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PREP Plus combined postrehabilitation programme to support upper limb recovery in community-dwelling stroke survivors: protocol for a mixed-methods, cluster-assigned feasibility study

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ABSTRACT

Introduction Poor recovery of the upper limb following a stroke has been recognised as a significant problem in the UK. Although there is good evidence that early, intense rehabilitation can lead to upper limb recovery, often this is not maintained, with less than 50% of people regaining the ability to use their upper limb for independent function at 6 months. Upper limb recovery potential is reported for many years poststroke, yet current long-term provision is insufficient.

Methods and analysis 60 participants will be recruited into this feasibility study, with 30 allocated to a Post Rehabilitation Enablement Programme (PREP) alone and 30 allocated to a combined programme, PREP Plus, consisting of PREP and the Graded Repetitive Arm Supplementary Programme (GRASP). We will aim to complete four iterative waves. Within each wave, the intervention design will be refined, based on participant feedback. Within each wave, there will be one cluster unit (one intervention group ;PREP Plus) and one control group ;PREP alone)). A total of five PREP sites within Northern Ireland Health and Social Care Trusts will be used for this study. PREP Plus will have a home exercise component along with exercises logs and a behaviour contract. Qualitative and quantitative measures will evaluate the acceptability and feasibility to determine how feasible it is to embed the intervention into practice, as well as to determine the feasibility of a larger, mixed-methods, randomised controlled trial to assess intervention efficacy. Clinical endpoints will also be explored.

Ethics and dissemination This study has been approved by the Health and Social Care Research Ethics Committee A, IRAS project ID (278620). Participants will provide informed consent prior to participating in the study. Information outlining the purpose of the study, what data will be collected and how the data will be managed will be provided. Results will be published in peer-reviewed journals and any published data will be available on the university data repository. The project management group will advise on different avenues for dissemination to ensure it reaches appropriate audiences.

Trial registration number NCT05090163.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Investigates the feasibility of merging two established stroke rehabilitation programmes.
⇒ A strength of this study is that it has broad inclusion criteria, which will allow a greater number of survivors of stroke to participate.
⇒ A limitation of this study is not including a follow-up period at this time, which will prevent us from assessing longer-term changes.

INTRODUCTION

Size of the problem

Stroke is the third-leading cause of disability worldwide, with five million people annually becoming permanently disabled.[1] This places a significant economic and resource burden on healthcare systems. Poor recovery of the arm and hand has been recognised as a significant problem in the UK with around 80% of people with acute stroke having an upper limb impairment.[2] Fifty per cent of stroke survivors still have problems at 6 months,[3] which is partly explained by the primary physiological impairment. Others demonstrate a disconnect between what can be done with the limb and the actual use of the arm and hand in daily life.[4] This lack of real-world use of the limb in daily life leads to learnt non-use; a process in which stroke survivors rely more on their less impaired upper limb resulting in further impairment.[5]

The gap we wish to address

Rehabilitation is one of the most important aspects of care following a stroke, leading to better recovery and higher levels of independence.[6] Clinical guidelines and a robust evidence base indicate this rehabilitation

should involve repetitive, intensive and task-oriented practice.[7 8] Despite rehabilitation gains within the acute and subacute stages poststroke, many individuals do not go on to use their affected upper limb.[9 10] The significant gap we wish to address is how best to provide opportunities for continued supervised practice of the upper limb, in the community, once statutory services are complete.

However, to maintain any gains experienced in this acute phase and to overcome learnt non-use, it is crucial that people can embed limb practice into their daily lives and are provided additional opportunities for supervised practice. People poststroke, healthcare professionals and researchers[8 11] have all recognised this gap in longer-term upper limb rehabilitation provision. This provision is crucial to optimise and maintain the effects of rehabilitation delivered in the acute phase. We also know that upper limb recovery has been reported many years after stroke[12] but the question remains as to how we best support community stroke survivors to complete this upper limb practice?

Why the gap exists

Lack of resources and access to evidence-based therapies longer-term poststroke contribute to an overall reduced level of satisfaction of upper limb rehabilitation from stroke survivors and caregivers.[11] Within the resource provision of the National Health Service, it is not possible to deliver the long-term input required and, therefore, stroke survivors need support to complete this rehabilitation. Currently across the UK at approximately 3 months poststroke, most rehabilitation provision has ceased; a time when arm recovery is still ongoing.[13–15] Furthermore, stroke survivors at this point are medically stable, have settled into a new/adapted living environment and may be more motivated to focus on upper limb rehabilitation in order to improve their overall independence.[2 16 17]

How we could address the gap

A community group-based rehabilitation provides an accessible route to allow a large number of stroke survivors to gain access to evidence-based upper limb rehabilitation. Not requiring one-to-one supervision and thereby reducing cost, the concept of community programmes is compatible with healthcare policy to prevent secondary disabilities for persons living with long-term conditions.[5] Research shows a strong evidence base for group-based rehabilitation of the upper limb,[18 19] however, translation into long-term care pathways within Northern Ireland has been poor.[11]

Northern Ireland Chest Heart and Stroke (NICHS) has an established and extremely well-attended postrehabilitation enablement programme (PREP) for stroke survivors, which is embedded within the stroke services in Northern Ireland. This programme aims to address the need for further rehabilitation once stroke survivors have been discharged from statutory services. The Exercise Training after Stroke Study[20] looked at the effects of including an exercise programme with a combination of endurance and resistance training after stroke for 12 weeks.

Based on the Exercise Training after Stroke Study,[20] PREP is a physiotherapy-led 6-week course that provides a group-based structured exercise programme once per week, with embedded sessions of health education that promote social engagement. A previous internal evaluation by NICHS highlighted many benefits including improved physical function, self-efficacy and quality of life. The majority of the PREP exercises focus on cardiovascular and the lower limb. The ball lift and lower, and the wall press are the two upper limb exercises and they focus on the shoulder as well as the biceps and triceps muscles. There is no specific task-orientated, repetitive practice provision for the upper limb, and especially lacks fine motor movements as recommended in the evidence.[20]

Since 2018, 1170 stroke survivors have completed the PREP programme, highlighting the local implementation success in Northern Ireland (numbers obtained from NICHS database). PREP provides an excellent opportunity to integrate an evidence-based upper limb programme into an established community-based programme. The Graded Repetitive Arm Supplementary Programme (GRASP) is a stroke-specific upper limb programme designed to improve upper limb performance and use of the upper limb in activities of daily living. Evidence has demonstrated improvement in daily use of the upper limb after this programme in both the acute[21 22] and chronic stage poststroke[5] in addition to community-based programmes.[18] Within the PREP programme, there is no homework, or home exercise aspect to it, therefore, there is a lack of emphasis on incorporating everyday movement. Unlike PREP, GRASP has a homework component, where participants are asked to complete an hour a day of the upper limb exercises.[23] The purpose of PREP Plus is to merge both PREP and GRASP. This would enhance the existing PREP programme by adding in more upper limb exercises and homework to emphasise daily activities along with having the therapist-led exercises and social aspect of PREP.

This study will help build on a body of work which is the broad aim of establishing how best to support community-dwelling stroke survivors to practice upper limb rehabilitation. The aim of this study is to evaluate the feasibility of an upper limb intervention, based on GRASP, to increase use of the upper limb in daily life compared with PREP alone. The findings should help to determine how feasible it is to embed the intervention into practice, as well as to determine the feasibility of a larger, mixed-methods, randomised controlled trial to assess intervention efficacy with respect to upper limb function.

OBJECTIVES

Based on key areas of focus for feasibility studies[24–26] our objectives are:

1. To assess the acceptability of and demand of the study procedures, placed on stroke survivors.
2. To assess the acceptability of and demand of the PREP Plus intervention, placed on people with stroke and their carer.
3. To identify any necessary adaptations of the PREP Plus intervention in order to optimise its design, uptake in people with stroke and delivery by therapists.
4. To determine the resources requirements to deliver the PREP Plus programme (therapy training, updates to training, time to complete paperwork, deliver the intervention, consumables needed).
5. To explore the preliminary effects of the intervention on use of the affected upper limb in day-to-day life.

METHODS AND ANALYSIS

Patient and public involvement

A combination of service users and stakeholders have been actively involved in the design of this proposal and will continue to be involved throughout the delivery and dissemination.

Previous work with stakeholders highlighted that upper limb rehabilitation is a key priority for stroke survivors, creating the rationale for this study. Further discussions with NICHS coordinator and a PREP therapist identified upper limb rehabilitation as a gap within current PREP delivery. Telephone consultations with a range of therapists from the community stroke teams in Northern Ireland (who refer patients into the PREP programme) identified (1) Upper limb rehabilitation as a priority at this stage and (2) GRASP as an appropriate upper limb programme. Our coapplicant, stroke survivor was consulted on priorities important to service users at this stage.

All members of the project management group including a stroke survivor affirmed the importance of this research topic. The NICHS co-ordinator and therapist informed the design of the intervention, specifically the appropriate methodology of recruitment and intervention delivery including resource requirements. The project management group has been established and will consist of patient and carer representatives, healthcare professionals (community stroke team therapists), academics and service users (NICHS coordinators, community stroke team member). During the project, members will inform and monitor recruitment, address any delivery concerns, oversee the data management and collection, complete administration tasks and identify/address any potential issues arising within the project.

Study design

A mixed-methods, cluster-allocated, controlled feasibility study will be conducted. A cluster in this study consists of one control group and one intervention group. Participants will be recruited in several waves allowing qualitative analysis of focus group be completed between each wave of intervention delivery. On the final day of the 6 weeks, the participants in the intervention group, will attend a focus group and the therapist will be asked to take part in a 1:1 interview. This analysis will allow for minor adaptions in the delivery of the next wave. We will complete a total of four waves of recruitment. The therapist will remain the same for each intervention site (to prevent confounding factors). Each site will deliver 6 weeks of the intervention/control with a new set of participants before postintervention where qualitative measures are used to inform the design of the next wave as seen in figure 1. The Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines[27] were used in the write-up of this protocol (online supplemental appendix 1).

Setting

PREP is available across all of the Northern Ireland Health and Social Care Trusts.[28] For this pilot, we will have two sites for control and three sites for intervention. One site will deliver the intervention programme (PREP Plus) and

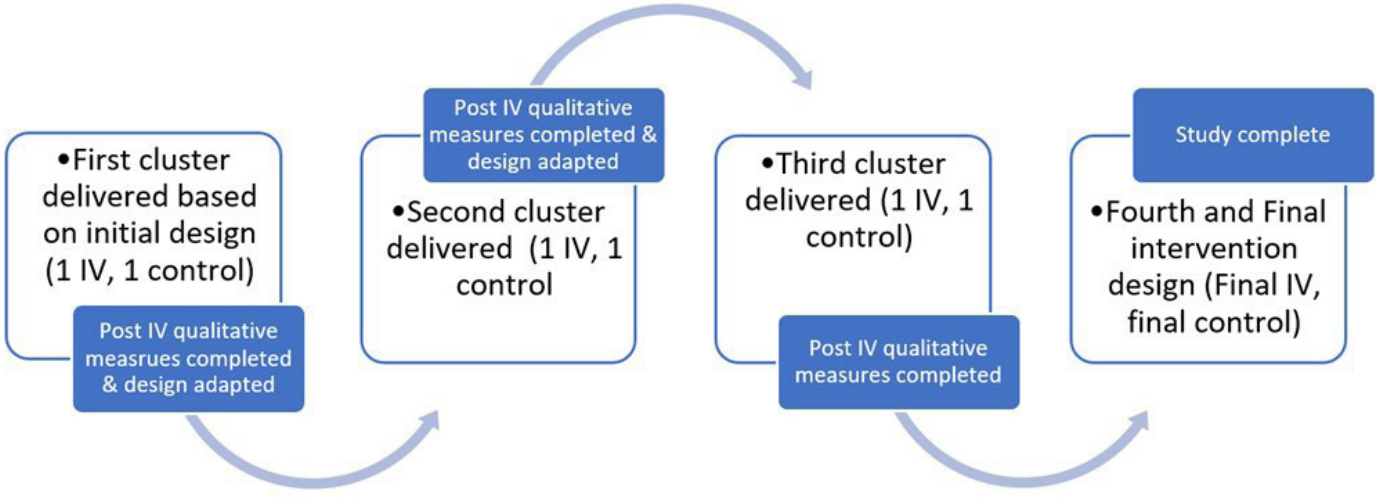

Figure 1 Study waves. The phases of the study from start to finish, showing the time points for study adaptions and outcomes.

one site will deliver the control programme (PREP) for 6 weeks. This period of 6 weeks (with one intervention site and one control site) will be one wave.

Study population

Stroke survivors who are referred to the PREP programme through standard referral pathways. Information about the research study will be provided to the community stroke teams who refer into the PREP programme.

The following inclusion and exclusion criteria will apply.

Inclusion criteria

Diagnosis of stroke (Can have previous strokes).

Have completed statutory rehabilitation, such as hospital inpatient/outpatient, early discharge or community stroke rehabilitation.

Able to follow two part written or spoken commands.

Medically fit to participate in an exercise programme, as determined by their general practitioner.

Have an impairment of their upper limb, as identified by the participant and/ or their community stroke team.

Exclusion criteria

Self-reported pain score of 5/more in their impaired upper limb.

Not participating in any other research studies.

Recruitment

Participant recruitment strategies will integrate with those used for the current PREP programme. Stroke survivors are currently referred by the community stroke team to a family support worker and inform them about the research study being conducted ask them if they are happy for their details to be passed to the research associate (RA).

The RA will first telephone the individual to determine if they are interested in taking part in the study and answer any queries they may have. Participants will be asked for an email so an electronic version of the consent form can be sent and signed. A paper copy for handwritten signatures will be available on day 1 of the 6-week course for those who do not have access to computers or prefer to sign the consent form in person. All documents will be kept in a locked cabinet in a locked room. Electronic documents will be password protected.

If the participant declines participation in the study, the reason will be recorded if known, as this will be used to determine if it was the potential intervention or being part of a research study that influenced their decision.

The participant will attend the group on day 1 as planned and at this stage will be informed whether their exercises will include the GRASP programme (intervention) or not (control).

On referral into a specific PREP site, each participant will be informed about the research study being undertaken at that site. If the participant wishes to find out more about the research, the RA will contact the participant with further information. After consenting into the study, the participant is informed whether the site is a control or intervention site. Suspected and confirmed adverse events will be reported to the study management team, the sponsor and the ethical bodies. Any confirmed adverse events will be reported to all active study participants. The study will pause while any suspected adverse events are investigated.

Sample size

In line with the guidelines set out for a feasibility study, it is recommended that 30 participants are recruited for each group. We aim to recruit up to 60 participants, 30 in the intervention group and 30 in the control group.[26 29]

Each PREP group will have more than five participants and, therefore, eight groups will be involved in the study making up in total, four intervention groups and four control groups.

The first wave of participants for the intervention and control sites were recruited in January 2022. The study is projected to continue till March 2023 with the last wave starting in January 2023.

Blinding and allocation concealment

The community stroke team determine eligibility but will not be aware of the allocation for the sites. For the purposes of the research study, the RA will complete all upper limb outcome measures at baseline and postintervention.

Therapist training

Therapists delivering the intervention (PREP Plus) will attend a 2-hour training with the international expert in GRASP (Dr Janice Eng), with support from neurotherapist, KP. Training will be recoded so future therapists can be trained. There will be additional 1:1 support offered to therapists by KP. The programme will introduce the therapists to the GRASP structure, content, support material and delivery. This may require additional training as the protocol is adapted and will be delivered by the principal investigator and supported by Dr Eng and the RA. Therapists delivering the control intervention will be offered training materials and online supported learning at the end of the study with support from Dr Eng. The training will also include elements specific to the study methods and protocols.

INTERVENTION

Control group: PREP

There will be no change in how this is currently delivered by NICHS. PREP will be delivered by a therapist, once per week for 6 weeks. Participants will complete 1 hour of circuit-based exercises, followed by refreshments and 1 hour of education, for example, benefits of exercise, dealing with emotions poststroke and lifestyle choices.[28] Figure 2 shows the seven exercises within the PREP circuit. Five of these stations focus on the lower body/ cardiovascular fitness and two are strength-based upper limb exercises. The amount of time spent at each station

Figure 2 PREP circuit exercises. The seven exercises that every PREP class uses. PREP, postrehabilitation enablement programme.

will be increased as the 6 weeks progress, starting at 30 s before progressing to 3 min. Twenty-seven per cent of the time is spent on upper limb exercises during the PREP classes.

Intervention group: PREP plus

Participants will complete the normal PREP model (exercise circuit, refreshments, 1-hour education) as described above. Those who will be in the PREP Plus group will congregate in a different room or away from the other PREP members for 15 min if another room is not available. During the first week, the therapist will ask the GRASP participants to fill in the behaviour contract, have a look through the book, and go over the purpose of the group. Exercises will be prescribed based on the individuals' upper limb function. Within GRASP there are five topics covered in the booklet:

1. Upper limb stretching.
2. Arm strengthening.
3. Hand strengthening.
4. Coordination.
5. Hand skills.

There is a home exercise component to GRASP where the participants are encouraged to complete 60 min of the assigned upper limb exercises. Each week at the end of PREP, the therapist will as the GRASP members how they worked on the exercises during the week, troubleshoot any issues that may arise and prescribe new/different exercises. At the end of the 15 min, all members of PREP and PREP Plus will rejoin and continue on with the PREP education session.

For those participants with a flaccid upper limb (no movement), assisted movement will be completed using their other upper limb to assist. Participants will work with the therapist in the GRASP sessions on how best to aid their flaccid arm in the exercises prescribed.

OUTCOMES

The feasibility and acceptability of the intervention will be evaluated in terms of recruitment, retention and adherence rates to the study. Where available, reasons for these rates will be recorded (study objective 1). A record will be kept of all information on instances of adverse events, including mental and physical problems and any reports of difficulty with intervention components (study objective 3).

Exploratory clinical outcomes will be measured at baseline and postintervention and are described below.

Taken at baseline and postintervention

1. The Rating of Everyday Arm-use in the Community and Home (REACH) Scale is a self-report measure for individuals with stroke that captures how the affected arm and hand is being used outside of the clinical setting.
2. A 10 m walk test is a measure to test for functional performance measure through their walking speed for 10 m.
3. Edinburgh Warwick Questionnaire. This measures the mental well-being and quality of life through a 7-question or 14-question measure. We will use the 7-question questionnaire.
4. Time Get Up and Go test. This test measures the lower limb functional performance, such as mobility and balance.

Outcome 1, The REACH Assessment, will be the only additional outcome measure added in conjunction to the three that are recoded by NICHS for all PREP participants.

Qualitative measures

The qualitative component of the study will consist of three methods at the end of each 6-week intervention period:

1. Focus group using semistructured questions (investigating user experience of the study procedures, acceptability of the intervention and their perceived impact of the intervention on their upper limb function).
2. 1:1 semistructured interview with the intervention therapist (investigating the acceptability of delivery of the intervention). Only therapists delivering the PREP Plus intervention will be invited to participate in the 1:1 interview.
3. A bespoke caregivers' questionnaire (investigate carer impact as a result of the potential change in service user upper limb function). This questionnaire will consist of a set of multiple-choice questions and open answer questions to allow the caregiver to add feedback.

All three methods will also include questions which focus on potential refinements for the next wave of intervention delivery.

The audiorecordings of the focus groups and interviews will be transcribed by RA. Focus groups will be conducted at the intervention site location, on the last day of the intervention. This session will be 30 min before the PREP course.

The questionnaires will be provided to carers on the last day of the 6-week intervention period. On the final day of the PREP Plus study, all study participants will be provided

with a carer pack. This will include the carer participant information sheet, a blank carer consent form, the questionnaire and a self-addressed prepaid postage envelope. Carers will be provided a period of 3 weeks to return the consent form and questionnaire.

All carers will be eligible to complete the questionnaire. If they are unable to provide written responses, a family member can assist in completing the questionnaire.

Results from all three qualitative elements will be combined after each 6-week period and presented to the project team to inform decisions on adaption of the next wave of intervention delivery.

For all qualitative methods processes for rigour and trustworthiness will be included. Triangulation will focus on using both the qualitative and quantitative measures in addition to member checking to ensure credibility of the findings. Participant information will be given a code and all data will be kept in a locked room in a locked filing cabinet, ensuring confidentiality. Any electronic data will be password protected. Feasibility will be reflected by usage of statistics, and acceptance will be reflected by positive feedback.

Data collection and analysis

Statistical analysis will be overseen by an experienced statistician.

For the primary aim to evaluate feasibility, we will calculate the acceptability of the study procedures through recruitment and retention rates and the acceptability of the intervention to stroke survivors, caregivers and intervention therapists.

1. A number of people recruited as a percentage of those screened will be calculated. Reasons for not participating will be recorded.

Recruit sufficient participants into the study and

1. How many participants complete >60% the intervention (The completion rate of >60% relates to the cut-off we has defined for adherence with attendance to the exercise programme based on the number of classes attended).
2. Qualitative feedback. Analysis of reason for refusal will use as a third determiner. For the secondary aim to determine the optimal intervention design, resource requirement and impact on upper limb function, qualitative and quantitative measurement will be used.

The following criteria would suggest that a larger, mixed-methods, efficacy randomised control trial is not feasible: recruitment rate falls short of 70% of that anticipated (recruit 18/60 participants), overall drop-out of over 40%, feedback from participants that they were unable to complete the intervention, feedback from therapists they were unable to deliver the intervention, adverse events and or excessive resource costs. Data monitoring will be completed by a statistician who is independent to the sponsor of the study. However, due to the feasibility nature of the study, interim analysis will not occur.

Data analysis

For analysis, all quantitative data will be coded and entered into SPSS (IBM V.24). Appropriate exploratory and descriptive analysis of the quantitative and qualitative data will be completed to reflect feasibility study design. Intervention effects will be represented by point estimates, and 95% CIs will be estimated postintervention.

All semistructured interviews and focus groups will be transcribed verbatim. After data familiarisation, a coding framework will be developed to facilitate coding of key concepts related to feasibility and acceptability of the intervention, followed by identification of the relevant themes as they emerge. Interim analysis will be completed after two cluster units are completed (one intervention group and one control group) and will inform minor protocol refinements. This analysis will include qualitative and quantitative data.

Auditing

Auditing will occur by the sponsor or ethical bodies as requested by such bodies.

ETHICS AND DISSEMINATION

A study information document will be given to all interested participants. This will outline the purpose, how the data are collected, stored and kept confidential, and who to contact if any questions or concerns arise. Consent will be taken, and copies given to the participant and stored in a secure location within the university. Data collected will be anonymised. Results will be published in peer-reviewed journals and any published data will be available on the university data repository.[30] Any person who has a significant contribution to the conduct, analysis and write-up of the study will be offered authorship. This study has been approved by the Health and Social Care Research Ethics Committee A, IRAS project ID (278620). The project management group will advise on different avenues for dissemination to ensure it reaches appropriate audiences. The study is registered at ClinicalTrials.gov, NCT05090163.

Contributors The study concept and idea was developed and refined by KP, NK and SM. JJE, JH, NH, ZC, AS and NK assisted in the refining of the study design and materials. All authors contributed to writing of the protocol. JH advised on grant proposal lay summary. All authors reviewed the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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