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A study looking at a new walking intervention for stroke survivors

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
17/03/2016

Overall study status
Completed

Last Edited
12/10/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 excpected 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
sarah.besser@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Alison Wright

ORCID ID
http://orcid.org/0000-0002-0373-5219

Contact details
Dept of Primary Care & Public Health Sciences,
Faculty of Life Sciences & Medicine
King’s College London
5th Floor
Addison House
Guy’s Campus
London
United Kingdom
SE1 1UL
+44 20 7848 6605
Alison.Wright@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

20598

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 (≥ 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 ≤ 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 (≥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 ≥ 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 SLSR, 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?
HRA research summary			28/06/2023	No	No