 2006). In an effort to clarify understanding of patient involvement in healthcare decision-making, Thompson (2007) presents a typology identifying five levels of patient-desired involvement. Patient involvement, according to Thompson, concerns 'a degree of transfer of power from the professional to the patient in the form of increased knowledge, control and responsibility' (p. 1307-1308). As in Thompson's article, 'involvement' rather than 'participation' will be used in this review as the umbrella term for describing the varying degrees in which patients take part in the decision-making process.

### **1.1 Patient involvement in goal setting for stroke and brain injury rehabilitation**

Increasing patient involvement in determining rehabilitation goals is said to promote patient motivation and autonomy, thus enhancing adherence to rehabilitation interventions and their outcomes (Pollock, 1993). However the impact of greater patient involvement is yet to be established. Moreover, the rehabilitation literature suggests that collaborative goal setting can be difficult to facilitate and within neurological settings, patient cognitive and communication difficulties present additional challenges for the process (Levack, Dean, McPherson & Siegert, 2006a). Examining how to facilitate patient involvement in goal setting was voted second of five top priorities at a recent conference of leading research-practitioners in the field of goal setting for neurological rehabilitation (Playford, Siegert, Levack & Freeman, 2009).

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<sup>1</sup> For consistency in this review, the term 'patient' rather than 'client' or 'service-user' will be used to denote individuals in receipt of healthcare services.

## **1.2 Previous reviews of goal setting in rehabilitation**

The lack of agreed terminology concerning goal setting in rehabilitation has been acknowledged in a number of literature reviews (Hurn, Kneebone & Cropley, 2006; Levack, Taylor, Siegert, Dean, McPherson & Weatherall, 2006b; Scobbie, Wyke & Dixon, 2009). The terms 'goal-setting' and 'goal-planning' have been used inter-changeably to describe the process of establishing goals and the idea that goals are negotiated with patients may or may not be included. In the context of rehabilitation, a goal has been defined as 'how things will be at some specified time in the future and that it is a desired state that requires both action and effort' (Playford et al., 2009, p. 338). The current review will use 'goal setting' as a general term for the process of establishing goals.

Although previous literature reviews have examined different aspects of goal setting in rehabilitation, none have had a specific focus on patient involvement in the process. Reviews based on systematic searches of the literature have focused on the clinical use and impact of goal setting approaches (Hurn, Kneebone & Cropley, 2006; Levack et al., 2006b) or involved a more exploratory and theoretically-orientated focus (Levack, Dean, Siegert & McPherson, 2006b; Scobbie, Wyke & Dixon, 2009; Sivaraman-Nair, 2003).

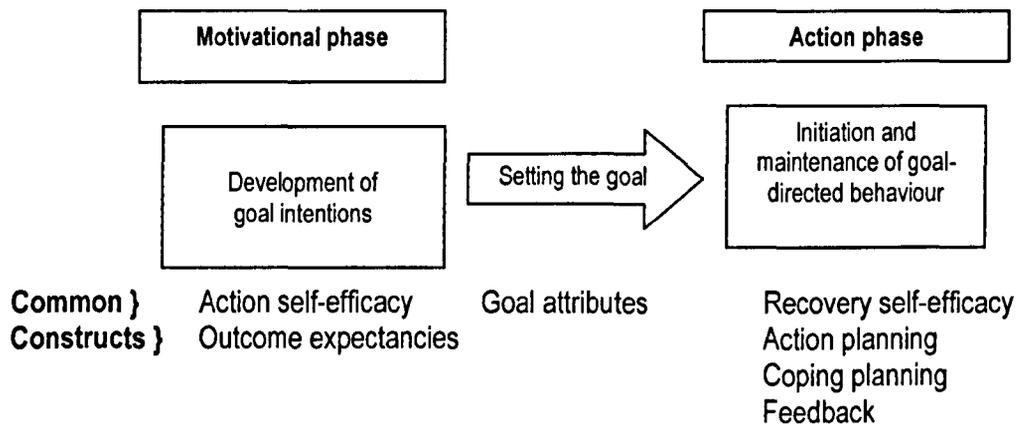
Sivaraman-Nair (2003) undertook a narrative review based on a range of articles ( $N=39$ ) concerning the nature of life goals, assessment of life goals, factors influencing life goals and significance of life goals to rehabilitation. Life goals are described as forming a complex hierarchy of objectives relating to an overriding reference value or idealised self-image. In relation to rehabilitation, the review illustrated that disabilities interfere with goal striving and motivation will be enhanced if treatment goals and routines are seen to relate to important life goals. Sivaraman-Nair concluded that further research was needed to evaluate the effects of focussing on life goals for rehabilitation outcomes.

Before embarking on a review of goal-setting effectiveness, Levack and colleagues undertook a thematic analysis of 123 articles to gain understanding of the intended purposes of goal setting (2006c). From this analysis, Levack and colleagues propose a typology of purposes and mechanisms of goal setting. Four intended purposes of goal planning were identified – (i) to improve outcomes; (ii) to enhance patient autonomy; (iii) to evaluate outcomes and (iv) to meet contractual, legislative or professional requirements. The framework outlines these purposes along with their underlying mechanisms and Levack et al. advocate its use to facilitate future research and practice.

By providing 'to enhance patient autonomy' as a purpose of goal planning, Levack et al.'s typology directly addresses the issue of patient involvement. In this model, promoting patient autonomy in rehabilitation is ethically desirable regardless of potential benefits for shaping interventions or influencing outcomes. There is little exploration of how, for example, enhanced patient autonomy could be a mechanism for improving outcomes or part of the process of evaluating outcomes.

Scobbie et al.'s review (2009) also aimed to provide a clearer theoretical understanding of rehabilitation goal setting. From 24 systematically selected articles, Scobbie et al. proposed that three of five identified behaviour change theories were the most informative for the development of a goal-setting practice framework. Based on the overlapping constructs of Social Cognitive Theory (SCT, Bandura, 1997), Goal Setting Theory (GST, Locke & Latham, 2002) and the Health Action Process Approach (HAP, Schwarzer, 1992), this framework incorporates goal-setting as the link between a motivational phase and an action phase (see Figure 1 below).

Figure 1 *Theoretical constructs applied to the motivational and action phases of goal behaviour (Scobbie et., 2009, p.329)*



Perhaps not surprisingly, this framework is very similar to one depicted in a recent study authored by researchers involved in developing the HAP model (Wiedemann, Schuz & Sniehotta et al., 2009). Whilst the labelling of components differ, both models describe the intention-planning-behaviour relation. Unlike Weidemann et al.'s model, Scobbie et al. place action and coping planning in the action phase rather than at the point of goal setting (or planning). Goal intentions could also be seen as a consequence rather than a precursor of goal setting.

Scobbie et al. (2009) address patient involvement in as much as they consider how key constructs such as outcome expectancies, self-efficacy and action planning can be helpful in supporting collaborative goal setting. Patient-involving strategies can be elaborated on and understood within the constructs and phases of the proposed model. Provision of information and feedback, for example, could inform outcome expectancies at the motivational phase and support collaborative evaluation at the action phase.

Aspects of Sivaraman-Nair's (2003) findings on the role of life goals could be incorporated into both Levack et al.'s typology (2006c) and Scobbie's et al.'s framework (2009). In relation to Levack et al.'s typology, for example, developing treatment goals based on values which are important to patients could improve outcomes by enhancing patient motivation and/or treatment specificity. However, it is less clear how the models proposed by Levack et al. and Scobbie et al. might relate to each other. Motivation, for example, is viewed from different perspectives in each of the models; in Levack et al.'s typology, motivation is seen as being influenced by the goal setting process whereas in Scobbie et al.'s framework, motivation is depicted as the starting point and would, therefore be seen as an influential factor on goal setting.

The theoretically-orientated reviews offer useful conceptualisations for practice and research by identifying and delineating important goal-setting constructs and processes for rehabilitation. Sivaraman-Nair's review (2003) highlights the impact of acquired disability on goal-directed behaviours and the importance of goal relevancy for rehabilitation. Scobbie's et al.'s overarching framework (2009) could inform a systematic approach to individualised goal setting and clarity on the purposes of goal setting, as advocated by Levack et al. (2006c), could usefully inform choice of outcome measures.

The authors of these reviews acknowledge the limitations or provisional nature of their proposed models. Scobbie et al. (2009) recognise that the models they draw upon focus on goal setting at the individual level and that, in the context of rehabilitation, social and environmental factors need to be included. Both models are open to alternative interpretations of their constructs. For example, Levack et al. (2006c) point out that 'improving teamwork' could be seen as an intended purpose as well as a mechanism of goal setting (Table 1 footnote, p.744).

Despite difficulties establishing a theoretical framework, goal setting is seen as a cornerstone of rehabilitation practice (Wade, 1999). Two recent reviews have evaluated the clinical use and impact of goal setting approaches, one examining the use of goal setting to evaluate outcomes (Hurn et al., 2006) and one examining the effectiveness of rehabilitation goal setting (Levack et al., 2006c).

Hurn et al. (2006) undertook a systematic review of 15 studies using goal setting as a rehabilitation outcome measure. As the most extensively evaluated approach, Goal Attainment Scaling (GAS) was judged as having strong evidential support for its reliability and validity and its generalisability. There was some support for the validity of other goal setting approaches but evidence for their reliability and sensitivity was limited. Hurn et al. note that lack of standardisation for all reviewed approaches presents a major challenge for making comparisons and determining efficacy.

The effectiveness of goal setting in rehabilitation was examined by Levack and colleagues (2006b) in a systematic review of 19 randomised controlled trials. Mixed results were found for effects of goal setting on rehabilitation outcomes, with equal numbers of studies demonstrating positive effects and no effects. Evidence that goal setting influenced treatment adherence was limited by poor methodology. A series of more robust studies showed that prescribed, specific and challenging goals improved task performance. However, as these studies involved experimental tasks (e.g. arithmetic calculations) over a brief time period (approximately 1 hour) they lacked generalisability for rehabilitation practice. Levack et al. acknowledge the methodological challenges faced by rehabilitation researchers and advocate ways to improve study design and reporting of procedures and findings.

Whilst Hurn et al.'s review (2006) did not directly examine how patient involvement in goal setting impacts on the use of goal-based outcomes, nine of the fifteen studies reviewed involved some level

of patient involvement and, of these, only one found patient-set goals to be an invalid measure of outcome. Likewise, Levack et al.'s review (2006b) showed seven of twelve studies involving collaborative goal setting had greater gains in outcomes or treatment adherence. However as Levack and colleagues point out, these results are compromised by methodological weakness.

The reviews highlight challenges for theory and research in rehabilitation goal setting practice. There was some representation of literature concerning neurological rehabilitation across all the reviews although in the main, patient involvement in goal setting was not addressed specifically or in detail. Questions therefore remain as to how involvement in goal setting can be facilitated for patients with acquired brain injuries and what is the evidence for approaches designed to improve patient involvement in goal setting in neurological rehabilitation settings.

## **2 Method**

The UK Medical Research Council (MRC) advocates a phased approach for the design and evaluation of complex interventions. Exploratory studies and literature reviews are first undertaken to develop a theoretical understanding and to establish the acceptability and feasibility of interventions (Campbell, Fitzpatrick, Haines et al, 2000). As a multi-factorial treatment package, rehabilitation has been described as the 'archetypical complex intervention' (Bovend'Eerd, Botell & Wade, 2009).

In accordance with the MRC framework and calls for 'evidentiary pluralism' in rehabilitation research (Tucker & Reed, 2008), the present review considers the contributions of exploratory and qualitative research as well as controlled trials in relation to collaborative goal setting for stroke and brain injury rehabilitation.



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Articles were obtained and reviewed for all titles or abstracts which appeared to meet the inclusion criteria. Theoretical/discussion papers and articles reporting clinical audits were excluded. Manual searches of relevant articles and reviews were also undertaken to identify studies for inclusion.

## **2.2 Data Collection and analysis**

To fulfil the aims of this review, data extraction included (i) description of the goal setting procedure, (ii) stated theoretical/conceptual basis, (iii) study aims and design, (iv) participants and clinical setting, (v) evaluation methods and measures, (vi) main findings, and (vii) conclusions and implications. As the review involved studies with diverse methodologies, a hierarchical rating system was not used to assess quality of research evidence.

The first stage of analysis comprised a narrative review of the nature and value of approaches designed to facilitate collaborative goal setting in neurological rehabilitation. The second stage aimed to identify barriers and facilitators for collaborative goal setting, drawing upon qualitative evidence in the included studies and a wider range of studies examining participant views of goal setting for neurological rehabilitation.

## **3 Results and Discussion**

The electronic searches identified 161 articles and 29 were retrieved for further examination. Seven were excluded as they did not evaluate a specified goal setting approach or patient selected goals (e.g. Fischer, Gauggel & Trexler, 2004; Manly, Hawkins & Evans et al., 2002) and two were excluded as they did not describe the goal setting procedure in sufficient detail for evaluation (e.g. Monaghan, Channell & McDowell et al., 2005; Young, Manmathan & Ward, 2008). This yielded five review papers and 14 articles describing 12 evaluation studies. Hand searches of relevant reviews

and studies identified a further 7 studies for inclusion. A total of 21 articles involving 19 evaluative studies were selected for the review.

The selected studies showed considerable heterogeneity in relation to clinical context, goal setting procedures and in the methodologies used to evaluate them. Fourteen studies examined approaches emphasising general principles of patient-centred practice and five studies examined approaches based on theoretical models of self-regulation and brain injury recovery. Tables 3a and 3b summarise the study characteristics with presentation of the studies in accordance with this categorisation.

### **3.1 Sampling**

Sample sizes for quantitative analyses ranged from 8 to 201 (mean=47; median=29) and from 14 to 82 for qualitative analyses. Most studies excluded participants who were judged to have cognitive and/or communication difficulties that would impede informed consent or participation in study procedures. It is difficult to evaluate how representative samples were as the studies varied widely in reporting of sampling details. Although 10 studies provided data for drop-outs, only three had available information to ascertain rates of eligibility for inclusion or consent to participate.

In the 10 studies providing relevant data, attrition rates ranged from 0% to 65%. None of the quantitative studies reported intent-to-treat analyses for missing data. Disparity of attrition rates can be partly explained by variation in study design. For example, 0% attrition in a cohort study within a single clinical setting was achieved by having only routine measures, usual treatment and a consent to 'opt-out' procedure (Turner-Stokes et al, 2009) whereas a study involving comparison groups across two sites reported 42% attrition for the 206 patients who originally consented to take part

Table 3a *Studies of approaches based on general patient-centred principles*

Author & study aim	Design	Approach to goal setting	Clinical Context & Participants N (Attrition %)	Evaluation methods and measures	Main Findings
<b>Bodium, 1999</b> Utility of COPM	Single group pre-post study	Therapist interview, structured procedures for interview and patient ratings of goals	UK Inpatient neuro rehabilitation N=17 (11)	<i>Goal related:</i> N & descriptive; Patient ratings	Significant gains in goal based ratings. Smaller gains in goal satisfaction for participants with cognitive difficulties.
<b>Cup et al. 2003</b> COPM as outcome measure	Single group, repeat measures	Therapist interview, structured procedures for interview and patient ratings of goals	Dutch stroke services. N=26 (NR)	<i>Goal related:</i> N & descriptive; Patient ratings <i>Standardised:</i> Physical/mobility; Functional ability/activities; Quality of Life	Moderate and good test-retest reliability for COPM-set goals. <i>Validity</i> - Poor correlation of goal-based ratings with standardised outcomes. Discriminant validity indicated.
<b>Jenkinson, Ownsworth &amp; Shum, 2007</b> Utility of COPM	Pre-post study, random assignment to wait list control	Therapist interview, structured procedures for interview and patient ratings of goals	Australian outpatient neurorehabilitation N= 34 (11.4)	<i>Goal related:</i> N & descriptive; Patient ratings <i>Standardised (patient &amp; family):</i> Physical/mobility; Functional abilities/activities; Self-Awareness; Mood/wellbeing	Significant gains in goal based ratings for intervention group. Lower satisfaction ratings related to higher anxiety. Good test-retest reliability for goal performance ratings. Poor reliability for goal satisfaction ratings.
<b>Phipps &amp; Richardson 2007</b> Utility of COPM	Retrospective single group pre-post study	Therapist interview, structured procedures for interview and patient ratings of goals	US outpatient brain injury N=155 (NR)	<i>Goal related:</i> N & descriptive; Patient ratings	Significant gains in goal-based ratings.
<b>Trombly et al. 2003</b> Utility of COPM	Single group pre-post study; non-treatment control period	Therapist interview, structured procedures for interview and patient ratings of goals, hierarchical goal definition	US outpatient brain injury N=31 (24.4)	<i>Goal related:</i> N & descriptive; Patient ratings <i>Standardised (patient &amp; family):</i> Functional abilities/activities	Significant gains in goal-based ratings (ES=.94) in comparison with no-treatment period. No differences for standardised measure.
<b>Wressle et al. 2002</b> Utility of COPM	Non-randomised controlled trial: COPM and UT groups	Therapist interview, structured procedures for interview and patient ratings of goals	Swedish outpatient brain injury N=118 (42.7)	<i>Goal related:</i> N & descriptive; Patient ratings Structured interviews <i>Standardised:</i> Functional abilities/activities	Significant gains in goal-based ratings for intervention group. No differences in standardized measures across the groups. Intervention group gave more positive ratings of goal setting process.
<b>Bouwens et al. 2009</b> Utility of GAS	Single group pre-post study	Researcher interview, hierarchical goal definition	Dutch outpatient brain injury services N=39 (18.8)	<i>Goal related:</i> N & descriptive; Patient ratings <i>Standardised:</i> Functional abilities/activities	Significant gains in goal-based ratings. Subjectivity of GAS ratings noted.

NR = Not Reported; NA= Not Applicable; COPM = Canadian Performance Outcome Measure; GAS = Goal Attainment Scaling; UT = Usual treatment

Table 3a (continued): *Studies of approaches based on general patient centred principles*

Author & study aim	Design	Approach to goal setting	Clinical Context & Participants N (Attrition %)	Evaluation methods and measures	Main Findings
Lannin, 2003 Utility of GAS	Single group pre-post study	Therapist interview, hierarchical goal definition	Australia brain injury community OT service N=12 (NR)	<i>Goal related:</i> N & descriptive; Therapist ratings	Gains in goal-based ratings for 86% of sample.
Turner-Stokes, Williams & Johnson, 2009 GAS as outcome measure	Prospective Cohort, single group pre-post comparisons.	Therapist interview, hierarchical goal definition	UK In-patient neurorehabilitation unit N=164 (0)	<i>Goal related:</i> N & descriptive <i>Standardised</i> Physical/mobility; Functional abilities/activities	Goal-based ratings showed 74% goal attainment. Moderate correlations between goal-based ratings and standard measures. Divergent validity indicated.
Gagne & Hoppes, 2003 Goal setting Workbook	Non-randomised controlled pilot study. Workbook and UT groups	Therapist interview, workbook, guidance for goal definition	US Inpatient rehabilitation N =31 (NR)	<i>Standardised</i> Physical/mobility	Gains in standard measure for 'Notebook' group but only upper-body dressing reached significance.
Holliday et al. 2007a Goal setting Workbook Holliday et al 2007b Patient perceptions of goal setting	Non-randomised controlled trial. Workbook and UT groups  Thematic analysis, focus groups	Workbook and goal setting information prior to therapist interview	UK Inpatient neurorehabilitation  N=201 (NR)  N=28 (86)	<i>Goal related:</i> N & descriptive <i>Standardised:</i> Physical/mobility; Functional abilities/activities; Mood/wellbeing  Audiotaped focus groups	Significantly higher ratings for goal satisfaction & relevancy for intervention group. No group differences in goal attainment and functional outcomes.  Themes identified which influence patient experience of goal setting.
Conneeley, 2004 Perspectives of MDT procedure	Qualitative phenomenological; purposive sampling)	Goal setting information, MDT meetings	UK Inpatient neurorehabilitation N=57 (NA)	Semi-structured interviews Field diary	Positive perceptions of patient involvement, and benefits for motivation, autonomy and focus of treatment. Shortfalls identified by professionals.
McGrath & Adams, 1999 MDT procedure	Cohort studies: a) Qualitative – content analysis b) Single group pre-post analysis	Questionnaire, therapist interview, MDT meetings, hierarchical goal definition	UK Inpatient neuro-rehabilitation  a) N=82 (NR) b) N=23 (65.2)	<i>Goal related:</i> Interviews (a) <i>Standardised:</i> Mood/wellbeing (b)	a) Identified emotional responses to brain injury, disability and goal setting process. b) Significant improvement in mood over admission period.
Wilson, 2002 Patient-centred MDT procedure	Single case study	Therapist interview, MDT meetings, hierarchical goal definition	UK Inpatient Neuro-rehabilitation N=1	<i>Goal related:</i> N & descriptive; Clinical observation <i>Standardised:</i> Cognitive functioning	All goals achieved with detailed description of procedure and nature of goals.

NR = Not Reported; NA= Not Applicable; COPM = Canadian Performance Outcome Measure; GAS = Goal Attainment Scaling; UT = Usual treatment

**Table 3b** *Summary of studies investigating goal setting approaches based on self-regulation and brain injury recovery theories*

Study	Design	Approach to goal setting	Participants & Clinical Context N (Attrition%)	Evaluation methods and measures	Main Findings
<b>Levine et al 2000</b> GMT informed therapy	Single case study	Patient selected goal, clinical observation, steps for goal attainment	UK outpatient neurorehabilitation.  N=1	<i>Goal related:</i> Descriptive; Clinical observation Patient diary <i>Standardised:</i> Cognitive functioning	Significantly reduced errors for meal preparation. Diary report identified GMT strategies for improved performance.
<b>Mastos et al 2007</b> GDT informed therapy	Single case study (CS)	CS 1 – clinical observation, hierarchical goal definition  CS 2 – patient selected goal, clinical observation, hierarchical goal definition	Australia outpatient rehabilitation  N=2 (NA)	<i>Goal related:</i> Descriptive; Clinical observation Patient/therapist rating	CS 1 – Gain in goal-based rating to expected level of motor skill. CS 2 - Gain in goal-based rating reached above expected level of motor skill. Autonomy in goal setting process described.
<b>McPherson et al 2009</b> Novel approaches to goal setting <b>Ylvisaker et al, 2008</b> Study of IOGT group	Randomised controlled pilot study: GMT, IOGT and UT groups  Qualitative analysis - content analysis	<i>GMT</i> – Therapist interview, hierarchical goal definition, steps for goal attainment, <i>IOGT</i> – Therapist interview, guided imagery, hierarchical goal definition <i>UT</i> - Therapist interview, hierarchical goal definition	New Zealand inpatient & outpatient  N=25 (26.5)	<i>Goal related:</i> Patient/therapist rating; Descriptive Clinical observation; Interviews; Focus groups.	Gains in goal-based ratings achieved for all groups. Qualitative analysis supported acceptability of novel approaches; benefits and barriers identified.
<b>Thomas, 2004</b> PUP	Non-randomised controlled study. PUP and matched control groups. Quantitative and qualitative thematic analysis	Experiential learning, peer group sessions	Australia outpatient neurorehabilitation  N=22 (NR)	<i>Goal related:</i> Interviews <i>Standardised:</i> Quality of Life (QoL)	Significant gains in standard measure for Intervention group. Greater gains for Intervention participants who attended goal setting phase.  Qualitative analysis identified themes relating to tasks of recovery. Benefits of the goal-setting group identified.
<b>Walker et al 2006</b> Pilot study of PUP for goal planning	Single group pre-post pilot study	Experiential learning, peer group sessions	Australian outpatient neurorehabilitation  N=11 (NR)	<i>Goal related:</i> N & descriptive; Patient ratings <i>Standardised:</i> Functional abilities/activities; Mood/wellbeing	80.8% goals attained. Gains in mood and wellbeing measures were not significant. Subjective ratings of goal setting phase lower than for other phases of the programme.

NR = Not Reported; NA = Not Applicable; CS- Case Study; GDT = Goal Directed Training; GMT= Goal Management Training; IOGT = Identity Orientated Goal Trainig; UT = Usual Treatment

(Wressle et al, 2002). The most common reasons cited for participant drop-out and missing data include early or self discharge, poor attendance and decline in function or medical status.

### **3.2 Overview of approaches to facilitate patient involvement in goal setting**

#### **3.2.1 General patient centred approaches**

Although varying degrees of theoretical grounding or rationale were described in the fourteen studies within this category, all approaches were explicitly based on patient-centred principles or policy guidelines.

##### *The COPM and GAS approaches*

All nine studies examining the COPM and GAS involved only quantitative analyses. Of these, one was a non-randomised, controlled study of the COPM (Wressle et al., 2002) and the remaining eight were single group pre-post analyses.

The COPM and GAS are described as providing a structured and person-centred approach to setting and assessing goals (Wressle et al., 2002; Hurn et al., 2006). Patient involvement is more explicit in the COPM procedures as they include standard semi-structured interviews to elicit patient-identified goals and patient ratings of goal performance (COPM-P) and satisfaction (COPM-S) are an integral part of evaluation. GAS has less clearly defined procedures for establishing patient collaboration and there appears to be considerable reliance on therapist interpretations to specify and evaluate goal outcomes as being at, above or below an expected level of attainment (e.g. Lannin, 2003).

##### *Approaches involving workbooks*

The use of workbooks was described in two studies, (Gagne & Hoppes, 2003; Holliday et al., 2007a). Both studies included 'no workbook' control groups and although not randomised, allocation to

groups was based on systematic procedures to minimise bias. Gagne and Hoppes' study was designed around a single standardised measure of physical self-care and mobility. Holliday et al.'s study implemented a range of measures including standardised measures, goal attainment and patient perceptions of the goal-setting process. To gain a more in-depth picture of the patient perspective, Holliday and colleagues undertook a complementary qualitative study involving focus groups of participants from both conditions (Holliday, Ballinger & Playford, 2007b).

#### *Approaches in multi-disciplinary team contexts*

Three studies involved multi-disciplinary team (MDT) meetings within inpatient settings as a key part of the goal setting process. Conneeley, (2004) describes a qualitative study of participant perspectives of a revised goal setting procedure. Main features of the approach such as provision of information and involvement of patients and relatives in planning meetings are outlined but specific strategies for eliciting patient selected goals are not described.

A patient-centred, MDT 'Goal Planning' approach adopted by two neurorehabilitation units was evaluated in two studies (McGrath & Adams, 1999; Wilson et al, 2002). McGrath & Adams' study used mixed methods to examine the emotional impact of the procedure whereas Wilson et al.'s case study (2002) provides a detailed account of the development of goals and how they were achieved.

The 'Goal Planning' approach is based on models of goal directed behaviour and aims to promote patient-centred and individualised rehabilitation (Wade, 1999; Wilson et al., 2002). The use of one-to-one meetings with patients and the Life Goals Questionnaire are advocated to establish patient-identified goals (Wade, 1999). MDT meetings specify action plans and review progress. An important feature of the procedure is the development of a long-term objective as a reference point for short-

term goals formulated in accordance with the SMART acronym (S-specific, M-measurable, A-achievable, R-relevant or realistic, T-time-limited).

### **3.2.2 Approaches based on models of self-regulation and brain injury recovery**

The five studies in this category evaluated four approaches designed to facilitate patient involvement in goal setting by addressing aspects of brain injury impairments, self-regulatory behaviour and the recovery process.

#### *Approaches involving self-regulation and goal management skills*

Mastos et al. (2007) describe a Goal Directed Training (GDT) procedure for increasing autonomy and active problem solving based on motor learning theories. Two case studies are described involving individuals with diverse impairments. Although the first individual was unable to actively choose or communicate any goals, a clear rationale is provided for the selection of a meaningful goal. Descriptive information concerning application of GDT is presented and GAS was used to evaluate goal attainment.

Goal Management Training (GMT) was examined in two studies (Levine et al, 2000; McPherson, et al., 2009). Levine et al. present a case study involving GMT for a patient-selected activity and evaluation was based on a patient diary, clinical observations and statistical analysis across four assessment points.

GMT was compared with IOGT and usual treatment in a randomised controlled pilot study reported by McPherson and colleagues (2009). The exploratory study presents a predominantly qualitative analysis of clinical observations, interviews and focus groups. GAS measures were used to evaluate goal attainment.

GMT as described by Levine et al. (2000) is based on theories of cognitive impairment and goal neglect. This approach targets executive functioning deficits which effect ability to concentrate, self-monitor and problem-solve. To counteract these difficulties, GMT involves a stepped procedure and cues to activate goal directed behaviours.

#### *Approaches based on models of brain injury and recovery*

The IOGT procedure, as described by McPherson et al. (2009) aims to facilitate patient-selected goals by developing an identity map based on the characteristics of an admired figure. IOGT is grounded in theoretical concepts of goal directed behaviour, identity development and brain injury recovery which are detailed by Yvislaker et al. (2008).

Thomas (2004) and Walker et al. (2009) both evaluate the use of an outdoor adventure course (PUP) to provide a real world context for the development of personal goals and adjustment to brain injury. Thomas employed mixed methods in a non-randomised controlled study involving quantitative comparisons with a matched control group and a thematic analysis of interviews with PUP participants. Walker et al. (2009) undertook a pilot study with a single group pre-post design and presented quantitative data for goal attainment, standard outcome measures and patient ratings of the programme.

Whilst both studies follow the same PUP procedure, the authors emphasise different theoretical aspects of the process. Similar to IOGT, Thomas's rationale for the 'Potential Unlimited Programme' (PUP) involves a process of identity building following brain injury. In the model proposed by Thomas, planning and undertaking the adventure course leads to gains in personal knowledge which enable the individual to restructure old and new aspects of their identities and pursue relevant personal

goals. Walker et al.'s rationale for PUP is similar to GMT as it focuses on counteracting the brain injury and executive function impairments that impede goal setting and generalisation of learning.

### **3.3 Evaluation of the approaches**

Patient or therapist perceptions of patient involvement or satisfaction in the goal setting process were typically ascertained by qualitative methods such as interviews, self-report diary or focus groups (Holliday, 2007b; Conneeley, 2004; Levine et al., 2000; McPherson et al., 2009; Thomas, 2004).

Supportive qualitative evidence for the approaches found that patients valued the decisional autonomy, self-control or sense of ownership offered by the use of a personalised workbook (Holliday et al., 2007b), the collaborative MDT approach (Conneeley, 2003), GMT and IOGT (McPherson et al., 2009). Active involvement in goal setting was perceived by patients as having beneficial effects on motivation, confidence and mood (Conneeley, 2003; Holliday et al., 2007b; McPherson et al., 2009; Thomas, 2004) and in relation to recovery and adjustment (Holliday et al., 2007b; Thomas, 2004).

Patient involvement was also seen as being helpful for clarifying the direction of rehabilitation and developing individualised interventions (Conneeley, 2003; Holliday et al., 2007b). Specific aspects of approaches were identified as helpful or challenging in clinician and patient evaluations. These will be examined in further detail in Section 4.

With the exception of Wressle et al.'s study (2002), patient or therapist evaluations of the COPM and GAS procedures were not well represented. Non-systematically obtained qualitative data included patients valuing the COPM for providing time and space to think about and monitor goals (Bodium,

1999). Examples of patient difficulties with the abstract or numerical nature of COPM and GAS ratings were also described (Bodium, 1999; Bouwens et al., 2009).

Clinical observations provided evidence of generalised learning to other tasks for GMT (McPherson et al., 2009) and, for the more able participant of the GDT approach, progression to an 'autonomous' stage of active problem solving in the rehabilitation process (Mastos et al., 2007).

In comparisons with 'usual treatment' groups, quantitative analyses of patient perceptions provided mixed findings for the COPM (Wressle et al., 2002) and supportive findings for the use of a workbook (Holliday et al., 2007a). Although COPM participants perceived greater involvement in goal setting and could recall more goals, no significant differences were found for other aspects of the process such as satisfaction with treatment. Participants in the 'workbook' condition of Holliday et al.'s study perceived greater goal relevancy, involvement and satisfaction with the goal setting process.

Mixed results were found across the studies in relation to goal attainment and rehabilitation outcomes. Aside from goal attainment measures, the most commonly used quantitative methods of evaluation included standard rehabilitation outcome measures for functional activities, wellbeing or quality of life. These were employed to evaluate the overall impact of the rehabilitation intervention and to evaluate the utility of the COPM or GAS as outcome measures.

All the studies using the COPM or GAS to inform rehabilitation interventions reported significant gains in goal attainment as measured by the COPM ratings (Bodium, 1999; Jenkinson et al., 2007; Phipps & Richardson, 2007; Trombly et al., 2003; Wressle et al., 1999) or GAS ratings (Bouwens et al., 2009; Lannin, 2003; Trombly et al., 2009; Turner-Stokes et al., 2009). These results were all based

on single group pre-post analyses, including those from the only COPM or GAS study to include a 'usual treatment' control group (Wressle et al., 2002).

Bouwens et al. (2009) found that 95% of participants were able to formulate two or three goals within 45 minutes. Factors such as poor insight, emotional and communication difficulties and problems with specifying goals were cited as barriers to setting goals within a target time frame of 30 minutes.

Where performed, correlations between the COPM ratings and standardised measures were low or non-significant (Cup et al., 2004; Jenkinson et al., 2008; Trombly et al., 2003; Wressle et al., 2002) whereas for GAS, a moderate correlation was found (Turner-Stokes et al., 2009). Evidence of divergent validity showed less than 26% of COPM-identified goals and 62% of GAS-identified goals were addressed or 'feasibly reflected' across standard measures (Cup et al., 2004; Turner-Stokes et al., 2009).

Only the COPM studies included investigations of reliability using 'no treatment' conditions. These showed moderate to good test-retest reliability for identifying and rating goals (Cup et al., 2004; Jenkinson et al., 2007), although potential for low stability in the COPM-S was found in Jenkinson et al.'s 'wait list' control group.

In relation to using a workbook for goal setting, Gagne & Hoppes (2003) reported a trend towards greater gains for the 'workbook' condition but only functioning in one area of self care reached statistical significance. Participants in the 'workbook' condition of Holliday et al.'s study (2007a) set fewer goals and there were no group differences regarding goal attainment or standardised measures.

For the MDT 'Goal Planning' approach, evidence for goal achievement is descriptive and illustrated by graphed data in Wilson et al.'s case study. Reported achievement of goals stands in contrast to the lack of change shown in neuropsychological test scores. Evidence to support the hypothesis that the initial meeting of the 'Goal Planning' approach could be therapeutic in itself was presented in McGrath & Adams study. Here nearly 80% of 23 patients assessed on admission as having substantial distress levels showed a statistically significant decrease in anxiety and depression following the initial goal planning.

For the evaluation of GDT, gains in motor performance, as measured by GAS, were reported for both individuals in Mastos et al.'s case study of GDT (2007). Information on outcomes and participants' engagement in the GDT process are largely descriptive.

In Levine et al.'s case study of GMT (2000), naturalistic observations of the patient-selected task showed significant improvements from baseline to post-training and these were maintained at two follow-up assessments. In McPherson et al.'s (2009) comparison of GMT with IOGT and usual treatment, GAS measures showed similar gains across the groups but statistical analysis of these results was not provided. In acknowledgement of the general trend towards goal attainment for all groups, McPherson et al. argue that the GAS procedure appeared to act as an intervention in its own right and could be a potentially 'simpler method of engagement (p.307).

Both Thomas (2004) and Walker et al.'s (2009) studies provide some preliminary evidence for the use of PUP to set and achieve personal goals. Walker et al. found no significant gains in the standardised measures of wellbeing although scores were in the direction of improved outcomes and 80% of goals set were achieved.

Thomas' study (2004) did not provide data for goal attainment but a comparative analysis of a Quality of Life measure showed significant improvements for the PUP group participants. The impact of the goal setting follow-up group was demonstrated by large effect sizes for regular attenders and mild-to-moderate change for non-attenders.

Thomas (2004) and Walker et al. (2009) acknowledge the limitations of small sample size and self-selected participants. Walker et al. also advocate consideration of alternative 'discovery' courses in recognition that an outdoor adventure course would not suit or appeal to everyone.

### **3.4 Summary and methodological considerations**

The review identified two broad categories of approaches designed to facilitate patient involvement in goal setting for brain injury and stroke rehabilitation. Within each category, the findings as well as the methodologies were mixed. A consistent finding of weak relationships between goal-based outcomes and standard measures demonstrate the complexities of outcome evaluation in rehabilitation and the advantages of incorporating a range of outcome indicators where possible. The results of eleven studies providing quantitative evaluations were considerably limited by employing only one measure.

Whilst there is evidence for the added value or divergent validity of goal-based outcomes, the influence of greater patient collaboration or the nature of collaboration in goal setting is harder to discern. Many of the studies relied on single group pre-post comparisons and without adequate controls, it is unclear whether any gains can be attributed to more patient-involving procedures. Only a minority of the quantitative analyses examined patient satisfaction or ratings of the goal-setting process and none considered potential benefits for motivation or adherence to the rehabilitation programme.

A potential source of methodological difficulty and confusion, as pointed out by Levack, Taylor & Siegert et al. (2006), is that goal setting can be an independent variable and a dependent variable. This was particularly evident in the COPM and GAS studies where the approach under investigation also formed a primary outcome measure.

With its use of a 'usual treatment' control group, between group comparisons and range of measures, Holliday et al's quantitative study (2007a) stands out as providing the strongest evidence in relation to the value of increased patient involvement in goal setting. Although the use of a workbook to promote patient involvement did not influence goal attainment or functional outcomes, there were improved outcomes in relation to patient satisfaction and perceptions of autonomy.

In terms of the typology proposed by Levack and colleagues (2006c), Holliday et al.'s results (2007a) would provide support for use of collaborative goal setting to enhance autonomy and several studies provide support for the use of procedures such as GAS and COPM to evaluate outcomes. The evidence for using collaborative goal setting to improve outcomes on standard measures remains unclear as is how it may contribute to any underlying mechanisms for improving outcomes. For example, whilst increased specificity or individualisation of rehabilitation was a stated aim of collaborative goal setting for many of the approaches, this did not always result in improved outcomes on the standard measures.

#### **4 Barriers and facilitators to patient involvement in goal setting**

To ascertain views about barriers and facilitators for patient involvement in goal setting, the following section examines in greater detail, qualitative evidence from the reviewed studies (Conneeley, 2003; Holliday et al., 2007b; McGrath et al., 1999; McPherson et al., 2009; Thomas, 2004) and considers

this with a wider range of qualitative studies involving patient views about goal setting for neurological rehabilitation.

### *The therapeutic relationship*

The patient-therapist relationship is the starting point for collaborative goal setting and in the reviewed studies patients identified mutual understanding and hope as key ingredients for a collaborative relationship (Conneeley, 2003; Holliday et al., 2007b). For some patients, mutual understanding would include an appreciation of the need to adopt an active role in rehabilitation (Cott, 2004; Dixon, Thornton & Young, 2007; Maclean, Pound, Wolfe & Rudd, 1999). Clinicians have reported that developing an intimate understanding of patients is a pre-requisite for individualised goal setting (Conneeley, 2004).

Several studies demonstrated how lack of mutual understanding can occur when there is a mismatch between what professionals and clients prioritise for rehabilitation (Benz, 2003; Cott, 2004; Lawler, Dowswell, Forster & Young, 1999; Wressle et al., 1999). Rehabilitation professionals and programmes have been perceived as focussing on aspects of physical functioning and self-care activities whereas patients are often concerned with less concrete or psychosocial aspects of recovery (Cott, 2004; Benz, 2003; McGrath & Adams, 1999).

There can also be a mismatch in how progress is evaluated when, for example, 'onset of stroke' is a reference point for clinicians and 'life before stroke' is more pertinent for patients (Lawler et al., 1999). Patients can feel 'written off', their hopes dismissed when their ideas about recovery are not addressed (Cott, 2004). An explicitly patient-centred approach or procedure can help to redress the inherent power imbalance in the therapeutic relationship, providing patients with the freedom to have

their say, make choices and gain a sense of a decisional autonomy (Conneeley, 2004; McPherson et al., 2009).

Clinicians also identify hope as an important aspect of engagement in the goal setting process. For clinicians, hope plays a central role in developing the working relationship, promoting patient motivation and autonomy (Levack, et al., 2006a). For some patients hope can be easier or less painful to address than expectations (Lawler et al., 1999) and clinicians can also find patient expectations difficult to address, especially if they perceive them to be unrealistic (Conneeley, 2004; Lawler et al., 1999).

The development of achievable small goals towards a valued longer-term objective was reported as helping to foster hope and reduce patient anxiety about the future (Holliday et al., 2007b; Lannin, 2003; McGrath & Adams, 1999). Identity (re-)building strategies described in the IOGT and PUP approaches can be seen as offering hope by supporting clinicians and patients to access 'other aspects of being' (McPherson et al., 2009) and 'make the most of strengths and abilities' (Thomas, 2004). The notion that patients' hopes and motivation can be facilitated if they perceive goals as being based on potential, personal strengths and former identities was endorsed in other qualitative studies (Cott, 2004; Bendz, 2003).

Collaborative goal setting requires and demonstrates therapist respect and acceptance of patient wishes and choices (Cott, 2004; McPherson et al., 2009). Patients and carers can experience collaborative goal setting as reassuring and an indication of professional care (Young, Manmathan & Ward, 2008).

### *Factors associated with brain injury and cognitive impairments*

Patients identified that active involvement depends on an understanding of the illness condition and the goal setting process (Holliday et al., 2007b). Uncertainty and the unpredictability of recovery following brain injury compromise the content and process of goal setting (Conneeley, 2004; Dixon et al., 2007; Holliday et al., 2007b). Patients report that providing information about brain injury and recovery can help them cope with brain injury associated distress (McGrath & Adams, 1999).

Holliday et al's (2007b) study raised questions about the nature or timing of information provision as for one of the 'usual care' participants, information about natural recovery led to a lack of engagement in goal setting and the belief that 'going on about goals all the time is pointless' (p.392).

Patients have described being too traumatised or ill to actively engage in goal setting in the early stage of rehabilitation (Cott, 2004; Young et al., 2008). As patient needs change, responsive and flexible procedures are needed to offer different levels of patient involvement and maintain goal relevancy (Bouwens et al., 2009; Conneeley, 2004; Cott, 2004; McGrath & Adams, 1999).

Levine et al.'s GMT model (2002) outlines the ways in which cognitive impairments can interfere with the tasks of goal setting. In McPherson et al.'s study, free recall of the GMT steps proved challenging for individuals with memory impairments although, as the authors point out, independent utilisation of cue cards could be viewed as a development of self-regulatory behaviour. Structured procedures, written documentation and prompts were valued by patients for helping them to focus on and remember goal-related tasks (Holliday et al., 2007b; Levine et al., 2000; McPherson et al., 2009). Clinicians valued IOGT as an effective procedure for enabling patients with severe impairments generate ideas for goal setting (McPherson et al., 2009).

Lack of insight or awareness as a barrier to motivation and goal setting is an acknowledged concern within neurological rehabilitation (e.g. Ownsworth & Clare, 2006). Difficulties concerning patient understanding of goal setting and their brain injury were a recurring theme in the reviewed studies (Bouwens et al., 2009; Conneeley, 2003; Holliday et al., 2007b; McPherson et al., 2009). Patient perspectives illustrate how an attitude of adaptation to changed abilities and roles rather than recovery of abilities can support successful goal setting (Dixon et al, 2007). Insight and acceptance can be facilitated by the kind of experiential learning involved in the PUP intervention by promoting patient self-efficacy and understanding of what they 'can and can't do' (Thomas, 2004, p.1279).

### *Social Support*

The role of family support was more prominent in the background literature with patients valuing the emotional and practical support family members provide (Cott, 2004; Dixon et al., 2007). Over protection of family members (or therapists) has been seen as having a disabling effect, preventing expression of the patient viewpoint in the goal setting process (Maclean, et al., 1999). In Hedborg et al.'s (2008) analysis of audio-taped planning meetings, expression of patient perspectives and goals depended on family or professional advocacy and alliances with the patient.

The value of peer support for sharing experiences, providing encouragement and feedback for goal setting was reported across several studies (Cott, 2004; Dixon et al., 2007; Holliday, 2007b; McGrath & Adams, 1999; Thomas, 2004). However, negative comparisons with peers can also be demoralising (Maclean et al., 1999).

### *Organisational factors and resources*

Patient perspectives indicate how hospital settings and professionals' expert roles can cultivate patient passivity resulting in underutilisation of patient capabilities (Cott, 2004; Wressle, et al., 2002).

Clinicians have perceived the formality of MDT meetings as inhibiting patient viewpoints (Young et al., 2008) whereas the familiarity of the home environment is seen as providing strength and security for patients (Wressle et al., 2002).

Patient unfamiliarity with goal setting and its terminology was also seen by clinicians as a potential barrier to patient involvement (Lawler et al., 1999). In Holliday et al.'s study (2007b), client attitudes towards goal setting were influenced, and not always in a positive way, by their experiences of work-related goal setting and appraisal systems.

Clinicians perceive funding systems and professional roles as barriers to collaborative goal setting when time for 'therapeutic talk' is not recognised or valued (McPherson et al., 2009). Restraints on staff time and accessibility have also been viewed by patients as undermining the ability of professionals to represent their interests (Holliday et al., 2007b; Young et al., 2008). Bouwens et al.'s feasibility analysis of GAS (2009) illustrates the need for additional time to enable participants with cognitive and communication difficulties to actively participate in goal setting.

For some clinicians employing a more patient-centred approach to goal setting was not only time intensive but also represented a 'paradigm shift' (McPherson et al., 2009). However, clinicians welcomed opportunities for development in patient-centred approaches and highlighted the need for training and guidance to address the challenges of collaborative goal setting with patients who have cognitive or insight deficits (Conneeley, 2003; McPherson et al., 2009).

## **5 Conclusions and future directions**

The present review identified a range of approaches aiming to facilitate collaborative goal setting in neurorehabilitation settings. Development of some approaches was largely driven by patient-centred philosophies whereas other approaches have drawn upon theoretical models of goal setting and brain injury recovery. There was supportive evidence for the feasibility of collaborative goal setting in neurological rehabilitation and for its value in relation to patient perceptions of autonomy, affect, goal relevancy and satisfaction. However these benefits were not reflected in standardised outcome measures and the evidence for goal attainment was mixed.

The relationship between goal setting procedures and rehabilitation outcomes is likely to be complex; further theory-building and research would help to clarify the processes underlying this pathway. Further research could also establish whether goal-based outcomes offer added value (or divergent validity) in relation to standard measures as the studies examining the psychometric properties of COPM and GAS indicated.

To some extent methodological weakness and inconclusive quantitative findings, reflect the emergent status of research in this area and highlight the challenge of undertaking controlled trials in neurological rehabilitation settings (e.g. Kollen, Kwakkel & Lindeman, 2006). Methodological rigour could be improved, as Levack et al. (2006c) advocate, with better blinding procedures and control of study conditions. Strengthening and extending the single case or 'within participant' study design could also generate understanding of brain injury recovery and of rehabilitation interventions as a process rather than a single event in people's lives (Tucker & Reed, 2008).

Collaborative goal setting can be viewed within the wider context of shared decision making in healthcare and as such it would be beneficial for future research and interventions to incorporate

criteria and frameworks developed by the International Patient Decision Aids Standards Collaboration (IPDAS; Elwyn, O'Connor & Stacey et al. 2006) and the Cochrane Collaboration (Duncan, Best & Hagan, 2010).

Patient and therapist perspectives represented in qualitative studies have identified important considerations for collaborative goal setting in neurological rehabilitation. These include patient informational needs, representation for patients who are unwilling or unable to actively participate, use of structured procedures to compensate for brain injury deficits and therapist skill development. Addressing these concerns could inform research design and the development of greater personalisation and choice for this heterogeneous patient population.

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## **Section 2: Research Report**

### **Facilitating Diary Keeping and Participation in Valued Activities with Individuals who have had a Stroke: A Randomised Controlled Trial**

## Abstract

**Objective:** To investigate the use of 'if-then' plans to facilitate diary keeping and participation in valued activities in the context of stroke rehabilitation. **Study Design and Participants:** Participants (N=29) were assigned to a Diary Plan intervention group or a No Diary Plan control group using a randomised procedure. All participants were required to complete an activity diary which incorporated the formation of 'if-then' plans for valued activities. **Measures:** Number of diary entries was used to assess the effects of forming an 'if-then' plan for diary keeping. Pre and post-intervention measures of wellbeing and activity level were used to assess the effects of activity 'if-then' plans. Self-report measures of memory and Theory of Planned Behaviour (TPB) variables were administered at baseline to investigate predictor variables for diary keeping. **Results:** Overall rates of diary keeping were high across the groups and no significant effects for the diary 'if-then' plan were found. Increased number of diary plans was associated with higher post-intervention activity levels. **Conclusions:** The use of implementation intentions to facilitate diary-keeping in the context of stroke rehabilitation was not supported in this study. The formation of implementation intentions to plan and undertake valued activities showed potential for enhancing activity levels. However, these results should be interpreted with caution due to the small sample size. Therefore, further randomised studies are required to evaluate the use of implementation intentions to support interventions following stroke.

## Introduction

Difficulties re-establishing participation in meaningful activities following a stroke can have profound and persisting effects on an individual's quality of life and sense of self-identity (Bayley, London, Grunkemeier, & Lansky, 1995). Drawing upon cognitive models of motivation and behaviour change, an emerging area of stroke research has started to evaluate self-management interventions addressing psychosocial aspects of stroke recovery (Jones, 2006). Increasing recognition of these factors can facilitate understanding of people's experiences of stroke sequelae and their responses to rehabilitation interventions. Psychological models of goal planning may also offer promising strategies for enhancing motivation and engagement in stroke rehabilitation interventions within this framework

### *Interventions to address post-stroke depression and participation in valued activities*

Approximately, 150,000 people will have a stroke each year in the UK with an estimated 300, 000 people currently living with significant difficulties resulting from their stroke (The Stroke Association, 2009). As the leading cause of chronic disability, stroke can have complex and wide-ranging effects on an individual's functioning and perceptions of life satisfaction (Young & Forster, 2007). For many people there is a marked reduction in participation of leisure activities post-stroke (Parker, Gladman & Drummond et al., 2001) and depression is a recognised complication associated with problems in cognitive functioning and psychosocial adjustment (Kneebone and Dunmore, 2000). The relationship between subjective wellbeing and participation in valued activities has been demonstrated in cohort studies (e.g. Mayo, Wood-Dauphinee, Cote, Duncan & Carlton, 2002; Sveen, Thommessen & Bautz-Holter et al., 2004) and in qualitative studies (e.g. Bayley, London, Grunkemeier, & Lansky, 1995; Burton, 2000).

Sveen et al., (2002), found that for 82 individuals at 6 months post-stroke, self-reported leisure activities had a greater association with satisfaction measures than mobility and self care activities. Similar findings were reported by Mayo et al. (2002) in a larger comparative study examining participation and wellbeing also at 6 months post-stroke. Fifty-three percent of a stroke sample (N=365) reported a lack of meaningful activities in their daily lives in comparison with 16% of a non-stroke group (N=486). For the stroke group, greater participation in community activities was significantly associated with higher quality of life ratings. Associations between depression, dissatisfaction and limitations in activities and participation have been shown to persist at 1 year post-stroke (Hartman-Maeir, Soroker & Ring et al., 2007).

Recurring themes in the qualitative literature show how the experience of stroke is characterised by a sense of loss. For many people discontinuity in valued activities and roles represents a loss of self-identity and “the pre-stroke” self, resulting in feelings of sadness, helplessness and frustration (Salter, Hellings, Foley & Teasell, 2008).

The re-classification of the World Health Organization's (WHO) model of impairment and disability (the International Classification of Function – ICF, 2001) has seen greater recognition of the role of social, psychological and contextual factors as opposed to the focus on physical impairments and limitations in the preceding WHO model (International Classification of Impairments, Disabilities and Handicaps, ICDH, 1998). Likewise, stroke rehabilitation has traditionally prioritised physical aspects of recovery and only more recently started to address broader psychosocial concerns. However, to date, research evidence for interventions such as leisure therapy and cognitive behaviour therapy (CBT) for post-stroke depression (PSD) is been generally sparse with mixed or inconclusive findings (Kneebone & Dunmore, 2000; Walker, Leonardi-Bee. & Bath et al., 2004).

Interventions directed at leisure therapy are in the domain of occupational therapy (OT) and have been largely evaluated within that context. Thus, the leisure therapy interventions, which included a range of leisure pursuits, have been compared with conventional OT provision which is more focused on self care and activities of daily living. Earlier studies found no beneficial effects for either of the approaches (e.g. Logan, Gladman, Drummond & Radford, 2003) whereas a later meta-analysis showed differential benefits for both types of OT interventions which generally reflected the targeted areas (Walker, Leonardi-Bee & Bathe et al., 2004).

Kneebone & Dunmore (2000) undertook a review of psychological approaches for post-stroke depression and, on the basis of very few published studies at that time, could only conclude that the most promising approach for further development was cognitive behavioural therapy (CBT). The authors acknowledged that the CBT model embraces aspects of leisure therapy such as scheduling pleasant and fulfilling activities.

A more recent randomised trial of CBT investigated predictors for post-stroke depression as well as evaluating the CBT intervention (Lincoln & Flannaghan, 2003; Nicholl, Lincoln & Muncaster et al., 2006). Whilst no effects were found for the CBT intervention, (which the authors attributed to sampling and methodological issues), various correlates of post-stroke depression were identified. Baseline measures for communication difficulties and activity levels (including mobility and leisure) predicted depression at the start of the intervention. At the 6 month follow up, activity levels were no longer associated with depression whereas communication difficulties continued to predict depression. External locus of control (LOC) was also associated with severity of depression at the follow-up. This suggests the presence of a more complex interplay between depression, cognitions (e.g. Locus of Control - LOC), functional ability and activities.

The role of control cognitions (i.e. perceived personal control of recovery) and self-efficacy in the recovery process have recently been examined in relation to the development of theoretically grounded self-management interventions for stroke rehabilitation (Johnston, Bonetti & Joice et al., 2007; Jones, Mandy & Partridge, 2009). Whilst control cognitions have been shown to predict disability following stroke (Johnston et al., 2007), it has been more difficult to determine the relationships between emotions, cognitions and recovery. A randomised control trial of a workbook intervention designed to enhance control cognitions and autonomy found significant gains for recovery from disability but no effects for levels of distress and satisfaction (Johnston, Bonetti & Joice et al., 2007).

Bandura's (1997) concept of self-efficacy (i.e. an individual's belief in their ability to perform a task) has had a major influence on the development of self-management interventions for chronic conditions (e.g. Lorig & Holman, 2003). In an exploratory study, Jones et al., (2009) examined a work-book intervention for stroke rehabilitation which incorporated aspects of this approach and sources of self-efficacy (e.g. mastery, vicarious experience, feedback). Although limited by a case-series design, the intervention had a beneficial effect on self-efficacy measures and perceived control. The results were less conclusive, however, in relation to measures of functional activity and mood.

Despite mixed results, these interventions offer a promising way forward for understanding mechanisms of stroke recovery and for developing interventions based on theoretical models of motivation and goal directed behaviour.

### *Goal planning for health and rehabilitation interventions*

Although goal planning is seen as an essential component of rehabilitation (Wade & deJong, 2000), supportive evidence is limited due to methodological weakness and inadequate reporting of procedures (Levack, Taylor & Siegart et al., 2006a). There has also been a fundamental lack of theory development for rehabilitation goal setting and only more recently have researchers turned their attention to motivation and goal theories in the social psychology research literature (Siegart and Taylor, 2004; Scobbie, Wyke & Dixon, 2009).

Scobbie, Wyke & Dixon, (2009) undertook a recent review to identify the most useful and evidence-based behaviour change theories for developing a framework for rehabilitation goal setting. Based on a systematic search of the literature, Scobbie et al. propose a model based on the overlapping constructs of three of five identified behaviour change theories - Social Cognitive Theory (SCT, Bandura, 1997), Goal Setting Theory (GST, Locke & Latham, 2002) and the Health Action Process Approach (HAP, Schwarzer, 1992).

This framework incorporates goal-setting as the link between a motivational phase and an action phase and is, perhaps not surprisingly, very similar to one presented in a recent study by researchers involved in developing the HAP model (Wiedemann, Schuz, Sniehotta, Scholz & Schwarzer, 2009). Both models describe the intention-planning-behaviour relation (Wiedemann et al., 2009).

Intentions form a central construct within Azjen's Theory of Planned Behaviour (TPB, 1991) and are underpinned by important TPB constructs. These include perceived behavioural control (i.e. appraisals about ability to perform an action) and attitudes towards the behaviour or task (Connor & Sparkes, 2005). The inter-related components of the TPB model have been shown to account for variability in intentions and behaviours across a range of health contexts including substance misuse

and physical activity programmes (Connor & Sparkes, 2005). Weidemann et al. (2009) conceptualise 'intentions' (pre-goal setting motivation) as a continuous moderating factor for intended behaviour which can be mediated by action planning and thus have a greater impact on target behaviour.

Implementation intentions is an approach to goal planning developed by Gollwitzer (1999) and grounded in Ajzen's TPB model. An implementation intention specifies when, where and how a desired action will take place and is usually expressed as an 'if-then' plan (e.g. "if situation Y occurs, then I will initiate goal-directed behaviour Z!"). These action plans have been shown to be effective and flexible in promoting a range of 'health' change behaviours including uptake of cervical screening (Sheeran & Orbell, 1999) and healthy eating (Verplanken & Faes, 1999) and psychotherapy attendance (Sheeran, Aubrey & Kellett, 2007).

It is hypothesized that 'if-then' plans utilise automatic processes to achieve goal behaviours by first enhancing the accessibility of a specified future event (the 'if' part of the plan) and secondly by creating a strong association between the event and the desired behaviour (Sheeran, Webb & Gollwitzer, 2006). Specified events in the 'if' component of the plan act as cues to initiate targeted behaviour and can include internal states such as anxiety as well as environmental events. In doing this, implementation intentions are said to bridge the intention-behaviour gap and make the realisation of an intended action more likely.

This strategy can, therefore, promote the execution of tasks which rely on remembering (i.e. prospective memory) and self-initiated or effortful rather than habitual or automatic processing. Thus, researchers have explored the potential of 'if-then' plans for self managed treatment regimes which rely on prospective memory (e.g. Sniehotta, Scholz, Schwarzer, Fuhrmann & Voller, 2005) and as a supportive strategy where cognitive decline or deficits may impede memory functioning as in old age

(Park, Gutches, Meade & Stine-Morrow, 2007) and schizophrenia (Brandstatter, Lengfelder & Gollwitzer, 2001).

Park and colleagues recently undertook two studies examining the utility of implementation intentions to facilitate prospective memory tasks in older adults. The first study (Chasteen, Park, & Schwarz, 2001) showed that the formation of an implementation intention significantly increased the performance of participants undertaking a laboratory based memory task (writing the day of the week on response sheets) in comparison with participants who used alternative memory strategies. The second study (Liu & Park, 2004) demonstrated the value of implementation intentions for remembering a home-based glucose monitoring procedure. Participants who formed a plan for the procedure, on average performed 95% of their blood glucose tests within 30 minutes of the target time compared with 73% and 68% for participants who used alternative strategies.

In using automatic processes to achieve effortful tasks, forming implementation intentions is a potentially useful strategy to add to existing rehabilitation interventions designed to enhance independence and functionality for stroke survivors. Implementation intentions could be used to support adherence to 'homework' assignments or monitoring diaries for stroke rehabilitation and CBT. They may also be useful in supporting a self-management strategy when discharge from hospital or community services has taken place. Once initial training is undertaken to ensure understanding and ability to form 'if-then' plans, it would be a relatively low intensity intervention in relation to staff and patient time and resources.

### **Study Aims and Hypotheses**

The primary aim of this study was to investigate whether forming implementation intentions can facilitate diary keeping and participation in valued activities among individuals who have had a stroke.

The tasks involved diary keeping and behavioural goals to increase engagement in activities. Both these tasks, (diary keeping and activity planning), are typical components of CBT for depression (e.g. Coon & Thompson, 2002) and engagement in social and leisure activities may play a role in helping to improve or maintain psychological wellbeing in stroke patients (e.g. Sveen et al., 2004) and older adults (e.g. Klumb & Maier, 2007).

As with the tasks described in the studies undertaken by Park and her colleagues, remembering to complete a daily diary may be seen as an effortful memory task requiring self-initiated rather than automatic processing. Difficulties participants with stroke or acquired brain injury can have with diary keeping are illustrated in studies of diary-based interventions showing a rapid decline in diary entries over the intervention period (Frank, Johnston & Morrison et al., 2000; Ownsworth & McFarland, 1999).

It is thus hypothesised that forming an explicit 'if-then' plan that links the intention to complete a diary entry with specific situational cues will increase the likelihood that the cues will be noticed and elicit diary completion. Implementation intentions could also have potential for promoting attainment of activity goals. Engagement in valued activities might then be enhanced where diary entries involve the formation of such plans. The hypotheses for the current study were therefore:

*Hypothesis 1:* Participants who form an 'if-then' plan for diary-keeping will complete a greater number of diary entries over the intervention period than participants who do not form a diary 'if-then' plan.

*Hypothesis 2:* The formation of 'if-then' plans to undertake valued activities over the intervention period will predict activity levels and wellbeing at the end of the intervention period.

## METHOD

### Study Design Overview

A between groups comparison of a 'Diary Plan' (DP) condition with a 'No Diary Plan' (NDP) condition was used to evaluate the effects of forming an 'if-then' plan for completion of a daily diary. Across both groups, the effects of forming 'if-then' plans to undertake a specified daily activity over a two week period were evaluated in relation to self-reported mood and activity levels.

Instructions for diary-keeping were administered face-to-face in visits to participants' homes along with a questionnaire concerning pre-intervention intentions and attitudes towards diary-keeping. The primary measure for the 'diary plan' intervention was frequency of diary entries. In relation to the 'activity plan' intervention, primary measures for activity levels and wellbeing were in the form of postal questionnaires.

### Participants

Eligibility criteria included stroke diagnosis, completion of a rehabilitation programme delivered by community stroke team professionals, capacity to consent and ability to read and understand English sufficient to be able to complete questionnaires and diaries. Whilst participants could be supported in the recording of written responses, they were excluded if they were unable to read as the intervention required participants to read and memorise the 'if-then' plans.

Participants were recruited from two community stroke teams at the point of discharge and from a rehabilitation day centre. Potential participants were identified by stroke team professionals and provided with a letter inviting them to consider taking part in the study. The letter included a response slip for participants to give consent for the researcher to contact them (Appendix, 3a).

## **Procedure**

The study procedure was verbally explained by the researcher, either by telephone or face-to-face contact, to individuals who expressed an interest in taking part. If verbal consent was given to proceed, a written information sheet (Appendix 3b) was provided along with a consent form (Appendix 3c) and the Time 1 questionnaires for psychological wellbeing, activity levels and memory.

Using a computer-generated randomisation programme, participants were allocated into one of two study groups – a 'Diary Plan' (DP) condition and a 'No Diary Plan' (NDP) control condition. Following completion of the Time 1 questionnaires, the researcher undertook home visits to all participants to administer instructions for completion of an activity diary (Appendix 4e). A questionnaire concerning motivation for diary-keeping was administered after an initial overview of the diary was given and before going through detailed instructions for diary completion and formulation of the 'if-then' plans.

For participants in the DP intervention group, formulation of an 'if-then' plan to complete the diary was undertaken as part of the diary-keeping instructions (Appendix 4f). All participants were required to keep the diary over a two week period. After the two week intervention, Time 2 questionnaires were sent out to all participants with a stamped addressed envelope to return completed diaries and questionnaires.

The research proposal was submitted for internal review by the university and the study was monitored by an internal audit and review process (Appendix 2a). Ethical and governance approval was obtained from a local research ethics committee and the research governance board for the NHS Trust (Appendix 2b-d). Participants provided written consent and were informed that they could withdraw at any point.

### **The implementation intention interventions**

Participants in the DP condition formed an implementation intention (or an 'if-then' plan) to complete diary entries when the researcher administered instructions for diary keeping. For this, DP participants were required to specify when and where they would complete diary entries. Instructions and worked examples were provided in an introductory section of the diary booklet, (Appendix, 4b).

For all participants, completion of each diary sheet included construction of an implementation intention to undertake a specified activity the following day. For this, participants specified when and where they would undertake an activity of their choosing. Written instructions with worked examples were provided on pages 4 and 5 (for NDP and DP participants respectively) of the diary booklet and the researcher gave a verbal explanation when administering instructions for diary completion.

### **Measures**

Background demographic and clinical information was obtained from participants and included age, gender, living and support arrangements, length of hospital stay following the stroke and perceived physical and psychological impacts of the stroke.

Primary outcomes included number of diary entries and self-report measures of wellbeing, functional independence and participation in activities. Whilst the 'if-then' plans for diary-keeping and activities formed the main independent variables, measures of memory and motivation for diary-keeping were also included as possible predictor variables for completion of diary entries.

*Diary completion* was measured by number of diary entries. Diary booklets (Appendix, 4) provided a record of completed diary sheets and number of activity plans formulated. Each diary sheet included visual analogue rating scales (VAS) to measure self-reported mood (on a scale from "very negative"

to “*very positive*”), activity level (from “*very little*” to “*a great deal*”) and satisfaction with activity performance (“*not well at all*” to “*very well*”).

*Activity levels* were assessed by The Nottingham Extended Activities of Daily Living Scale - NEADL (Appendix 4a; Nouri & Lincoln, 1987). The NEADL was used as a measure of activity and functional independence. The NEADL is a self-report questionnaire designed for use with stroke populations and has 22 questions divided into four subsections (mobility, kitchen, domestic, leisure) about the ease or difficulty in performing extended activities of daily living. Scores on individual items range from 0 to 3 with higher scores indicating greater functional independence. The NEADL has been widely used as a stroke outcome measure with demonstrated validity (Parker, Gladman & Drummond et al., 2001) and reliability (Gompertz, Pound & Ebrahim, 1993).

*Psychological wellbeing* was assessed by the Hospital Anxiety and Depression Scale – HADS (Appendix, 4b; Zigmond & Snaith, 1983). The HADS is a widely used self-report measure of mood consisting of seven depression items and seven anxiety items. Scores for each item range from 0 to 3 with higher scores indicating increased presence of anxiety and depression symptoms. Validity and reliability data are available for stroke patients (e.g. Aben, Verhey & Lousberg et al., 2002; Johnson, Burvill & Andreson et al., 1995).

*Memory* was assessed by the Prospective and Retrospective Memory Questionnaire - PRMQ (Appendix 4c; Crawford, Smith & Maylor et al., 2003). The PRMQ is a sixteen item self-report measure of everyday memory failures. It consists of eight prospective memory and eight retrospective memory items which are rated on a 5-point Likert scale. Normative data has been established and the PRMQ has good reliability and validity (Crawford, Smith & Maylor et al., 2003).

*Motivation for diary keeping.* (Appendix 4d) Attitudes towards completing the activity diary were assessed by 6 items based on Theory of Planned Behaviour (TPB) questionnaires (e.g. Sheeran, Trafimow & Armitage, 2003). Each item included a seven point Likert scale. Intentions were assessed by 2 items (e.g. "I intend to complete an activity diary..."; 1=*strongly disagree*; 7=*strongly agree*"). Perceived behavioural control (PBC) was assessed by 2 items (e.g. "How confident are you that you will be able to complete an activity diary every day in the next couple of weeks?; 1=*not at all confident*; 7=*very confident*"). Two items assessed attitudes towards the diary keeping task (e.g. "For me, completing an activity diary everyday in the next couple of weeks will be..."; 1= *pointless*; 7=*very worthwhile*).

### **Statistical Analyses**

Descriptive statistics were used to describe the study sample in relation to demographic characteristics (age, sex, living arrangements) and indicators of stroke severity (length of hospital stay, paid home support). Multivariate analysis was used to check randomisation across the groups in relation to demographic characteristics and Time 1 measures.

For the first hypothesis, a one-way between-groups analysis of variance (ANOVA) with two levels (Diary Plan and No Diary Plan) was undertaken to assess the effect of the diary implementation intention on diary completion, with number of diary entries as the dependent variable. For the second hypothesis, moderated linear regression analyses were used to examine the contribution of activity implementation intentions for any variance in Time 2 wellbeing and activity measures. Separate analyses were to be undertaken for each of these measures in which Time 2 HADS or NEADL scores were entered as dependent variables. To control for the influence of baseline measures, Time 1 HADS or NEADL scores would be entered as independent variables at Step 1. 'Number of activity

plans' was to be entered as the independent variable at Step 2 to assess the ability of activity plans to predict Time 2 measures of wellbeing and activity.

Gollwitzer & Sheeran's recent meta-analysis (2006) showed that implementation intentions had a medium to large effect on behaviour ( $d = .65$ ). A power analysis ([www.math.yorku.ca/scs/online/power](http://www.math.yorku.ca/scs/online/power)) showed that 40 participants were required in each of two conditions (i.e. 'implementation intention' and 'no implementation intention') to achieve 82% power to detect a difference at the .05 alpha level.

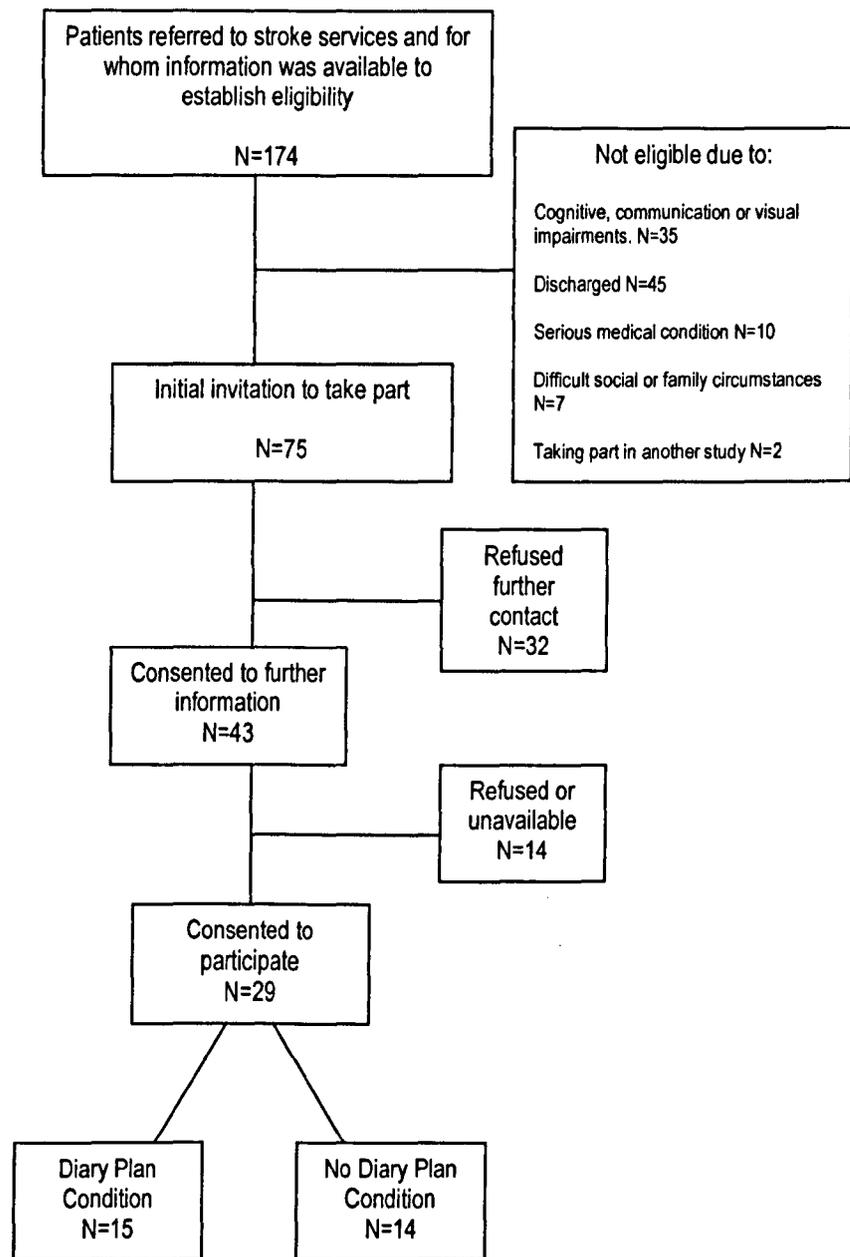
## RESULTS

### Participants

Figure 1 describes participant recruitment and group allocation. The researcher was able to establish the eligibility of 174 individuals referred to the stroke rehabilitation services from information provided by stroke professionals. Of this population, 35 individuals were judged as not meeting the study criteria due to cognitive or sensory difficulties, 45 were in the process of being discharged with no further contacts by key workers planned, 10 had serious medical problems, 7 had difficult social or family circumstances and 2 were taking part in another research study.

Out of a total of 75 individuals invited to take part in the study, 33 refused and 42 consented to the researcher's initial contact. Twenty-nine individuals agreed to take part on being provided with more information about the study and 14 declined or were unable to participate (including one person who died).

Figure 1. Flow chart of participant recruitment and group allocation



As described in Table 1, there were 16 women and 13 men in the study sample with a mean age of 69 years. Seventeen participants (60.7%) were living with partners or family, 9 (32.1%) were living on their own and 2 (7.1%) lived in supported accommodation. Eight participants (42.9%) had home care support from paid care staff and 8 participants attended a rehabilitation centre once a week.

In relation to pre-intervention HADS scores, 20.7% ( $N=6$ ) of the sample scored within the range for moderate to severe depression and 27.6% ( $N=8$ ) scored within the range for moderate to severe anxiety. These figures rise to 44.8% for depression and 51.7% for anxiety when scores for mild symptomology are included.

Table 1. *Participant Characteristics to assess randomisation across study groups*

<i>Characteristics</i>	<i>Diary Plan (N=15)</i>	<i>No Diary Plan (14)</i>	<i>All Participants (N=29)</i>
Male	6	7	13
Female	9	7	16
Age in years Mean (SD)	70.13 (12.69)	67.93 (12.24)	69.00 (12.30)
Duration of hospital admission in weeks Mean (SD)	8.97 (7.69)	10.86 (10.13)	9.88 (8.84)
Family	53.3	71.4	62.1
Alone	40.0	21.4	31.0
Supported accommodation (%)	6.7	7.1	6.9
Paid support (%)	53.3	35.7	44.8
Attends rehabilitation centre (%)	46.6	42.9	44.8
Time 1 Anxiety (HADS) Mean (SD)	8.40 (5.26)	6.50 (4.70)	7.48 (5.00)
Time 1 Depression (HADS) Mean (SD)	9.67 (3.94)	4.79 (3.17)	7.31 (4.31)
Time 1 NEADL Mean (SD)	28.57 (19.71)	37.71 (16.53)	33.14 (18.45)
Time1 PRMQ Mean (SD)	41.67 (15.74)	39.17 (13.94)	40.42 (14.60)

For continuous baseline variables, a MANOVA with study group (DP versus NDP) as the independent variable found a non-significant effect of study group, indicating randomisation had been successful:  $F(6,16) 1.42, ns$ .

## Attrition

Six participants (5 of the DP participants and 1 NDP participant) did not return activity diaries and Time 2 questionnaires giving an attrition rate of 20.7%. Statistics are as shown in Table 2. MANOVA with attrition (drop out vs completer) as the independent variable revealed a non-significant multivariate effect of attrition,  $F(6,16) = 2.29$ , ns.

*Table 2. Characteristics for participants who completed the study and participants who dropped out*

<i>Characteristics</i>	<i>Dropped out (N=6)</i>	<i>Completed (N=23)</i>
Male	3	10
Female	3	13
Age in years Mean (SD)	66.00 (10.16)	69.87 (12.88)
Duration of hospital admission in weeks Mean (SD)	15.50 (5.65)	8.41 (9.02)
Family	66.6	60.8
Alone	33.3	30.4
Supported accommodation (%)	0.0	8.6
Paid support (%)	83.3	34.8
Attends rehabilitation centre (%)	83.3	34.8
Time 1 HADS Anxiety Mean (SD)	9.17 (6.43)	7.04 (4.64)
Time 1 HADS Depression Mean (SD)	10.50 (4.46)	6.48 (3.95)
Time 1 NEADL Mean (SD)	12.50 (4.23)	38.77 (16.68)
Time 1 PRMQ Mean (SD)	47.80 (17.61)	38.39 (13.96)

### *Hypothesis 1: the effects of diary implementation intentions on diary-keeping*

Results of a 1-way between-groups ANOVA found no significant difference for number of diary entries between the DP and NDP conditions:  $F(1,21) = .07$ ,  $p > .05$ , ns. The mean number of diary entries over the 14 day intervention period was 12.00 for the DP group and 11.54 for the NDP group (see Table 3). There was also no significant difference found for the number of activity plans completed between the study groups as tested by a 1-way between groups ANOVA:  $F(1,23) = 0.78$ ,

ns. The mean number of activity plans completed by the DP group was 11.90 and 10.15 for the NDP group. Therefore the prediction that diary implementation intentions would facilitate diary keeping was not supported.

Table 3. *Diary completion across the study groups*

<i>Diary completion variables</i>	<i>Diary Plan Condition (DP) (N=10)</i>	<i>No Diary Plan Condition (NDP) N=13</i>
N Diary Entries Mean (SD)	12.00 (4.30)	11.54 (4.23)
N Activity Plans Mean (SD)	11.90 (4.28)	10.15 (4.98)

*Hypothesis 2: can activity implementation intentions predict activity levels and wellbeing at Time 2?*

Table 4 shows means, standard deviations and correlations for study variables. As would be expected all the baseline scores for activity (NEADL) and wellbeing (HADS anxiety and depression) predicted their counterpart scores at T2. Both of the diary completion variables, N activity plans and N diary entries, predicted T2 activity scores but not the T2 wellbeing measures.

A longer hospital admission with onset of stroke predicted lower activity scores at T1 and T2. However, length of hospital admission did not predict any of the wellbeing scores. Anxiety and depression were strongly associated at baseline ( $p=.01$ ) but the relationship was less significant at T2 ( $p=.05$ ). Participants with lower baseline activity scores had higher depression scores at T1 and T2. A higher baseline score for perceived memory failures (PRMQ) predicted higher depression level at T1 and T2.

Table 4. Means, standard deviations and correlations for study variables

Variable	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	Mean (SD)
	Activity Plans N=23	Diary Entries N=23	Wks In Hosp N=29	Intention1 (I intend to ....) N=29	Intention 2 (I will try to...) N=29	PBC N=29	Attitude to diary keeping N=29	PRMQ N=27	T1 HADS-A N=29	T1 HADS-D N=23	T1 NEADL N=29	T2 HADS-A N=22	T2 HADS-D N=28	T2 NEADL N=22	
1.	1.00	.85**	-.52*	.13	.08	.16	-.07	.14	-.01	.27	.45*	.05	.18	.58**	10.91 (4.67)
2.		1.00	-.62**	.18	.21	.41	.06	.17	-.13	.14	.50*	-.10	.06	.65**	11.74 (4.18)
3.			1.00	.02	.12	-.15	.05	.06	.22	.03	-.63**	.13	.14	-.72**	9.88 (8.84)
4.				1.00	.45*	.50**	.47**	.33	.21	.26	.06	-.10	-.09	.30	5.55 (1.24)
5.					1.00	.52**	.90**	.38	.16	.13	.11	.13	-.14	.28	5.55 (1.30)
6.						1.00	.62**	.35	-.24	-.11	.27	-.41	-.18	.39	4.65 (1.13)
7.							1.00	.29	.06	.02	.20	.09	-.25	.30	5.45 (1.23)
8.								1.00	.35	.51*	-.25	.26	.48*	.12	40.42 (14.60)
9.									1.00	.61**	-.30	.90**	.47*	-.25	7.48 (5.00)
10.										1.00	-.41*	.48*	.87**	-.13	7.31 (4.31)
11.											1.00	-.26	-.44*	.97**	33.14 (18.45)
12.												1.00	.44*	-.22	6.09 (3.78)
13.													1.00	-.40	6.78 (3.00)
14.														1.00	41.14 (17.08)

\*\*p<.05; \*\*\*p<.01; Diary completion (1 & 2), duration of hospital admission (3), Theory of Planned Behaviour questions (4,5,6,&7), Memory (8), Time 1 & 2 anxiety and depression (9,10,12 & 13) and Time 1 & 2 activity level (11 & 14). PBC=Perceived Behavioural Control; PRMQ=Prospective & Retrospective Memory Questionnaire; HADS-A or -D= Hospital Anxiety & Depression Scale – Anxiety or Depression; NEADL= Nottingham Extended Activities of Daily Living

Independent variables which were significantly correlated with time 2 activity levels, and thus potential predictor variables, included duration of hospital admission and both the diary completion variables (number of diary entries and number of activity plans). Although these independent variables were significantly correlated with each other, correlations between duration of hospital stay and the diary completion variables are less than the suggested threshold of 0.8 for multicollinearity (Field, 2005). The high correlation between the two diary completion variables was to be expected ( $r = 0.85$ ).

Other collinearity statistics (i.e. tolerance, variance inflation factors – VIF) and collinearity diagnostics (i.e. condition index, variance proportions) were computed for all variables within an exploratory hierarchical linear regression (see below). No condition index value was found to be greater than 30 and no VIF score was found to be above 10 indicating no multicollinearity was present. Tolerance statistics in the data were all above .2, also indicating there was no problematic collinearity within the data (Menard, 1996, cited in Field, 2005).

To ensure the residual terms are uncorrelated (or independent) a Durbin-Watson test was carried out. In this analysis, the Durbin-Watson statistic was 0.8 which was found to lie between the lower and upper bounds for critical values at 1% significance (Savin & White, 1977). This indicated that the residual terms could be correlated and, therefore, problematic.

Casewise diagnostics identified 4 cases with standardised residuals greater than 3 which is a greater proportion of extreme cases than would be expected for a normally distributed sample. Further checks for the influence of extreme cases found that no cases deviated substantially from boundaries for Cook's Distance, Mahalanobis Distance and Centred Leverage.

The assumption of homoscedasticity was met with non-significant results for Levene's tests of all variables entered into the regression analysis. Visual inspection of scatter plots for the residuals indicated that the assumptions for homoscedasticity, normality and linearity had been met (Appendix 5).

An exploratory hierarchical linear regression analysis was undertaken to assess the predictive validity of the variables correlated with T2 NEADL once baseline NEADL scores had been controlled for at Step 1<sup>3</sup>. Table 4 shows the results of this analysis.

Table 5. Hierarchical Linear Regression for N activity plans and Hospital Stay as predictors of Time 2 NEADL after controlling for T1 NEADL

Step	B	SEB	$\beta$	t	Significance
<i>Step 1</i>					
Constant	11.50	2.10		5.51	.000***
NEADL1	0.89	0.06	.97***	16.17	.000***
<i>Step 2</i>					
Constant	12.21	3.51		3.48	.003**
NEADL1	0.76	0.06	.82***	14.00	.000***
Hospital Stay	-0.23	0.12	-.12	-1.91	.07
N Activity Plans	0.54	0.20	.15*	2.75	.01*

Note:  $R^2 = .93$  for Step1;  $\Delta R^2 = .03$  for Step 2 ( $p < .05$ ). \* $p < .05$ , \*\* $p < .01$ \*\*\*,  $p < .001$

The addition of 'hospital stay' and 'N activity plans' at Step 2 explained 3% of the variance in activity levels at time 2,  $F(2,17) = 8.36$ ,  $p < .01$ , which was found to be a significant contribution. When looking at the contribution of each of these predictor variables, N Activity Plans significantly predicted NEADL at Time 2,  $\beta = .15$ ,  $p < .05$  whereas duration of hospital stay did not. Similar results were found for a separate analysis<sup>4</sup> substituting 'N diary entries' for 'N activity plans'.

<sup>3</sup> Correlations for duration of hospital admission and dairy completion variables with NEADL1 were also below the 0.8 multicollinearity threshold ( $r = 0.63$  for hospital admission;  $r = 0.50$  and  $r = 0.45$  for N diary entries and N diary plans respectively).

<sup>4</sup> Analysis in same equation would add nothing to the model due to the close association of 'N diary entries' and 'N activity plans'.

The hypothesis concerning the influence of activity implementation intentions on levels of activity and wellbeing can only be seen as being partially supported by these findings as activity implementation intentions were found to predict or influence T2 activity levels and not the wellbeing measures.

#### *Theory of planned behaviour variables*

A reliability analysis of the TBP questions showed that the two items representing attitudes towards the diary task (ratings from “good to bad” and “pointless to worthwhile”) formed a reliable scale (Cronbachs alpha = .81). At .69, the alpha coefficient for the PBC items (appraisal of ability to complete diary) was deemed close enough to the 0.7 threshold to be acceptable for exploratory research (Murphy & Davidshofer, 2001). The two intention items were analysed separately as they demonstrated low reliability (alpha = .45).

TPB variables were only significantly correlated with each other and thus explanatory analyses in relation to the TPB variables and diary keeping were not possible. The correlation between PBC and N diary entries (.41) almost reached significance at the  $p=.05$  level. Therefore a more positive appraisal about ability to complete the diary was marginally associated with an increased number of diary entries.

### **Discussion**

Many people experience depression and difficulties re-engaging in meaningful activities in the weeks and months following a stroke (Hartman-Maeir, Soroker, Ring, Avni & Katz, 2007). Furthermore discharge from hospital and community support services may be a particularly critical time as people are still in an early phase of adjustment to life after stroke (Wiles, Ashburn, Payne & Murphy, 2002).

The present study investigated a low intensity intervention involving the use of implementation intentions to facilitate diary keeping and activity planning following a period of stroke rehabilitation.

The study employed a randomised controlled procedure and between group comparisons to evaluate the effects of forming an implementation intention on diary keeping. The study also examined the effects of forming implementation intentions to undertake valued activities on psychological wellbeing and activity levels. All participants were required to complete a two week diary incorporating 'if-then' plans for chosen activities. Only participants in the study group formed an 'if-then' plan in relation to diary keeping. Psychological wellbeing and activity levels were assessed before and after the intervention. To evaluate correlates of diary keeping performance, self report measures of memory and motivation for diary keeping were also undertaken prior to the intervention. Measures of motivation were based on the theory of planned behaviour (TPB).

A total of 29 people consented to participate and were randomly allocated to either the intervention (Diary Plan) or control group (No Diary Plan). Six participants did not return completed diaries or T2 questionnaires leaving data for 23 participants available for analysis. Results of a MANOVA indicated that there were no overall differences between the people who dropped out and those that completed the study. Ten participants remained in the 'Diary Plan' intervention group and 13 in the 'No Diary Plan' control group.

In relation to the first hypothesis, the study found no differences between the groups in diary keeping as measured by number of diary entries. Thus, for this group of participants forming an implementation intention for diary keeping did not result in a higher rate of diary completion.

The second hypothesis considered the effects of forming implementation intentions for activities on levels of activity and wellbeing. Findings showed that increased activity plans predicted increased activity levels at T2. There was no relationship between number of diary plans and the wellbeing measures at T2. Despite these findings, there was evidence of a negative relationship between activity levels and depression, especially at T1, which is in accordance with cohort studies demonstrating an association between lower activity levels and lower scores on wellbeing and life satisfaction measures (e.g. Sveen et al., 2004).

In this study it appears that any beneficial effects of activity 'if-then' plans on activity levels were not reflected in perceptions of wellbeing. It could be argued that given their focus on activities, the diary completion variables would be expected to be more directly or strongly associated with activity measures than wellbeing measures.

Closer examination of the data shows that high rates of diary keeping were demonstrated by the study group as a whole with 78.3% ( $N=18$ ) completing diary entries for 12 or more days over the two week intervention period. This would explain the lack of group differences found for diary completion rates between participants who formed a diary implementation intention and those who did not. It would also inevitably make it difficult to detect any less direct or subtle interactions between activity implementation intentions and wellbeing measures.

Research suggests that relationships between activity participation and mood in the period following stroke are far from straightforward. One study found that the effects of undertaking meaningful activities on mood were indirect and modified by degree of hopeful thinking (Gum, Snyder & Duncan, 2006). Qualitative studies of patient and professionals perspectives have also identified hope as important for rehabilitation goal setting (e.g. Conneeley, 2003; Levack, Dean & McPherson et al.,

2006). Other studies have found cognitive variables such as 'control of recovery' cognitions and self-efficacy to be more directly associated with physical recovery and participation than mood (Johnstone et al., 2007; Jones et al, 2009). These findings indicate that interventions targeting cognitions, such as CBT and TPB interventions, offer a more direct route for effecting change than interventions specifically directed at changing negative mood states.

The recovery trajectory following stroke can be uneven and unpredictable although it is widely held that the majority of recovery takes place within the first three months (Kwakkel, Wagenaar, Kollen & Langhorst, 1996). Stroke survivors may, therefore, start the rehabilitation process with high expectations but as progress slows, their mood deteriorates (Wiles et al., 2002). Support for this was provided by Rochette, Bravo & Desrosiers (2007) who found positive appraisals of the situation decreased over the first 6 months following a stroke. Increased self-awareness as people return to life at home has been shown to contribute to a rise in the incidence and severity of depression symptoms in the first 2 months following hospital discharge (Fleming, Connoll, Tooth & Strong, 2002). Withdrawal of intensive but time-limited support provided by community teams may present an additional source of distress or difficulty in this transition period (Wiles et al., 2002).

Recruitment of more than half of the study sample was at this critical transition period and may explain some of the variability found in the wellbeing and activity measures both within and between the study groups. Whilst the incidence of moderate to severe symptoms of anxiety and depression was comparable or lower than estimates found in other studies (Hackett, Yapa & Parag et al., 2006<sup>5</sup>), scores ranged from 0-19 for anxiety and 0-16 for depression symptoms. The heterogeneity of stroke populations and fluctuating course of recovery are a recognised challenge for rehabilitation research,

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<sup>5</sup> Pooled estimate of 33% from systematic review.

making it difficult to detect group differences and assess the impact of interventions (Kollen, Kwakkel & Lindeman, 2006).

It was also difficult to evaluate the role of TPB variables in this study. Whilst the component constructs (i.e. intentions, PBC and attitudes) demonstrated positive correlations with each other, overall they appeared to have weak associations with completion of the diary task. Perceived behavioural control (PBC) did, however, demonstrate a moderate correlation with N activity plans (.41) and one of the PBC variables on its own – the confidence rating – showed significant correlations with number of diary entries (.47,  $p < .05$ ) and T2 NEADL (.52,  $p < .05$ ).

PBC is understood to be similar to Bandura's construct of self-efficacy in Social Cognition Theory – SCT (Ajzen, 1998; Bandura, 1997). Self-efficacy and autonomy are recurring themes in stroke and brain rehabilitation research (e.g. Conneeley, 2004; Holliday, Cano, Freeman & Playford, 2007) and have been key constructs in the development of self-management interventions in stroke rehabilitation (Jones et al., 2009; Johnston et al., 2007). As statements about personal control or controllability, PBC variables can be seen as being particularly salient for the concerns and situations of people with disabilities.

Self-efficacy can be influenced by interventions as well as being a predictor for intervention outcomes and as such has been considered an important target for intervention in self-management programmes (Jones et al., 2006). A large effect size was found for PBC variables following an implementation intention intervention to schedule physical activities amongst individuals with spinal cord injury (Latimer, Ginis & Arbour, 2006). The intervention group demonstrated higher 'barrier or coping self-efficacy' cognitions (i.e. confidence in ability to overcome obstacles) as well as greater confidence for scheduling physical activities. However it was unclear, in this study, whether the larger

effect size found for the PBC variables were due to the implementation intention initiating change in the control perceptions or a more a favourable construal of the target behaviour. As was possibly indicated by the current study, self-efficacy and PBC variables may, therefore, be particularly relevant for stroke recovery and rehabilitation interventions.

### *Limitations*

Methodological limitations require a cautious interpretation of the study findings. Recruitment to the study proved difficult and consequently the study sample did not meet the power analysis requirements of 40 participants per group. The participants who did not return diaries or T2 measures ( $N=6$ ) represented nearly a fifth of the study sample and a third of the intervention group ( $N=5$ ). This attrition rate is comparable with other stroke and brain injury studies including those with much larger samples. In Johnstone et al's study (2007) of a workbook based stroke intervention over a fifth (22.2%) of the 203 participants dropped out mostly due to medical reasons, with higher attrition for the intervention group.

High participant drop-out and loss to follow-up are common in longitudinal studies of stroke populations due to high rates of fatigue, frailty and mortality within the first year of a stroke (Jeffries, Grimmer-Somers & Luker, 2009). A recent feasibility study for undertaking well powered repeated measures research for examining wellbeing following stroke, concluded that recruiting enough participants to allow for a 25% drop out was not viable from a single site (Jeffries et al., 2009).

An additional methodological limitation in the current study concerned a lack of variability in rates of diary entries. Nearly 80% of participants completed 12 out of a possible 14 diary entries. This may reflect a sampling bias in that people who consented were more willing to take part and consequently

more motivated to complete the diary task than those who declined. Meeting the researcher in person at T1 may also have influenced participants' commitment to the task or role of research participant. Number of activity plans was closely aligned with diary entries and therefore it is difficult to determine if possible effects found for T2 activity levels are a function of number of activity plans *per se* or diary completion as a whole.

It could be the case that participants with established routines and effective strategies for remembering tasks were well (or over) represented in this sample. Scholz, Sniehotta, Burkert & Schwarzer (2007) investigated planning and memory strategies in older (65-82 years) and younger participants (55 years and below). It was found that the older participants reported a higher rate of 'coping planning' (i.e. anticipating difficulties and planning ways to overcome them) which the authors discuss in terms of older people's experienced-based learning and the development of strategies to compensate for memory or cognitive decline in later life. In the current study, over 80% ( $N=24$ ) of the study sample were over 55 years and as such may have demonstrated a more proficient approach to the diary task as suggested by Scholz et al.'s study.

The small sample size and lack of variability in diary completion inevitably precluded detection of group differences and as such explanatory analyses of the diary implementation intention were not possible. These factors were further compounded by variability in mood and activity measures, also a common feature of stroke and brain injury research (Jones et al., 2009; Kollen et al., 2006). Variable mood levels may also have been an indicator of the challenge faced by participants at an early stage of adjustment following a stroke. Undertaking this diary-based intervention at a more stable phase of recovery might have proved a better strategy for a preliminary evaluation of a novel intervention.

Although lack of follow-up measures is a serious limitation for this study design, it is probable that there would have been further attrition from the sample. For exploratory studies and where the researcher is not embedded in the service or is unable to achieve high/frequent visibility at the point of recruitment, it may be more feasible for future evaluations of these types of interventions to undertake case series designs, in the way that Jones et al. (2009) did in their recent study of a workbook intervention. A case series design with a more sustained intervention period and multiple measures over time could have provided more meaningful results.

It would have been useful to have undertaken a systematic analysis of the content or quality of the activity implementation intentions as it was clear that some participants did not complete the plans as instructed. Johnston et al., (2007) reported a similar finding in relation to their workbook intervention for stroke rehabilitation indicating that some participants would require ongoing support to undertake this kind of intervention.

For participants in the current study, instructions for the activity 'if-then' plans may have been too open resulting in some plans looking like a list of intentions and activity goals rather than specifying the conditions for undertaking one activity. Variability in targeted behaviours might obscure the effects of intentions or other TPB variables for making plans and initiating desired behaviours. Wiedemann et al. (2009) found a greater magnitude of intentions was required in order for planning to affect the initiation of more complex target behaviours (physical activity as a more complex behaviour than dental hygiene). This suggests greater control of the nature or complexity of tasks is needed in order to determine interactions between implementation intentions and TPB variables.

Future research examining the potential for implementation intentions in relation to rehabilitation goals might consider asking participants choose a small number (2-3) of goals they would like to work on over the intervention period. As well as tying in with rehabilitation practice and the format of 'if-

then' plans, performance on these activities could be tracked more systematically. It might also be easier to determine mood correlates with goals and activities which are more highly specified.

Informal examination of the content and quality of diary entries in the current study suggested there were diverse responses to the diary task, some reflecting a positive response and others showing signs of finding the task difficult or taxing. Methodological limitations notwithstanding, the high rate of diary completion achieved overall could be seen as providing some endorsement for the feasibility of employing diary workbooks for goal planning in stroke rehabilitation. A larger sample or larger number studies available for systematic review would help to identify participant characteristics associated with higher adherence to and benefit from diary based self-management interventions.

## **Conclusion**

Recovery from stroke is clearly highly individualised and complex. In the current study, inconclusive results were found for the use of implementation intentions to facilitate diary keeping, activity planning and participation in activities in the context of stroke rehabilitation. These findings are not inconsistent with large-scale and small N studies of similar workbook based stroke interventions (e.g. Jones, et al., 2009; Johnston et al., 2007).

There is a dearth of evidence supported interventions in the field of stroke rehabilitation and especially in relation to interventions supporting self-management strategies in the community (e.g. Jones et al., 2009). Inherent difficulties in achieving sufficiently powered and robust research studies present considerable challenges for theory and intervention development this field. However it is important that researchers continue to investigate relationships between key predictors of stroke recovery and explore potential points of intervention.

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# Appendices

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## *Appendix 1*      *Formats*

- 1a**    Letter of approval of specified journals
- 1b**    Instructions for authors for literature review (Clinical Psychology Review)
- 1c**    Instructions for authors for research report (Rehabilitation Psychology)



Department Of Psychology.  
**Clinical Psychology Unit.**

Doctor of Clinical Psychology (DClin Psy) Programme  
 Clinical supervision training and NHS research training  
 & consultancy.

Clinical Psychology Unit  
 Department of Psychology  
 University of Sheffield  
 Western Bank  
 Sheffield S10 2TP UK

Telephone: 0114 2226550  
 Fax: 0114 2226610  
 Email: [c.harrison@sheffield.ac.uk](mailto:c.harrison@sheffield.ac.uk)

28 April 2009

Rebecca Fido  
 Third year trainee  
 Clinical Psychology Unit  
 University of Sheffield

Dear Rebecca

I am writing to indicate our approval of the Journal(s) you have nominated for publishing work contained in your research thesis.

**Literature Review:** Clinical Psychology Review

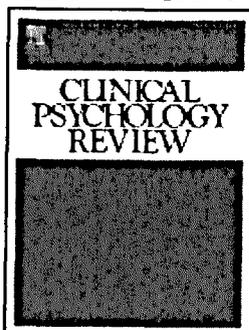
**Research Report:** Rehabilitation Psychology

Please ensure that you bind this letter and copies of the relevant instructions to Authors into an appendix in your thesis.

Yours sincerely

Dr Andrew Thompson  
 Director of Research Training

# Clinical Psychology Review



ISSN: 0272-7358  
Imprint: ELSEVIER

## Guide for Authors



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## **Preparation**

### **Use of wordprocessing software**

It is important that the file be saved in the native format of the wordprocessor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the wordprocessor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. Do not embed "graphically designed" equations or tables, but prepare these using the wordprocessor's facility. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier: <http://www.elsevier.com/guidepublication>). Do not import the figures into the text file but, instead, indicate their approximate locations directly in the electronic text and on the manuscript. See also the section on Electronic illustrations. To avoid unnecessary errors you are strongly advised to use the "spell-check" and "grammar-check" functions of your wordprocessor.

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Manuscripts should be prepared according to the guidelines set forth in the Publication Manual of the American Psychological Association (6th ed., 2009).

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If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on.

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*Author names and affiliations.* Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author within the cover letter.

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A concise and factual abstract is required (not exceeding 200 words). This should be typed on a separate page following the title page. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separate from the article, so it must be able to stand alone. References should therefore be avoided, but if essential, they must be cited in full, without reference to the reference list.

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Immediately after the abstract, provide a maximum of 6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, "and", "of"). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

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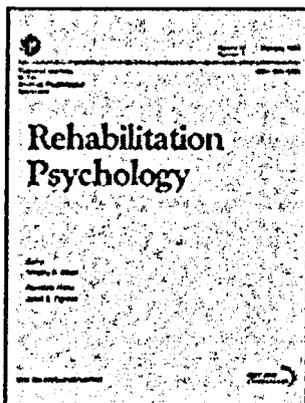
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Rehabilitation psychologists consider the entire network of biological, psychological, social, environmental, and political factors that affect the functioning of persons with disabilities or chronic illness. Given the breadth of rehabilitation psychology, the journal's scope is broadly defined.

Suitable submissions include

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- outcome studies
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- Manuscript Preparation
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- References
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- Publication Policies
- Ethical Principles

## Submission

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New and revised manuscripts are to be submitted electronically (.rtf and .pdf files are preferred) through the Manuscript Submission Portal.

General correspondence and express mail may be directed to

Timothy R. Elliott, PhD, Editor  
*Rehabilitation Psychology*  
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Texas A&M University  
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E-mail: Editorial Office

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Masked reviews are preferred, but it is incumbent upon authors who wish masked reviews to make every effort to see that the manuscript itself contains no clues to their identities. Authors' names, affiliations, and contact information should be included only in the cover letter.

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The cover letter accompanying the manuscript submission must include all authors' names and affiliations to avoid potential conflicts of interest in the review process. Addresses and phone numbers, as well as electronic mail addresses and fax numbers, if available, should be provided for all authors for possible use by the editorial office and later by the production office.

Authors should include in their submission letter

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- a statement that the manuscript or data have not been previously published and that they are not presently under consideration for publication elsewhere
- a statement that all listed authors have contributed significantly to the work submitted for consideration

Authors are required to submit copies of any papers under review, in press, or previously published whose content closely relates to that of the manuscript in question and that might be perceived as constituting duplicate publication.

Authors may also suggest qualified reviewers of the manuscript, but these are considered advisory only.

## Style of Manuscripts

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The journal considers theoretical, empirical, and commentary papers relevant to rehabilitation psychology. Brief reports are considered.

## Brief Reports

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This format may be appropriate for empirically sound studies that are limited in scope, contain novel or provocative findings that need further replication, or represent replications and extensions of prior published work. Brief Reports are intended to permit the publication of soundly designed studies of specialized interest that cannot be accepted as regular articles because of lack of space.

Brief Reports must use a 12-point Times New Roman type and 1-in. (2.54-cm) margins, and not exceed 265 lines of text plus references. These limits do not include the title page, abstract, author note, footnotes, tables, or figures.

## Randomized Clinical Trials: Use of CONSORT Reporting Standards

---

*Rehabilitation Psychology* encourages the use of the CONSORT (Consolidated Standards of Reporting Trials) reporting standards (i.e., a checklist and flow diagram) for randomized clinical trials, consistent with the policy established by the Publications and Communications Board of the American Psychological Association.

CONSORT offers a standard way to improve the quality of such reports and to ensure that readers have the information necessary to evaluate the quality of a clinical trial.

Manuscripts that report randomized clinical trials are required to include a flow diagram of the progress through the phases of the trial and a checklist that identifies where in the manuscript the various criteria are addressed. (The checklist may be placed in an appendix of the manuscript for review purposes.)

When a study is not fully consistent with the CONSORT (Consolidated Standards of Reporting Trials) statement, the limitations should be acknowledged and discussed in the text of the manuscript.

Visit the CONSORT Statement Web site for more details and resources.

## Nonrandomized Trials: Use of TREND Statement

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*Rehabilitation Psychology* encourages the use of the most recent version of the TREND criteria (Transparent Reporting of Evaluations with Non-randomized Designs for nonrandomized designs that often are used in public health interventions; available from the TREND Web site).

- Emerging Issues in Geriatric Rehabilitation Psychology
- Outcome Measurement in Rehabilitation
- Research and Methodological Advances and Issues in Rehabilitation Psychology

## Overview

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The following instructions pertain to all journals published by APA and the Educational Publishing Foundation (EPF).

Please also visit the web page for the journal to which you plan to submit your article for submission addresses, journal-specific instructions, and exceptions.

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Prepare manuscripts according to the *Publication Manual of the American Psychological Association* (6<sup>th</sup> edition). Manuscripts may be copyedited for bias-free language (see Chapter 3 of the *Publication Manual*).

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Review APA's Checklist for Manuscript Submission before submitting your article.

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---

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List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

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**Chapter In an Edited Book:**

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## Other Information

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- Appeals Process for Manuscript Submissions
- Preparing Auxiliary Files for Production
- Document Deposit Procedures for APA Journals

*Appendix 2      Ethical Approvals*

- 2a**    Letter of agreement for university sponsorship
- 2b**    Letter for conditional ethical approval
- 2c**    Letter of confirmation for ethical approval
- 2d**    Letter for research governance



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**Clinical Psychology Unit.**

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Telephone: 0114 2226570  
 Fax: 0114 2226610  
 Email: [dclinpsy@sheffield.ac.uk](mailto:dclinpsy@sheffield.ac.uk)  
 Please address any correspondence to Ms. Christie  
 Harrison, Research Support Officer

30<sup>th</sup> May 2008

To: Research Governance Office

Dear Sir/Madam,

**RE: Confirmation of Scientific Approval and Indemnity of enclosed Research Project**

**Project title:** Can implementation intentions facilitate completion of an activity diary following a period of stroke rehabilitation?

**Investigators:** Rebecca Fido (DClin Psy Trainee, University of Sheffield); Prof Paschal Sheeran (Academic Supervisor, University of Sheffield), Dr Tom Webb (Academic Supervisor, University of Sheffield), Dr Jane Barton (NHS Supervisor).

I write to confirm that the enclosed proposal forms part of the educational requirements for the Doctoral Clinical Psychology Qualification (DClin Psy) run by the Clinical Psychology Unit, University of Sheffield.

Three independent reviewers appointed by the Clinical Psychology Unit Research Sub-committee have scientifically reviewed it.

I can confirm that all necessary amendments have been made to the satisfaction of the reviewers, who are now happy that the proposed study is of sound scientific quality. Consequently, the University will also indemnify it, and would be happy to act as research sponsor once ethical approval has been gained.

**Given the above, I would remind you that the Unit already has an agreement with your office to exempt this proposal from further scientific review.** However, if you require any further information, please do not hesitate to contact me.

Yours sincerely

Dr. Zaffer Iqbal  
 Director of Research Training

Cc. Rebecca Fido, Prof Paschal Sheeran, Dr Tom Webb, Dr Jane Barton



The University Of Sheffield.

The Research Office.

A Section of the Academic Division, Research Services

New Spring House  
231 Glossop Road  
Sheffield  
S10 2GW

Ms Rebecca Fido  
(c/o Christie Harrison)  
Clinical Psychology

Telephone: +44 (0) 114 222 1448  
Fax: +44 (0) 114 222 1452  
Email: r.j.hudson@sheffield.ac.uk

6<sup>th</sup> June 2008

Dear Rebecca

**CONDITIONAL AGREEMENT TO BE THE PROJECT'S RESEARCH GOVERNANCE SPONSOR**

Title: 122754

URMS Reference: Can Implementation intentions facilitate completion of an activity diary following a period of stroke rehabilitation?

This is to confirm that in respect of the above project, of which your Supervisor is Dr Tom Webb, the University of Sheffield agrees conditionally to be the project's 'research governance sponsor'. In agreeing conditionally to be the research governance sponsor the University confirms that:

1. The research proposal has been discussed with the Supervisor and investigator and agreement in principle to sponsor the research is in place;
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality;
3. Any necessary indemnity/insurance arrangements will be in place before the research starts;
4. Arrangements will be in place before the study starts for the research team to access resources & support to deliver the research as proposed;
5. Arrangements to allocate responsibilities for the management, monitoring & reporting of the research will be in place before the research starts;
6. The duties of the research governance sponsor will be undertaken in relation to the research.

Please enclose this letter with your ethics application when submitting it to the NHS Research Ethics Committee (in the sponsor declaration section of the NHS ethics form state 'please refer to the enclosed letter from the University of Sheffield'). In due course please provide Mr Richard Hudson ([r.j.hudson@sheffield.ac.uk](mailto:r.j.hudson@sheffield.ac.uk)) with evidence of independent ethical approval (e.g. a copy of the letter from an NHS Research Ethics Committee).

Please note Annex 1 attached to this letter where the responsibilities of the Supervisor and Head of Department in relation to research governance are outlined. The expectation is that the Supervisor's responsibilities are fulfilled with your support and input.

Yours sincerely

*RJS*

 **Robert Sykes**  
Head of Planning & Operations Section  
The University of Sheffield



INVESTOR IN PEOPLE  
Central Services have achieved the Investors in People Standard



THE QUEEN'S ANNIVERSARY PRIZES  
for Merit in Higher Education  
2008

To access the University's research governance website go to:  
[www.shef.ac.uk/researchoffice/gov\\_ethics\\_grp/governance/gov.html](http://www.shef.ac.uk/researchoffice/gov_ethics_grp/governance/gov.html)

### Monitoring responsibilities of the Supervisor:

The primary responsibility for project monitoring lies with the Supervisor. You agree, with the support and input of the supervised-student, to:

1. Establish a **site file** before the start of the project and ensure it remains up to date over the project's entire lifetime:  
[www.shef.ac.uk/researchoffice/gov\\_ethics\\_grp/governance/rgp/rg-forms.html](http://www.shef.ac.uk/researchoffice/gov_ethics_grp/governance/rgp/rg-forms.html)
2. Provide **standard monitoring progress reports** to the Head of Department at the following intervals in a project's lifetime:
  - a. three months after the project has started; and
  - b. on an annual basis (only if the project lasts for over 18 months); and
  - c. at the end of the project.
 See: [www.shef.ac.uk/researchoffice/gov\\_ethics\\_grp/governance/rgp/rg-forms.html](http://www.shef.ac.uk/researchoffice/gov_ethics_grp/governance/rgp/rg-forms.html)
3. Report **adverse events**, should they occur, to the Head of Department:  
[www.shef.ac.uk/researchoffice/gov\\_ethics\\_grp/governance/rgp/rg-forms.html](http://www.shef.ac.uk/researchoffice/gov_ethics_grp/governance/rgp/rg-forms.html)
4. Provide progress reports to the research funder (if externally-funded).
5. Establish appropriate arrangements for recording, reporting and reviewing significant developments as the research proceeds – i.e. developments that have a significant impact in relation to one or more of the following:
  - the safety or physical or mental integrity of the participants in the project;
  - the project's scientific direction;
  - the conduct or management of the project.
 The Head of Department should be alerted to significant developments in advance wherever possible.

\*\*\*\*\*

### Monitoring responsibilities of the Head of Department

You agree to:

1. Review the **standard monitoring progress reports**, submitted by the Principal Investigator, and follow up any issues or concerns that the reports raise with the Principal Investigator.
2. Verify that **adverse events**, should they occur, have been reported properly and that actions have been taken to address the impact of the adverse event(s) and/or to limit the risk of similar adverse event(s) reoccurring.
3. Verify that a project is complying with any **ethics conditions** (e.g. that the information sheet and consent form approved by ethics reviewers is being used; e.g. that informed consent has been obtained from participants).
4. Introduce a form of **correspondence** (e.g. regular email, annual meeting) with a project's Principal Investigator, that is **proportionate to the project's potential level of risk**, in order to verify that a project is complying with the approved protocol and/or with any research funder conditions. Whatever correspondence is chosen the Head of Department should, as a minimum, ensure that s/he is informed sufficiently in advance about significant developments wherever possible.

**National Research Ethics Service**

**South Yorkshire Research Ethics Committee**

1st Floor Vickers Corridor  
 Northern General Hospital  
 Herries Road  
 Sheffield  
 S5 7AU

Telephone: 0114 226 9153  
 Facsimile: 0114 256 2469  
 Email: joan.brown@sth.nhs.uk

30 September 2008

Ms Rebecca Fido  
 Trainee Clinical Psychologist - Sheffield Care Trust  
 Clinical Psychology Unit  
 Department of Psychology  
 University of Sheffield  
 Western Bank  
 S10 2TP

Dear Ms Fido

**Full title of study:** Can implementation intentions facilitate completion of an activity diary following a period of stroke rehabilitation?  
**REC reference number:** 08/H1310/70

The Research Ethics Committee reviewed the above application at the meeting held on Thursday 25 September 2008. Thank you for attending to discuss the study.

**Documents reviewed**

The documents reviewed at the meeting were:

Document	Version	Date
Application		01 September 2008
Investigator CV		20 August 2008
Protocol	1	01 August 2008
Covering Letter		01 September 2008
Letter from Sponsor		06 June 2008
Questionnaire: Theory of Planned Behaviour (TPB)	1	01 August 2008
Questionnaire: Prospective & Retrospective Memory Questionnaire (PRMQ)		
Questionnaire: Nottingham Leisure Questionnaire		
Questionnaire: Hospital Anxiety & Depression Scale (HADS)		
Letter of invitation to participant	1	01 August 2008
Participant Information Sheet	1	01 August 2008
Participant Consent Form	1	01 August 2008
Confirmation of Scientific Approval		30 May 2008
Key Collaborator's CV - Jane Barton		

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority  
 The National Research Ethics Service (NRES) represents the NRES Directorate within  
 the National Patient Safety Agency and Research Ethics Committees in England

Supervisor's CV - Thomas Webb		
Instruction Sheet for Diary	1	01 August 2008
Activity Booklet & Diary	1	01 August 2008

### Discussion

It was pointed out that the protocol, participant information sheet and consent form all had a different title to that on the NRES application form. These documents should be resubmitted with the same title as the one on the application form.

Your application referred to an Activities of Daily Living Questionnaire but this was not included with the documentation. It was queried whether this was actually one and the same as the Nottingham Leisure Questionnaire. At the time of the review you were not clear about this and it was requested that you clarify this issue and confirm whether the documents are the same. If they are not, you should submit a copy of the Daily Living Questionnaire.

It was observed that you intended to measure the memory before the intervention but not after it and it was suggested that you may wish to consider this. This is only a suggestion and not a condition of approval.

There were some additions required to the Participant Information Sheet (see below)

### Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

### Further information or clarification required

- Resubmit the protocol and consent form with the correct title (Version 2 with a new date)
- Resubmit participant information sheet (Version 2 with a new date) to include the following:
  - Correct title
  - Under a heading "General information about research" insert "Independent advice can be obtained from the Patients' Advisory Liaison Service (PALs) and give their contact details"
  - Under a heading "Who has reviewed this study?" insert "The South Yorkshire Research Ethics Committee has reviewed this study. A Research Ethics Committee (REC) is a body appointed by the Strategic Health Authority. It consists of a number of members both medical and non-medical who review proposed research within the health district. Their role is to consider the ethical merits of any research, that is to say, a view is taken as to whether the potential advantages of the proposed research, outweigh significant risk to which the participant may be exposed. Research projects are not undertaken unless REC approval has been gained".
- Clarify the discrepancy regarding the Activities of Daily Living Questionnaire and the Nottingham Leisure Questionnaire if they are not the same document; submit a copy of the Activities of Daily Living Questionnaire.

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When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 27 January 2009.

#### Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. However, all researchers and local research collaborators who intend to participate in this study at NHS sites should seek approval from the R&D office for the relevant care organisation.

#### Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H1310/70

Please quote this number on all correspondence

Yours sincerely

*J Brown*

*JP* Jo Abbott  
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Research Governance Administrator, Sheffield Health & Social Research Consortium, Research Office, Fulwood House, Old Fulwood Road, Sheffield, S10 3TH

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority

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**South Yorkshire Research Ethics Committee**

**Attendance at Committee meeting on 25 September 2008**

**Committee Members:**

<b>Name</b>	<b>Profession</b>	<b>Present</b>	<b>Notes</b>
Jo Abbott	Senior Nurse Manager, Public Health, Rotherham PCT	Yes	
Dr A H Abdelhafiz	Consultant Physician, Elderly Medicine	Yes	
Reverend Joan Ashton	Co-ordinator of Chaplaincy Services	Yes	
Miss Helen Barlow	Knowledge Manager	Yes	
Professor Nigel Beal	Consultant Clinical Psychologist & Professor of Psychology	Yes	
Mr Ian Cawthorne	Chief Pharmacist	Yes	
Mr Paul Fryers	Public Health Specialist	Yes	
Dr Peter Macfarlane	Consultant Paediatrician	Yes	
Mr Neil Marsden	Police Communications Officer	Yes	
Dr Anton Mayer	Consultant in Paediatric Intensive Care	No	
Mrs Andrea Porritt	District Nurse/Practice Educator	No	
Dr Ganesh Rao	Consultant Clinical Neurophysiologist	No	
Mr Jaydip Ray	ENT Consultant	No	
Ms Stephanie Rhodes	Neonatal Sister	Yes	
Dr Saïl R. Sen	General Practitioner	Yes	
Dr Paul Spencer	Consultant Radiologist	No	
Dr Jonathan Train	Consultant Anaesthetist	No	

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority

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## National Research Ethics Service

South Yorkshire Research Ethics Committee

1st Floor Vickers Corridor  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Telephone: 0114 226 9153  
Facsimile: 0114 256 2469  
Email: joan.brown@sth.nhs.uk

27 October 2008

Ms Rebecca Fido  
Trainee Clinical Psychologist  
Sheffield Care Trust  
Clinical Psychology Unit  
Department of Psychology  
University of Sheffield  
Western Bank  
S10 2TP

Dear Ms Fido

**Full title of study:** Can implementation intentions facilitate completion of an activity diary following a period of stroke rehabilitation?  
**REC reference number:** 08/H1310/70

Thank you for your letter of 17 October 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised subject to the conditions specified below.

### Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

#### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Confirmation of Scientific Approval		30 May 2008
Key Collaborator's CV - Jane Barton		
Supervisor's CV - Thomas Webb		
Letter from Sponsor		06 June 2008
Covering Letter		01 September 2008
Investigator CV		20 August 2008
Application		01 September 2008
Letter of invitation to participant	1	01 August 2008
Questionnaire: Theory of Planned Behaviour (TPB)	1	01 August 2008
Questionnaire: Prospective & Retrospective Memory Questionnaire (PRMQ)		
Questionnaire: Hospital Anxiety & Depression Scale (HADS)		
Instruction Sheet for Diary	1	01 August 2008
Activity Booklet & Diary	1	01 August 2008
Questionnaire - Nottingham Extended ADL Scale		
Participant Consent Form	2	17 October 2008
Participant Information Sheet	2	17 October 2008
Protocol	2	17 October 2008
Letter of response to Committee's provisional letter dated 30.9.08		17 October 2008
Response to Request for Further Information		17 October 2008

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

~~This Progress and safety reports~~ This Progress and safety reports by committee to Yorkshire and The Humber Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES directorate within  
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- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

08/H1310/70

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

J Brown

PP Jo Abbott  
Chair

Enclosures: "After ethical review – guidance for researchers" SL-AR2

Copy to: Mr Richard Hudson  
Research Office, University of Sheffield, New Spring House,  
231 Glossop Road, Sheffield, S10 2GW

Research Governance Administrator, Sheffield Health & Social  
Research Consortium, Research Office, Fulwood House,  
Old Fulwood Road, Sheffield, S10 3TH

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES directorate within  
The National Patient Safety Agency and Research Ethics Committees in England

Fulwood House  
Old Fulwood Road  
Sheffield  
S10 3TH

05 December 2008

Ms Rebecca Fido  
27 Town Street Walk  
Leeds  
LS7 4NE

Tel: 0114 2718804  
Fax: 0114 2716736  
Email: [shsrc@shsc.nhs.uk](mailto:shsrc@shsc.nhs.uk)  
[www.shsrc.nhs.uk](http://www.shsrc.nhs.uk)

Dear Ms Fido

**Consortium Reference: ZK17**

**Full Project Title: Can implementation intentions facilitate completion of an activity diary following a period of stroke rehabilitation?**

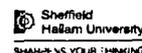
**Please find enclosed two copies of an Honorary Contract for your involvement in Sheffield Primary Care Trust in order to regularise your position with the Trust.**

**Please note that the copy of the contract marked 'file copy' should be signed and dated by you on the last page and returned to the Consortium.**

You now have **Research Governance approval from this Consortium** to carry out research as described in documentation you have supplied to us.

We also advise you of the following conditions which apply to all receiving Research Governance Approval through the Consortium:

1. Please inform us of the actual project start date immediately you do start and at that time inform us also of the expected end date.
2. In order to comply with the NHS Research Governance Framework, please copy the Consortium into all future project monitoring forms that you send to the relevant Research Ethics Committee, including the "Declaration of End of Study".
3. The Consortium recommends the attached format for maintenance of your project site file to ensure all documentation is readily accessible.
4. You will also need to seek approval for every future change to protocol or project title and I suggest you do this by sending us a draft of the submission you will also have to make to the NHS REC and that you do so at the same time as that submission to the REC. See the following web reference for details:  
[www.nres.npsa.nhs.uk/applicants/review/after/amendments.htm](http://www.nres.npsa.nhs.uk/applicants/review/after/amendments.htm)
5. The Consortium recommends the attached amendment log in order to track amendment submissions to, and approvals from, the relevant REC and R&D office(s)
6. As Chief Investigator, you have an obligation to report all research-related adverse events directly to the Consortium.



7. As Chief Investigator, you are reminded of your obligations in relation to the Mental Capacity Act 2005. See the following web reference for details:  
[www.rdforum.nhs.uk/docs/mca\\_guidance.doc](http://www.rdforum.nhs.uk/docs/mca_guidance.doc)
8. You are reminded to familiarise yourself with our partner organisation(s) Information Governance policies and procedures regarding the storage of patient-identifiable data
9. You need to seek Consortium approval for any additions to your research team not already included in documentation sent to us. For this purpose, please send a short CV, preferably in the format required by the NHS REC.
10. This Research Governance approval is given on the understanding that the findings of the research will be appropriately disseminated in peer-reviewed journal(s) and to research participants and any organisations representing their interests.

We wish you every success with the project and please feel free to contact us if you need further assistance from the Consortium.

Yours sincerely



Dr Robert Dixon  
Consortium Manager

Enc 2 Copies of Honorary Contract  
Site File Guidance  
Amendment Log

Cc Project File  
Dr Jane Barton

Ecc: Dr John Skinner

*Appendix 3*

*Letters for participant recruitment*

**3a** Initial invitation letter

**3b** Information sheet

**3c** Consent Form



Department Of Psychology.  
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy)  
Programme  
Clinical supervision training and NHS research  
training & consultancy.

**Clinical Psychology Unit  
Department of Psychology  
University of Sheffield  
Western Bank  
Sheffield S10 2TN UK**

---

Dear Sir/Madam

I would like to invite you to take part in a research study I am undertaking. The aim of the study is to see how people get on after stroke rehabilitation and consider ways to promote independence and wellbeing.

If you are interested in taking part or would like to know more about this research, please complete the slip below giving consent for me to contact you in the next couple of weeks.

Thank you for your time  
Yours sincerely,

Rebecca Fido,  
Clinical Psychologist in Training  
University of Sheffield

.....

Tear off this slip and give it to your Community Stroke Team Worker who can then pass it on to Rebecca Fido

**Consent for researcher contact**

I give permission for Rebecca Fido to contact me by telephone about the research study.

*Please put your initials in the box if you **do** give your consent and complete the following*

Signed: .....

Print Name: .....

The best telephone number to contact me on is: .....



Department Of Psychology.  
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin  
Psy) Programme  
Clinical supervision training and NHS  
research training & consultancy.

**Clinical Psychology Unit  
Department of Psychology  
University of Sheffield  
Western Bank  
Sheffield S10 2TN UK**

---

### INFORMATION SHEET

**Research Project:** The use of 'If-Then' plans for diary-keeping following stroke.

**Researcher:** Rebecca Fido, Trainee Clinical Psychologist,  
University of Sheffield

#### **What is the research about?**

Thank you for considering taking part in this study. Research has shown that keeping active and participating in social and leisure activities can be a difficult but important part of recovery and adjustment for people who have had a stroke. This study will be investigating whether a simple mental exercise can help people to plan and carry out valued activities in their daily routine once they have been discharged from stroke rehabilitation services.

#### **Who will be doing the research?**

The research will be carried out by Rebecca Fido, a Clinical Psychologist in Training, as part of her doctoral qualification at Sheffield University. She will be supervised by Professor Paschal Sheeran and Dr Tom Webb at the Department of Psychology, Sheffield University and also by Dr Jane Barton, Consultant Clinical Psychologist, Sheffield Care Trust Community Stroke Service.

#### **What will be involved if I take part in the study?**

The researcher will have first contacted you by phone to provide information about the study, arrange a time to visit you and gain your consent to send out a questionnaire for you to complete. The questionnaire involves multiple-choice tick boxes for questions about your wellbeing, daily activities and memory. The visit involves an interview with the researcher about the activities you value and what would like to do over a two week period. The interview should take less than an hour of your time and deciding what activities you want to do and when would be up to you.

To see how you get on over the two week period, you will be asked to complete a daily diary about activities and your mood. The diary also includes a simple exercise to plan activities. To test out different ways of helping people to do the diary and plan activities, we need to compare different methods. We do this by randomly putting people into two groups with different instructions for the diary and activity plans. The results are then compared to see which method is best.

After the two week period, the researcher will send the same questionnaire as before and a Freepost envelope to return the completed questionnaire along with your diary booklet.

**What are the possible disadvantages and risks of taking part?**

This study should not involve any additional inconvenience other than already described. Participants will be given details of who to contact should they become concerned or upset about any of the questionnaires or activities involved in the study.

**What are the possible benefits of taking part?**

We cannot say whether the study will help you individually but the information we get might help to improve the treatment of stroke rehabilitation patients. Some participants may find that incorporating valued activities in their daily routines has a positive effect on mood and functioning.

**Can I change my mind about taking part in the study?**

You can decide not to take part at any stage during the research. This will not affect any current or future treatment.

**Will the information I give be confidential?**

All information about your participation in this study will be kept confidential. Your name or any other identifying information will not be included in the write up of this research or shown on any of the completed questionnaire or diary sheets.

**Who has reviewed this study?**

The South Yorkshire Research Ethics Committee has reviewed this study. A research ethics committee (REC) is a body appointed by the Strategic Health Authority. It consists of a number of members both medical and non-medical who review the proposed research within the health district. Their role is to consider the ethical merits of any research, that is to say, a view is taken as to whether the potential advantages of the proposed research, outweigh significant risk to which the

participant may be exposed. Research projects are not undertaken unless REC approval has been gained.

**General information about research**

Independent advice can be obtained from the Patients' Advisory Liaison Service (PALS) by contacting the PALS Officer, Sheffield Health and Social Care NHS Foundation Trust, Fulwood House, Old Fulwood Road, Sheffield S10 3TH.  
Telephone: 0114 2718768; [PALS@sct.nhs.uk](mailto:PALS@sct.nhs.uk).

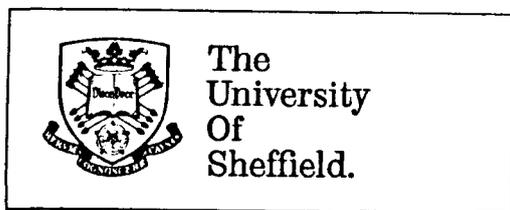
**Who do I contact if I have any questions or concerns regarding this study?**

You can leave a message at the University of Sheffield Clinical Psychology Unit for Rebecca Fido to call you back. To do this please contact Research Support Officer, Christie Harrison, on 0114 2226650.

**What if I wish to complain about the way in which this study has been conducted?**

If you have *any* cause to complain about *any* aspect of the way in which you have been approached or treated during the course of this study, please contact the project co-ordinator, Dr Thomas Webb, Psychology Department, University of Sheffield, Western Bank, Sheffield S10 2TN.

Otherwise you can use the normal University complaints procedure and contact the following person: Dr David Fletcher, Registrar and Secretary's Office, University of Sheffield, Firth Court, Western Bank, Sheffield S10 2TN.



Department Of Psychology.  
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy)  
Programme  
Clinical supervision training and NHS  
research training & consultancy.

**Clinical Psychology Unit  
Department of Psychology  
University of Sheffield  
Western Bank  
Sheffield S10 2TN UK**

**Consent Form**

**Title of Project:** The use of 'If-Then' plans for diary-keeping following stroke.  
**Name of Researcher:** Rebecca Fido

**Please put your initials in the box if you agree with the statement**

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being effected.
  
3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
  
4. I agree to the Sheffield Care Trust Stroke Rehabilitation Service being informed of my participation in the study.
  
5. I give permission for the researcher to contact me by telephone if any information relevant to the study needs to be followed up e.g. missing responses on the questionnaires.

Signature: .....  
Print Name: .....

## *Appendix 4*      *Measures*

- 4a**    Nottingham Extended Activities of Daily Living
- 4b**    Hospital Anxiety and Depression Scale
- 4c**    Prospective and Retrospective Memory Questionnaire
- 4d**    Theory of planned behaviour questionnaire
- 4e**    Diary instructions and recording sheets for both conditions
- 4f**    Implementation intention for diary keeping

### Nottingham Extended ADL Scale

The following questions are about everyday activities. Please answer by ticking ONE box for each question. Please record what you have ACTUALLY done in the last few weeks.

DID YOU .....	Not at all	With help	On your own with difficulty	On your own
Walk around outside?				
Climb stairs?				
Get in and out of a car?				
Walk over uneven ground?				
Cross roads?				
Travel on public transport?				
Manage to feed yourself?				
Manage to make yourself a hot drink?				
Take hot drinks from one room to another?				
Do the washing up?				
Make yourself a hot snack				

DID YOU .....	Not at all	With help	On your own with difficulty	On your own
Manage your own money when you were out?				
Wash small items of clothing?				
Do your own housework?				
Do your own shopping?				
Do a full clothes wash?				
Read newspapers and books?				
Use the telephone?				
Write letters?				
Go out socially?				
Manage your own garden?				
Drive a car?				

### HAD Scale

Please read each statement below and indicate how often, over the last seven days, this is true for you by underlining the statement which is closest to how you feel. Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long thought-out response.

**I feel tense or 'wound up'**

Most of the time  
A lot of the time  
Time to time, occasionally  
Not at all

**I feel as if I am slowed down**

Nearly all the time  
Very often  
Sometimes  
Not at all

**I still enjoy the things I used to enjoy**

Definitely as much  
Not quite so much  
Only a little  
Hardly at all

**I get a sort of frightened feeling like 'butterflies' in the stomach**

Not at all  
Occasionally  
Quite often  
Very often

**I get a sort of frightened feeling as if something awful is about to happen**

Very definitely and quite badly  
Yes but not too badly  
A little, but it doesn't worry me  
Not at all

**I have lost interest in my appearance**

Definitely  
I don't take as much care as I should  
I may not take quite as much care  
I take just as much care as ever

**I can laugh and see the funny side of things**

As much as I always could  
Not quite as much now  
Definitely not so much now  
Not at all

**I feel restless as if I have to be on the move**

Very much indeed  
Quite a lot  
Not very much  
Not at all

**Worrying thoughts go through my mind things**

A great deal of the time  
A lot of the time  
Not too often  
Very little

**I look forward with enjoyment to**

As much as I ever did  
Rather less than I used to  
Definitely less than I used to  
Hardly at all

**I feel cheerful**

Never  
Not often  
Sometimes  
Most of the time

**I get sudden feelings of panic**

Very often indeed  
Quite often  
Not very often  
Not at all

**I can sit at ease and feel relaxed**

Definitely  
Usually  
Not often  
Not at all

**I can enjoy a good book or radio or television programme**

Often  
Sometimes  
Not often  
Very seldom

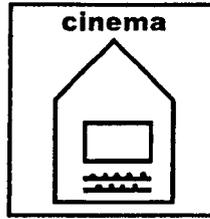
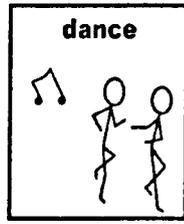
### Remembering to do things

The following questions are about minor memory mistakes which everyone makes from time to time. Please indicate how often these things happen to you by ticking the appropriate box.

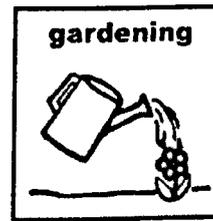
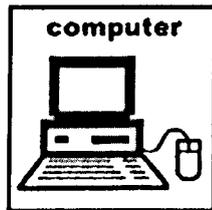
	Very Often	Often	Sometimes	Rarely	Never
Do you decide to do something in a few minutes time and then forget to do it?					
Do you fail to recognise a place you have visited before?					
Do you fail to do something you were supposed to do a few minutes later even though it's there in front of you, like take a pill or turn off the kettle?					
Do you forget something that you were told a few minutes before?					
Do you forget appointments if you are not prompted by someone else or by a reminder such as a calendar or diary?					
Do you fail to recognise a character in a radio or television show from scene to scene?					
Do you forget to buy something you planned to buy, like a birthday card, even when you see the shop?					
Do you fail to recall things that have happened to you in the last few days?					
Do you repeat the same story to the same person on different occasions?					
Do you intend to take something with you, before leaving a room or going out, but minutes later leave it behind, even though it's there in front of you?					

	Very Often	Often	Sometimes	Rarely	Never
Do you mislay something that you have just put down, like a magazine or glasses?					
Do you fail to mention or give something to a visitor that you were asked to pass on?					
Do you look at something without realising that you have seen it moments before?					
If you tried to contact a friend or relative who was out, would you forget to try again later?					
Do you forget what you watched on television the previous day?					
Do you forget to tell someone something you meant to mention a few minutes ago?					





## Activity Booklet and Diary



Study Number:  
PID:

## Using this booklet

Keeping active and participating in social and leisure activities can be a difficult but important part of recovery and adjustment for people who have had a stroke.

## Activity planning

Keeping a daily diary can help you plan and carry out activities. It will also help us to keep track of how you get on over the next couple of weeks.

Each diary sheet has three parts:

*Part 1* has a simple scale to rate your overall mood for that day

*Part 2* is to record information about any activities you have undertaken.

*Part 3* involves an exercise to help you plan an activity for the following day.

*What if I can't do the planned activity or forget?*

If you forget or are unable to do the activity and diary as planned, **DON'T WORRY** – just complete the next relevant sheet when you remember or can continue with the task. If you can, for the days you did not do the activity, it will be helpful to make a brief note stating why you did not do it. By keeping a record of the dates, we can work out how you got on and how often you were able to do the planned activity.

### Planning Activities

Think of any straightforward tasks and activities you would like to do. Make a list of these activities in the box below. You can include activities to aid recovery and adjustment, new interests and also activities you would like to do more often.

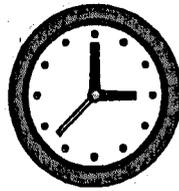
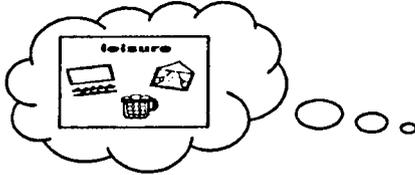
This list will help you to plan an activity in Part 3 of the diary sheets.

Activities			
 <p>music</p>	 <p>computer</p>	 <p>gardening</p>	 <p>sports centre</p>
e.g. reading a magazine, going for a walk, gardening, visiting a friend			

## Planning Activities

Use these instructions to help you to complete Part 3 of each diary sheet. This exercise is to help you to do one of your chosen activities on the following day.

First think about an activity from your list that you would like to do tomorrow. Imagine when, where and how you might do it. What would be the best time to do the activity? e.g. a specific time such as 11 o'clock in the morning, after a routine event such as lunch or if you notice that you have nothing to do or are fed-up.



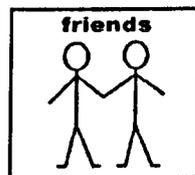
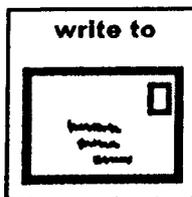
In the first example shown below someone decided that mid-morning, after they had finished breakfast was a good time to go for a walk. In the second example, someone decided that after lunch if they noticed they had nothing to do then that would be a good time to write a letter.

### EXAMPLE PLAN 1

If it is  
and I am  
and I

*mid-morning  
in the kitchen  
have finished breakfast*

Then I will go for a walk



### EXAMPLE PLAN 2

If it is  
and I am  
and I

*after lunch  
on my own  
notice that I have nothing to  
do*

Then I will write a letter to a friend.

## Activity Diary

Day: \_\_\_\_\_

Date: \_\_\_\_\_

Time: \_\_\_\_\_

### Part 1: Mood Rating

1. What was your overall mood today?

Very Negative

Very Positive



|-----|  
*Please put a mark on the line to indicate your response.*



### Part 2: Interests and Activities

2. How much have you done today?

Very little

|-----| A great deal  
*Please put a mark on the line to indicate your response.*

3. How well did you get on with any activities you planned to do today?

Not well at all |-----| Very well  
*Please put a mark on the line to indicate your response.*

4. If you did any tasks or activities that are not on your list, please state what you did in the space below:

### Part 3: Planning an activity for tomorrow

Use the instructions and examples on page 4 as a guide to help you complete the 'if-then' plan below.

**My plan to do an activity tomorrow**

**If** it is .....  
and I am .....  
and I .....

**Then** I will .....

Now please read the entire plan (from the first word **If** to the last word) back to yourself quietly at least three times. It is important to concentrate as you do this. When you can repeat the entire plan to yourself correctly without reading it, tick this box

You can use the space below to note any thoughts or feelings that you have today about doing this diary or planned activities:

### Keeping an Activity Diary

The following exercise is designed to help you complete the diary as part of your routine towards the end of each day. You can do this by making a plan to do the diary at the same time as you do something else at the end of the day (e.g. after your evening meal or after you have switched the TV off for the night).

Imagine when, where and how you might do it.

In the example below someone decided that early evening, after the 6 o'clock news was a good time to do their diary.

**Example 1**

If it is 7pm  
 and I am in the living room  
 and I have just watched the evening news  
Then I will complete the activity diary

Now make your own plan specifying when you will fill in the diary. Use the example as a guide.

**MY PLAN**

If it is .....

and I am .....

and I .....

Then I will complete the activity diary

Now please read the entire plan (from the first word **If** to the last word **diary**) back to yourself quietly at least three times. It is important to concentrate as you do this. When you can repeat the entire plan to yourself correctly without reading it, tick this box