

# A study looking at a new walking intervention for stroke survivors

<b>Submission date</b> 17/03/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/03/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is paralysis (hemiplegia) or weakness (hemiparesis) on one side of the body. This can make movements such as walking very difficult and so many patients need extensive physiotherapy to help them recover. Following discharge from hospital, it is important that stroke survivors walk as much as they can so that they are able to keep fit and maintain their independence. This study is looking at a new walking programme designed to help stroke survivors to feel motivated to walk more and to fit walking into their daily lives. The aim of this study is to find out whether this walking programme is more effective at encouraging walking than a brief written information leaflet about the benefits of walking after suffering a stroke.

### Who can participate?

Stroke survivors who have been discharged from hospital who are able to walk outside for 15 minutes and live in the area covered by the South London Stroke Register (SLSR).

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a short leaflet by post which contains information about the importance of physical activity after stroke. Those in the second group take part in the walking programme. This programme involves one-to-one sessions with a walking coach, which aims to improve patient's attitudes towards walking. Participants in both groups complete a number of questionnaires at the start of the study, one week and six months after the end of the walking programme. They are also asked to wear a device that measures their physical activity levels for seven days at the same times.

### What are the possible benefits and risks of participating?

Benefits of participating are unknown, however it is expected that participants increasing their level of physical activity will have a positive impact on wellbeing and social participation. The risks involved in increasing levels of physical activity are potential increased risk of falls, and

muscle discomfort or pain associated with increased movement. However, a number of steps will be taken to minimise these risks, including falls assessments before and during the study and information about when to stop walking.

Where is the study run from?

Guy's & St Thomas' Foundation NHS Trust and King's College Hospital NHS Foundation Trust (UK)

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

March 2016 to December 2016

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Sarah Jane Besser

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

A feasibility study of a psychologically-informed, community-based walking intervention for stroke survivors

### Study objectives

The aim of this study is to find out whether it is feasible to deliver a newly developed walking intervention for stroke survivors and to evaluate it using a randomised controlled design.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

City Road & Hampstead & London – City & East REC, 10/11/2015, ref: 15/LO/1566

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Community

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type

### Interventions

Participants are randomly allocated to one of two groups.

Brief written information group: This is an active control group, who will receive a postal written information leaflet about the importance of physical activity after stroke. The leaflet was created by the stroke association, and is titled: 'exercise and stroke.'

Novel walking intervention group: This intervention encompasses a wide range of behaviour change techniques, to include:

1. Goal setting (outcomes): what are the patient's desired walking destinations?

2. Increasing positive affective attitudes to walking by discussing patient's most valued benefits of walking
3. Increasing self-efficacy for walking by focusing on patient's previous successes at achieving goals and showing similar others who have successfully increase their walking
4. Increasing positive instrumental attitudes via printed information

## **Intervention Type**

Other

## **Primary outcome measure**

Eligibility rate is recorded during the telephone and face-to-face screening phase, by totalling the number of participants who were screened and identified as eligible/not eligible: the study inclusion and exclusion criteria, the Abbreviated Mental Test and the Timed 'Up and Go' test.

## **Secondary outcome measures**

1. Recruitment rate is recorded using details of the following participant contacts /correspondence, in which a potential participant:
  - 1.1. Does not wish to participate (to include any reason the individual provides regarding the basis for this decision)
  - 1.2. Feels they no longer meet the inclusion/exclusion criteria (plus any further details the individual chooses to provide)
  - 1.3. Has a query about the study
  - 1.4. Does wish to participate
  - 1.5. Letter returned to sender
2. Retention rate is assessed throughout the study via recording date of attrition
3. Missing data at each timepoint for both questionnaires and accelerometer data is assessed at baseline, week 12 and week 24 using SPSS
4. Proportion of intended sessions of the novel intervention actually delivered is measured during weeks 0-7 (intervention delivery period) on the intervention delivery log
5. Extent to which the novel intervention is delivered as intended in each session (i.e. the walking coach discusses all the things specified in the intervention manual with the participant) is measured using the stroke impact scale at baseline, 12 and 24 weeks
6. Standard deviation of social participation scale scores is measured using the stroke impact scale at baseline, 12 and 24 weeks
7. Acceptability of the intervention from participants' perspectives is measured using an interview at 24 weeks

## **Overall study start date**

01/12/2014

## **Completion date**

05/12/2016

# **Eligibility**

## **Key inclusion criteria**

1. Aged > 18 years
2. Lives in Lambeth or Southwark
3. Discharged from hospital after stroke, and from formal, community-based stroke rehabilitation
4. Completed 3-month post stroke SLSR assessment

5. People who report walking outside for fifteen minutes at least once in the last 3 months on the version of the Frenchay Activities Index most recently completed as part of SLSR data collection
6. No known cognitive impairment at time sent invitation pack (Abbreviated Mental Test (AMT) score is 8/10 or greater at most recently completed SLSR data collection time point)
7. Not known to be living in a care home or other institution
8. Not taking part in any other research studies (apart from SLSR)
9. Able to walk outside their home and has done so for at least 15 minutes in the last 3 months
10. Able to understand spoken English to the level required to be able to actively participate in the intervention
11. Able to use a telephone and will have consistent access to one during the study.
12. Willing to wear an accelerometer to measure their physical activity during the study
13. No history of recent falls (any fall in the past 3 months)
14. No history of recurrent falls ( $\geq 2$  falls in past 12 months)
15. Has not received, is not currently receiving or on the waiting list for a falls prevention intervention (e.g. falls clinic, strength and balance classes targeted at those at risk of falling, 1:1 physiotherapy to mitigate falls risk)
16. Is not currently receiving or awaiting physiotherapy for any health problem
17. Is not awaiting hip or knee replacement surgery
18. Does not have a cardiac pacing device (the accelerometers used to monitor physical activity in this study may potentially interfere with the operation of cardiac pacing devices)
19. No experience of fainting/blackouts since discharge from hospital for most recent stroke
20. Does not report walking outdoors for more than 30 minutes consecutively, or if able to walk for 30 minutes consecutively, does not do so on more than 4 days per week
21. AMT test score is 8/10 or greater when screened by the study RA over the phone.
22. Not currently pregnant
23. No known allergy/sensitivity to both hypafix and tegaderm adhesive dressing tape (used to apply the accelerometers)
24. Timed up and go test score  $\leq 12.34$  seconds

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 40; UK Sample Size 40

**Key exclusion criteria**

1. Lacking capacity to provide consent
2. Aged  $< 18$  years
3. Live outside of Lambeth, or Southwark
4. Have not been discharged from hospital after their most recent stroke
5. Have not completed the 3 month South London Stroke Register follow-up

6. Live in a care home or other institution
7. Are unable to walk outside at least a little
8. Are currently taking part in other research studies
9. Have fallen over in the last 3 months
10. Have a history of recurrent falls ( $\geq 2$  falls in the last year)
11. Currently receiving or on the waiting list for falls prevention intervention (s
12. Currently receiving physiotherapy for another health problem
13. Awaiting hip or knee replacement
14. Have a cardiac pacing device
15. Have experienced fainting/blackouts since discharge from hospital for most recent stroke
16. Scored 7/10 or less on AMT
17. Are currently pregnant
18. Are unable to speak English to the level required to actively participate in the intervention
19. Are unwilling to wear an accelerometer
20. Have an allergy to the components of both Tegaderm and Hypafix
21. Completed the timed "up and go" test  $\geq 12.34$  seconds, which indicates a risk of falls

**Date of first enrolment**

04/03/2016

**Date of final enrolment**

30/09/2016

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Guy's & St Thomas' Foundation NHS Trust**

R&D Department

16th Floor

Tower Wing

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**

**King's College Hospital NHS foundation trust**

Friends Stroke Unit

Fifth floor

Ruskin Wing

Denmark Hill

London

United Kingdom  
SE5 9RS

## Sponsor information

### Organisation

Guy's and St. Thomas' NHS Foundation Trust

### Sponsor details

BRC Facility, Great Maze Pond  
London  
England  
United Kingdom  
SE1 9RT

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/00j161312>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

- 1. Data from the study will be used in a report of the findings of the feasibility study published in a peer-reviewed, academic journal as well as in presentations at academic conferences that focus on stroke and on health-related behaviour. Further, versions of published papers will be made available on the King’s research portal, which is an open access online repository run by KCL to aid dissemination of KCL staff and student research outputs.
- 2. A lay summary of the study findings will be circulated to participants and published in “Forward”, the newsletter for individuals participating in the SLSP, as well as made available on the relevant part of the HSCR website. Finding will also be presented at a meeting of the “Stroke Research Patient and Family Group”.

## Intention to publish date

05/12/2017

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No