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Self-management intervention for mobility for people with stroke

Submission date
23/09/2021

Recruitment status
No longer recruiting

Registration date
30/09/2021

Overall study status
Completed

Last Edited
19/09/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Individuals' lives after stroke are affected by multiple levels of disability. Appropriate rehabilitation services can help them to regain their functions and improve their quality of life. In the UK, there has been a tendency toward the early supported discharge from hospital after a stroke with the aim of providing care at home after discharge. However, stroke survivors' needs after discharge from the hospital have been unmet as the health care services lack sufficient resources. Self-management strategies have been developed to help stroke survivors improve their self-efficacy and independence and play an active role in their rehabilitation process. The effectiveness and appropriateness of self-management as an additional component to the current practice have been examined in several contexts, but there has been limited research around self-management strategies to improve walking after stroke. The aim of this study is to develop and examine the feasibility of implementing a new self-management-based intervention to improve functional mobility for stroke survivors after their discharge from the hospital.

Who can participate?
Stroke survivors aged 18 to 99 years who are medically stable, within the first 6 months after discharge from hospital, able to walk independently or with the assistance of one person maximum (with or without aid device), able to communicate reasonably, and have a device that can launch the Zoom programme if they need to participate remotely from home

What does the study involve?
Participants will be randomly allocated to either one of the two following groups:
1. A control or a standard care group that gets the opportunity to attend (in person or on Zoom) a talk on improving walking ability and safety in walking
2. A treatment group where they will participate in the self-management for walking program. This group will attend an education session about the mobility training and safety, participate in setting goals and develop action plans for their walking, attend group exercise sessions every 2 weeks for 12 weeks and evaluate their own progress. The group exercise session will include exercises for a warm-up and cool down such as stretching, strengthening, endurance (stamina) and balance which will take between 30 to 45 minutes to perform. Due to the COVID-19 pandemic, the intervention will take place over Zoom or in person if government restrictions

permit. This group will also be given a booklet with similar exercises to complete at home and a diary to record the activities they perform in an electronic copy, or these documents can be posted to them as hard copies if they prefer. Participants will be encouraged to involve their family or carer in carrying out the activities at home. Once every 2 weeks the researcher will call each participant over the phone to review their progress. All assessment and interventional activities can take place over Zoom if necessary. Assessments will be arranged at a time convenient to the participants. There will be no financial reimbursement for this part of the study. The total length of involvement in this study will be 6 months.

What are the possible benefits and risks of participating?
Participants' contribution to this study is highly valued since it will help to identify whether the new self-management intervention is feasible and effective at improving confidence and walking ability for stroke survivors. It is possible that participants will personally benefit by improving their knowledge about improving walking as well as the confidence to manage their rehabilitation if they are in the group having the self-management intervention. With the knowledge that participants share the researchers hope to further refine the processes and improve the quality of care delivered for future patients with stroke.
The risks involved in participating in this study are minimal. Participants may feel fatigue, which is a common symptom during the recovery after stroke, but no major problems have been found with people who have used similar training programs. Participants will be supervised in group sessions by the researcher and at home by a family member to keep them safe. If a participant lives alone, exercises of a level suitable for their capacity that they can do unsupervised will be prescribed for them. In case they have any concerns about the conduct of the study, they will be referred to Dr Sheeba Rosewilliam, who is the chief investigator for this study, for further help.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
February 2019 to February 2023

Who is funding the study?
University of Birmingham (UK)

Who is the main contact?
1. Dr Sheeba B Rosewilliam, s.b.rosewilliam@bham.ac.uk
2. Mr Ahmad Sahely, axs1638@student.bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sheeba Rosewilliam

Contact details
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham

United Kingdom
B15 2TT
+44 (0)121 414 2910
s.b.rosewilliam@bham.ac.uk

Type(s)
Public

Contact name
Mr Ahmad Sahely

Contact details
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 7564 179 129
axs1638@student.bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
269079

Protocol serial number
IRAS 269079

Study information

Scientific Title
Feasibility of a self-management intervention for improving mobility for patients following stroke in the community

Acronym
SMIMPS

Study objectives
Self-management integrated interventions can better improve mobility outcomes than usual care alone for people with stroke

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 17/06/2020, HRA and Health and Care Research Wales (HCRW) Ethics Committee (Health Research Authority, Level 3, Block B, Bristol Research Ethics Committee Centre, BS1 2NT, UK; +44 (0)2071048071; approvals@hra.nhs.uk), ref: 269079

Study design
Mixed-methods design including a pilot randomized controlled trial and focus groups

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Rehabilitation of mobility for people in subacute stage post-stroke

Interventions
The participants will be randomly allocated to treatment or control groups by an administrator using a computer-generated randomisation chart. The treatment group will receive the self-management intervention for mobility training for 3 months in addition to the usual care. The developed SM intervention will include education sessions on improving mobility, self-management components including goal-setting, action-planning, peer support, home exercises booklet, self-monitoring using recording diary, and five group exercise sessions for mobility described below. The participant will complete a recording diary and goal setting record that will be provided to them as paper copies. The control group will receive the usual care provided by the local NHS and community services. Both groups will receive education about walking safely using a PowerPoint presentation.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate: the number of participants who consent to participate in the study by 6 months
2. Retention rate: the number of participants who consent to participate who remain in the study until the end of follow up at 6 months
3. Evaluation of the randomisation and blinding process and ability to reduce contamination using descriptive analysis of the process at the end of data collection period (12 months)
4. Eligibility criteria evaluated using the number of participants eligible for each criterion measured at the end of the recruitment period (6 months)
5. Participants' adherence to the intervention and follow up (the number of days the participants did their exercise and recorded in diary) measured every 2 weeks in a phone call with the researcher and at 6 months
6. Fidelity and acceptability of the new intervention: the lived experiences and perspectives of participants about the intervention collected using focus groups at 6 months (3 months from the end of the intervention period
7. Feasibility of the self-management and performance outcome measures (the validity of selected initial outcomes) measured using descriptive analysis at the end of the study (12 months)

Key secondary outcome(s))
1. Self-efficacy assessed using the stroke self-efficacy questionnaire at baseline, 3 months (end of intervention) and 6 months (follow up)
2. Goal achievement measured using the Goal Attainment Scale (GAS) every 2 weeks in a phone call with the researcher
3. Functional mobility measured using the Functional Gait Assessment (FGA) at baseline, 3 months (end of intervention) and 6 months (follow up)
4. Balance, mobility, and walking ability measured using the Timed Up and Go (TUG) at baseline, 3 months (end of intervention) and 6 months (follow up)
5. Walking endurance measured using the 6 Minutes Walking Test (6MWT) at baseline, 3 months (end of intervention) and 6 months (follow up)
6. Maximum walking speed measured using the 10-meter Walking Test (10-mWT) at baseline, 3 months (end of intervention) and 6 months (follow up)
7. Walking distance measured using a pedometer, collected every two weeks in a phone call with the researcher
8. Cognitive status measured using the Montreal Cognitive Assessment (MoCA) at baseline, 3 months (end of intervention) and 6 months (follow up)
9. General health status measured using the General Health Questionnaire-12 at baseline, 3 months (end of intervention) and 6 months (follow up)

Completion date
03/02/2023

Eligibility

Key inclusion criteria
Individuals will be eligible to participate in the study if they:
1. Are adults (18 years to 99 years)
2. Have had a diagnosis of a first stroke
3. Are within the first 3 months post-discharge from the hospital. This will be extended to participants who have had a stroke within the past 6 months
4. With Functional Ambulation Category (FAC) 2. This means that the person is at least able to walk with a maximum of one person assistance, with or without a gait aid (Mehrholz et al., 2007)
5. Have cognitive capacity that allows them to communicate and consent to participate in the study. The Montreal Cognition assessment (MoCA) (Cumming et al., 2013) and the FAC will be used for screening. Moreover, clinicians will be involved in determining patient's ability to participate prior to approaching any participant about this study
6. Can understand English. However, the feasibility of including participants who speak Punjabi or Urdu will be explored using translated information sheets and interpreters when possible using family members who speak English
7. Have access to a suitable device that can launch the ZOOM Programme

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
Patients will be excluded if they:
1. Are unable to participate or unable to give consent to participate in the programme due to marked cognitive impairment
2. Suffer from severe cardiopulmonary diseases or severe arthritis or have other major co-morbidities, which might be a risk for community walking
3. Have severe aphasia
4. Have severe spasticity or fatigue post stroke

Date of first enrolment
01/10/2021

Date of final enrolment
03/02/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Moseley Hall Hospital
Old Hall
Alcester Rd
Birmingham
United Kingdom
B13 8JL

Study participating centre
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be collected for this project only. The paper copies will be stored in the researcher's office at the University of Birmingham and only the research team members will have access to the records. Due to the COVID-19 pandemic the data will be collected on electronic copies of the forms using emails or using zoom and telephone questioning. All information from assessment questionnaires and focus groups will be made anonymous and stored securely in password-protected computers and hard copies will be stored in filing cabinets in the University office. All personal data will be made anonymous using codes. Data will not be shared with any person other than those involved in the project. Reports for the University and published data will not include personal details of the participants. The anonymous data will be securely stored for 10 years at the University and contact details will be stored for 3 years in case the researchers need to share findings with participants. After this time the data will be destroyed or deleted.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			19/09/2023	No	No
Participant information sheet	version 10	24/04/2021	28/09/2021	No	Yes
Protocol file	version 10	28/04/2021	28/09/2021	No	No