

Regaining Confidence after Stroke – a feasibility study.

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Abstract

Background:

Stroke is a common health condition with an incidence rate of 152,000 new strokes every year in the UK. Stroke survivors frequently experience mood disorders and reduced confidence post stroke, which have a significant impact on quality of life. There is limited research providing evidence for the effectiveness of group psychological support interventions, such as the Regaining Confidence after Stroke (RCAS) programme, which aims to address low mood and confidence post stroke. This study was designed to assess the feasibility of delivering the RCAS intervention to stroke survivors (and their carers) and of completing a randomised controlled trial (RCT) to evaluate its effectiveness.

Method:

A feasibility randomised controlled trial was conducted which aimed to recruit 60 participants. Methods of recruitment, screening, and gaining consent were explored. Participants were recruited from two different recruitment sources either through postal invitation letter or by face to face invitation and provided with study information. A screening tool was used to exclude participants who did not meet the study criteria. All eligible participants provided written consent to participate in the study. Carers of participants were also invited to participate in the study. Randomisation was completed using a computer programme for

random number generation and allocation. Participants were allocated to two groups; intervention and control. The intervention participants and their carers were invited to attend the 11 week RCAS group intervention which was delivered in a community venue by a trained rehabilitation support worker and assistant psychologist. The control participants and their carers were not invited to the RCAS group. All study participants continued to receive 'usual care'. Attendance and fidelity of the intervention were measured through RCAS records, patient interviews and video recordings of the intervention. Semi structured interviews were completed with intervention group participants three months after randomisation to measure acceptability of the RCAS intervention.

Baseline and follow up questionnaires measuring mood, confidence and functional ability were completed at three and six months after randomisation with all willing study participants. Carer mood and strain were also assessed through questionnaires. Interviews were transcribed, coded and analysed using framework analysis. RCAS session video recordings were analysed against a checklist of criteria devised from the RCAS manual. Participant and carer questionnaire outcomes were analysed to describe the sample and to examine for evidence of effectiveness of the intervention.

Results:

Forty seven out of six hundred and forty (7%) people with stroke contacted were recruited into the study. Of the 47 participants, 22 were allocated to the intervention group and 25 to the control group. As 47 out of the proposed 60 participants were recruited, 78.3% of the target sample size was achieved.

The intervention was delivered to four separate groups of participants. A median of 8.1 out of the possible eleven sessions were attended by the participants. At the three month follow up 35 (77.8%) of the participants returned the questionnaires, and 30 (66.7%) were returned at the six months follow up. Of all the questionnaires sent, 38 (42.2%) were returned fully completed. The General Health Questionnaire for mood was the most fully completed by participants, with 78.5% of participants fully completing the measure. The COPE questionnaire for coping was the least fully completed with 63.1% of participants fully completing this measure.

Interviews were completed with eight of the intervention group participants. The interviews highlighted that participants enjoyed attending the intervention, and found support from sharing experiences, however there was mixed opinion on the preferred number of people attending the intervention sessions. The interviews highlighted that the majority of participants felt that the intervention had improved their mood and that the skills of the intervention leader had a key role in participant's experience of the group.

Conclusion:

The results from this study provide evidence that a definitive RCT to evaluate the RCAS intervention can be completed. People with stroke can be recruited into a study to evaluate the RCAS intervention but the return rate to postal invitations was low. They engaged with the intervention, enjoyed attending the sessions and felt that the skills of the instructor were important to the success of the intervention. The participants returned the follow up questionnaires at a high enough rate to suggest that outcome data could be collected by post. However the amount of missing data on the individual outcome measures is a concern and needs to be explored more fully.

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List of abbreviations

ADL	Activities of Daily Living
CAQDAS	Computer Aided Qualitative Data Analysis System
CASM	Confidence after Stroke Measure
CLRN	Comprehensive Local Research Network
CSI	Carer Strain Index
DH	Department of Health
GCP	Good Clinical Practise
GHQ	General Health Questionnaire
IQR	Inter Quartile Range
MRC	Medical Research Council
NCCP	Nottingham CityCare Partnership
NEADL	Nottingham Extended Activities of Daily Living
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NSF	National Service Framework
NUH	Nottingham University Hospitals

PSD	Post Stroke Depression
RCAS	Regaining Confidence after Stroke
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
R&D	Research and Development
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
SST	Sheffield Screening Test

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CHAPTER ONE

Introduction

1.1 Introduction

This chapter will describe the prevalence, effects and consequences of stroke, focusing on the psychological impact. The results of a literature review are used to describe and assess the effectiveness of psychological interventions in improving mood following stroke. The review was focused on group interventions delivered in community rehabilitation settings. The chapter concludes with the aims of the study.

1.2 Stroke

Stroke was defined by the World Health Organisation as ‘Rapidly developed signs of focal or global disturbance of cerebral function, with symptoms lasting 24 hours or longer, or leading to death, with no apparent cause other than vascular origin’ (World Health Organization, 2012)

Stroke is a sudden and devastating health condition with figures from the Stroke Association in 2013 stating that there are 152,000 strokes in the UK every year and approximately 1.1 million stroke survivors living in the UK (Stroke Association, 2013). Globally, it is estimated that there are 4.5 million deaths a year from stroke and over 9 million stroke survivors, with stroke being the leading cause of adult disability (Wolfe 2000).

1.3 Effects of stroke

NICE (the National Institute for Health and Care Excellence) described the range of impairments experienced following stroke as numerous and that they can include difficulties with Activities of Daily Living (ADL), depression and anxiety, and speech and communication difficulties (NICE clinical knowledge summaries 2013).

The range of impairments resulting from a stroke depends on which blood vessels supplying the brain are affected and the type of interruption to the blood supply (either ischaemia or haemorrhage). The resulting damage to the brain tissue due to a lack of oxygen causes stroke symptoms such as physical impairment (loss of balance, mobility and function) (Hellstrom et al 2003, Langhorne et al 2009), speech and language problems and cognitive impairment (Langhorne et al 2011).

In addition to physical limitations, Whyte and Mulsant described how stroke has a major impact on survivors due to a loss of both health and social role functioning (Whyte and Mulsant 2002).

Stroke survivors report a varied path of recovery from stroke, with the process of restructuring life after stroke incorporating physical social and emotional issues (Burton 2000). Although physical recovery following stroke can happen rapidly within the first few months, it can take several years for stroke survivors to accept the long term impact of

stroke on their lives and make the necessary psychological adjustments (Townsend 2003).

It is recognised that psychological support needs after stroke can often go unrecognised, which can have a significant effect on stroke survivors ability to adjust to and cope with the consequences of stroke (McKevitt 2011). Furthermore there is a significant cost associated with stroke in the UK. Saka et al (2009) found that stroke accounts for around 5% of the total UK NHS costs. They calculated that the total societal cost of stroke in the UK (which includes direct care, income loss and benefits payments) was in the region of £8.9 Billion a year.

1.4 Emotional problems after stroke

Emotional problems following stroke include depression and anxiety (Lincoln, Kneebone et al 2012). Psychological distress such as depression and anxiety following stroke, results in mood problems and can severely impact stroke survivor's daily lives (Thomas and Lincoln 2008).

In 2005 Hackett performed a systematic review of the frequency of depression following stroke and reported that as many as a third of all stroke survivors experience depressive symptoms at some point post stroke (Hackett, Yapa et al. 2005). Furthermore, the 2013 NICE 'long term rehabilitation after stroke guidelines' highlighted that mood disorders such as depression and anxiety occur frequently after stroke

and the authors identified that this causes distress to people with stroke, and their families and carers and can adversely affect outcomes (NICE 2013).

In 2011, Korpershoek described how Post Stroke Depression (PSD) was associated with poor rehabilitation outcomes and an impeded recovery process for stroke patients (Korpershoek, van der Bijl et al. 2011). The authors found that there were important consequences of PSD including lower functional status, slower functional recovery, higher morbidity, less participation in social activities, and a lower quality of life (Hackett and Pickles 2013, Korpershoek, van der Bijl et al. 2011). A study by Hafsteinsdottir in 2007 indicated that patients were often not able to cope with the psychosocial consequences of stroke even if they made a good physical recovery (Hafsteinsdottir 2007). She also recommended early assessment and identification of depression after stroke stating that timely treatment of depression improves functional status and overall recovery, including health related quality of life (Hafsteinsdottir 2007). There is an acceptance, then, that addressing patient's emotional needs following stroke is paramount and that providing some form of psychological intervention post stroke is essential (Vohora and Ogi 2008).

In addition stroke survivors have highlighted the need for research into the psychological effects of stroke and national surveys have reported that patients living in the community regard psychological support as an

unmet need (Radford 2008). A systematic review in 2005 by Hackett, Yapa et al found that few stroke patients receive effective management for their depression. Standard treatments provided by primary care services included anti-depressant medication and psychological therapies (cognitive behavioural therapy), but evidence of their effectiveness was limited (Hackett 2006). Whilst there has been research into medical management of post stroke depression, few studies have considered the use of psychological interventions in the treatment of depression following stroke (Lincoln and Flannaghan 2003).

1.5 Interventions to prevent psychological distress after stroke

A literature review of psychological interventions to manage post-stroke depression concluded that the research is preliminary and unsophisticated (Kneebone 2000). Lincoln et al (2012) suggest that it is better to aim to prevent development of mood disorders post stroke rather than to wait for them to develop and then treat them and state that by reducing likelihood of psychological distress, onset of anxiety and emotional difficulties can be avoided. The following are approaches to addressing the prevention of psychological distress after stroke:

1.5.1 Rehabilitation

Rehabilitation is defined as:

‘ a process of assessment, treatment and management by which the individual (and their family/carers) are supported to achieve their maximum potential for physical, cognitive, social and psychological function, participation in society and quality of living’ (NHS England, 2014).

Providing specialist stroke rehabilitation by a multidisciplinary team on a stroke unit has been found to reduce levels of psychological distress (measured by the General Health Questionnaire [GHQ-28]) and improve adjustment to life following stroke at 6 months (Juby, Lincoln and Berman 1996). Juby et al suggested that both the increased intensity of treatment and the presence of a clinical psychologist in the Multi-Disciplinary Team (MDT) increased engagement in rehabilitation (Juby et al 1996). Since inactivity can be linked to low mood (White et al 2008) this could explain the reported better outcome in mood.

1.5.2 Problem solving interventions

A randomised control trial by Forster and Young (1996) evaluated an intervention based on an enabling model and counselling which was delivered by specialist nurses in a community setting. The intervention provided training for stroke survivors around problem solving and goal setting as well as the provision of information booklets and advice.

Although it is recognised that provision of information improves mood

(Hunt and Smith 2004), the Forster study did not demonstrate significance difference on the Nottingham Health Profile assessment, which is a valid and sensitive measure of perceived health (Hunt et al 1980). Later qualitative evaluation, however, indicated that participants had found the intervention useful and had facilitated emotional adjustment for some people (Dowswell et al 2000).

A further study by Goldberg et al (1997) incorporated a problem solving approach, using a multidisciplinary team to deliver weekly phone contact, monthly home visits and home based therapy as required. The intervention (Stroke Transition after Inpatient Rehabilitation [STAIR]), provided information and support in order to identify and address psychosocial stressors. The study demonstrated positive qualitative feedback and higher activity levels but no conclusive demonstration of improvement in general health or quality of life.

1.5.3 Motivational interviewing

A review of non-drug strategies to resolve psychosocial difficulties after stroke was performed by Knapp et al (1999) but the findings were largely negative for the interventions reviewed (provision of information and education, leisure therapy, support workers and counselling). As a result of this review Watkins identified the need to explore alternative approaches to addressing psychological issues after stroke and designed a randomised control trial to evaluate the use of

motivational interviewing at an early stage after stroke (Watkins et al 2007). Motivational interviewing is a specific talk based therapy used to make changes in health behaviour through improving motivation (Miller et al 2002). In the study the technique was used to encourage patients to make psychological adjustments and practical adaptations in order to increase confidence and identify realistic personal recovery goals. The study reported beneficial effects on mood using the GHQ-28 although no effect on functional activities (Barthel). The intervention was delivered at an acute stage post stroke and depended on a high level of psychology based specific training for staff delivering the intervention.

1.5.4 A review of reviews of coping and psychological support post stroke

There are a limited number of systematic reviews considering the benefits of psychological support post stroke. For those that are available the student has reviewed the review findings. Reviews that were reviewed are discussed individually:

Cochrane review by Hackett et al 2008 considering interventions for the treatment of depression – this review aimed to determine if pharmacological, psychological and electroconvulsive therapies (ECT) were effective in improving stroke outcomes. The review included RCTs which compared drug therapies with placebo or those that compared psychotherapy or ECT with standard care and which had the intention of treating depression. Of the 16 trials included in the study only 4

looked at psychotherapy interventions. The interventions included problem solving therapies with counselling, CBT, motivational interviewing a supportive intervention which included education. Hackett found it difficult to compare the interventions as they were diverse in their content and delivery and used a wide range of outcome measures to establish effectiveness. The conclusion was that there was no evidence of benefit.

Cochrane review by Hackett et al 2008 considering interventions for preventing depression – this review included 4 RCTs which compared psychotherapy against standard care in stroke patients up to seven months post stroke. The interventions included had to have a direct interaction between patients and professionals around any type of psychological therapy. It excluded studies that only considered information giving or leisure therapy as the intervention. It included studies offering a problem solving, adjustment, or talk therapy based approach. The review concluded that there was a small but significant benefit in using psychological therapies and that they improve mood and may prevent depression as measured by a reduction in a psychological distress score (GHQ28). However, Hackett recognised that there were narrow inclusion criteria in most of the studies making the sample sizes small and the generalisability of the findings limited. Overall there was limited evidence to support the use of psychological therapies in preventing depression post stroke.

Donellan et al 2006 reviewed studies that used coping strategies to impact on psychological adaptation to stroke – this review identified 14

studies and sought to evaluate measures that's quantify coping strategies in stroke and to identify which coping strategies are typically used in the stroke population. Donellan described that from the literature there are two widely accepted coping strategies recognised; problem solving strategies and emotionally focused coping strategies (Taylor 1990, Affleck 1996, Roth 1986). Donellan describes that coping skills are a key psychological resource to rebuild the impact on lives of the deficits caused by stroke. This review identified conflicting findings on the use of problem solving vs emotion focused strategies and highlights the scarcity of research on the processes of coping post stroke.

Broomfield et al 2010 reviewed the evidence base for the use of CBT in post stroke depression – this review identified three studies .The first by Lincoln et al in 1997 was a small pilot which demonstrated some benefit in half the sample and a further small study by Rasquin et al in 2009 showed some inconsistent improvement in mood. The third study included was a follow up study by Lincoln et al in 2003 which included larger numbers of participants and was an RCT but did not identify any difference between the groups. Broomfield identified some limitations in the studies including sample size in the smaller studies and the short duration and low intensity of the intervention across all studies. The review also raises questions that in Lincolns later study the intervention was not delivered by an experienced CBT therapist and there may have been some contamination as the same person delivered the intervention and the control interviews. Broomfield concluded that whilst

these studies do not demonstrate the effectiveness of CBT as a treatment for post stroke depression, the weakly positive findings in two of the studies alongside the limitations of the studies may indicate a need for further definitive trials.

Lennon et al 2013 reviewed the evidence for self-management programmes specific to stroke – this review included 15 studies where participants had a diagnosis of stroke and in which self-management interventions were explored. Self-management was defined as an individual's ability to manage the symptoms and physical and psychological consequences of living with a chronic disease. The purpose of a self-management approach was identified as a method of training individuals to change their behaviour and influence their ability to make adaptations and cope with their health and social care issues. There was a varied content found to the approaches used in the studies, with some using self-efficacy theory, but others not describing any theoretical basis to the intervention used. The sample sizes were generally small and the content and delivery methods variable. Although a significant treatment effect was found in 9 of the studies relating to measure of disability, confidence in recovery and quality of life, Lennon concludes that the optimal content, timing and delivery of such an intervention remains unclear.

Jones 2011 reviewed the influence of self-efficacy on stroke outcomes – this review included 22 studies considering two factors. Firstly the influence of self-efficacy on rehabilitation outcomes post stroke and secondly the evidence to support self-management interventions based

on self-efficacy principles for stroke survivors. Self-efficacy is based on people's beliefs about their capabilities (Bandurra 1977) and resonates with stroke patient's ability to sustain progress and cope with setbacks. The review considered studies which tested the relationship between self-efficacy and stroke rehabilitation outcomes and considered a range of interventional and observational studies using quantitative measures. The review concluded that there is some evidence that self-efficacy is associated with improved outcomes post stroke including quality of life, depression and function but more research is required.

Knapp 2000 reviewed trials aimed at specifically improving psychosocial outcomes after stroke – this review included 12 trials which were all of a randomised design. There was a range of interventions delivered in the studies including interventions based on information provision and education, leisure therapy, counselling and stroke support workers. Several limitations to the review were identified including the variations in timing, intensity and intervention type and the small size of most of the studies. In some studies intervention was delivered by therapist not trained in psychological interventions and in some studies the intervention was not based on an explicit psychological theory. There was also a possibility that as some of the studies took place in integrated stroke services there may have been good holistic standard care that it would be more difficult to demonstrate the effects of an intervention. Knapp concludes that the review does not establish ineffectiveness of psychosocial interventions but that it highlights that existing studies provide little evidence to

support its effectiveness and there is a need to conduct further research.

Legg 2011 Cochrane review of an evaluation of the effectiveness of interventions targeted to informal carers of stroke survivors or targeted to care givers and stroke survivors – this review considered 8 RCTs of non-pharmacological interventions to reduce care giver demands or stress. It included any type of intervention delivered by any professional through any delivery method. This included studies focusing on education and counselling, and those which reduced the responsibility for care giving through the provision of external support. All studies measured a reduction in carer stress, strain or wellbeing. Only one single centre small study demonstrated a significant change, which was a study considering provision of vocational education to caregivers prior to the stroke survivors discharge from hospital. Legg identified difficulty in characterisation of the target population since there were no demographic criteria to provide heterogeneity of participants. Legg concluded that no conclusions for clinical care could be drawn from the review.

1.6 Group Interventions aimed at providing psychological support following stroke

There have been few studies which have evaluated interventions delivered as a group to prevent psychological distress (Lincoln, Kneebone et al 2012), yet it is known that stroke groups can play an important role by providing an enjoyable social gathering, an opportunity to feel understood by others, a normalisation of their experiences and post stroke way of life, and a source of providing practical tips (Ch'ng et al 2008). Ch'ng completed a qualitative study that used focus groups to identify coping mechanisms in a group of stroke support members and found that helpful strategies described by participants centred around three core themes; social support, active / behavioural strategies and cognitive strategies. The stroke survivors also reported that there was insufficient attention paid to their emotional needs during the process of recovery and that support was often difficult to access.

Whilst Ch'ng's work identified the value of stroke support groups there is a need to consider the value of more specific group interventions aimed at helping survivors cope with psychological difficulties post stroke. This was recognised by Vohora and Ogi, who described a lack of literature on group interventions with stroke patients at the rehabilitative stage (post-acute phase) (Vohora et al 2008). They developed an inpatient group aimed at normalising reactions and emotions experienced by

stroke survivors through encouraging discussion in the group and sharing of experiences. Feedback indicated that patients valued sharing experiences but minimal conclusions can be drawn since this was only a pilot study with a small sample size of six participants. The author concluded that it provides evidence of the crucial need to address patients emotional needs post stroke and to provide psychological intervention.

A study by Barton et al in 2002 described a seven session psychological programme designed to support patient's psychological adjustment to stroke through sharing and processing experiences in a group setting. The programme was delivered through weekly sessions and covered personal experiences, stroke information, rehabilitation and goal setting, coping with feelings of loss and anger and moving on. Although the authors report that ratings for feelings of coping showed positive change and initial feedback was positive, they state that a more thorough and systematic review is needed (Barton et al 2002).

Gurr recognised the need for ongoing research into the effectiveness of psychological treatments for stroke patients and developed and trialled an emotional support group (Share Your Story) for stroke survivors (Gurr 2009). The group was designed to enable the sharing of thoughts and feelings related to the stroke and to provide a safe environment for mutual support. Share your Story was developed in response to the National Service Framework for older people (DH 2001) which

acknowledged the significant impact of stroke on people's lives, and the National Stroke Strategy (DH 2007) which set out a standard to deliver emotional support throughout the stroke pathway. Share your Story was an inpatient group intervention that was developed at Poole hospital stroke unit for stroke patients in the early stages of recovery. The aim was to enable sharing of thoughts and feelings, provide a safe environment for emotional support, and to optimise peer support. The group did not demonstrate a significant improvement in participant's moods but the length of intervention was very short (two to three weeks) due to the high turnover of patients in the acute hospital.

1.7 Regaining Confidence after Stroke programme

Confidence is one component of psychological distress (Stone 2004) and low levels of confidence have been shown to be associated with not getting out of the house (Logan 2004) which in turn causes stroke patients to miss hospital appointments, doctors' appointments, attendance at stroke clubs, luncheon clubs and visiting family and a loss of self-identity (Clarke 2005). In a study by Horne et al (2014) which explored the meaning of confidence, several themes were identified: loss of identity, fear, social confidence, role confidence, mastering skill and attitudes and belief. It was clear that confidence is a multi-faceted and complex phenomenon, but furthermore that it has significant impact on the lives of stroke survivors. There is little literature addressing the management of confidence in stroke rehabilitation.

Self-efficacy is a psychological construct likened to perceived confidence and can be defined as ‘the belief in ones capabilities to succeed in a particular situation’ (Bandura 1997). Bandura explains the theory of self-efficacy as being confident in a number of skills and that mastery of new skills develops individual’s confidence in their ability to learn and hence an increase in their efficacy.

In 2003 the Regaining Confidence after Stroke (RCAS) programme was developed by Stella Townsend (consultant clinical psychologist) for Telford and Wrekin NHS Primary Care Trust. This programme had similar objectives to Barton’s programme (Barton 2002) targeting long term recovery in the community by encouraging communication between stroke survivors and sharing of similar problems.

The ‘Regaining Confidence after Stroke’ (RCAS) course was designed for community stroke patients to help them adjust to the effects of stroke and to teach strategies to cope with anxiety and depression (Townsend 2003). The course aims to encourage stroke survivors to use coping mechanisms already available to them alongside structured support from others in a similar situation in order to promote psychological recovery and adjustment post stroke. The programme is community based and encourages self-management through communication between people with similar problems. It encourages stroke survivors to move away from reliance on professionals for

support (e.g. therapists) and to use the opportunity for sharing information and support with other stroke survivors to develop the knowledge and skills necessary to become capable in leading their own lives once more following stroke.

Townsend (2003) developed the RCAS intervention manual for group leaders to guide them through the delivery of this 11 week course for stroke survivors and their carers to help them adjust to the effects of a stroke, to teach strategies to cope with anxiety and depression and to increase confidence levels. The manual was updated in 2009 (Townsend 2009). The manual describes a programme that is delivered weekly in the community where each session lasts around two hours and is delivered to a closed group, facilitated by a group leader. Townsend recommended that the course is delivered by any staff member working with stroke survivors who has at least one year's experience of providing specialised stroke care. Alternatively it can be delivered by a stroke survivor who has previously attended the course. She also recommended that the course leader is accompanied by a second person for support and that the leader was skilled in leading group discussion and was able to be organised and directive. At the UK Stroke Forum Conference in Harrogate UK in 2013 several NHS clinicians reported delivering the RCAS intervention. Delivery of the intervention was reported by NHS staff from Derby, Nottinghamshire and Shropshire.

Feedback from stroke survivors who have attended the course has been reported as positive, for example there was a small study completed by Ford and Foley (2008) who reported an increase in confidence and mood in 12 stroke survivors who participated in the course (unpublished, cited in Lincoln et al 2012). However, there is a lack of evidence for the effectiveness of the RCAS intervention. There is a need to undertake further research to determine if the intervention is of clinical benefit to stroke survivors. In order to establish this, the MRC framework for evaluating a complex intervention (Medical Research Council 2008) recommends first completing a feasibility study. The aim of feasibility studies are to clarify the design parameters required for a randomised controlled trial (RCT) and test the feasibility of implementing the intervention in a clinical setting. Feasibility studies commonly aim to establish a sample size calculation, test the integrity of the study protocol, test methods for recruitment and data collection, determine acceptability of an intervention and select the most appropriate outcome measure (Lancaster 2004). The MRC originally published guidance on developing, piloting, evaluating, reporting and implementing a complex intervention in 2000 and this was updated in 2008. The updated guidance identified that it was a lengthy process which rather than being a linear process was more cyclical. The framework describes a complex intervention as having several interactive components, for example a number of different elements within an intervention package, variability in outcomes or variation in the target population. The framework also highlights the need to

understand a whole range of effects and possible causes of variation.

The process seeks to identify how a complex intervention works by

asking 'what are the key ingredients?' The stages include:

- Development of the intervention
- Feasibility and pilot testing
- Implementation
- Evaluation

These stages may be repeated several times within the process, for example the intervention may be developed through a series of pilot studies which develop the intervention and explore the design of study methods which evaluate the intervention. The intervention should be developed to a stage where a worthwhile effect can be expected before substantial evaluation takes place, which may be established through searching relevant literature and identifying expected change.

Feasibility testing of the intervention can be established through testing acceptability, recruitment and retention rates and sample size calculations. It would be usual to achieve this through a series of pilot studies involving a mix of qualitative and quantitative research methods.

This feasibility study was investigating an intervention that can be classified as being complex when considered against the MRC criteria for complex interventions. There were a number of different elements to the intervention as it involved interactions with stroke survivors and their carers as well as delivering a programme of discussion and problem solving in accordance with a manual. Additionally there was an expected variation in the target population due to the complex nature of

the condition of stroke and is considered complex as it can be delivered by a number of different professionals. The intervention was already developed but had been designed several years ago and the acceptability of the intervention had not been explored. The feasibility study sought to explore issues around fidelity of delivering the intervention, compliance with attendance and patient experience of the intervention. A range of qualitative and quantitative data were collected to explore these factors. In addition the feasibility study incorporated a literature review of the intervention in order to identify any evidence base for the intervention. The study provided information to inform future studies of the intervention in terms of sample size, recruitment methods and rates, and follow up data collection methods – this is in line with the best practise advised in the guidance of a systematic and phased approach to testing of complex interventions. The study fits into the MRC framework for evaluation of complex interventions by contributing to the development and feasibility stages of the process. Further feasibility / pilot testing of the intervention is likely to be required and there may be a recommendation for further development of the original intervention going forwards. There is sporadic use of the intervention in clinical practise currently and there is a need for further evaluation of the effectiveness of the intervention before wider implementation could be recommended.

1.8 Context of the study

The MPhil student was a co-applicant on a successful grant application for Research Capability Funding to deliver feasibility randomised controlled trial of RCAS. The student was the lead researcher in delivering the study. The student worked with the wider research team, which comprised academics, clinicians and a stroke survivor as part of a project group. The student was actively involved in developing the study protocol, methodology, analysis, dissemination of results and future research plans. The student was responsible for all study procedures which included organisation of the sending of study invitation letters to participants and for screening processes to identify that inclusion criteria had been met. The student recruited participants to the study, completed baseline and follow up questionnaires with participants, interviewed participants, managed the data, analysed the data, wrote interim reports and presented the data at conferences. The student independently analysed all data collected during the study. The student did not deliver the intervention for the study. The feasibility randomised controlled trial (ref.14452) was delivered in Nottingham between April 2013 and August 2014.

1.9 Aims of the study

Since feasibility studies provide information in the planning and delivery of a Randomised Controlled Trial (RCT), a clear identification of study aims and objectives is essential (Lancaster 2004). The aim of this study

was to determine whether it is possible to run a RCT in order to evaluate the clinical and cost effectiveness of the RCAS course. The study objective was to determine the research parameters required to deliver an RCT. The specific study aims therefore were:

1. To determine a suitable sample size for a RCT
2. To identify likely recruitment rates and preferred recruitment methods
3. To test whether the intervention can be delivered in accordance with the manual instructions (fidelity)
4. To identify the acceptability of the intervention
5. To identify the most appropriate primary outcome measure for a future study

CHAPTER TWO

Methods

2.1 Research design

A randomised controlled design was considered the most appropriate method for this feasibility study. Randomized controlled studies are seen as the gold standard for assessing the effectiveness of therapeutic agents (Byar 1976) because of their ability to minimise bias and avoid false conclusions. Random assignment of individuals to different treatment groups is the best way of achieving a balance between groups for the known and unknown factors that influence outcome (Stephenson 1998). Randomisation seeks to balance out external influences between groups so that the true effect of an applied intervention is detectable (Stephenson 1998). By randomly allocating participants to different treatment groups the results of the two groups can be compared against each other when using measurable outcomes (Jadad 1998). Randomisation ensures that every member of the target sample has an equal chance of being selected for the intervention.

There are different methods of randomisation including using random number tables and computer generated programmes. Using randomisation to allocate participants to intervention or control groups results in a decreased chance of outcomes being distorted by individual differences as such differences will be evenly distributed across the two groups.

Group interventions such as RCAS are accepted as complex interventions (Campbell 2000), that is interventions that include several

components. Evaluation of complex interventions requires use of qualitative and quantitative evidence (Campbell 2000). This study therefore used quantitative analysis alongside qualitative data to evaluate the intervention.

To gather data on the acceptability of the RCAS intervention semi structured one to one interviews were chosen as the preferred method since this style of open ended questions facilitates gathering as much information as possible about people's experience of the intervention (Cresswell 2008).

It was acknowledged that there were a variety of methods available to collect qualitative experience data, including interviews, focus groups and observations. The choice of data collection depends on the research question that is to be answered and practical considerations including resources, time, and characteristics of the sample (Ritchie 2014). Ritchie states that 'Interviewing is a core and effective method of qualitative data collection'. One to one interviews enable an in depth and personal insight into people's feelings and experiences through verbal communication (Layder 2013; Ritchie 2014). Since communication difficulties can be one of the symptoms of stroke, it was felt that an individual interview rather than focus group approach was more appropriate for participants.

2.2 Recruitment

2.2.1 Identifying Participants and Carers

Participants were recruited through three different methods which allowed exploration of different recruitment routes. These were:

1) Nottingham University Hospitals (NUH), which was approved as a Participant Identification Centre (PIC) by Trent CLRN. Invitation letters were sent to stroke survivors identified through the NUH stroke database who were registered with a Nottingham City GP, and had been discharged alive from the hospital stroke wards in the last two years.

2) Nottingham CityCare Partnership (NCCP), which is a community stroke rehabilitation provider service. They sent letters to stroke survivors who had used the community stroke service within the last two years.

3) Nottingham CityCare community stroke service rehabilitation assistants, who invited patients to take part at the point of discharge from the routine rehabilitation service by face to face invitation.

It was decided to target recruitment from stroke survivors who had accessed services during the last two years as it was anticipated that two years was recent enough for potential participants not to have moved out of area, died or become unwell with other co-morbidities.

An invitation letter was sent by post to stroke survivors from recruitment source one and two. The letter contained a tear off slip to complete and return with name and contact details of potential study participants who wished to express an interest in finding out more about the study. A stamped addressed envelope was provided for return of this information as well as the researcher's telephone and email contact details being provided as another method of expressing interest in the study. A copy of the letter sent out to patients from NUH and NCCP can be found in Appendix A.

For recruitment source three, stroke survivors attending a group exercise programme known as StrokeAbility, were approached face to face and given the same invitation letter. They were asked to express an interest in finding out more about the study either verbally at that time or by completing the tear off slip.

The number of patients approached through each recruitment source was recorded and the methods of reply to the invitation letter were also recorded. All respondents to the invitation letters were contacted by telephone by research assistant (KH) or research assistant (JS) and screened on the telephone using a checklist of inclusion criteria. The inclusion criteria are listed and discussed in section 2.2.3. A copy of the telephone screen check list document can be found in Appendix B. The numbers of stroke survivors excluded during telephone screening were recorded. Reasons for exclusion were also recorded.

2.2.2 Sample size

As this was a feasibility study no formal sample size calculation was completed. There was no requirement to power this study as the aim was not to compare outcomes of the intervention and control groups and identify significant difference. The feasibility study focused on whether it would be possible to run a definitive RCT and the design parameters for such a study. The target recruitment number was 60 participants which exceeds the recommended sample size of 30 or greater in pilot studies (Lancaster 2004). This target enabled us to run four RCAS groups with around eight people in each group. This was compliant with the recommendation in the RCAS manual that groups should be delivered to between eight and twelve participants (or less if participants had additional communication support needs) (Townsend 2003). Running several smaller groups also enabled delivery of several different groups to allow a broader range of data to be collected.

2.2.3 Participant criteria

The inclusion criteria were:

1. People with a clinical diagnosis of stroke
2. People who were able to give informed consent
3. People who had been discharged from all other rehabilitation therapies
4. People who were not involved in trials of other psychological interventions

5. Stroke survivors had not previously attended the RCAS course as this may have affected their expectations of the outcome
6. Stroke survivors over the age of 18 as the intervention was developed for adults rather than children

The criteria ensured that all participants had been confirmed as having had a stroke and that potential participants were able to understand the study and be able to provide verbal consent in accordance with GCP guidelines (NIHR 2014). It was necessary to ensure that participants were not receiving other active therapy to avoid contamination of both the intervention and control participants. Criteria three was also chosen in line with the RCAS programme intention to aim it at stroke survivors during the time that discharge from all therapies occurs to help prepare people to continue their own recovery without dependence on health professionals such as therapists. Patients needed to be exclusively involved in this study as participation in other trials of psychological therapy could affect the outcomes of this study and also increase the burden on participants.

If inclusion criteria were met an appointment was made to visit the stroke survivor at home and an information sheet about the study was posted to them. This information sheet can be found in Appendix C. During the home visit the study was explained further, any questions answered, and a screening tool document for identifying exclusion

criteria was completed to confirm eligibility for the study. This can be found in Appendix D.

The exclusion criteria were:

1. Dependency on others for personal activities of daily living as indicated by a score of less than ten on the Barthel Index (Mahoney and Barthel 1965)
2. Unable to verbally communicate as indicated by a score of less than eight on the Sheffield Screening test (Syder 1993)
3. People who did not speak enough English to enable them to be able to participate in the intervention, assessed by the research assistant at the home visit appointment

The reasons for choosing these exclusion criteria were as follows:

As the RCAS intervention was delivered in a group setting in a community venue with only two leaders it was deemed impossible for this study to be safely able to accommodate a patient who needed help with personal activities, such as getting to the toilet. A Barthel score of ten indicated sufficient functional ability to attend to personal activities of daily living at a community group. As the RCAS intervention consists of group activities where participants work together on tasks and support each other through talking, it was not appropriate to recruit any stroke patients who could not communicate sufficiently to actively participate, either due to speech and language difficulties or not

speaking English as a first language. The numbers excluded through these criteria were recorded.

2.2.4 Consent

If respondents were eligible for the study they were given a further copy of the study information (Appendix C) which was discussed with them and any questions or concerns were answered. If respondents were willing to give consent to participate in the study they were asked to provide written consent. This was done by completion of a consent form, a copy of which can be found in Appendix E. Since the study information sheet had already been provided by post prior to the appointment and the potential participants had been able to ask questions on the telephone it was appropriate to take written consent at this appointment. If respondents were not eligible the reasons were explained and they were thanked for their time and not included in the study.

Eligible respondents who provided consent were asked if they would like their carer to be invited into the study, as two of the RCAS sessions include carer's attendance. Carers were only invited to attend once the stroke patient's eligibility had been confirmed and they had consented both to the study and their carer being approached for inclusion into the study. Carers were considered appropriate if the participant identified them as their carer. There were no inclusion or exclusion criteria for

carers. Carer study information sheets (see Appendix F) were sent by post prior to the home visit appointment at the same time as the participant study information sheet. A further copy of the study information sheet was provided at the home visit which was discussed with them and any questions or concerns were answered. If carers were willing to give consent to participate in the study they were asked to provide written consent for participation in the study. This was done by completion of a consent form, a copy of which can be found in Appendix G. If there was no carer or the carer declined to participate this did not exclude the stroke patient from participation in the study.

2.3 Assessments

2.3.1 Baseline

Characteristics of the participants were collected by a research assistant in the participant's home after consent had been given. Age, gender, and number of months since stroke were recorded. General health information (past medical history, functional ability) and social history (living alone, next of kin) were also taken at this point to ensure that the group leader had sufficient participant information to run the intervention safely.

Baseline outcome measures were completed with all consenting participants. The research assistant read out the questions and

answers as they were presented in the battery questionnaire and filled in the answer indicated by the participant. If participants preferred to self-complete the questionnaire this was allowed. A variety of assessment measures were chosen to be used in this feasibility study.

Measures completed with participants were:

- Independence in activities of daily living ability was measured using the Nottingham Extended Activities of Daily Living (NEADL) - a ranked assessment scale for ADL's that are important to stroke patients who have been discharged home (Nouri and Lincoln 1987). The Nottingham Extended Activities of Daily Living Scale is a scale of 22 activities which was designed to be a self-reported measure of instrumental ADL activities in community stroke patients. During development of the measure test-retest data analysis demonstrated an acceptable reliability for the measure to be used as a postal questionnaire for stroke patients living at home. (Nouri and Lincoln 1987). Further testing of the measure in a study by Lincoln and Gladman in 1993, looked at the validity of the NEADL using scores from a large study (DOMINO) comparing domiciliary and hospital rehabilitation for stroke survivors. They concluded that the data endorsed the validity of the measure and its ability to detect differences in outcomes in the stroke population. A study of community Occupational Therapy for stroke patients by Walker

(2004) showed that the NEADL score is sensitive to demonstrating change in community stroke patients. Since the RCAS intervention aims to improve confidence to do activities, the NEADL was deemed an appropriate measure as a change in the NEADL score would suggest increased activity which could be attributed to increased confidence. The NEADL is a 22 question assessment which asks about every day activities and for participants to rate whether they have completed these activities in the last few weeks on a scale from 'not at all' to 'on my own'. A numerical score is associated with each response as follows:

Not at all = 0

With help = 0

On my own with difficulty = 1

On my own = 1

The highest total possible score for this questionnaire is 22 where the higher the score, the more able in everyday activities a stroke survivor is.

- Ability to use appropriate coping strategies was measured using the COPE inventory- Coping Orientation for Problem Orientated Experiences (Carver, Scheier and Weintraub 1989). The COPE

was developed as a multidimensional coping inventory to assess different ways of coping by Carver and Scheier in 1989. It was one of only a few tools available to assess coping strategies; as identified through a study by Donellan and Hevey (2006). In stroke, the assessment of how patients deal with the emotional effects of stroke focuses on their coping mechanisms and ability to adjust emotionally (Lincoln book). It was therefore appropriate to include a measure of coping in the feasibility study as the intervention aims to improve confidence through a variety of mechanisms including sharing coping strategies. The student accepts that there is little data on the psychometric properties of the measure. Although Carver and Scheier did claim good test retest reliability of the tool when it was developed this has been questioned in a study by Lyne and Roger (2000) suggesting the original analysis of reliability is unstable. A further study by Gregorio et al in 2014 did a systematic review of coping assessment tools after acute brain injury and found that although there was little information on psychometric properties of the tools reviewed, the COPE came out the strongest. Its psychometric properties have not been established to support the wider use of the tool in stroke. The measure was included in the study in the knowledge that it had limitations but in the hope that a measure of coping as an exploratory measure would provide additional useful data.

The COPE is a 60 question measure which asks about how people deal with stress by asking participants to identify what they usually do in stressful events. Responses are chosen from four possible options:

I don't usually do this at all (1)

I usually do this a little bit (2)

I usually do this a medium amount (3)

I usually do this a lot (4)

Participants identify their response by recording the associated number against each question. The inventory incorporates 15 conceptually distinct scales which are scored separately. The scales are:

COPE 1: Active Coping

COPE 2: Planning

COPE 3: Seeking Instrumental Social Support

COPE 4: Seeking Emotional Social Support

COPE 5: Suppression of competing Activities

COPE 6: Turning to Religion

COPE 7: Positive Reinterpretation and Growth

COPE 8: Restraint Coping

COPE 9: Acceptance

- COPE 10: Focus on and Venting of Emotions
- COPE 11: Denial
- COPE 12: Mental Disengagement
- COPE 13: Behavioural Disengagement
- COPE 14: Alcohol / Drug Use
- COPE 15: Humour

Each of the 15 domains has a maximum score of 16, where a higher score indicates more frequent use of that type of coping strategy.

- Level of psychological distress was measured using the General Health Questionnaire (GHQ-30) (Goldberg and Hillier 1979). Townsend (2009) highlighted the difficulty of measuring mood in stroke survivors for several reasons – the overlap of stroke symptoms with depression, emotional lability, cognitive and perceptual issues and communication difficulties. General Health Questionnaire was used in this study as it is a widely used, well validated measure with good reliability as a screening assessment to identify psychiatric disorders in neurological patients. (Wade1992). A study of 105 patients, six months post stroke by O'Rourke and MacHale (1998) studied its accuracy to detect psychological morbidity after stroke and concluded that it demonstrated sensitivity and specificity in identifying mood disorders in this population. Other studies (Goldberg 1979, De

Paulo 1978) have also demonstrated reliability, validity and sensitivity of the measure. A study by Robinson compared several mood assessment tools with in-depth psychiatric interview assessment and found that GHQ scores correlated highly with both the interview findings and other assessment tools including the Hamilton depression scale and Zung self-rating depression scale (Robinson 1982). In addition Robinson demonstrated that there was high test retest correlation when the GHQ was repeated. It is a self-reported screening instrument intended to detect psychological distress rather than specifically depression which compares the present state with the usual state, making it unlikely to detect chronic disturbances (Lincoln 2014).

This measure consists of 30 questions which asks participants to consider their health over the past few weeks and to underline one of four response options that best matches their current / most recent health status (rather than past health status). The four possible responses vary in wording for each question but example responses are:

Better than usual (0)

About the same (1)

Less well than usual (2)

Much less well than usual (3)

Each of the four responses is assigned a score from zero to three, giving a highest total possible score of 90, where the higher the score, the more distressed the individual is.

- Level of confidence was measured using the Confidence after Stroke Measure (CASM) - this measure was under development during the study and the version used for the feasibility study was the version under development (Horne 2014). A literature review performed by Horne as part of a PhD thesis (2016) identified that there are no measures to specifically look at confidence after stroke. Whilst other measures exist which consider aspects of confidence, such as Jones's Stroke Self Efficacy Questionnaire (SSEQ) (Jones 2008), they are limited, in this case to measuring confidence in performing basic functional tasks rather than more complex ADL. There are other broader assessment measures that incorporate confidence within the measure but these also have limitations: The Stroke Impact Scale (Duncan 2002) only measures social confidence and the burden of stroke scale (Doyle 2002) which aims to measure the burden of stroke but asks about confidence as part of the psychological distress domain. Horne (2016) concluded the need to develop a confidence measure for stroke which included both social and psychological components of confidence. The CASM measure was deemed to be the most appropriate measure of

confidence available for this study which investigated an intervention aimed at improving confidence. During development of the measure Horne demonstrated strong test retest correlation, good internal consistency and a statistically significant relationship between the CASM and the SSEQ. Sensitivity to change was not fully established. A 27 point item measure has now been developed which has been shown to be valid and reliable. This measure was chosen because there are no other measures of confidence developed specifically for stroke survivors. This measure, at the time of the study, consisted of 53 questions asking about a range of confidence concepts (identity, fear, social confidence, role confidence, mastering skills, attitude and belief).

The four possible response options are:

Strongly agree

Agree

Disagree

Strongly disagree

The responses are scored from zero to three depending on whether the question was negatively or positively worded, resulting in a highest possible total score of 159, where a high score indicates higher levels of confidence.

The questionnaire booklet therefore comprised of four measures (NEADL, COPE, GHQ30, CASM) totalling 165 individual questions in this order. A copy of the participant baseline questionnaire booklet can be found in Appendix H.

Baseline measures were also completed with consented carers. Carers were asked to self-complete the questionnaires but were offered assistance by the research assistant if required. Measures used for carers were:

- Carer Strain using the Carer Strain Index (Robinson 1983). This measure was chosen because it is a brief and easily administered scale designed to identify strain in informal care providers. This measure consists of 13 questions with a choice of 'no' or 'yes' as answers. 'No' scores zero and 'yes' scores one, resulting in a total possible highest score of 13, where a higher score indicates increased carer strain.
- Mood using the GHQ-30 (Goldberg and Hillier 1979). As identified previously, this measure covers a range of psychiatric symptoms including anxiety and low mood which could be issues for carers of stroke survivors.

A copy of the carer baseline questionnaire booklet can be found in Appendix I.

2.4 Randomisation

Following gaining consent and completion of baseline measures all participants recruited to the study were randomly allocated to either the intervention group or the control group using a secure computer based randomisation service. This was usually on or around the same date as recruitment and baseline assessment was completed or very shortly afterwards.

An independent researcher from a different department performed the randomisation process and held the randomisation schedule to ensure there was allocation concealment from the recruiting researcher. A simple random allocation method was used and the process was conducted on a computer based randomisation programme. This ensured that each participant allocation was independent of the others and that there was no researcher bias during the allocation process. The two sets of random group numbers were generated and one set was assigned to the intervention group and the other set to the control group. At the point at which participants gave consent to the study, a study ID number was allocated to them which was from a consecutive list of ascending numbers beginning 1001 up to 1060 (since the target recruitment for the study was 60 participants). After the consent

process the independent researcher was contacted to identify which group their number belonged to and hence which arm of the study they had been randomised into. Carers were allocated to the same group as the stroke participant they cared for.

Participants allocated to the intervention group were offered the intervention as described below. Intervention participants were placed on a waiting list for group attendance; when sufficient numbers (minimum of 5) had been randomised to the intervention group a group was then delivered. Those allocated to the control group were not offered any additional intervention. All participants in both the intervention and control groups continued to receive usual care from any community services, medical staff or social care they were involved with.

2.5 Control group

The control participants did not receive the RCAS intervention. They received routine medical and social care but details of this were not recorded. Since the local health service in the area where the study was taking place did not routinely deliver the RCAS programme no treatment was being withheld from the control group. Control participants were offered the RCAS intervention when they had completed their six month follow up assessment. No further follow up

data was collected from these control group participants after they had received the RCAS intervention.

2.6 Intervention group

All intervention participants were offered the Regaining Confidence after Stroke course which was delivered according to the second published version of the RCAS manual (Townsend 2009). A community venue that was free of charge was sourced and it was ensured that the venue met the recommendations of the RCAS manual, which included:

- Level access
- Disabled toilet facilities close to the meeting room
- Appropriate chairs and tables for group work
- Kitchen facilities for hot drinks
- Accessible transport links including public transport and parking facilities

The RCAS course was held at a time of day to avoid conflict with other local support groups and to avoid fatigue due to early morning starts or late afternoon finishes. Significant thought was put into finding a venue that was geographically centrally situated, had accessible facilities and was free of charge – this proved difficult to achieve and the compromise was using a venue on the outskirts of the City. Transport in the form of taxis was offered to participants if necessary in order to reduce the stress of attending and to facilitate attendance. The same venue was used for each course.

The sessions were delivered by an Assistant Practitioner (JS) who was skilled in stroke rehabilitation and had experience of leading stroke therapy groups. The RCAS manual recommends the course is delivered by either stroke survivors who have previously attended the course or by staff who work with stroke patients. It is recommended that course leaders have a minimum of one year's experience specialising in stroke care (stroke survivors, carers or staff). The group leader was chosen to deliver the intervention since she had a background of leading a stroke group exercise and advice programme (StrokeAbility). The Assistant Practitioner was supported by an Assistant Psychologist (KM), to meet the recommendation in the RCAS manual of two staff per group. The same members of staff delivered the whole course to provide continuity and to encourage trust from participants and therefore confidence to contribute during the sessions. Carers were asked to attend sessions one, six and eleven as per the RCAS instructions.

The sessions followed the published RCAS manual (Townsend 2009) and were:

1. You and Your Supporter: Getting to know one another in the group and sharing experiences
2. Problems in Common: Identifying and solving common problems
3. Setting Realistic Targets: How realistic targets can help recovery

4. Setting Realistic Targets-2: Reviewing goals and planning steps to achieve goals
5. Worry: Understanding what worry is, what effect it can have, and how to manage it
6. Understanding One Another
7. Other People in Your Life: Identifying people who affect your feelings
8. Gloom: Why people feel depressed after stroke and ways to stop it occurring
9. Living a New Life: Coping with change and building confidence in coping with change
10. Living a New Life: Looking at what is still the same and what is different following the stroke
11. Summing up: Thoughts on the course and talking about the next steps to recovery

Sessions ran weekly and lasted around 2 hours each session, as per the instructions in the manual. The session plans and format provided in the RCAS manual were followed which included master sheets for presentation to the group, step by step guides to session delivery, video materials, participant hand-outs and notes for group leaders.

Participants were given folders to take home which contained hand-outs from the sessions detailing the content covered and participants were encouraged to review them each week before the following

session. See Appendix J for example of session plan. Ground rules were agreed at the beginning of session one and referred back to at the beginning of each session. These focused on giving everyone a chance to speak and confidentiality.

To assess compliance with and acceptability of the intervention, the number of participants at each session was recorded and the total number of sessions attended by each participant was recorded. If participants missed any sessions the reasons were recorded. The attendance data was kept by the group leader as a paper register and then transferred to an excel spreadsheet by the researcher to facilitate analysis of the data. If participants attended the majority of the sessions using eight or more as the threshold, acceptability of the intervention was assumed. Acceptability was also considered through analysis of qualitative data obtained during participant interviews which is described in sections 2.8.2 and 2.10.2.

It was necessary to operate a waiting list for participants to commence the intervention as a group of participants were needed. When sufficient numbers had been randomised to the intervention group an RCAS course was delivered. Towards the end of the recruitment period there were insufficient numbers to deliver the RCAS intervention so groups three and four included additional attendees who were study control participants who had completed their participation in the study

and who wished to access the RCAS intervention. No further follow up data was collected from this cohort of RCAS group attendees.

2.7 Fidelity of the intervention

To assess the fidelity of the Regaining Confidence after Stroke (RCAS) intervention sessions were video recorded. The films were observed by an individual (CS) with no prior experience of the RCAS programme or any associated research and the content was measured against checklists of session specific criteria which had been developed using the RCAS manual (2nd edition). A copy of the checklist can be found in Appendix K. If the criteria had been met a mark of 1 was awarded. A set of general criteria was also developed from guidelines in the introduction of the RCAS manual. These were less rigid, so could be partly met and were marked out of 2, scoring 1 if partly met and 2 if fully met. This set of criteria can be found in Appendix L. The total number of marks available differs from session to session due to the varying number of session specific criteria. It was agreed that fidelity had been achieved if there was 75% overall compliance with criteria.

2.8 Follow up

2.8.1 Quantitative data collection

Participants and carers were followed up three and six months after recruitment to the study. Questionnaires were sent out by post at three calendar months and six calendar months from the date of randomisation into groups. The follow up questionnaire booklet comprised the same four questionnaires used at the baseline assessment (NEADL, COPE, GHQ30, and CASM). All participants and carers in both the intervention and control groups were asked to complete the questionnaire booklets at each time point. The three and six month questionnaires were administered by post with a covering letter – this can be found in Appendix M. A stamped addressed envelope was included for return of the questionnaire. If the questionnaires were not returned within four weeks after they had been posted, one follow up telephone call was made to prompt the participant (and carer if appropriate) to return it. A further questionnaire was sent out at this point if requested. If questionnaires were still not returned no further attempt was made to contact the study participants.

2.8.2 Qualitative data collection

An interview schedule was devised for the face to face semi-structured interviews and the interviews took place three months after randomisation with all willing participants of the first and second

intervention groups in order to explore their experiences. The interview schedule can be found in Appendix N.

Appointments were made over the telephone to visit the participants who agreed to be interviewed in their own home. Further written consent was not required as the interviews were identified within the study information previously provided and the previous consent form signed at the beginning of the study covered consent to be interviewed. It was, however, explained to participants being interviewed what the process would involve so that verbal consent to the process could be established. The interviews were completed by two members of research staff (KH and KS) who had not been involved in the delivery of the course to avoid any bias. The number of interviews completed was recorded. All the interviews were recorded on a digital device and the length of the interviews were recorded. Audio files were transcribed verbatim by KH and GA.

2.9 Data storage

All participant's identifiable data was held on a secure excel database on the main University of Nottingham computer system, which was password protected, and any paper records were stored in a locked filing cabinet. All identifiable data was kept separate from outcome data. All non-identifiable data was stored in a secure SPSS (Statistical package for the Social Sciences) file, version 21, on the University of

Nottingham's main computer system. Interviews were stored as audio files which were in a password protected folder on the University of Nottingham's main computer system and interview transcripts were stored as a word document in a password protected file on the University of Nottingham's main computer system.

2.10 Data analysis

2.10.1 Quantitative Data analysis method

Missing data was excluded from analysis and only complete data sets were analysed, with no replacement of any missing values. The data was analysed using the SPSS programme (version 21). For each of the baseline characteristics and baseline outcome measures, normality of the data was assessed. This was assessed by:

1. Visual assessment of Histogram shape (where a reasonably symmetrical bell shaped curve within the graph is suggestive of normally distribute data)
2. Assessment of normal probability plots (where having the data clustered around a straight diagonal line rising from the bottom left to top right of the graph supports normal data distribution)
3. Calculation of the Kolmogorov- Smirnov statistic within SPSS (where a non-significant value of > 0.05 supports normality of the data)

Descriptive statistics (counts, %, means, SD, and ranges) were computed in order to present baseline characteristics for each group. The response rate for returned questionnaires at three and six months was calculated separately for both the intervention and control. The amount of missing data in individual questionnaires and in total was also calculated. As this was a feasibility study it was of interest to identify both the number and proportions of participants who returned questionnaires and the percentage of missing data as well as the actual scores of the measures used.

The scores for each outcome measure in the follow up questionnaires were compared at three and six months to look for any trends in effectiveness of the intervention.

The choice of statistical test used to analyse the data was made based on consideration of whether certain assumptions could be made:

- That the data being compared has continuous variables
- The data used has been sourced by random sampling
- The data is independent of one another (cannot be influenced by one another)
- The data is normally distributed
- The population of the groups have equal variances
(demonstrated by a Levene test where the significance value is >0.05)

Pallant (2006) states that if these assumptions can be made, then parametric testing can be used. An independent samples t test was considered but since the sample size for both groups was relatively small and there was not clear normal distribution for each characteristic, non-parametric statistical testing was chosen for analysis. A Mann Whitney U test was therefore performed. The SPSS programme was used to perform the statistical tests to test for any differences in outcome measure scores, at three and six months, between the intervention and control groups.

As the study sample size was not powered, testing was only done to identify if any differences existed rather than attempt to demonstrate any statistically significant differences. Testing also provided information for a power calculation to inform a future study.

2.10.2 Qualitative data analysis method

The transcribed interviews were analysed using a coding process within the software programme NVivo (version 10). NVivo is a brand of computer-assisted qualitative data analysis software (CAQDAS). This enabled the qualitative data to be stored and managed more easily and facilitated the coding and analysis processes (Cresswell 2008). Themes were developed from the coded data using a framework analysis as this facilitated summarisation of the data whilst retaining its context to the research question (Cresswell 2008).

2.11 Ethical approval

Ethical approval for the study was granted by the NRES Committee East Midlands-Nottingham1 (REC reference 12/EM/0319) in 2011. The original ethics approval was amended to enable recruitment from additional sources. NHS R&D approval to conduct the study (ref. 14452) within Nottingham CityCare Partnership was sought and granted by Nottingham City PCT in 2013. Ethical approval was sought for this study and granted.

Ethical issues that needed to be considered are identified by Cresswell (2008) and were addressed in this study as follows:

- It was important to provide assurance that recruitment to the study was voluntary and that participants were able to withdraw from the study at any time. This was clearly documented within the study protocol documentation on the study information sheet and was discussed with potential participants during the consent process.
- The safe and secure storage of confidential participant data and information needed to be established. This was ensured through keeping all paper information in a locked filing cabinet and by keeping electronic data on a secure database with password protected files.
- The exclusion criteria needed to be proportionate to the constraints of the study. This was achieved by keeping the inclusion criteria to be as inclusive as possible within the parameters of the study.

- Studies should aim to ensure all participants benefit from the intervention, even control participants. To address this, all control group participants were offered the opportunity to go on a waiting list to receive the intervention after they had completed the six month follow up.
- Studies should not harm patients or put them at risk. Since the intervention being studied is known to have been used in an NHS setting this offered assurance that the delivery of the intervention should be safe. In addition the interviews with participants asked about intervention experiences. This provided an opportunity for the student to raise adverse events concerns with the study team and if needed the study could have been stopped. Studies need to consider any risk to vulnerable populations, which was pertinent to this study since stroke survivors may have cognitive and communication difficulties which increase their vulnerability. This potential risk was reduced by setting exclusion criteria for anyone not able to provide informed consent and for those with significant communication problems.

CHAPTER THREE

Results

3.1 Recruitment

Six hundred and forty invitation letters were sent to potential participants using the three different methods. The results from the response to invitation letters can be seen in Table 1.

Table 1, Invitation letter response rates

	n (%)
Letters sent between March 2013 and April 2014:	640
Breakdown by recruitment source:	
NUH Stroke service	560
NCCP Stroke service records	60
NCCP Stroke service staff invitation	20
Number of responses received.	93/640 (14.53%)
Breakdown by recruitment source:	
NUH Stroke service	62/560 (11%)
NCCP Stroke service records	18/60 (30%)
NCCP Stroke service staff invitation	13/20 (65%)

As can be seen from Table 1 there was a large difference in the percentage response rate by source. The lowest response rate was from the original participant identification centre (NUH). This recruitment source had the highest number of letters sent out but produced only an 11% rate of stroke survivors expressing an interest in finding out further information about the study. There was a higher rate of response from the letters sent to the community stroke service provider (30%). The highest rate was by face to face invitation which resulted in 65% of

stroke survivors positively responding to an invitation to find out further information about the study.

A proportion of stroke survivors expressing an interest in the study were excluded at both the telephone screening stage and the face to face screening assessment stage. During telephone screening a total of 42 stroke survivors were excluded. Three categories were identified for exclusion at this point of the study; declined, did not meet criteria and researcher unable to make contact.

Thirteen people were excluded for the reason 'declined'; this included four stroke survivors who felt they were too well and did not feel the study was appropriate for them and seven people who did not give a reason for declining. Additionally one stroke survivor declined as they did not feel they could commit to the 11 week programme from a time perspective, and one declined as they would not be willing to be placed in the control group.

Twenty two potential participants were excluded at this stage as they did not meet the inclusion criteria for the following reasons; they were receiving rehabilitation or other psychological therapies (n=13), were physically too dependent / unable to leave the house to attend (n=2), or were too unwell (n= 4). In addition a further one stroke survivor was excluded due to aphasia, one due to speaking insufficient English and one who stated they had not been diagnosed with stroke (total n=3).

A further seven people were excluded as they were unable to be contacted from the contact details they provided in their response to the invitation letter for the study.

At the face to face interview stage there were a further four stroke survivors excluded as they did not meet the criteria. One stroke survivor was excluded due to a low Barthel score, two due to still being in rehabilitation, and one could not commit to attending for 11 weeks if they were placed in the intervention group. Table 2 shows the numbers excluded and reasons for exclusion.

Table 2, Screening exclusion rates

	n (%)
Respondents excluded at telephone screen	42/93 (45.2%)
Reasons:	
Declined	13
Did not meet criteria	22
Unable to make contact	7
Respondents not excluded at telephone screen	51/93 (54.8%)
Respondents excluded as ineligible on face to face assessment	4/51 (7.84%)
Reasons:	
Did not meet criteria	4
Respondents not excluded at face to face screen	47/51 (92.16%)

Following the screening processes 47 participants provided consent for recruitment to the study. This was 78.3% of the target for recruitment (60). Following the randomisation process, 22 participants were allocated to the intervention group and 25 participants were allocated to the control group. In the time between group allocation and the intervention being delivered, two of the 22 participants allocated to the intervention group withdrew from the study; one participant died and another identified that they did not wish to continue in the study. A summary of group allocation is shown in Table 3.

Table 3, Group allocation

	n (%)
Allocated to the intervention group:	22/47 (46.8%)
Received the intervention as allocated:	20 (1 died prior to intervention starting and 1 withdrew)
Allocated to the control group	25/47 (53.2%)

All of the recruitment data is summarised in the flowchart in Figure 1.

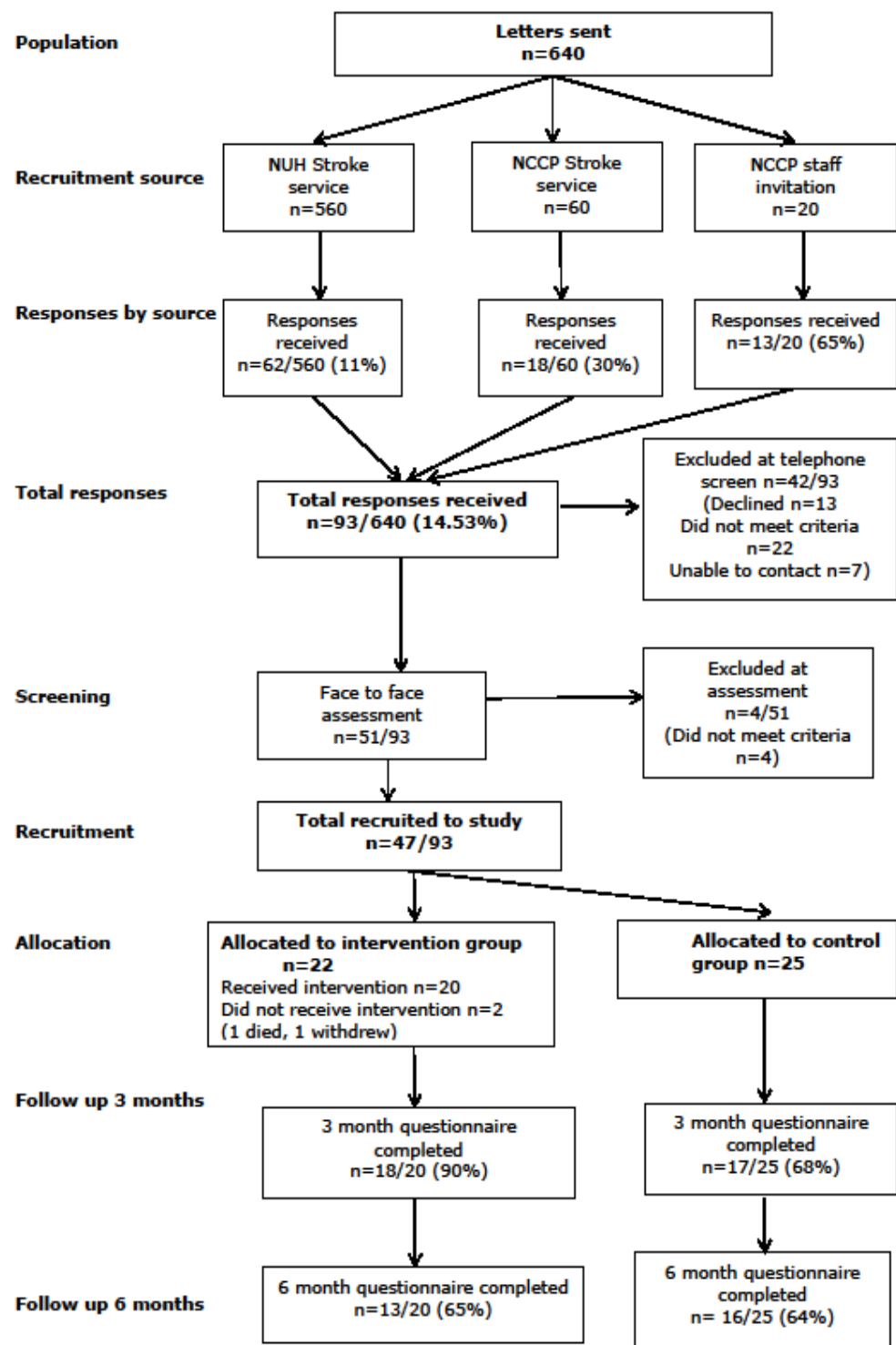


Figure 1

3.2 Participant characteristics

Participant characteristic data was collected at baseline assessment and summarised using descriptive statistics. Normality of participant characteristic data was assessed. Assessing normality of the data from the histogram shapes was inconclusive, but the normality plots and Kolmogorov-Smirnov (K-S) statistic were suggestive of normality of all the baseline characteristic data. Histograms and normality plots are available from the author on request. The K-S values for each characteristic are shown in Table 4.

Table 4, K-S values for participant characteristics

Characteristic	K-S value control group	K-S value intervention group
Age	0.123	0.098
Months post stroke	0.228	0.194
Barthel	0.284	0.250
Sheffield Screening Test	0.204	0.227

Since the participant characteristic data appeared to be of a normal distribution the descriptive statistics are presented for normally distributed data. The results are shown in Table 5.

Table 5, Participant characteristics

	Intervention group n=22	Control group n=25
Age:		
Mean (SD)	69.64 years (14.05)	64.2 years (15.7)
Age range	38 to 94 years (56)	36 to 92 years (56)
Gender	11 (50%) Men, 11 (50%) Women	15 (60 %) Men 10 (40%) Women
Months since stroke:		
Mean (SD)	15.77 months (11.4)	15.76 months (7.9)
Range	3 to 48 months (34)	5 to 39 months (45)
Barthel score:		
Mean (SD)	18.5 (1.82)	18.64 (1.89)
Range	14 to 20 (6)	14 to 20 (6)
Sheffield Screening Test score:		
Mean (SD)	18.14 (1.8)	17.88 (2)
Range	14 to 20 (6)	12 to 20 (8)

Each characteristic is described in the section below.

3.2.1 Age

For the characteristic of age the data shows that participants in the intervention group were around five years older than those in the control group. There was a wide distribution in the age ranges in both groups. The Standard Deviation (SD) figures demonstrate a wide spread of the data which is further supported by the large age range of participants (56 years in both groups).

3.2.2 Gender

For the characteristic of gender there were equal numbers of men and women in the intervention group, but an inequity of numbers of males and females in the control group. There were 11 of each gender in the intervention group, but 15 males and only 10 females in the control group. Since the intervention was not developed as a gender specific intervention, the difference in gender numbers across the groups is not of concern.

3.2.3 Number of months post stroke

For the characteristic of months post stroke, the mean is similar for both groups, demonstrating that the participants in both groups were at a similar time point post stroke in each group. However, there was a larger range of months post stroke in the intervention group and a higher standard deviation. This is explained by having an outlier in the intervention group who was 48 months post stroke.

3.2.4 Barthel score

For the characteristic of Barthel score, the mean and range of scores across the two groups are similar suggesting the groups were comparable in their levels of functional independence.

3.2.5 Sheffield screening test score

For the Sheffield screening test score characteristic there was a slightly lower mean and wider score range in the control group. However since both groups mean scores were at the higher end of the scale this suggests good levels of verbal communication in both groups.

3.3 Participant baseline data

The baseline outcome data were assessed for normality using the same approach as for the characteristic data. Assessing normality of the data from the histogram shapes was again inconclusive, but the normality plots and Kolmogorov-Smirnov (K-S) statistic were suggestive of normality of all the baseline outcome measure data. The K-S values for each characteristic are presented in Table 6.

Table 6, Kolmogorov-Smirnov values baseline measures

Outcome measure	K-S value control group	K-S value intervention group
NEADL	0.144	0.188
COPE1	0.145	0.156
COPE2	0.193	0.179
COPE3	0.159	0.149
COPE4	0.147	0.164
COPE5	0.151	0.176
COPE6	0.267	0.122
COPE7	0.175	0.192
COPE8	0.165	0.141
COPE9	0.152	0.160
COPE10	0.130	0.156

Outcome measure	K-S value control group	K-S value intervention group
COPE11	0.150	0.134
COPE12	0.108	0.200
COPE13	0.194	0.170
COPE14	0.500	0.539
COPE15	0.161	0.179
GHQ	0.131	0.127
CASM	0.216	0.194
CARER GHQ	0.276	0.214
CARER CSI	0.253	0.196

Since the baseline outcome data appeared to be of a normal distribution the descriptive statistics are presented for normally distributed data. Table 7 shows the results for the baseline outcome measures data collected for all study participants and carers at the point of consent into the study.

Table 7, Participant baseline outcome data

	Intervention group n= 22	Control group n=25
NEADL : Mean (SD) Range Median (IQR)	13.76 (4.9) 6 to 21 (15) 13 (9)	14.44 (5.03) 5 to 21 (16) 15 (7)
COPE 1: Mean (SD) Range Median (IQR)	11.95 (1.81) 9 to 16 (7) 12 (3)	11.13 (3.08) 4 to 16 (12) 11.5 (4)
COPE 2: Mean (SD) Range Median (IQR)	10.68 (2.63) 4 to 16 (12) 10 (2)	10.13 (3.35) 4 to 15 (11) 10.5 (4)

	Intervention group n= 22	Control group n=25
COPE 3: Mean (SD) Range Median (IQR)	10.09 (3.46) 4 to 16 (12) 11 (6)	9.79 (3.39) 4 to 16 (12) 10 (6)
COPE 4: Mean (SD) Range Median (IQR)	10.64 (3.43) 6 to 16 (10) 11.5 (7)	9.46 (3.89) 4 to 16 (12) 10 (6)
COPE 5: Mean (SD) Range Median (IQR)	10.27 (2.12) 6 to 14 (8) 10.5 (3)	9.17 (3.02) 4 to 16 (12) 8.5 (4)
COPE 6: Mean (SD) Range Median (IQR)	8.68 (3.75) 4 to 16 (12) 9 (7)	7.63 (4.45) 4 to 16 (12) 5.5 (7)
COPE 7: Mean (SD) Range Median (IQR)	11.32 (2.28) 7 to 16 (9) 11 (3)	11.26 (2.7) 6 to 15 (9) 12 (4)
COPE 8: Mean (SD) Range Median (IQR)	10.32 (2.72) 6 to 15 (9) 10.5 (5)	10.38 (2.91) 5 to 16 (11) 10.5 (4)
COPE 9: Mean (SD) Range Median (IQR)	12.50 (1.71) 10 to 16 (6) 12 (2)	12.13 (3.15) 4 to 16 (12) 13 (4)
COPE 10: Mean (SD) Range Median (IQR)	10.05 (2.94) 5 to 15 (10) 10.5 (4)	9.21 (3.2) 4 to 15 (11) 9 (5)
COPE 11: Mean (SD) Range Median (IQR)	8.55 (3.32) 4 to 16 (12) 8 (5)	7.38 (2.63) 4 to 12 (8) 7 (6)
COPE 12: Mean (SD) Range Median (IQR)	8.82 (2.75) 4 to 14 (10) 8.5 (5)	9 (2.34) 6 to 15 (9) 9 (4)
COPE 13: Mean (SD) Range Median (IQR)	8.36 (2.54) 4 to 13 (9) 9 (3)	7.21 (3.08) 4 to 14 (10) 6 (5)
COPE 14: Mean (SD) Range Median (IQR)	4.09 (0.43) 4 to 6 (2) 4 (0)	4.46 (1.44) 4 to 10 (6) 4 (0)

	Intervention group n= 22	Control group n=25
COPE 15: Mean (SD) Range Median (IQR)	9.5 (4.17) 4 to 16 (12) 10 (9)	9.04 (3.61) 4 to 16 (12) 9 (7)
GHQ : Mean (SD) Range Median (IQR)	26.78 (10.94) 2 to 47 (45) 27 (15)	29.05 (13.26) 13 to 66 (53) 26 (17)
CASM : Mean (SD) Range Median (IQR)	150.10 (17.53) 129 to 197 (68) 149 (22)	147.23 (15.51) 100 to 181 (81) 148 (11)

3.3.1 NEADL

The mean NEADL score was slightly higher in the control group at baseline and there was a large range in the scores for both groups. The scores in both groups are suggestive of a moderate level of disability post stroke and indicate that the participants had sufficient functional ability to attend a group.

3.3.2 COPE

The mean COPE scores were overall broadly similar for both groups at baseline. The majority of the domains were all used with some frequency, however, there was a difference in some domain scores with domain 9 (acceptance) being the most frequently used coping strategy and domain 14 (use of alcohol) being the least frequently used coping strategy in both groups.

3.3.3 GHQ

There was a small difference between the groups for the GHQ where the intervention group had a lower mean score and the upper and lower limits of the score ranges were lower. This is suggestive of there being less psychological distress in the intervention group compared to the control group when measured by the GHQ30 at baseline.

3.3.4 CASM

There was a small difference between the groups for the CASM score, with the intervention group having a higher mean score and a higher upper and lower limit of score ranges compared to the control group. This could suggest an increased level of confidence in the intervention group.

3.3.5 Missing participant baseline data

There was some missing data in the baseline questionnaires in those booklets where participants had completed them independent of the researcher. The missing responses were not detected until the point of data analysis. A breakdown of the missing data for each outcome measure within the questionnaire booklet is provided in Table 8.

Table 8, Participant missing data at baseline

	Intervention group – nos. of booklets with missing data n (%)	Control group– nos. of booklets with missing data n (%)
NEADL	1/22 (4.5%)	0/25 (0%)
COPE	1/22 (4.5%)	2/25 (8%)
GHQ	4/22 (18.2%)	4/25 (16%)
CASM	2/22 (9.1%)	3/25 (12%)

The results in Table 8 demonstrate that the smallest amount of missing data was within the NEADL and the highest amount of missing data was within the GHQ in both groups.

3.4 Carer recruitment and baseline data

Carer recruitment data (including gender) is shown in Table 9.

Table 9, Carer recruitment data

	Carers recruited total	Carers in intervention group	Carers in control group
Number and gender	11/ 47 (10 Female, 1 Male)	7/11 (6 Female, 1 Male)	4/11 (4 Female)

Since carers were allocated to the same group as the stroke survivor they cared for, the group allocation for carers was not a randomised process. This resulted in there being an unequal distribution of carers between the groups and hence three more carers in the intervention group than the control group. The descriptive statistics for the carer baseline measures are shown in Table 10.

Table 10, Carer baseline outcome data

	Intervention group n= 7	Control group n= 4
GHQ:		
Mean (SD)	21 (3.29)	25 (3.61)
Range	16 to 26 (10)	22 to 29 (7)
Median (IQR)	21 (4)	24 (-)
CSI :		
Mean (SD)	3.86 (3.08)	1.67 (1.53)
Range	1 to 9 (8)	0 to 3 (3)
Median (IQR)	3 (6)	2 (-)

- '-' denotes insufficient data to calculate

As can be seen from Table 10 the mean and median GHQ score for the control group participants was higher than in the intervention group suggesting there was more psychological distress in the control group carers at baseline. Conversely the CSI score had a higher mean in the intervention group participants which would indicate more carer stress

in the intervention group carers at baseline. There was a small amount of missing data in the carer's baseline questionnaires as a result of most carers completing the booklet independent of the researcher and the booklet not being checked for full completion at the time. A breakdown of where the missing data occurred within the carer questionnaire booklet is provided in Table 11.

Table 11, Carer missing data at baseline

	Intervention group – nos. of carer booklets with missing data n (%)	Control group– nos. of carer booklets with missing data n (%)
GHQ	1/7 (14.3%)	0/4 (0%)
CSI	0/7 (0%)	0/4 (0%)

This data demonstrated that the only missing data occurred for the GHQ within the intervention group, with only one carer in total not fully completing the booklet across both groups.

3.5 Intervention delivery

3.5.1 Participant data

The intervention was delivered over a period of 11 months and participants were split into four groups for delivery of the intervention. There was a waiting list to receive the intervention following

randomisation to ensure sufficient numbers were available to form a group. The mean wait time between randomisation and starting the group was 37.5 days (SD 21.5) with the shortest wait being six days and the longest wait being 80 days. The groups were delivered on the dates shown in Table 12.

Table 12, Dates of intervention delivery

Group	Start date	End date
1	22/07/2013	14/10/2013
2	12/10/2013	18/12/2013
3	18/03/2014	04/06/2014
4	15/05/2014	14/08/2014

Groups one and two comprised only of intervention group participants attending. In groups three and four there were additional participants who had been randomised to the control group and who had completed their participation in the study after the six month follow up point as per protocol. There was a small uptake of this opportunity with only five of the 25 control participants (20%) accessing the RCAS group after completion of their participation in the study. Since these control participants had completed their participation in the study and there was no further follow up data collected from this cohort, there was no contamination of the data. There was also no crossover of participants in the groups that is to say that no participants swapped their group allocation during the study.

The characteristics of each group in terms of gender, attendance and numbers per group are described in Table 13. The figures in the first column indicate how many intervention participants attended each group. The bracketed number is the number of total participants in each group including those from the control group who took up the offer of the intervention after their six month assessment.

In total 20 out of the 22 participants allocated to the intervention group received the intervention due to two participants withdrawing from the study following randomisation. One of the 'withdrawn' participants was allocated to receive the intervention in group one and the other to group two.

Table 13, Group attendance data

	Intervention participants by group (total number attending group)	Gender	Mean number of sessions attended (SD)- intervention participants	Median number of sessions attended (IQR) – intervention participants
Group 1	7 (7)	(3M, 4F)	5.29 (3.64)	5 (7)
Group 2	6 (6)	(2M, 4F)	6.33 (3.72)	7.5 (6.25)
Group 3	6 (8)	(5M, 3F)	10.17 (1.6)	11 (1.75)
Group 4	3 (6)	(4M, 2F)	9.33 (0.58)	9 (-)

The mean and median scores for the attendance data presented in table 13 includes all participants who were allocated to the intervention group (22) but does not include the additional attendees from the control group. Of the 11 treatment sessions per group delivered, across the groups there was a mean of 7.78 sessions (70.7%) and a median of 8.125 sessions (73.86%) attended by participants. Four out of the 22 participants allocated to the intervention group (18.18%) attended all sessions. Thirteen out of 22 (59.1%) participants attended 8 or more sessions (the attendance threshold set for acceptability).

As two of the 22 participants (9.1%) did not attend any sessions due to withdrawal from the study before the intervention was delivered, this has influenced the attendance data. If attendance data is analysed including only participants who attended at least one group session, the mean sessions attended rises to 8.2 per participant; this further supports acceptability as it meets the threshold set.

Using the attendance registers from the groups, a summary of the number of missed sessions, and reasons, per participant was calculated. These results can be seen in Table 14.

Table 14: Reasons for non-attendance at RCAS sessions

Reason	Participants affected	Total number of sessions missed
Unwell	4	24
Medical appointments.	3	4
Admitted to hospital	2	13
Holiday	3	5
Other commitments	1	1
Leader cancelled	3	3
No reason given	2	5
Died	1	11
Withdrew from study	1	11

The total number of sessions that could have been delivered and attended by the 22 intervention group participants was 242 sessions (22 participants x 11 sessions each). There were a total of 77/242 missed sessions (31.8%). As can be seen, the reasons given by participants for why they had missed any of the sessions were varied with illness and hospital admission being the most common. Four participants missed a total of 24 sessions due to illness, missing between 4 and 9 sessions each. This accounted for 31.2% of the missed sessions. Two participants missed a total of 13 sessions due to hospital admission; one missed six sessions and another missed seven sessions. This accounted for 16.9% of the missed sessions. Medical appointments and holidays accounted for 5.2% and 6.5% of the missed sessions respectively. There were 22 sessions missed due to the withdrawal of the two intervention participants from the study prior to

the intervention being delivered: this accounted for 28.6% of the missed sessions. One session in group 4 was missed by all participants as the group leader had to cancel the session due to illness. This accounted for 3.9 % of sessions missed.

3.5.2 Carer data

Carers of participants in the intervention group were invited to attend three of the eleven sessions with the stroke survivors. Attendance of carers at group sessions is identified in Table 15.

Table 15, Carer attendance data

	Numbers of carers in group	Number of sessions attended
Group 1	2	3, 0
Group 2	2	3, 1
Group 3	2	3, 1
Group 4	1	2, 2

The mean number of sessions attended by carers was 2.14 out of a maximum possible of 3 sessions (71.3%). Three out of seven carers (42.9%) attended all the sessions. Reasons for non-attendance were not collected but on all the occasions for carer non-attendance, the participant also did not attend. It is assumed that reasons for carer non-attendance therefore linked to the participant's reasons for non-

attendance. It would be inappropriate for carers to attend without the participant for whom they care.

3.6 Follow up

3.6.1 Participants three month follow up

There were 45 study participants available for three month follow up who were sent follow up questionnaires - 20 in the intervention group (as two were lost to follow up) and 25 in the control group. Follow up questionnaires were only sent to participants remaining in the study at the follow up stage. Of the 45 remaining study participants, 13 returned questionnaires within four weeks from them being sent and without any reminder (28.9%): seven from the control group and six from the intervention group. The remaining 32 participants were all contacted once by telephone to prompt them to return the questionnaire booklet. This resulted in a further 22 questionnaire booklets being returned (48.9%): 10 from the control group and 12 from the intervention group.

A total of 35 (77.8%) of the three month follow up questionnaire booklets were returned – 17 from the control group and 18 from the intervention group. Although similar numbers were returned from each group, there was a difference in the return rates with 17/25 (68%) returned from the control group and 18/20 (90%) from the intervention group.

3.6.2 Carer three month follow up

Three month follow up questionnaires were sent to all eleven carers recruited to the study and seven were returned (63.6%): 2/4 from the control group (50%) and 5/7 from the intervention group (71.4%).

3.6.3 Participant six month follow up

There were 45 study participants available for six month follow up who were sent follow up questionnaires (20 in the intervention group and 25 in the control group). Of these, five participants returned questionnaires within four weeks of them being sent out and without any reminder (11.1%): three from the control group and two from the intervention group. The remaining 40 participants were contacted once by telephone to prompt them to return the questionnaire booklet. This resulted in a further 25 questionnaire booklets being returned (55.5%): 13 from the control group and 12 from the intervention group.

A total of 30 (66.7%) of the six month follow up questionnaire booklets were returned in total – 16 from the control group and 14 from the intervention group. This was a return rate of 16/25 (64%) for the control group and was 14/20 (70%) for the intervention group.

3.6.4 Carer six month follow up

Six month questionnaires were sent to all 11 carers and eight were returned (72.7%): 4/4 (100%) from the control group and 4/7 (57.14%) from the intervention group.

3.6.5 Missing data

There was missing data in some of the participant questionnaires at both three and six months follow up. Table 16 shows a summary of the completion rate of participant questionnaires for both the intervention and control groups at both data collection points.

Table 16, Number of participant completed questionnaires

	3 months		6 months	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Fully completed	11 (55%)	11(44%)	7 (35%)	9 (36%)
Partially completed	7 (35%)	6 (24%)	7 (35%)	7 (28%)
Not returned	2 (10%)	8 (32%)	6 (30%)	9 (36%)

At the three month follow up there was a higher percentage of fully completed questionnaires from the intervention group. At six months there was a roughly equal percentage of fully completed questionnaires in both groups. There was a higher percentage of questionnaires returned with missing data (partially completed) within the intervention

group compared to the control group at both three and six months. There was a higher percentage of questionnaires not returned in the control group at both three and six months, with the biggest difference being at three months. The combined total response rate for all follow up questionnaires sent to both groups at three and six months is shown in Table 17.

Table 17, Combined follow up questionnaire return rate

Returned fully completed	38/90 (42.2%)
Returned Partially completed	27/90 (30%)
Not returned	25/90 (27.8%)

There was also some missing data in the questionnaires returned from the 11 carers in the study at both three and six months. Table 18 shows an overview of the completion rate of the returned questionnaires for carers in both the intervention and control groups at both data collection points.

Table 18, Number of carer completed questionnaires

	3 months		6 months	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Fully completed	4/7 (57.1%)	2/4 (50%)	3/7 (42.9%)	4/4 (100%)
Partially completed	1/7 (14.3%)	2/4 (50%)	1/7 (14.3%)	0
Not returned	2/7 (28.6%)	0	3/7 (42.9%)	0

As can be seen there was a difference in the completion rates at each time point between the groups. At the three month follow up there was a higher percentage of partially completed questionnaires returned from the control group. Conversely at the six month follow up there was a higher percentage of partially completed questionnaires returned in the intervention group. The number of carer questionnaires returned was small so it is difficult to determine any patterns in completion rates based on the data presented.

The partially completed questionnaire booklets had different data missing within them which is summarised in Tables 19 and 20.

Table 19 shows the frequency of missing participant data at three and six months, where n denotes the number of questionnaires out of the sample that were returned that had data missing for each outcome measure listed.

Table 19, Participant missing data at follow up

	3 month data		6 month data	
	Intervention group n (%)	Control group n (%)	Intervention group n (%)	Control group n (%)
NEADL	5/18 (27.8%)	2/17 (11.8%)	7/14 (50%)	5/16 (31.3%)
COPE	8/18 (44.4%)	4/17 (23.5%)	8/14 (57.1%)	4/16 (25%)
GHQ	5/18 (27.8%)	1/17 (5.9%)	5/14 (35.7%)	3/16 (18.8%)
CASM	7/18 (38.9%)	2/17 (11.8%)	8/14 (57.1%)	5/16 (31.3%)

As can be seen, the measures which most frequently had missing data were the COPE and the CASM. This occurred at its highest at the six month follow up and for the intervention group. The mean percentage of frequency of missing data within each outcome measure overall was calculated. Table 20 shows the combined frequency (at three and six months) of missing data for each outcome measure in total.

Table 20, Combined frequency of missing data at follow up

	Overall mean % of missing data
NEADL	29.2%
COPE	36.9%
GHQ	21.5%
CASM	33.8%

This demonstrates that overall the COPE was the outcome measure that most frequently contained missing data and the GHQ least

frequently contained missing data in those questionnaires that were returned.

There was some missing data in the carer questionnaires that were returned at both three and six months follow up. Some of the questionnaires returned did not have all the outcome measures fully completed. Table 21 shows a breakdown of which outcome measures within the returned carer questionnaires had missing data for both the intervention and control groups at both data collection points.

Table 21, Carer missing data at follow up

	3 months		6 months	
	Intervention group n = 7	Control group n = 4	Intervention group n = 7	Control group n = 4
GHQ 30	0/7	0/4	1/7	0
CSI	1/7	2/4	0/7	0

As can be seen, the GHQ had minimal missing data (4.5% overall) which only occurred in one returned questionnaire at the six month follow up. The CSI had slightly more missing data (13.6% overall) which only occurred at the three month follow up.

3.6.6 Comparison of outcome data at 3 and 6 month follow-up

Descriptive statistics for the outcome measure data for participants at three and six months are shown in Table 22.

Table 22, Participant follow up outcome data

	Intervention group		Control group	
	3months	6months	3months	6months
NEADL Mean (SD) Range Median (IQR)	12.86 (6.11) 18 12.5 (11)	13.5 (5.78) 16 14.5 (10)	14.6 (6.25) 22 15 (9)	14.33 (6.29) 19 15.5 (11)
COPE 1 Mean (SD) Range Median (IQR)	10 (2.8) 11 10 (4)	8.22 (2.64) 9 8 (3)	11.23 (4.4) 11 14 (8)	9.85 (3.44) 11 9 (5)
COPE 2 Mean (SD) Range Median (IQR)	8.64 (2.98) 11 9 (4)	9.38 (3.38) 11 9.5 (4)	10.69 (4.92) 12 12 (11)	9.08 (4.09) 12 8 (8)
COPE 3 Mean (SD) Range Median (IQR)	9.07 (2.9) 9 10 (5)	8.89 (4.4) 11 7 (9)	9.31 (3.86) 10 10 (8)	8.77 (3.90) 12 9 (7)
COPE 4 Mean (SD) Range Median (IQR)	9.43 (3.84) 12 8.5 (6)	8.3 (4.44) 12 8 (8)	10.23 (3.8) 12 12 (7)	9.00 (3.56) 12 8 (6)
COPE 5 Mean (SD) Range Median (IQR)	9.0 (2.96) 11 9 (4)	8.67 (3.67) 12 9 (5)	7.54 (3.07) 10 6 (5)	7.62 (2.69) 9 8 (5)
COPE 6 Mean (SD) Range Median (IQR)	8.71 (4.91) 12 7 (10)	7.33 (4.21) 12 6 (7)	7.38 (4.65) 11 4 (9)	7.00 (4.6) 12 4 (6)
COPE 7 Mean (SD) Range Median (IQR)	9.14 (3.18) 11 8.5 (5)	9.56 (3.43) 11 9 (5)	11.36 (3.84) 11 12 (7)	10.15 (3.65) 12 9 (7)
COPE 8 Mean (SD) Range Median (IQR)	9.69 (2.18) 8 10 (3)	9.56 (3.21) 9 9 (6)	9.93 (3.22) 10 11 (6)	9.62 (2.84) 10 10 (4)
COPE 9 Mean (SD) Range Median (IQR)	11.07 (2.27) 8 11 (3)	11.22 (2.91) 8 11 (6)	12.23 (3.72) 12 13 (5)	12.69 (3.4) 11 13 (6)
COPE 10 Mean (SD) Range Median (IQR)	9.79 (2.69) 8 10 (5)	10.33 (3.12) 11 10 (4)	8.71 (3.69) 11 8.5 (7)	8.31 (3.07) 10 8 (6)

	Intervention group		Control group	
	3months	6months	3months	6months
COPE 11 Mean (SD) Range Median (IQR)	7.29 (3.15) 12 7 (4)	7.78 (3.07) 8 9 (6)	7.00 (2.89) 8 7 (5)	5.62 (1.76) 4 5 (4)
COPE 12 Mean (SD) Range Median (IQR)	8.86 (2.28) 9 8.5 (3)	8.11 (2.47) 7 8 (4)	9.00 (3.84) 11 8.5 (8)	7.77 (3.03) 11 8 (5)
COPE 13 Mean (SD) Range Median (IQR)	7.71 (2.37) 9 7.5 (3)	7.22 (3.46) 11 6 (3)	7.00 (2.8) 7 7 (6)	7.31 (3.3) 11 6 (5)
COPE 14 Mean (SD) Range Median (IQR)	4 (0) 0 -	4 (0) 0 -	5.23 (3.42) 12 4 (0)	4.92 (1.94) 6 4 (1)
COPE 15 Mean (SD) Range Median (IQR)	7.07 (3.47) 10 6 (6)	8 (3.67) 12 7 (5)	8.62 (4.65) 11 6 (10)	8.77 (3.03) 10 8 (4)
GHQ Mean (SD) Range Median (IQR)	32.47 (12.54) 41 32 (19)	36.55 (21.27) 77 33 (24)	36.06 (19.86) 55 30.5 (40)	30.36 (16.64) 57 26 (18)
CASM Mean (SD) Range Median (IQR)	144.23 (18.28) 55 143 (28)	135.13 (15.28) 48 137 (22)	147 (25.85) 84 152 (41)	150.42 (25.16) 99 157 (33)

- denotes insufficient data to calculate

This data demonstrates that at both three months and six months the NEADL mean score was higher in the control group than in the intervention group, indicating an increased ability in ADL in the control group at both time points. At three months the mean GHQ was higher in the control group- this would indicate increased levels of distress within this group. However, at six months there was a higher GHQ score within the intervention group. At both three and six months, the CASM mean score was higher in the control group which would indicate

higher levels of confidence within the control group. There is a much higher range of CASM scores in the control group compared to the intervention group at both three and six months.

Looking at change across time in both groups, for the NEADL, there was a decrease in the intervention group score between baseline and three month follow up but an increase between three and six month follow up. Overall there was a small decrease in score from baseline to six months. For the control group the NEADL was fairly constant across all time measurement points. For the GHQ there was an increase in the intervention group score between baseline and three month follow up and between three and six month follow up, indicating an overall increase in psychological distress across time. For the control group the GHQ increased between baseline and three months but decreased between three and six months with an overall very small increase in score between baseline and six months. For the CASM, there was a decrease seen in the intervention group between baseline and three months and between three months and six months, indicating a reduction in confidence over time. For the control group there was minimal change in the CASM score at each time point.

A Mann Whitney U test was performed to ascertain any trends in the data and to provide information for power calculations for a future study.

A Mann Whitney U test was completed between groups at three and six months. Table 23 shows the results of the between group statistical significance test for each outcome measure.

Table 23, Mann Whitney U test results participant outcome data

	'p' value 3 months	'p' value 6 months
NEADL	.331	.734
GHQ	.953	.317
COPE 1	.579	.262
COPE 2	.220	.697
COPE 3	.830	1.000
COPE 4	.650	.556
COPE 5	.169	.512
COPE 6	.458	.695
COPE 7	.104	.744
COPE 8	.616	.948
COPE 9	.116	.235
COPE 10	.376	.186
COPE 11	.830	.082
COPE 12	.874	.601
COPE 13	.583	1.000
COPE 14	.519	.393
COPE 15	.458	.431
CASM	.586	.057

The Mann Whitney U test results do not demonstrate any statistically significant difference between the 2 groups (as the probability value 'p'

is not less than or equal to 0.05) on any of the participant outcome measures at three or six months.

Table 24 shows the descriptive statistics for the carer outcome measures at three and six months.

Table 24, Carer follow up outcome data

	Intervention group (carers) n=7		Control group (carers) n=4	
	3 months	6 months	3 months	6 months
GHQ				
Mean (SD)	21.8 (7.56)	25 (7)	25 (14.8)	30 (16.145)
Median (IQR)	20 (14)	28 (-)	18 (-)	27 (31)
CSI				
Mean (SD)	3.75 (1.5)	5.5 (3.1)	2 (0)	5.5 (4.80)
Median (IQR)	4 (3)	4.5 (6)	2 (-)	6 (9)

- denotes insufficient data to calculate

This table shows that the mean GHQ score was higher in the control group at both three and six months. The mean CSI was higher in the intervention group at three months but equal in both groups at six months.

Table 25 shows a summary of the Mann Whitney U test results for each measure.

Table 25, Mann Whitney U test results carer outcome data

	'p' value 3 months	'p' value 6 months
GHQ	1.000	1.000
CSI	.400	1.000

The Mann Whitney U test results do not demonstrate any statistically significant difference between the two groups on either of the carer outcome measures at three or six months.

3.6.7 Interview findings

Eight out of the eleven (73 %) intervention participants from groups one and two agreed to be interviewed. Two participants in group one and one participant in group two could not be interviewed due to ill health (total three unable to be interviewed). Interviews with participants from groups three and four were not conducted as no new data was emerging during the 8th interview. The shortest interview was 11 minutes and 2 seconds and the longest interview was 1 hour 12 minutes and 54 seconds. The mean length of the interviews was 24.47 minutes (SD 19.83) and the median was 17.79 (IRQ 3.96).

Analysis of the transcribed interview data resulted in 20 node codes within Nvivo which can be found in Appendix O. These codes were grouped by similarity which resulted in the identification of six key themes which were:

1. Group dynamics
2. Group leader
3. Group delivery
4. Mood and confidence
5. Perceived group benefits
6. Potential barriers

The six themes are described below:

1. Group dynamics:

This theme included comments made about the number of people in each group, the participant mix, attendance and group support.

There was a lack of consensus on preferred group size, with comments being made in support of both small and larger group sizes:

'I liked it when there is about 10.....I prefer the bigger groups.' (1005)

'The little groups are good but the big groups are better.' (1005)

'I wished there was more people there though. It was too small.' (1026)

Versus,

'The group that started was about eight.... that was alright but obviously when you're one to one you get through more and you talk more about each little thing, which was good.' (1006)

'It was a small group, I thought that were nice.' (1020)

It is not possible to determine an optimum group size from these results as there appears to be benefits to both smaller and larger groups.

There also seems to be an element of individual preference around the size of the group.

A number of participants discussed the interaction of group participants relating to their characteristics, specifically gender and levels of disability. Some participants found the lack of commonality within the group a particular problem. One participant stated:

'It made me feel worse because they've got two hands.....they was walking into Arnold, I can't walk.' and *'they'd all got two hands- that makes a difference.'* (1003)

This participant felt that being more severely affected by stroke was highlighted by attending the group, as other participants were more

able than her. A further participant found that being less impaired by stroke compared to the other group participants was equally problematic and commented.

'All the folks there were in a worse state than me...quite frankly when they were all talking together about their problems they got on me.'
(1019)

Conversely, other participants found comfort from meeting other people with similar problems stating:

'When you meet people what's had it and people what's worse off than you.....it takes that weight from you, you think well I'm not the only one in the world what's got this'. (1004)

'It proved to me that I wasn't the only one- we all felt the same.' (1006).

One male participant found that he was in the minority from a gender perspective when the other male participant in his group was unable to attend, leaving him as the sole male participant in the group and commented:

'It would have been nice to have had a couple of guys (in the group).....I'd have liked a balance of men and women.' (1026)

The interview data also highlighted recognition that attendance was impacted by illness and there were comments made by participants acknowledging this:

'I didn't finish it (the course) because me back started playing up.'
(1020)

'A lady, she was ill and had to stop the class.' (1013)

There was one participant who commented on carer attendance stating:

'I'd like her to go (his carer) every time we went- she'd pick things up and get it first hand.' (1004)

There was considerable discussion around the dynamic of support that developed between the participants during the sessions. There appears to have been bonding between participants and a sense of belonging. One participant commented:

'We were strangers then we got to know each other...you'd blend in like a jigsaw puzzle.....It reminded me of a family gathering.' (1004)

There was an element of sharing information, stories and coping mechanisms, which the participants found offered support.

'To hear other people I found that so supportive. It was somewhere to go and meet people. We could sit and tell each other.' (1005)

'You think you're the only one but when you get talking it seems as though it evaporates. When you meet people what's worse off than you it takes that weight from you.' (1004)

These comments suggest benefits from meeting regularly with a group of people with similar problems. This was an important finding since the aim of the programme was to encourage stroke patients to share their problems, feelings, and ways of coping.

In summary, these discussions provided data to support the overall acceptability of the group nature of the intervention, although individual preferences made it difficult to determine a set recipe for the delivery of the programme relating to group dynamics.

2. Group leader:

Several participants discussed the group leader during interview when asked about positive aspects of the course. Descriptors used included *'professional'*, *'expert'* and *'good at her job'*.

Group leadership skills are not necessarily inherent in health care staff but the group leader's experience in this area appears to have been a

vital component of the participant's positive experience. The participants appeared to respect not only her knowledge and experience but also her specific skill and expertise in group leadership:

'(She is) a real good man manager....she really knows how to work people.....she knows how to put a question to draw the best out of you.'
(1006)

'She'd just talk and then you'd find a difference in what she knows and what we were trying to learn....she knew what she was on about...she was never stumped for an answer.' (1004)

'She explained everything to us. She understood the situation.' (1019)

There also appears to have been an element of 'likeability' of the group leader which contributed to the participant's positive experience. Participants described the leader as 'great' and felt that she was someone they could really talk to and in whom they developed confidence and trust:

'She were brilliant talking to us, putting us minds at rest in lots of ways. She gave you confidence.' (1026)

'I knew her from StrokeAbility. She was friendly. She seemed a natural.'
(1020)

To summarise within this theme, issues emerged relating to the knowledge, experience and personability of the group leader. These appear to be key factors which contributed to the group's acceptability.

3. Group delivery:

This theme included comments made about the length of the course and frequency of the sessions, the course content and the delivery location and venue.

One participant commented on a desire for the group to run for more weeks:

'You got 11 weeks and you think blimey that's a long time, but I wish it'd been longer. A few more weeks.' (1004)

Another felt that the frequency was appropriate:

'Once a week was fine.' (1026)

Since the interviews were semi-structured and did not specifically ask about course length or frequency these were isolated comments but they provided some preliminary data for considering acceptability of the intervention.

There were several comments by the participants around the content of the programme being both useful and helpful. For example:

'I did find it really helpful, it really helped me.' (1005)

'It was refreshing...a different session every Monday.' (1004)

'I liked the idea of giving us some things to think about for the week and writing it down in a folder then dissecting it the following week.' (1006)

'On the television she showed different people and how they was coping, getting back to work and things. I liked that.' (1020)

One participant, however, found that there was too much discussion:

'We all compared notes each week-it was alright sitting talking about things but I wanted to get on and do things, for myself.' (1019)

Whilst these comments did not provide significant detail around the specific content of the sessions, they do support a conclusion that the overall content was of benefit. One participant (1006) discussed the helpfulness of having information provided to take home in a folder at the end of each session. It appeared that there was value in providing this information and that it complemented the outcomes of the group

sessions by allowing participants to further reflect on the topics discussed.

There were some comments about where the group was delivered, with one participant describing the venue as:

'It was a decent room. It was nice and warm.' (1020)

Another participant found the venue was too far away and stated:

'It was a long way to go. I finished up not going.' (1003)

Although there was not a lot of data relating to the group venue and its geographical location, they appear to be a consideration for some participants when invited to attend the group. The analysis of the data within this theme would suggest that there were no significant areas of concern around the content of the programme sessions, but more practical matters of travelling to the venue impacted on some participant's experience.

4. Mood and confidence:

This theme describes any comments made by participants around mood and confidence. The interviews provided data to suggest that the intervention had a positive effect on the mood of participants, at least in the short term. Comments included:

'You come out feeling good.....a lot better than you went in. I'd come out feeling pleased with myself.' (1006)

'They really cheered me up they have.....they couldn't even get a smile out of me...but yes that has changed.' (1005)

'When you came out you felt a lot better, as if there were a ton weight off ya back. You go in a bit depressed and you come out and feel as though the sun is shining even if it's raining. When you get talking it seems to evaporate that self-pity feeling.' (1004)

These comments describe an improved mood at the time of the intervention but what is not known is how long that effect lasted.

The other comments around mood relate more to a sense of loss when the group ended. Several participants commented on how much they missed the group when it ended:

'It upset me when, I tell you it nearly broke me heart when we had to leave. I miss it.' (1004)

'Since the group I feel lost.' (1005)

One participant stated that they hoped the groups would continue after the study saying:

'They (the groups) make me feel you haven't died and you have a life left to live.' (1013)

These statements indicate that there is a real danger that the benefits of the intervention could be short-lived and that any positive impact on mood could be reversed once the programme ends.

There were several comments expressing a feeling of improved confidence in participants:

'It gave you confidence. Confidence when people tell you what you can do and somebody tells you how to take that step.' (1004)

'I'd lost all my confidence but I'm gradually getting it back- I just do it one step at a time.' (1005)

'It gave me a bit more confidence- more bubbly. A release.' (1026)

There was, however, one negative comment relating to the impact of the course on confidence by one participant:

'I didn't feel any more confident when I'd been. It didn't really do anything for me.' (1019)

Whilst the majority of comments suggested improved confidence as a result of attending the course, it is important to acknowledge that this was not the case for all group attendees.

It is reasonable to conclude from the comments within this theme that there is positive indication that the intervention can improve mood and confidence and that participants are verbalising the feeling of an improved sense of wellbeing as a result of the intervention.

5. Perceived group benefits:

This theme was established in order to capture the wider benefits around receiving the RCAS intervention. There was an overall feeling of participant satisfaction with the intervention indicated by the use of a lot of positive language by participants when describing the group:

'Brilliant.' *'I have enjoyed it.'* *'I liked it, I really liked it.'* *'It was a brilliant course, it was well worth going for.'* (1004)

'It was really interesting.' *'I felt all of it was good. It's amazing.'* (1005)

There were also specific comments made around the benefits participants had experienced as a result of attending the programme. These included comments around being motivated / encouraged to do more as a result of the course:

'It made me think I'm going to go out for a walk and I've been doing it, going out on my own.' (1013)

'Going to those classes opened up a big world for me, it has given me a hell of a lot to aim for. I aimed for a goal each time and I have achieved quite a lot up to now.' (1005)

Participants also seemed to perceive benefits of attending the course from self-reflection:

'It was a chance to write my feelings down.' (1026)

'Made you think differently about things.' (1020)

Also, there was a sense of learning / gaining knowledge through attendance:

'You were learning whilst you was talking.' (1004)

'It helped me think about what causes a stroke' and 'it was really interesting finding out what help is there.' (1005)

These reports of an overall positive experience of participating in the group further support the acceptability of the intervention.

6. Potential barriers:

One key barrier was identified around transport to and from the venue.

Several participants who accepted the offer of taxi transport experienced difficulties with this. One participant needed a wheelchair taxi and informed the interviewer:

'They keep sending me the wrong taxis.' (1003)

A further participant experienced a range of taxi problems including lateness, going to a wrong address and the driver not knowing how to get to the venue. He commented:

'The taxi driver asked me how to get there and I don't know I never been before.' (1004)

A further participant expressed a general dissatisfaction with the taxi company stating:

'They (the taxi drivers) were all miserable buggers!' (1026)

It is key to recognise that participants experienced problems with transport to and from group sessions as it could have impacted on attendance and experience.

Other issues discussed in the previous themes should also be considered as possible barriers to successful delivery of the intervention. All the following could be potential barriers to group delivery: the impact of participants group dynamics and potential incompatibility within the group (based on gender, personality and disability levels), potential for illness (which may prevent completion of the course) and the difficulty in finding and travelling to a suitable venue.

In summary, the interview data provided a breadth of information within the six key themes that has resulted in useful knowledge for considering factors for delivering the group in a future study.

3.7 Fidelity of the intervention

Of the 44 intervention sessions intended to be delivered, 19 (43.2%) were video recorded. Sessions 1,2,3,6,8,9,10,11 were video recorded but sessions 4, 5 and 7 were not recorded. Recordings were made at some point during each of the four groups delivered. Table 26 identifies which sessions were recorded during each group.

Table 26, Video recordings of sessions

Session number	Group(s) in which recording was made
1	Group 4
2	Groups 3 and 4
3	Groups 2 and 4
4	No recordings
5	No recordings
6	Groups 1, 2 and 3
7	No recording
8	Groups 1 and 3
9	Groups 1, 3 and 4
10	Groups 1 and 3
11	Groups 1, 2, 3 and 4

Using the fidelity check lists (Appendices K and L) the 19 recorded sessions were compared to the printed intervention manual. Sessions were awarded marks based on the criteria scoring system described in the methods section. There were some sessions unable to be scored as either the criterion number was not applicable in that session or the criterion could not be marked as the session material containing that criterion had not been recorded. Of the 19 sessions recorded, seven (36.8%) had incomplete recordings. Sessions three, six, eight, ten and eleven all had some incomplete recordings. The marks for the sessions are generally good with 16 of the 19 recorded sessions (84.2%) being carried out in close compliance with the manual according to the threshold set of 75% or more compliance with criteria. Full scoring details of all sessions recorded can be seen in Appendix P.

A summary of the compliance scores can be seen in table 27.

Table 27, Overall criteria compliance

Session number	1	2	3	6	8	9	10	11
% of specific criteria met	86%	75%	100%	90%	80.5%	100%	95%	70%
% of general criteria met	80%	65%	85%	80.3%	77.5%	70%	75%	82.5%
Combined % of all criteria met	83%	70%	92.5%	85.2%	79%	85%	85%	76.3%

The results show that sessions two and 11 had the lowest mean compliance score when measured against the specific criteria but that overall compliance with specific criteria for sessions was good. The compliance with general criteria was less for all the sessions except session 11. Table 28 shows a summary of the compliance scores for each general criteria, across all sessions, using the scores recorded when video was available for analysis.

Table 28, General criteria compliance

General Criteria number	Score and %
1. Outline of aims	19/36 (52.78%)
2. Topic compliance	31/38 (81.58%)
3. Light atmosphere	38/38 (100%)
4. Group management	34/38 (89.47%)
5. Emotional patients managed	4/4 (100%)
6. Answered questions	11/26 (42.31%)

The total possible score for each aim was 38 if full compliance was achieved. If the session criteria was unable to be marked due to incomplete recording or the criteria was not applicable, the total possible score was reduced. 100% compliance was achieved for criteria three (Kept the atmosphere light) and criteria five (Dealt with emotional patients in the correct manner), however as can be seen from the data in the table, there was minimal data available for analysis for criteria five. There was least good compliance with criteria one (Outlined aims and running order of the session) and criteria six (Closed well and answered any questions patients may have). For the session specific criteria, as the criteria were different for each session, it is not possible to compare compliance scores for each of the criteria across the sessions recorded.

The results indicate close compliance with the criteria set for fidelity of the intervention delivery and it can be concluded that fidelity has been demonstrated and achieved.

3.8 Power calculation

A power calculation was performed in order to establish the required sample size for future studies. This was done using an online calculator tool, Sealed Envelope Ltd. 2012

(<https://www.sealedenvelope.com/power/continuous-superiority>).

Where the primary outcome measure is GHQ at three months, 666 patients are required to have an 80% chance of detecting, as significant at the 5% level, an increase in the primary outcome measure from 36.0625 in the control group to 32.4667 in the experimental group.

CHAPTER FOUR

Discussion

4.1 Main Findings

4.1.1 Summary of results

In summary, the results of this chapter demonstrate several key findings:

It is possible to recruit stroke patients to such a study, although there was a difference in success of recruitment rates dependant on the recruitment source. Face to face recruitment resulted in a much higher recruitment rate than by postal invitation letter.

Attendance rates indicated acceptability of the intervention for participants, but ill health and medical appointments impacted on compliance with attendance.

The intervention is able to be delivered in accordance with the RCAS instruction manual, demonstrating fidelity of the study.

Qualitative data analysis identified that group dynamics and group leader qualities and skills impact on participant's experience of the intervention. The qualitative data also suggests a largely positive experience of the intervention.

Follow up by postal questionnaire resulted in an acceptable return rate but missing data was an issue. The amount of missing data indicates

the need to review the choice of outcome measures and method of follow up in future studies.

The main findings of the results of this feasibility study are further discussed below:

4.1.2 Recruitment

The results for recruitment to this study show that there was a large difference in the number of responses received to invitation letters based on the source and method. Reasons for non-response may be for a variety of reasons, which weren't explored in this study although mistrust of the study, travel and time constraints, and failure to recognise a perceived personal benefit have all been highlighted in previous studies as possible reasons (Nathan 1999, Chang 2004, Blanton 2006). The first part of the recruitment process depends on identifying the eligible patient populations (Blanton et al 2006) so it is vital to ascertain an appropriate recruitment source. Previous studies have used several different recruitment methods including clinic referrals, advertisements, telephone recruitment and letters (Maurer 1995, Chang 2004). Since this study initially only used invitation letters as a recruitment method this may have contributed to the relatively low response rate (11%) from this source (the acute hospital stroke service), however it was higher than in Maurer's study where the response rate to invitation letters was only 4.7% (Maurer 1995).

The community recruitment source in this study produced a combined response rate of 47.5% comprising a 30% response rate from letters sent by the community stroke service provider and a 65% response rate through face to face invitation. Since the community service provider was delivering the intervention this may have influenced response rates, as stroke patients may have recognised the clinical service or because it provided an opportunity for the study to be discussed face to face. Face to face recruitment clearly demonstrated a positive impact on recruitment in this study.

Once potential participants had expressed an interest in finding out more about the study, they were screened over the telephone for compliance with inclusion criteria which resulted in exclusion of 45.2% of potential participants. Following this at a face to face assessment appointment a further 7.8% were excluded. Overall this meant that only 7.3% of stroke survivors contacted about the study were recruited. This is comparable to some other stroke studies which also only recruited less than 10% of prospective participants (Blanton 2006, Werner 1996).

The number of carers recruited to the study were low; only 11/47 participants (23.4%) had carers willing or able to participate in the study with them. Study design factors including exclusion criteria, travel requirements, tolerance of the intervention and an option to receive the

intervention after control data is collected, can all affect the response rate to research study invitations (Blanton 2006).

It is noted that participant recruitment is considered to be one of the most difficult aspects of the research process (Chang et al 2004) with up to 85% of trials not concluding on schedule or failing to reach an endpoint in participant accrual (Nitkin 2003). This study managed to achieve 78.3% of its target recruitment within a 13 month period, when it was decided to cease attempts at further recruitment assuming saturation of the sample had been achieved. This is comparable to feasibility RCT which recruited 76% of the expected sample size (Walker et al 2015).

It is important, therefore, that in future similar studies, careful consideration is given to both the recruitment source and recruitment method.

The randomisation process resulted in an inequity of group sizes. Since there was a prior assumption that 60 participants would be recruited (as that was the target number) there was a risk that different group sizes would result, which is known in risk in small studies using this process (Jadad 1998). The difference in group size was further impacted when two participants from the intervention group withdrew from the study, meaning there was a difference in numbers available for follow-up between the groups. The benefits of using a recognised method of

randomisation in this RCT outweigh any concerns around difference in group size.

4.1.3 Participant characteristics

Overall, the groups were well matched on baseline characteristics, although there were more males than females recruited to the study. This is not similar to reported statistics which state that although men are at 25% higher risk of stroke at a younger age, women live longer and hence there is an overall increased incidence of stroke in women (Stroke Association 2016). This imbalance in recruitment gender resulted in more males than females in the control group but an equal amount of males and females in the intervention group. Despite this, there were unequal numbers of males and females in the individual groups in which the intervention was delivered. This resulted as groups were delivered when a waiting list of randomised intervention participants had enough participants to make the group viable (minimum of five). Since the RCAS intervention is not gender specific this should not have impacted on the study, however, the gender imbalance in some groups was an issue for one male participant who found himself as the only male in his group and identified his dissatisfaction with this during interview. The mean age of participants recruited to this study (66.92 years) is consistent with the average age of stroke according to the literature; the Stroke Association reports that 75% of strokes occur in those aged 65 and over (Stroke Association 2015; DH 2007).

There were similarities in both the Barthel score and number of months post stroke across both groups. The mean and median Barthel scores for both groups were high suggesting that participants were functionally independent in most ADL. The mean number of months post stroke across both groups (15.765) was reflective of stroke patients having completed rehabilitation.

The results of analysis of the descriptive statistics demonstrates that the GHQ score was relatively high in both groups, from baseline measurement and throughout the study. This is indicative of a relatively high level of psychological distress in the participant sample. Although the GHQ measure does ask users to answer based on their health over the 'past few weeks' it may be difficult for participants to have separated their longer term stroke needs from their current health status. Since this is a requirement of reliable use of the GHQ this may need more emphasis to participants if using this measure in future studies. It is noted that the range of scores in both groups was high at each measurement point and therefore outlying data may have impacted on the mean scores.

The descriptive statistics analysis also indicates high CASM scores across both groups, indicating high levels of confidence in all participants throughout the study. Again there is a wide range of scores, which may have impacted on the analysis. Since the CASM

measure was under development during the study, the refined measure should result in a more sensitive / reliable measure of confidence and it is this published version of the CASM tool that would be recommended for use in future studies.

4.1.4 Attendance

One key discussion point here is whether the level of attendance truly indicated acceptability of the intervention. The results showed that only 18.2% of intervention participants attended all 11 sessions. The mean number of sessions attended was 7.78 which was short of the threshold set of attendance at eight sessions to indicate acceptability, although the median was 8.13 sessions attended. However, 59.1% of intervention participants did manage to attend 8 or more sessions.

When analysis of the reasons for non-attendance is considered, it can be seen that the main reason was health related with 53.25% of sessions missed being due to either illness, medical appointments or hospital admission. It is to be expected that people with stroke may have ongoing medical problems due to the long term nature of the condition and this should be considered when setting attendance targets in future studies.

The two intervention group participants who were withdrawn from the study prior to intervention delivery had an impact on attendance data as

they both recorded zero attendance. If their data had been withdrawn from analysis of attendance data the mean attendance would have increased and met the threshold for acceptability. It was decided not to exclude the data, however, as the study was delivered on an intention to treat basis meaning all data for recruited participants should be analysed. This is seen as good practise as the approach maintains treatment groups that are similar apart from random variation and it is recognised as most suitable for pragmatic trials such as this study (Hollis and Campbell 1999).

This study did demonstrate good carer attendance (mean attendance 2.14 sessions out of a maximum of three sessions) which suggests that it is feasible to engage carers in the intervention throughout the period of the course delivery. That said, relatively small numbers of carers were recruited to the study and only seven carers were allocated to the intervention group meaning limited conclusions can be drawn about acceptance of the intervention to carers from this data. Future studies may wish to consider interviews with carers as well as stroke participants to gain more information about carer's experience of the course and its acceptability.

Interview results demonstrated some problems with attendance related to the location of the venue, with some participants finding it too far to travel and not completing the programme as a result. Taxi transport was offered to individuals who identified transport difficulties but even

that was problematic at times, resulting in participants not arriving at the group on time. The location of the venue chosen for the group was recognised by the RCAS manual author as an important factor (Townsend 2009) but it should be highlighted that finding a suitable venue can come at a high financial cost which would impact both on future trial costs and clinical delivery of the intervention.

Interviews also highlighted that some participants found that being in a group with stroke survivors who were functionally more able was quite distressing. Other participants found it reassuring to meet people with similar disabilities and felt positive if they were relatively well in comparison to the group. Whilst the randomisation process of a RCT will result in a range of levels in disabilities in different groups, the group leader should be aware of the distress some participants may experience from attending a group intervention and be sensitive to individual needs.

Overall this study demonstrates similar attendance to a comparable study by Holmes et al (2011) looking at attendance at a psychological support group for people with Multiple Sclerosis. In Holme's study 61% of participants demonstrated attendance at a minimum of 4/6 (66.6%) sessions (Holmes et al 2011) compared to 59% of participants in the RCAS study attending at least 8/11(72.7%) of sessions.

The author concludes that attendance rates were high enough to deem the intervention acceptable and that it is feasible for stroke survivors to attend a programme of this duration and frequency.

4.1.5 RCAS intervention delivery

The time taken in recruiting to the study and the initial low response rate resulted in difficulties being able to randomise enough participants together at one time to run a group which led to some small group sizes. At times there were very small numbers of attendees in the group sessions, and this was raised as a concern during interview by one participant. However, consensus on optimum group size was not agreed by participants, with some preferring the intimacy of smaller groups for sharing stories and others preferring the camaraderie of larger groups. It is noted that groups three and four had larger numbers of attendees due to the addition of the control group participants who had completed the six month follow up. The mean attendance for these groups was much higher than in groups one and two and although it is unknown if it was the group size that influenced attendance rates this may be relevant. It is a factor that should be considered when determining group sizes for future studies.

When considering the fidelity of delivery of the intervention, the results show that high compliance scores were achieved when the videos were compared to the intervention manual. This indicates that the RCAS intervention was delivered in accordance with the manual by an

assistant practitioner and an assistant psychologist with professional supervision. The scoring system for measuring fidelity was based on two sets of criteria and the results show that there were more marks lost in the 'general criteria' section than in the 'session specific' section. As the general criteria were interpreted from the introduction of the RCAS manual, they were more open to interpretation and as a result were less consistently achieved during the scoring process. There were limitations to the fidelity analysis as not all sessions were recorded and some sessions were not recorded in full. In future studies it is recommended that each session delivered should be recorded at least once to ensure sufficient data is available for analysis.

The interviews resulted in a strong theme of the group leader's knowledge, skills and qualities having a positive impact on the participant's experience of the group. Since the same group leaders delivered all groups for the intervention arm of the study, it is not known if this was related to the individuals or their professional backgrounds. However, using the same group leaders ensured a consistency of group delivery across all four groups and enabled group participants to build a rapport with the group leaders and develop a sense of trust in them over the course of the intervention delivery. Although it can be concluded that a health care worker (Assistant Practitioner) without professional formal training successfully delivered the intervention for this study, it is not known which of the skills that she used made the experience so positive for participants. Using an assistant practitioner to

deliver the intervention is also cost effective and in a clinical setting this would make it a relatively inexpensive intervention which would be important in the current NHS financial climate (NHS England 2014: five year forward view). However, it cannot be concluded that this is the optimum style of delivery as alternative delivery methods were not trialled in this study. More feasibility work is needed to explore the optimum way of delivering the RCAS.

From the experience of this study it is recommended that the RCAS leaders, as a minimum, have experience of group leadership and are trained in stroke rehabilitation.

4.1.6 Follow up - Questionnaire return rate, outcome measures and missing data.

79% of all participants returned the three month follow-up questionnaire and 67% returned the six month questionnaire. This gives an overall follow up questionnaire return rate of 73% for this study. Asking participants to complete the questionnaires independently and return them by post could have impacted on both the return rate and amount of missing data in returned questionnaires. Although this is an acceptable return rate, it was worse than the return rate in a similar stroke rehabilitation study (CALM) that used alternative methods of follow up (Thomas 2013). The CALM study had an overall return rate of 85% for follow up questionnaires and it is of note that these were

completed face to face with participants (Thomas 2013). This is consistent with the fact that there was minimal missing data in the baseline questionnaires completed in the RCAS study which were completed face to face between the researcher and participant.

It must be remembered that there are cost implications, practical difficulties and the risk of bias if researchers are assisting participants to complete follow up questionnaires when conducting face to face follow up (Parker and Dewey 2000). This study did not allocate resources to enable research staff to visit participants at home to assist in completing the three and six month follow up data. This method may have increased the return rate and reduced the amount of missing data in questionnaires. If this method was used there would need to be provision for an independent research assistant to carry out the visits to reduce the risk of any bias. This person should be someone who was not involved in delivering the intervention and who is blind to the randomisation group allocation.

There are recognised methods of increasing postal questionnaire return rates including sending personalised cover letters with the questionnaires, providing stamped addressed envelopes, prompting participants by telephone before and after the questionnaire has been sent and providing non-respondents with a second copy of the questionnaire (Edwards et al 2002). Most of these strategies were employed in this study, although no telephone call was made prior to

sending the questionnaire and only one follow up telephone call was made to non-responders.

It is also recommended that questionnaires are designed for ease of completion in terms of layout and design (e.g. large enough font size, use of tick boxes) (Parker and Dewey 2000). The order in which the questionnaires are presented in a battery of assessments may also be relevant and seeking preliminary feedback on the design and content of questionnaire booklets prior to a future study is recommended.

A further consideration in analysing the return rates for questionnaires for this study is the timings of when follow up questionnaires were sent. It was within the study protocol to send the follow up questionnaires at three and six months post randomisation. Since participants were placed on a waiting list for attendance at the group following randomisation, some participants had to wait several weeks for a group to start meaning they were still completing the intervention at the point when they were being asked to complete the three month follow up questionnaire. It may have been confusing for participants to be asked to complete a follow up questionnaire when they had not finished attending the group. This could have been a contributory factor to the observed decrease in score across time in the results of the CASM in the participant group. In a future RCT study seeking to establish the effectiveness of RCAS, it is recommended that participants have a

chance to complete the intervention before they are asked to evaluate it.

The results demonstrate an issue with missing data at follow up. Of all follow up questionnaires sent there were 30% returned incomplete. The total number of returns was 65 meaning that of the questionnaires returned 41.5% of them had missing data. This was similar to the amount of incomplete questionnaires returned in the TOTAL study which also used postal questionnaires as a follow up method and 43% were incomplete. From the amount of missing data it appears that the COPE (60 item questionnaire) and the CASM (53 item questionnaire) appeared to be the most problematic for a number of participants to complete. The CASM questionnaire was under development during the study but has since been shortened to 27 items (Horne 2015) and should therefore be less onerous for stroke patients to complete. The COPE was the lengthiest questionnaire at 60 items and contained some sensitive questions in domain 14 about drug and alcohol use.

Recommendations for increasing response rates to postal questionnaires include using short questionnaires and avoiding questionnaires containing questions of a sensitive nature (Edwards et al 2002). Future studies need to review whether outcome measures of this length are the most appropriate questionnaires to use.

Whilst consideration needs to be given to which outcome measures most appropriately evidence the desired study outcomes, the measures

must also be acceptable to participants in terms of content and length of time to complete. The scope of the interviews for this study did not include discussion around the acceptability or ease of completion of the outcome measures but it would provide useful information in trying to determine why there were high amounts of missing data. This would also inform the choice of outcome measures for future studies.

From the results of this study the author recommends not using the COPE as it had poor completion rates and is also complex to draw conclusions from its results having 15 separate domains to analyse. The amended version of the CASM may result in better completion rates as it is shortened and as it is the only measure available to measure confidence post stroke, the author would recommend its use in a future study. The GHQ 30 is a reliable and valid measure of psychological distress in community samples (Huppert 1989) which has been found to be sensitive in stroke patients (Lincoln 2003) and would be appropriate to use in future studies evaluating the RCAS intervention.

4.1.7 Follow up - Qualitative findings

The same interview schedule was used throughout the interviews and was not developed in response to the emerging data. Amending the interview schedule in response to interviewer experience and information received would have enabled the interviews to be

developed to respond to new findings and therefore improve data collection. In order to achieve this, the interviews would need to be transcribed and analysed after each interview rather than at the end of all the interviews and this was not possible in this study.

Two different interviewers completed the interviews and this is pertinent as it is inevitable that there would be different interview styles used due to experience and personality. Neither interviewer was experienced in interview skills which could have influenced the quality and quantity of the results gained. It is important that neither interviewer was involved in the delivery of the intervention as this could influence participant's response and introduce bias.

Interviews were stopped as data saturation point had been reached, although if the interview schedule had been developed during the process this may not have been the case after only eight interviews. Interviews were completed in participants own homes which avoided the need for travel to a venue which may have facilitated engagement with the interview process.

The interview process was limited to interviewing intervention participants only. Carers were not excluded from the interview if they were present when it was carried out, but they were not invited to participate in a separate interview about their experience of the intervention from a carer's perspective. The group leaders were not

interviewed about their experience of delivering the group, which would provide an extra dimension of data around acceptability of the group. It is recommended that if time permits in a future study, participants, carers and group leaders should all be invited to participate in interviews and that the interview schedule is developed during the process.

There were no field notes collected during this study, other than basic attendance records, however, it would be beneficial to include this in a future study. This would ensure that any lessons learnt from the experience of the group leaders can be used to influence future study protocols. Analysis of field notes would assist in identifying further data about optimum group delivery factors.

4.2 Strengths of the study

This study was a feasibility study which set out to explore the delivery of a known intervention – RCAS. The intervention was delivered by the NHS in a clinical service setting, rather than in a research clinic, making this a pragmatic trial which reflects issues that occur in real clinical practise. The study design was that of a randomised controlled study which is seen as the 'gold standard' in research. Principles of allocation concealment and blinding were followed and bias was avoided at all stages.

4.3 Limitations of the study

This study did not reach its target for recruitment, due to recruitment difficulties, although the sample size was still acceptable for a feasibility study. The resulting delay in delivery of groups whilst waiting for sufficient participants did impact on the ability to collect follow up data at an appropriate time after delivery of the intervention.

Although the interviews showed a positive experience for participants, the study could not draw firm conclusions about what factors contributed to this. It is possible that the benefits reported may have been due to the social element of similar people meeting together for support, rather than being specifically attributable to the intervention. In a future study, the opportunity to compare the RCAS intervention with both a control group of usual care and a social support group without a structured programme should be considered.

There was limited patient and public involvement in this study. Although there was a stroke survivor on the project steering group for this study, that was the limit of patient involvement in the delivery of this study. There may be scope for a wider role for patient involvement in the design of a future study.

4.4 Relation to previous studies and recommendations for future work

Although there is literature to support using group psychological interventions for stroke patients in a hospital setting, as described by Vohora et al 2008, Barton 2002 and Gurr 2009, there is limited literature to support the use of group psychological interventions later in the stroke pathway. RCAS is designed to be delivered in the community when other rehabilitation and therapies have ceased, at a time when stroke patients may be feeling abandoned by healthcare services. There are no similar studies published relating to the RCAS intervention. This feasibility study provides preliminary data to support acceptability of the intervention and evidence that it is feasible to conduct an RCT of the RCAS intervention.

4.5 Conclusion

Since the need for psychological support post stroke is clearly identified in the literature, there is a need to identify if the RCAS intervention works. The feasibility study data indicates that it is possible to deliver a full RCT. It is recommended that this is carried out using the GHQ30 as the primary outcome measure. This is since this was the most acceptable to participants (demonstrated by the highest completion rate in questionnaires) and it specifically measures mood, which the RCAS intervention aims to improve. The measure was assessed at three and

six months and for the purposes of sample size calculation, the outcomes at three months have been used. This is since there was a decrease in score shown in the intervention group, suggesting improved mood, at three months but there was an increase in scores in the intervention group at six months.

In conclusion, the aims of this study were to consider a range of feasibility factors including recruitment, delivery of the intervention, acceptability and follow up. In addition the study sought to identify a primary outcome measure and a recommended sample size for a future study. The author concludes that all of the study aims have been met.

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Appendix A – Study invitation letter



Evaluation of the “Regaining Confidence after Stroke” course for stroke survivors and their carers: a feasibility trial

The ‘Regaining Confidence after Stroke’ course (RCAS) is a group therapy that is designed to help stroke survivors when they have finished rehabilitation to improve confidence in daily life.

We are recruiting for a study to evaluate the acceptability of the RCAS course in improving confidence, mood, adjustment, and increasing activity levels in stroke survivors, as well as improving mood and coping in their carers.

If you would like to receive more information about this study, please contact:

Mrs Kate Hooban or Mrs Jennifer Scott

Tel: 0115 823 0274

Email: kate.hooban@nottingham.ac.uk

jennifer.scott@nottingham.ac.uk

or return the reply slip below in the enclosed prepaid envelope.

.....
Yes, I would like to find out more information about the Regaining Confidence after Stroke Feasibility study.

Name

Address

.....

.....

.....

Telephone number

Email (optional).....

Appendix B – Telephone screen checklist

RCAS Telephone Screen.

- Introduce ourselves, where we are calling from, and what study.
- E.g. my name is ————— I'm calling from the University of Nottingham about the Regaining Confidence after Stroke study you have kindly replied that you are willing to help us with.
- Give more information on the study if required, keep it clear and simple.
- When was your stroke? (must not be more than 2 years ago) RCAS criteria.
- Are you having any treatment currently? (Course is designed for those who are coming to the end of treatment. Also must not be involved with other trials of psychological interventions.)
- I would like to arrange a visit to come and see you at your home (if that's ok with you) to discuss what the study will involve and answer any questions you have about it.
- We will post a letter to confirm your appointment and also send you some information on the study, which if you could read before our visit would be great.
- Thank you for your time.

Appendix C – Participant information sheet

Information for Participants (Final Version 3.0: 04/04/2013)

Title: Evaluation of the "Regaining Confidence after Stroke" course for stroke survivors and their carers: a feasibility trial

Investigators: Prof. N. B. Lincoln, Prof P Logan, Mrs J Horne, Mrs K Hooban, Mrs J Scott

Thank you for contacting us about this research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Some patients who have had a stroke experience a loss of confidence and psychological distress, which includes depression and anxiety. It can affect the success of rehabilitation. The 'Regaining Confidence after Stroke' course (RCAS) is a group therapy that is designed to help stroke survivors with low mood or adjustment difficulties when they have finished rehabilitation. The purpose of this study is to evaluate the acceptability of the RCAS course in improving confidence, mood, adjustment, and increasing activity levels in stroke survivors, as well as improving mood and coping in their carers. The study will also provide information about the feasibility of conducting a randomised control trial to evaluate the effectiveness of the course.

Why have I been chosen?

We are inviting 80 people who have suffered a stroke within the last two years to take part. We are also inviting their carers to take part. However, participants with a stroke have the right to object to their carer taking part in the study without affecting their own right to take part.

Do I have to take part?

It is up to you as to whether or not to take part. If you do want to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care that you receive.

What will I have to do?

You will be asked to complete four questionnaires about your mood and how you have adjusted to life following your stroke. This will take approximately 20 minutes. After that, you may be selected to attend the RCAS course. The chance that you will be selected to attend the course is 1 in 2. This course is made up of 11 two-hour weekly group sessions and will be led by a psychologist or occupational therapist. Some of the group sessions will be recorded to ensure the correct delivery of the course material. If you do not have the opportunity to attend the RCAS course, you will receive all other rehabilitation and community support that is usually available.

Three months after agreeing to take part in the study you will be sent four further questionnaires to complete and return in a pre-paid envelope. In addition, if you attended the RCAS course you may also be invited to take part in an interview that will ask about the useful and unhelpful aspects of the course. This interview will take place in your own home and will be tape recorded.

Six months after agreeing to take part in the study you will once again be sent four questionnaires to complete and return in a pre-paid envelope.

What are the possible disadvantages and risks of participating?

There are no particular risks associated with this study.

What are the possible benefits of taking part?

We hope that attending the RCAS course will help to improve your mood and reduce adjustment difficulties, but we do not know for certain whether it will. The information we get from this study will help us decide how to evaluate the course in the future.

What if new information becomes available?

Sometimes during the course of a research project new information becomes available about the treatment being studied. If this happens you will be informed about it and we will discuss whether you wish to continue to take part in the study. If you decide to continue you will be asked to sign an updated consent form.

What happens when the research study stops?

If you have not had opportunity to attend the RCAS course as part of the study you will be offered the opportunity once you have completed the final set of questionnaires, six months after you start in the study.

What if something goes wrong?

If you have any concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. Contact details are shown below. If you remain unhappy and wish to

complain formally, you can do this through Nottingham University Hospitals Trust Patient Advice and Liaison Service (PALS) on 0800 183 0204.

Will my information be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it. Your personal data (address, telephone number) will be kept for 12 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or your family member at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be informed of your participation in the study.

What will happen to the results of the research study?

The results of the study will be presented at conferences arranged by professional organisations which are attended by healthcare professionals, as well as at local stroke groups. The results may also be published in a scientific journal. There will be no way that you could be identified in any

published reports. If you wish to know the results of the study we will send you a summary of the findings.

Who is organising and funding the research?

The research is organised by the University of Nottingham and funded by the Stroke Association.

Who has reviewed the study?

All research in the NHS is reviewed by a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by (Nottingham) Research Ethics Committee.

Contact for further information

Mrs Kate Hooban

Tel: 0115 8230274

Email: kate.hooban@nottingham.ac.uk

OR

Mrs Jennifer Scott

Tel: 0115 8230274

Email: Jennifer.scott@nottingham.ac.uk

Thank you for reading this information

Appendix D –Screening assessment tool



Regaining Confidence after Stroke feasibility study

Screening tools document

Date of completion:	
Completed by:	
Study ID:	
Participant initials:	

Sheffield Screening Test for Acquired Language Disorders

Score Sheet

Client's Name Date of Birth
Tester's Name Date of Test
Full instructions for administration and scoring are contained in the *Manual*

Receptive Skills (Section 2)

1. Verbal Comprehension of Single Words	Score
I'm going to ask you to point to some of the things in the room...	
door _____ light _____ chair _____	
ceiling _____ corner _____	☐

2. Comprehension of Sequential Command	
a) Point to the window and then to the door.	☐
b) Before pointing to the ceiling, touch the chair.	☐

3. Comprehension of a Complex Command	
Tap the chair twice with a clenched fist, while looking at the ceiling	☐

4. Recognition of differences in Meaning Between Words	
I'm going to read you a list of words and I want you to tell me which is the odd one out:	
a) chicken, duck, apple, turkey	☐
b) run, drink, walk, sprint	☐
c) small, large, massive, huge	☐

5. Comprehension of a Narrative	
a) I'm going to read you a short paragraph and then ask you a question about it. John went to the shop to buy a pen. When he got there he found that he had forgotten his wallet, so he came home and made himself a cup of tea	
What should he have taken with him?	☐
b) I'm going to read you another paragraph.	
Mrs Smith visited several shops. She bought a newspaper, a cauliflower, a stamp and some sausages.	
What was the second shop she visited?	☐

Expressive Skills (Section 3)

6. Word finding

Tell me the names of three well-known places
in *the client's home town*.

Score one mark if three names are given correctly.

☐

7. Abstract Word Finding

Tell me another word that means the same as:

a) beautiful;

☐

b) angry;

☐

c) ridiculous.

☐

8. Sequencing

Describe how you would make a cup of tea.

☐

A correct answer contains two or more appropriate stages in the right order.

9. Definitions

Describe what the following words mean:

a) home;

☐

b) search;

☐

c) ambitious.

☐

10. Verbal Reasoning

I'd like you to tell me:

a) why you would use an umbrella;

☐

b) why people go on holiday;

☐

c) what would you do if you were locked out of the house.

☐

Expressive Skills: Total Score

☐

Receptive and Expressive Skills: Total Score

☐

BARTHEL INDEX

BOWELS	0 = Incontinent 1 = Occasional accident 2 = Continent	☐
BLADDER	0 = Incontinent/Catheterised 1 = Occasional accident (max 1 per day) 2 = Continent (for over 7 days)	☐
GROOMING	0 = Needs Help 1 = Independent (face/hair/teeth/shaving)	☐
TOILET USE	0 = Dependent 1 = Needs some help but can do something 2 = Independent	☐
FEEDING	0 = Unable 1 = Needs help cutting/spreading butter 2 = Independent	☐
TRANSFER	0 = Unable 1 = Major help (1-2 people, physical) 2 = Minor help (verbal or physical) 3 = Independent	☐
MOBILITY	0 = Immobile 1 = Wheelchair independent, incl corners 2 = Walks with help of 1 person (verbal/physical) 3 = Independent (may use aid, eg stick)	☐
DRESSING	0 = Dependent 1 = Needs help, but can do about half unaided 2 = Independent	☐
STAIRS	0 = Unable 1 = Needs help (verbal or physical, carrying aid) 2 = Independent up and down	☐
BATHING	0 = Dependent 1 = Independent	☐
TOTAL		

INCLUSION/ EXCLUSION CRITERIA RESULTS

Sheffield screening score ≥ 8 Y / N

Barthel score ≥ 10 Y / N

Able to understand and speak English Y / N

If YES to all of the above, participant meets inclusion criteria-
proceed to Regaining Confidence Screening Interview

If NO to any of the above, participant does not meet inclusion
criteria- DO NOT PROCEED

DECISION

INCLUDE / EXCLUDE from study

Appendix E – Participants consent form



The University of
Nottingham

UNITED KINGDOM • CHINA • MALAYSIA

PARTICIPANT CONSENT FORM

(Final version 2.0: date 23/04/2013)

Title of Study: Evaluating the "Regaining Confidence after Stroke" course for stroke survivors and their carers: a feasibility trial

REC ref: 12/EM/0319

Name of Researcher: Prof N. B. Lincoln, Prof P Logan, Mrs J Horne, Mrs K Hooban, Mrs J Scott

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number dated..... for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I agree to take part in the above study. ☐

Name of Participant Date Signature

Name of Person taking consent Date Signature

2 copies: 1 for participant and 1 for the project notes

Appendix F – Carer information sheet



Information for Carers

(Final Version 2.0: 04/04/2013)

Title: Evaluation of the "Regaining Confidence after Stroke" course for stroke survivors and their carers: a feasibility trial

Investigators: Prof. N. B. Lincoln, Prof P Logan, Mrs J Horne, Mrs K Hooban, Mrs J Scott

You are being invited to take part in a research study as you are the relative or carer of someone who has already agreed to consider taking part. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Some patients who have had a stroke experience a loss of confidence and psychological distress, which includes depression and anxiety. It can affect the success of rehabilitation. The 'Regaining Confidence after Stroke' course (RCAS) is a group therapy that is designed to help stroke survivors with low mood or adjustment difficulties when they have finished rehabilitation. The purpose of this study is to evaluate the acceptability of the RCAS course in improving confidence, mood, adjustment, and increasing activity levels in stroke survivors, as well as improving mood and coping in their carers. The study will also provide information about the feasibility of conducting a randomised control trial to evaluate the effectiveness of the course.

Why have I been chosen?

We are inviting 80 people who have suffered a stroke within the last two years to take part. We are inviting the relatives or carers of those involved also to take part. However, participants with a stroke have the right to object to their carer taking part in the study without affecting their own right to take part.

Do I have to take part?

It is up to you as to whether or not to take part. If you do want to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do not wish to take part your relative or the person you are caring for will still be able to take part in the study if they wish.

What will I have to do?

You will be asked to complete three questionnaires about your mood and how you have adjusted to life as a carer. This will take approximately 20 minutes. After that, the person for whom you care may be selected to attend the RCAS course. The chance that you will be selected to attend the course is 1 in 2. This course is made up of 11 two-hour weekly group sessions and will be led by a psychologist or occupational therapist. If the person for whom you care is selected to attend the course you will be invited to attend the first and final sessions. Some of the group sessions will be recorded to ensure the correct delivery of the course material.

Three months after agreeing to take part in the study you will be sent four further questionnaires to complete and return in a pre-paid envelope. In addition, if you attended the RCAS course you may also be invited to take part in an interview that will ask about the useful and unhelpful aspects of the course. This interview will take place in your own home and will be tape recorded.

Six months after agreeing to take part in the study you will once again be sent questionnaires to complete and return in a pre-paid envelope.

What are the possible disadvantages and risks of participating?

There are no particular risks associated with this study.

What are the possible benefits of taking part?

We hope that attending the RCAS course will help to improve your mood and reduce adjustment difficulties, but we do not know for certain whether it will. The information we get from this study will help us decide how to evaluate the course in the future.

What if new information becomes available?

Sometimes during the course of a research project new information becomes available about the treatment being studied. If this happens you will be informed about it and we will discuss whether you wish to continue to take part in the study. If you decide to continue you will be asked to sign an updated consent form.

What happens when the research study stops?

If you have not had opportunity to attend the RCAS course as part of the study your relative or the person for whom you care will be offered the opportunity and you will also be invited to attend. This will occur after you

have both completed the final set of questionnaires, six months after you start in the study.

What if something goes wrong?

If you have any concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. Contact details are shown below. If you remain unhappy and wish to complain formally, you can do this through Nottingham University Hospitals Trust Patient Advice and Liaison Service (PALS) on 0800 183 0204.

Will my information be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database.

Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 12 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or your family member at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If

you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be informed of your participation in the study.

What will happen to the results of the research study?

The results of the study will be presented at conferences arranged by professional organisations which are attended by healthcare professionals, as well as at local stroke groups. The results may also be published in a scientific journal. There will be no way that you could be identified in any published reports. If you wish to know the results of the study we will send you a summary of the findings.

Who is organising and funding the research?

The research is organised by the University of Nottingham and funded by the Stroke Association.

Who has reviewed the study?

All research in the NHS is reviewed by a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by (Nottingham) Research Ethics Committee.

Contact for further information

Mrs Kate Hooban

Tel: 0115 823 0274

Email : kate.hooban@nottingham.ac.uk

Or

Mrs Jennifer Scott

Tel : 0115 823 0228

Email : Jennifer.scott@nottingham.ac.uk

Or

Mrs Jane Horne

Tel: 0115 823 0724

Thank you for reading this information

Appendix G – Carer consent form



The University of
Nottingham

LEICESTER • CHINA • MALAYSIA

CARER CONSENT FORM

(Final version 2.0: date 23/04/2013)

Title of Study: Evaluating the "Regaining Confidence after Stroke" course for stroke survivors and their carers: a feasibility trial

REC ref: (to be added after approval given)

Name of Researcher: Prof N. B. Lincoln, Prof P Logan, Mrs J Home, Mrs K Hooban, Mrs J Scott

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number dated..... for the above study and have had the opportunity to ask questions.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

☐

3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.

☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports.

☐

5. I agree to take part in the above study.

☐

Name of Participant

Date

Signature

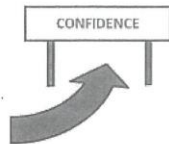
Name of Person taking consent

Date

Signature

2 copies: 1 for participant and 1 for the project notes

Appendix H – Participant baseline questionnaire booklet



Regaining Confidence after Stroke feasibility study

Baseline questionnaire booklet for participants

Date of completion:	
Completed by:	
Study ID:	
Participant initials:	

Questionnaire 1 (NEADL)

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
1. Walk around outside?	☐	☐	☐	☐
2. Climb stairs?	☐	☐	☐	☐
3. Get in and out of a car?	☐	☐	☐	☐
4. Walk over uneven ground?	☐	☐	☐	☐
5. Cross roads?	☐	☐	☐	☐
6. Travel on public transport?	☐	☐	☐	☐
7. Manage to feed yourself?	☐	☐	☐	☐
8. Manage to make yourself a hot drink?	☐	☐	☐	☐
9. Take hot drinks from one room to another?	☐	☐	☐	☐
10. Do the washing up?	☐	☐	☐	☐

	Not at all	With help	On your own with difficulty	On your own
11. Make yourself a hot snack?	☐	☐	☐	☐
12. Manage your own money when out?	☐	☐	☐	☐
13. Wash small items of clothing?	☐	☐	☐	☐
14. Do your own housework?	☐	☐	☐	☐
15. Do your own shopping?	☐	☐	☐	☐
16. Do a full clothes wash?	☐	☐	☐	☐
17. Read newspapers or books?	☐	☐	☐	☐
18. Use the telephone?	☐	☐	☐	☐
19. Write letters?	☐	☐	☐	☐
20. Go out socially?	☐	☐	☐	☐
21. Manage your own garden?	☐	☐	☐	☐
22. Drive a car?	☐	☐	☐	☐

Questionnaire 2 (COPE)

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to deal with stress. This questionnaire asks you to indicate what you generally do and feel when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress.

Then respond to each of the following items by choosing one number for each, using the response choices listed below:

- | | |
|---------------------------------------|------------------------------------|
| 1 = I don't usually do this at all | 2 = I usually do this a little bit |
| 3 = I usually do this a medium amount | 4 = I usually do this a lot |

Please try to respond to each item separately in your mind from each other item. Choose your answers thoughtfully, and make your answers as true FOR YOU as you can. Please answer every item. There are no 'right' or 'wrong' answers, so choose the most accurate answer for YOU - not what you think 'most people' would say or do. Indicate what YOU usually do when YOU experience a stressful event.

- | | |
|---|--------------------------|
| 1. I try to grow as a person as a result of the experience | ☐ |
| 2. I turn to work or other substitute activities to take my mind off things | ☐ |
| 3. I get upset and let my emotions out | ☐ |
| 4. I try to get advice from someone about what to do | ☐ |
| 5. I concentrate my efforts on doing something about it | ☐ |
| 6. I say to myself 'this isn't real' | ☐ |
| 7. I put my trust in God | ☐ |
| 8. I laugh about the situation | ☐ |
| 9. I admit to myself that I can't deal with it and give up trying | ☐ |
| 10. I restrain myself from doing anything too quickly | ☐ |
| 11. I discuss my feelings with someone | ☐ |
| 12. I use alcohol or drugs to make myself feel better | ☐ |
| 13. I get used to the idea that it happened | ☐ |
| 14. I talk to someone to find out more about the situation | ☐ |
| 15. I keep myself from getting distracted by other thoughts or activities | ☐ |
| 16. I daydream about things other than this | ☐ |
| 17. I get upset, and am really aware of it | ☐ |
| 18. I seek God's help | ☐ |

19. I make a plan of action	☐
20. I make jokes about it	☐
21. I accept that this happened and that it can't be changed	☐
22. I hold off doing anything about it until the situation permits	☐
23. I try to get emotional support from my friends and relatives	☐
24. I just give up trying to reach my goal	☐
25. I take additional action to try to get rid of the problem	☐
26. I try to lose myself for a while by drinking alcohol or taking drugs	☐
27. I refuse to believe that it has happened	☐
28. I let my feelings out	☐
29. I try to see it in a different light, to make it seem more positive	☐
30. I talk to someone who could do something positive about the problem	☐
31. I sleep more than usual	☐
32. I try to come up with a strategy about what to do	☐
33. I focus on dealing with this problem and, if necessary, let other things slide a little	☐
34. I get sympathy and understanding from someone	☐
35. I drink alcohol or take drugs, in order to think about it less	☐
36. I kid around about it	☐
37. I give up the attempt to get what I want	☐
38. I look for something good in what is happening	☐
39. I think about how I might best handle the problem	☐
40. I pretend that it hasn't really happened	☐
41. I make sure not to make matters worse by acting too soon	☐
42. I try hard to prevent other things from interfering with my efforts at dealing with this	☐
43. I go to the cinema or watch television, to think about it less	☐
44. I accept the reality of the fact that it happened	☐
45. I ask people who have had similar experiences what they did	☐
46. I feel a lot of emotional distress and I find myself expressing those feelings a lot	☐
47. I take direct action to get around the problem	☐
48. I try to find comfort in my religion	☐
49. I force myself to wait for the right time to do something	☐
50. I make fun of the situation	☐
51. I reduce the amount of effort I'm putting in to solving the problem	☐
52. I talk to someone about how I feel	☐
53. I use alcohol or drugs to help me get through it	☐
54. I learn to live with it	☐
55. I put aside other activities in order to concentrate on this	☐
56. I think hard about what steps to take	☐
57. I act as though it hasn't even happened	☐
58. I do what has to be done, one step at a time	☐
59. I learn something from the experience	☐
60. I pray more than usual	☐

Questionnaire 3 (GHQ-30)

Please read this carefully:

We should like to know if you have had any medical complaints, and how your health has been in general, *over the past few weeks*. Please answer ALL the questions simply by underlining the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those you had in the past. It is important that you try to answer ALL the questions.

Thank you very much for your co-operation.

HAVE YOU RECENTLY:

1 – been able to concentrate on whatever you're doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2 – lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3 – been having restless, disturbed nights?	Not at all	No more than usual	Rather more than usual	Much more than usual
4 – been managing to keep yourself busy and occupied?	More so than usual	Same as usual	Rather less than usual	Much less than usual
5 – been getting out of the house as much as usual?	More so than usual	Same as usual	Less than usual	Much less than usual
6 – been managing as well as most people would in your shoes?	Better than most	About the same	Rather less well	Much less well
7 – felt on the whole you were doing things well?	Better than usual	About the same	Less well than usual	Much less well
8 – been satisfied with the way you've carried out your task?	More satisfied	About the same as usual	Less satisfied than usual	Much less satisfied
9 – been able to feel warmth and affection for those near to you?	Better than usual	About the same as usual	Less well than usual	Much less well

10 – been finding it easy to get on with other people?	Better than usual	About the same as usual	Less well than usual	Much less well
11 – spent much time chatting with people?	More time than usual	About the same as usual	Less time than usual	Much less than usual
12 – felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
13 – felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less capable
14 – felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
15 – felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
16 – been finding life a struggle all the time	Not at all	No more usual	Rather more than usual	Much more than usual
17 – been able to enjoy your normal day-to-day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
18 – been taking things hard?	Not at all	No more than usual	Rather more than usual	Much more than usual
19 – been getting scared or panicky for no good reason?	Not at all	No more than usual	Rather more than usual	Much more than usual
20 – been able to face up to your problems?	More so than usual	Same as usual	Less able than usual	Much less able
21 – found everything getting on top of you?	Not at all	No more than usual	Rather more than usual	Much more than usual
22 – been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
23 – been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
24 – been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual

25 – felt that life is entirely hopeless?	Not at all	No more than usual	Rather more than usual	Much more than usual
26 – been feeling hopeful about your own future?	More so than usual	About same as usual	Less so than usual	Much less hopeful
27 – been feeling reasonably happy, all things considered?	More so than usual	About same as usual	Less so than usual	Much less than usual
28 – been feeling nervous and strung-up all the time?	Not at all	No more than usual	Rather more than usual	Much more than usual
29 – felt that life isn't worth living?	Not at all	No more than usual	Rather more than usual	Much more than usual
30 – found at times you couldn't do anything because your nerves were too bad?	Not at all	No more than usual	Rather more than usual	Much more than usual

Questionnaire 4 (CASM)

Please rate your
level of
AGREEMENT with
a tick ✓



		Strongly Agree	Agree	Disagree	Strongly Disagree
Even though I practice tasks, I don't improve	CAS1	☐	☐	☐	☐
I think positively about myself	CAS2	☐	☐	☐	☐
I feel robbed of my identity	CAS3	☐	☐	☐	☐
I feel alone	CAS4	☐	☐	☐	☐
I am afraid of having another stroke	CAS5	☐	☐	☐	☐
Other people would say I was confident	CAS6	☐	☐	☐	☐
I feel less capable	CAS7	☐	☐	☐	☐
I feel I can push myself to achieve	CAS8	☐	☐	☐	☐

Please rate your level of AGREEMENT with a tick ✓






		Strongly Agree	Agree	Disagree	Strongly Disagree
I am confident in my home	CAS10	☐	☐	☐	☐
I feel comfortable looking in a mirror	CAS11	☐	☐	☐	☐
I can usually handle what comes my way	CAS12	☐	☐	☐	☐
I do not have much to be proud of	CAS13	☐	☐	☐	☐
I believe I am a failure	CAS14	☐	☐	☐	☐
It is hard for me to achieve my goals	CAS15	☐	☐	☐	☐
It is difficult to handle situations that are unplanned	CAS16	☐	☐	☐	☐
My attitude helps me to be confident	CAS17	☐	☐	☐	☐

Please rate your level of AGREEMENT with a tick ✓					
		Strongly Agree	Agree	Disagree	Strongly Disagree
I avoid important everyday tasks	CAS19	☐	☐	☐	☐
I believe I can achieve what I want to	CAS20	☐	☐	☐	☐
I am able to do things as well as most people	CAS21	☐	☐	☐	☐
I worry I am not safe to use electrical equipment or appliances	CAS22	☐	☐	☐	☐
I have a fear of failure	CAS23	☐	☐	☐	☐
I achieve more when I enjoy what I am doing	CAS24	☐	☐	☐	☐
I am able to push myself	CAS25	☐	☐	☐	☐
I believe you can do anything if you try hard enough	CAS26	☐	☐	☐	☐
I believe I have inner strength	CAS27	☐	☐	☐	☐

Please rate your
level of
AGREEMENT with
a tick ✓



		Strongly Agree	Agree	Disagree	Strongly Disagree
I manage to solve problems if I try hard enough	CAS29	☐	☐	☐	☐
I do not feel comfortable in public places	CAS30	☐	☐	☐	☐
I feel home is the only place where I am safe	CAS31	☐	☐	☐	☐
I am confident enough to leave the house	CAS32	☐	☐	☐	☐
I am worried about how others see me	CAS33	☐	☐	☐	☐
I feel terrified meeting people I don't know	CAS34	☐	☐	☐	☐
I do not feel able to attend social events	CAS35	☐	☐	☐	☐
Other people's comments knock my confidence	CAS36	☐	☐	☐	☐

Please rate your
level of
AGREEMENT with
a tick ✓



		Strongly Agree	Agree	Disagree	Strongly Disagree
I worry I will fall and hurt myself when I am out	CAS38	☐	☐	☐	☐
I feel I am not very good company	CAS39	☐	☐	☐	☐
I feel other people overprotect me	CAS40	☐	☐	☐	☐
I don't like people seeing me using aids, such as, walking aids	CAS41	☐	☐	☐	☐
I feel other people judge how I look	CAS42	☐	☐	☐	☐
It bothers me that I can't do things like I used to	CAS43	☐	☐	☐	☐
I have learnt do to things differently since my stroke	CAS44	☐	☐	☐	☐
I do well when I do 'a bit at a time'	CAS45	☐	☐	☐	☐

Please rate your level of AGREEMENT with a tick ✓






		Strongly Agree	Agree	Disagree	Strongly Disagree
I feel scared to go out	CAS47	☐	☐	☐	☐
I am able to do things at my own pace	CAS48	☐	☐	☐	☐
It is hard to find a hobby that I value	CAS49	☐	☐	☐	☐
I feel terrified when I try to do something new	CAS50	☐	☐	☐	☐
I get frustrated when I can't do as much as I want to	CAS51	☐	☐	☐	☐
I get excited about learning new things	CAS52	☐	☐	☐	☐
My family/friends encourage me to do things	CAS53	☐	☐	☐	☐
Other people push me to achieve more than I think I can	CAS54	☐	☐	☐	☐

Please rate your
level of
AGREEMENT with
a tick ✓



		Strongly Agree	Agree	Disagree	Strongly Disagree
I get a lot of positive encouragement from my family/friends/neighbours	CAS56	☐	☐	☐	☐
I am encouraged by my health professionals	CAS57	☐	☐	☐	☐
I feel people speak down to me	CAS58	☐	☐	☐	☐
When people tell me I've done well it makes me feel more confident	CAS59	☐	☐	☐	☐

THIS COMPLETES THE QUESTIONNAIRES,
THANK YOU FOR COMPLETING THEM.

**YOUR INFORMATION WILL BE STORED CONFIDENTIALLY BY
THE RESEARCH TEAM.**

Appendix I - Carer baseline questionnaire booklet



Regaining Confidence after Stroke feasibility study

Baseline questionnaire booklet for carers

Date of completion:	
Completed by:	
Study ID:	
Carer initials:	

Questionnaire 1 (GHQ-30)

Please read this carefully:

We should like to know if you have had any medical complaints, and how your health has been in general, *over the past few weeks*. Please answer ALL the questions simply by underlining the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those you had in the past. It is important that you try to answer ALL the questions.

Thank you very much for your co-operation.

HAVE YOU RECENTLY:

1 – been able to concentrate on whatever you're doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2 – lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3 – been having restless, disturbed nights?	Not at all	No more than usual	Rather more than usual	Much more than usual
4 – been managing to keep yourself busy and occupied?	More so than usual	Same as usual	Rather less than usual	Much less than usual
5 – been getting out of the house as much as usual?	More so than usual	Same as usual	Less than usual	Much less than usual
6 – been managing as well as most people would in your shoes?	Better than most	About the same	Rather less well	Much less well
7 – felt on the whole you were doing things well?	Better than usual	About the same	Less well than usual	Much less well
8 – been satisfied with the way you've carried out your task?	More satisfied	About the same as usual	Less satisfied than usual	Much less satisfied
9 – been able to feel warmth and affection for those near to you?	Better than usual	About the same as usual	Less well than usual	Much less well
10 – been finding it easy to get on with other people?	Better than usual	About the same as usual	Less well than usual	Much less well

11 – spent much time chatting with people?	More time than usual	About the same as usual	Less time than usual	Much less than usual
12 – felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
13 – felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less capable
14 – felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
15 – felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
16 – been finding life a struggle all the time	Not at all	No more usual	Rather more than usual	Much more than usual
17 – been able to enjoy your normal day-to-day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
18 – been taking things hard?	Not at all	No more than usual	Rather more than usual	Much more than usual
19 – been getting scared or panicky for no good reason?	Not at all	No more than usual	Rather more than usual	Much more than usual
20 – been able to face up to your problems?	More so than usual	Same as usual	Less able than usual	Much less able
21 – found everything getting on top of you?	Not at all	No more than usual	Rather more than usual	Much more than usual
22 – been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
23 – been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
24 – been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual

25 – felt that life is entirely hopeless?	Not at all	No more than usual	Rather more than usual	Much more than usual
26 – been feeling hopeful about your own future?	More so than usual	About same as usual	Less so than usual	Much less hopeful
27 – been feeling reasonably happy, all things considered?	More so than usual	About same as usual	Less so than usual	Much less than usual
28 – been feeling nervous and strung-up all the time?	Not at all	No more than usual	Rather more than usual	Much more than usual
29 – felt that life isn't worth living?	Not at all	No more than usual	Rather more than usual	Much more than usual
30 – found at times you couldn't do anything because your nerves were too bad?	Not at all	No more than usual	Rather more than usual	Much more than usual

Questionnaire 2 (Caregiver Strain Index)

I am going to read a list of situations. They may relate to your experience of caring for

_____. Would you please tell me if any of them apply to you?

	YES	NO
Sleep is disturbed (e.g. because _____ needs help to go to the toilet).		
It is inconvenient (e.g. because helping takes so much time).		
It is a physical strain (e.g. because of lifting in and out of bed).		
It is confining (e.g. helping restricts free time).		
There have been family changes (e.g. because helping has disrupted routine/ there is no privacy)		
There have been changes to personal plans (e.g. couldn't go on holiday).		
There have been other demands on my time (e.g. from other family members).		
There have been emotional adjustments (e.g. because of arguments).		
Some behaviour is upsetting (e.g. incontinence, memory problems).		
It is upsetting to find _____ has changed so much from his/her former self. (E.g. they seem a different person from how they used to be).		
There have been work adjustments (e.g. having to take time off).		
It is a financial strain.		
Feeling completely overwhelmed (e.g. because of worry, concerns about how you will manage).		
TOTAL SCORE		

(Scoring Yes = 1, No = 0)

Appendix J – Example RCAS session plan

SETTING REALISTIC TARGETS - 2

SESSION OUTLINE:

- Sharing your thoughts about your goals since last week
- Smart Goals
- Breaking goals down into smaller steps
- **Quiz** - Useless and useful goals
- Planning the steps to your goal

Appendix K – Session specific criteria checklist

Session specific criteria

Marked on a 2 point scale with 0 being 'not met' and 1 being 'met'.

Session One

1. General welcome of everyone
2. Group together and discuss changes in day to day life
3. Reconvene, outline problems discussed
4. Group together and discuss "What would help now?"
5. Reconvene, feedback from each group
6. Outline what the sessions are for
7. Make plans for carer/supporter meetings if these are wanted

Session Two

1. Emphasise that skills and tactics already possessed can be applied to problems they have now, this session will pull those out
2. View "Tips and Tricks" and discuss
3. View "Memory Aids" and discuss
4. View "Communication" and discuss
5. Outline top tips
6. Set task for next time

Session Three

1. Begin with progress report on problems identified at the last meeting
2. View "Where are they now?"
3. Share expectations people had of recovery at different points and emphasis that they alter with time
4. View "At work" and "Leisure" and discuss
5. Discuss areas group members want to achieve more in, set task

Session Four

1. Recap key points of last session
2. Share goals group members have been thinking about
3. Present information about S.M.A.R.T. goals
4. Divide into pairs/groups for next master sheet
5. Offer to see group members individually to give whatever help is needed in planning steps to achieve goals

Session Five

1. Start with feedback from last sessions take home exercise
2. View "Emotional Ups and Downs", stopping part way through to fill in part of master sheet
3. Use any combination of remaining master sheets
4. Close with take home exercise

Session Six

1. Share ideas from take home exercise
2. View "Understanding one another" and use master sheet to summarise themes raised
3. Fill in master sheets in groups (survivors and supporters) and use to feedback to group

4. In groups discuss what would help now
5. Close with quote

Session Seven

1. Recap last session
2. View “Other people in your life” and “Barclays Brainstorm” and discuss
3. Discuss where group members already go or would like to go, who they meet and possible difficulties
4. Use selection of sheets to discuss problems faced by all parties
5. If group members mention problems with health and social care professionals, use sheet to discuss, sharing ideas to resolve
6. Close with what members will attempt before the next session with respect to other people in their lives

Session Eight

1. Take feedback from take home exercise
2. View “Introduction” and follow with discussion, with sheet if needed
3. Talk about gloom and depression using sheets
4. Give out hand-outs, to be read in detail at home
5. View “Dave’s Story” and “Coping” and discuss
6. Small groups or pairs for sheet and feedback
7. Suggest trying something specific to boost mood before the next session

Session Nine

1. Feedback from take home task
2. Distribute sheet and discuss
3. Pairs/small groups discussing major life changes before stroke
4. View “Coping With Change” and discuss
5. Pairs/small groups for sheet, feedback briefly
6. Set take home task

Session Ten

1. Feedback on take home task
2. View “I’m still me” and discuss

3. Explain the idea of an anchor and use sheet
4. View “Barclay’s Brainstorm” and discuss
5. Give out “Stroke recovery first aid kit” as take home task

Session Eleven

1. Take any feedback about “first aid kit”
2. Ask for feedback about the course from attenders and their supporters
3. Discuss what members feel they need next in terms of continuing support
4. Discuss projects they would like to undertake, if any
5. Close by clarifying what will happen now for each group member and what the arrangements are for follow on meetings if these are being organised

Appendix L – General criteria checklist

General Criteria

Marked on a 3 point scale with 0 being 'not met', 1 being 'partly met' and 2 being 'fully met'.

1. Outlined aims and running order of the session
 2. Kept on topic
 3. Kept the atmosphere light
 4. Managed the whole group well
 5. Dealt with emotional patients in the correct manner *
 6. Closed well and answered any questions the patients may have
- * This criterion was disregarded if no patient became emotional during the session.

Appendix M – Follow up cover letters

Evaluation of the 'Regaining Confidence after Stroke' course for stroke survivors and their carers

Date

Dear

It is now over 3 months since you agreed to take part in this research study. At the beginning of the study you completed four questionnaires about your mood and how you have adjusted to life following your stroke. The next stage of the study involves repeating the four questionnaires. All participants are asked to complete these questionnaires again whether or not they took part in the Regaining Confidence group sessions. Enclosed are a questionnaire booklet and a pre-paid envelope. We would be most grateful if you could complete the enclosed questionnaire booklet and return in the envelope provided.

If you need any assistance completing the questionnaires or if you have any questions please do not hesitate to contact us:

Mrs Kate Hooban

Tel: 0115 8230274

Email: kate.hooban@nottingham.ac.uk

OR

Mrs Jennifer Scott

Tel: 0115 8230274

Email: Jennifer.scott@nottingham.ac.uk

Thank you

Evaluation of the 'Regaining Confidence after Stroke' course for stroke survivors and their carers

Date

Dear

It is now 6 months since you agreed to take part in this research study. At the beginning of the study and 3 months later, you completed four questionnaires about your mood and how you have adjusted to life following your stroke. The next and final stage of the study involves repeating the four questionnaires. All participants are asked to complete these questionnaires again whether or not they took part in the Regaining Confidence group sessions. If your carer agreed to participate in the study they are also asked to complete the carer questionnaire booklet again at this point of the study. Enclosed are a participant questionnaire booklet, a carer questionnaire booklet if appropriate, and a pre-paid envelope. We would be most grateful if you could complete the enclosed questionnaire booklet(s) and return in the envelope provided. This will be the final time you will be asked to provide information for this study. Thank you very much for your participation in this study.

If you need any assistance completing the questionnaires or if you have any questions please do not hesitate to contact us:

Mrs Kate Hooban

Tel: 0115 8230274

Email: kate.hooban@nottingham.ac.uk

Appendix N – Interview schedule

Topics to be covered at interview
(Final version 2.0: date 23/04/2013)

Title: Evaluation of the “Regaining Confidence after Stroke” course for stroke survivors and their carers: a feasibility trial

Investigators: Prof. N. B. Lincoln, Prof. P. Logan, Mrs J Horne, Mrs K Hooban, Mrs J Scott

The interviews will be unstructured and flexible. There are no set questions other than the introductory one. The aim is to allow participants to tell us what they thought with the minimum of prompting.

Introductory question

1. Please tell me what you thought about the Regaining Confidence after Stroke Course.

Topics to be explored

- ☐ Positive aspects
- ☐ Negative aspects
- ☐ Potential changes to content and structure
- ☐ Effect on mood
- ☐ Effect on confidence
- ☐ Effect on social identity
- ☐ Importance of social context

Appendix O – Interview analysis node codes

Interview analysis node codes

1. Group expectations
2. Group leader
3. Group numbers
4. Group participant mix
5. Group session content
6. Long term group effects
7. General negative comments
8. General positive comments
9. Transport
10. Venue
11. Carer attendance
12. Confidence
13. Session length
14. Group location
15. Group frequency
16. Attendance
17. Group benefits
18. Group support
19. Improved mood
20. Low mood

Appendix P – Criteria checklist data

Criteria table showing scores

Session	1	2		3		6			8		9			10		11			
Group	4	3	4	2	4	1	2	3	1	3	1	3	4	1	3	1	2	3	4
Specific criteria																			
1.	1	0	1	-	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1
2.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	-	0	0
4.	1	1	1	1	1	1	0.5	1	0	0	1	1	1	1	1	1	-	1	0
5.	1	0	0	-	1	-	1	1	1	-	1	1	1	-	0.5	0	-	0	0
6.	1	1	1	n/a	n/a	n/a	n/a	n/a	1	-	1	1	1	n/a	n/a	n/a	n/a	n/a	n/a
7.	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	1	-	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
% specific criteria met	86%	67%	83%	100%	100%	100%	90%	80%	86%	75%	100%	100%	100%	100%	90%	80%	100%	60%	40%
General criteria																			
1.	1	1	1	-	1	0	1	1	1	1	1	0	1	0	2	2	2	2	1
2.	2	1	2	2	1	2	2	2	2	2	1	1	2	1	2	1	2	1	2
3.	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
4.	2	1	2	2	2	1	2	2	2	1	2	2	2	2	2	2	2	2	1
5.	n/a	n/a	n/a	n/a	n/a	2	n/a	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
6.	1	1	0	-	1	-	-	1	1	-	1	1	1	0	-	1	-	1	1
% general criteria met	80%	60%	70%	100%	70%	70%	88%	83%	80%	75%	70%	60%	80%	50%	100%	80%	100%	80%	70%
% of all criteria met	83%	63.5%	76.5%	100%	85%	85%	89%	81.5%	83%	75%	85%	80%	90%	75%	95%	80%	100%	70%	55%

- ‘ – ’ denotes criterion unable to be marked as the part of the session containing it was not recorded
- ‘ n/a ’ denotes criterion was not applicable in this session