Study Information Sheet for Participants - Version 10

Study title: Feasibility of a self-management intervention for improving mobility for patients following stroke in the community -Intervention information.

Why are we doing this study?

After a stroke, individuals' lives can be affected by various disabilities. They are cared for in the NHS by a team of doctors, nurses, and therapists. But when they get discharged, many people feel confused or feel left out by the healthcare services. They may struggle to cope with their condition in the community.

One way to help a person cope better with the after-effects of stroke is by teaching them to manage their health and rehabilitation by themselves with some support from health professionals. This means of self-help is called Self-management (SM). Self-management programs can empower patients by providing the knowledge and skills to better understand and manage their condition.

Walking is affected in 75% of people following a stroke. Gaining the ability to walk after having a stroke has been mentioned as their most important goal for rehabilitation. The purpose of the study is to test the use of a self-management intervention to improve mobility for people with stroke after their discharge from hospital.

This project is part of a PhD study. We invite you to take part in this project which will give you opportunities to gain better knowledge about your walking ability. So please consider participation in this project. Please read the following material and decide if you would like to participate. You can discuss the information with others and the researcher involved before you agree to take part in the study. We thank you for the time and effort spent on considering your participation in the study.

Who is doing the study?

This is a project done by researchers from the University of Birmingham in collaboration with the Birmingham Community Hospitals NHS foundation trust. University of Birmingham is the sponsor for this study. Dr. Sheeba Rosewilliam is a lecturer and physiotherapist registered with the Health and Care Professions

Council who teaches at the University of Birmingham and is carrying out this work with Mr. Ahmad Sahely as part of his PhD program. Mrs. Carron Sintler is a consultant physiotherapist who works in the Moseley Hall hospital and will be working on this project with the researchers.

Are you eligible to join the study?

All stroke survivors who are medically stable, within the first six months post-discharge from hospital, able to communicate reasonably, and have a device that can launch ZOOM programme if they need to participate remotely from home are eligible to take part in this study. It is important to note that your participation is entirely voluntary and you are not obliged to support this study. The standard of care you receive or your legal rights will not be affected in any way if you do not wish to participate in this study. Even if you decide to take part you will have the right to change your mind and may withdraw at any time without giving any reason. Even after you begin to participate, if you decide to withdraw at any time, this will not affect the standard care provided by the NHS. Any data collected up to withdrawal may still be used for research purposes. But no further data will be collected from you. You can find out more about how we use your information by asking one of the research team by sending an email to the researchers below.

What happens if you decide to participate?

If you decide to participate in the study, you will be given more information about your role in the study. We will read out the consent forms over zoom or on the phone and ask you for consent for each statement. We will send the consent forms electronically and you can either sign it electronically or send an email stating you are consenting to participate. You will be asked to sign consent forms electronically by one of the persons conducting the project. Your GP will be informed of your participation using a letter.

In order to be able to test the effectiveness of the self-management program you 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 OR

2) a treatment group where you will participate in the self-management for walking program. You will attend an education session about the mobility training and safety. You will participate in setting goals and develop action plans for your walking. You will attend group exercise sessions every two weeks for twelve weeks

and evaluate your own progress. The group exercise session will include exercises for 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 pandemic, the intervention will take place over zoom or in person if government restrictions permit.

The treatment group will also be given a booklet with similar exercises to complete at home and a diary to record the activities you perform in an electronic copy. Or these documents can be posted to you as hard copies if you prefer. You can do as much exercises as possible at home and you are not forced to complete the training every day. However, regular exercise training has been shown to improve recovery and we would encourage you to try and complete the exercises as often as you can. Please make sure that you involve your family or carer in carrying out the activities at home for your own safety reasons. Once every two weeks the researcher will call you over the phone to review your progress.

Each participant in both the treatment and standard care groups will be assessed for their walking performance, confidence and emotional status three times during the project (at the start when you join the study, after 12 weeks and after 6 months). We will do assessments of your self-efficacy or confidence, goal-achievement, and the ability for self-monitoring your progress. This will be done using questionnaires, validated scales and recording diaries/documents that will be given to you either in an electronic format or completed over the phone. Other physical assessments include your physical function (time taken to walk 6-metres, maximum walking speed, distance walked in the community using a small pedometer sent to you by post), emotional and social performance using validated tests and questionnaires. The assessments will be done by a researcher who has had training in doing these assessments. Additionally, type of stroke, gender, date of birth, marital status and cognitive status will be recorded. Due to the COVID pandemic the data can be collected on electronic copies of the forms using emails or using zoom and telephone questioning.

All assessment and interventional activities can take place over zoom. Assessments will be arranged at a time convenient to the participants. Please note that there will be no financial reimbursement for this part of the study. The total length of your involvement in this study will be 6 months.

How to Join A Zoom Meeting?
If you are unfamiliar with the zoom, the researcher will call you on your phone to help you set up zoom on a suitable electronic device. They will also have trial zoom meetings before the actual study meetings to make sure you can use zoom.
Here's a step-by-step guide to join a Zoom meeting quickly:
Note: The same steps apply to both your laptop and your phone.
To join Using A Meeting Link, if you have a meeting link, just click on it or paste it into your web browser to join the meeting.

With your agreement we may invite you to participate in a group discussion about your experience in this project and further details of this will be provided at the three-month assessment.

How will we use information from you?
We will need to use information from you for this research project. We will have your name and contact details for communication purposes. We will keep all information about you safe and secure. All your assessment information will be made anonymous and stored securely in the researcher's office.
The electronic consent forms will have your name and contact details. These will be stored safely in password protected computers at the University of Birmingham. 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 your personal details. Please note that the anonymous data will be securely stored for 10 years at the University and contact details will be stored for 3 years in case we need to share findings with you. After this time the data will be destroyed or deleted.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- leaflet available from Mr.Ahmad Sahely
- by asking one of the research team listed below
- by sending an email to [axs1638@student.bham.ac.uk], or [s.b.rosewilliam@bham.ac.uk] or

- dataprotection@contacts.bham.ac.uk
- by ringing us on 07564179129.

Why should I participate in the study?

Your contribution to this study is highly valued since it will help us to identify whether the new self-management intervention is feasible and effective in improving confidence and walking ability for stroke survivors. It is possible that you will personally benefit by improving your knowledge about improving your walking as well as confidence to manage your rehabilitation if you are in the group having the self-management intervention. With the knowledge that you share with us we hope to further refine the processes and improve the quality of care delivered for future patients with stroke.

Are there any risks?

The risks involved in participating in this study are minimal. You 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. You will be supervised in group sessions by the researcher and at home by a family member to keep you safe. If you live alone, exercises of a level suitable for your capacity that you can do unsupervised will be prescribed for you. In case you have any concerns about the conduct of the study, you will be referred to Dr. Sheeba Rosewilliam who is the chief investigator for this study for further help. Regardless of this, if you wish to complain, or if you have any concerns about any aspect of the way you have been approached or treated during the course of this study, please write to the research governance email address given below. The University has in force a Public Liability Policy, which provides cover for claims for “negligent harm”, and the activities here are included within that coverage.

What happens at the end of the study?

If this new intervention is found to be effective, then it will be recommended for wider practice. The findings will be written up. These findings will then be published in health journals and presented to professionals at conferences. The findings will also be disseminated in the local NHS trusts in the form of presentations and posters. If you would like to know the outcome of the study please feel free to contact the researcher involved and copies of reports will be sent to you. Anonymous data from this study will be used to support other similar research in the field of rehabilitation.

Thank you

Thank you for taking time to read the information sheet and considering participation in the study.

Contacts

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