

Feasibility study of an intervention to reduce sedentary behaviour in people after stroke

Submission date 09/07/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/08/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Time spent in sedentary behaviour (sitting/lying down) has recently emerged as an important topic. Too much time spent in sedentary behaviours is linked with ill health and mortality. This seems to be independent of physical activity, a short burst of activity such as an exercise class will not offset the detrimental health effects of many hours spent sitting. Survivors of stroke are among the most sedentary individuals in the population, spending up to 80% of their waking day sitting or lying down.

Interventions to reduce sitting time have enormous potential, would be low cost and may be more achievable than a structured exercise programme, particularly in stroke survivors afraid of another stroke or of falling.

Our focus is on reducing sitting time in survivors of stroke in their own homes once they have been discharged from hospital and therapy services. However, to achieve this we feel it is important that stroke survivors are appropriately informed and supported in reducing sedentary behaviour from the time of their stroke, learning techniques which they can continue at home when no longer in receipt of therapy.

This study is part of a programme of research which aims to develop and test strategies to reduce sedentary behaviour in patients after stroke and improve outcomes. In previous studies in the research programme we investigated sedentary behaviour and developed an intervention to reduce/ break up sedentary behaviour in stroke survivors.

In the present study, we will test out this intervention in three stroke services including approximately 30 stroke survivors in each service.

Our aims include investigating how easy or difficult it is for staff to deliver the intervention to stroke survivors; whether the intervention is acceptable to stroke survivors, their family/friends and/or carers and staff; and to prepare for a future study (a large randomised trial). We also aim to assess whether we can recruit enough patients, whether the outcome measures are acceptable and whether there are any unforeseen problems.

Who can participate?

Stroke survivors aged 16 years or over at time of stroke who have a confirmed primary diagnosis of new stroke and are still in receipt of active rehabilitation in a participating stroke service; are able to stand independently or with the help of one person; have been/are being discharged home to live in the community (not a care home). Carers of stroke survivors who are aged 16 years or over, a family member/close friend and/or carer of a stroke survivor participating in the study and identified by the stroke survivor as someone they engage with on a regular basis (meet at least once a fortnight), are able and willing to provide informed consent.

What does the study involve?

Patients are asked to join the study after they have had a stroke. They are asked to complete a number of questionnaires after they have joined the study and four and six months later. They are also asked to wear a small activity monitor on their thigh for eight days at each timepoint. A number of participants are also asked to have an interview with us to ask their views on the ease of taking part in the intervention. Recruited carers of stroke survivors taking part in the study are asked to complete a number of questionnaires after they have joined the study and four and six months later. A number of carers are also asked to have an interview with us to ask their views on the ease of taking part in the intervention.

What are the possible benefits and risks of taking part?

Being involved is unlikely to benefit stroke survivors directly. However, it may help improve future services and support for people who have had a stroke. Stroke survivors may find some of the topics covered in questionnaires and/or interviews upsetting. However, stroke survivors do not have to answer any questions they do not wish to. Wearing the activity monitor may be inconvenient and there is a small chance that it might irritate the skin.

Where is the study run from?

The Academic Unit of Elderly Care and Rehabilitation, University of Leeds, Bradford Institute for Health Research, Bradford, United Kingdom.

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

September 2018 to July 2020

Who is funding the study?

The National Institute for Health Research (NIHR) via a Programme Grant for Applied Research

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

261159

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS PROJECT ID 261159; CPMS 41604

Study information

Scientific Title

Feasibility study of an intervention to reduce sedentary behaviour in people after stroke, part of the research programme: Reducing sedentary bEHaviour After sTrokeE

Acronym

RECREATE

Study objectives

To explore and clarify implementation strategies for an intervention to reduce sedentary behaviour in people after stroke devised in previous studies in the research programme using a case study approach, and clarify procedures for a future definitive, randomised trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 08/05/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (St Luke's Hospital, Extension Block, Little Horton Lane, Bradford, BD5 0NA; 0207 104 8018; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 19/YH/0080
2. Approved 04/04/2019, Scotland A Research Ethics Committee (0131465 5680; sesres@nhslothian.scot.nhs.uk), ref: 19/SS/0037

Study design

Non-randomised; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Qualitative

Primary study design

Interventional

Secondary study design

Feasibility study

Study setting(s)

Hospital

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

Stroke

Interventions

Objectives of the study relate to:

1. Feasibility of delivering each component of the intervention: clarify methods of delivery; identify contextual influences on implementation; examine the fidelity of intervention delivery and identify local individual/organisational barriers and facilitators to intervention delivery.

2. Exploration of costs and core resource use associated with delivering the intervention.
3. Assessing acceptability of the intervention to patients, their family/friends and/or carers and staff.
4. Clarify and refine the proposed logic model for the intervention.
5. Trial procedures will be clarified and tested as follows:
 - 5.1 Patient eligibility criteria, recruitment process, data collection
 - 5.2 Measures of fidelity with the intervention will be developed and their acceptability will be tested
 - 5.3 The appropriateness of outcome measures assessed (ease of use, level of missing data, need for prompts for return of the activity monitor; outcome returns)
6. Convene a Seminar to determine whether intervention, implementation methods and outcome assessment need revision before the definitive trial.

There are five interlinked components in each of the three services (cases):

1. An implementation group will be created in each of the three services (cases) to regularly review and refine implementation strategies and compliance and fidelity assessments.
2. Outcome Assessments: Stroke survivor and their family member/friend and/or carer self-completed questionnaires will be collected to assess the usefulness of potential outcome measures ahead of the planned definitive trial. Stroke survivors will also be asked to wear an activity monitor.
3. Semi-structured Interviews: Interviews will be completed with a sample of stroke survivors and their family member/friend and/or carer to obtain feedback on the acceptability of the intervention and the outcome assessments.
4. Semi-structured Interviews: Interviews will be completed with a sample of healthcare professionals who had delivered the intervention to obtain feedback on its acceptability, including barriers and facilitators to delivering the intervention.
5. Observation of intervention delivery will be undertaken to gain insight into fidelity of delivery.

Seminars: At the end of this feasibility study, seminars consisting of staff from the three participating sites and national experts will be held to draw together the lessons and experiences learnt through this feasibility work.

Intervention Type

Behavioural

Primary outcome measure

As this is a feasibility study in preparation for a planned definitive trial a range of potential outcome measures are being tested for appropriateness.

We wish to capture the physical, psychological and behavioural factors which may be affected by reducing time spent sitting. In this feasibility study we seek to gain information on the optimum assessments to use. The assessments below will be used but not all will necessarily be administered with all participants.

Secondary outcome measures

Potential outcome measures to be used in the definitive trial:

1. Patient-centred outcomes assessed by the WHODAS 2.0
2. Warwick-Edinburgh Mental Well-being Scale (positive mental wellbeing)
3. PHQ-9 (for depressive symptoms)
4. EQ-5D-5L, (plus any alternative candidate measure that may better capture relevant data, if one is identified) to assess health related quality of life and enable calculation of quality

adjusted life years (QALYs) for the economic evaluation

5. Fatigue Assessment Scale

6. Time spent in sedentary behavior, assessed by use of the activPAL activity monitor, which will include: Sitting time (total); Sitting time accumulated in bouts >30 minutes; proportion of the day sedentary; Standing time; Stepping time; number of sit-to stand transitions; as measured by activity monitor

7. Sedentary Behaviour Questionnaire – Measure of Older Adults' Sedentary Time (MOST) and a sedentary behaviour Visual Analogue Scale

8. Nottingham Extended Activities of Daily Living (NEADL), this may be used in place of the WHODAS 2.0

9. Patients will also be asked to answer questions on whether they have fallen and whether or not this led to injury. At baseline this will be related to in hospital falls and for the six months prior to hospital admission

10. Use of walking aid

11. Mechanisms of change questionnaire, which asks questions about influences on the intervention target behaviour

12. Stroke Impact Scale v0.3

13. Caregiver Burden Scale (measured for carer)

Overall study start date

01/09/2018

Completion date

16/07/2020

Eligibility

Key inclusion criteria

1. Stroke survivors aged 16 years or over at the time of stroke
2. Confirmed primary diagnosis of new stroke and are still in receipt of active rehabilitation in a participating stroke service (either in hospital, at home or at an outpatient clinic)
3. Able to stand independently or with the help of one person (defined as Functional Ambulatory Categories 3-6)
4. Have been/are being discharged home to live in the community (not a care home)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

90 (30 per site)

Total final enrolment

39

Key exclusion criteria

1. In receipt of end of life care (documented in medical notes)
2. Discharged (or planned discharge) to an address outside the remit of the participating stroke service (including care home)

Date of first enrolment

19/07/2019

Date of final enrolment

31/10/2019

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Study participating centre**Fairfield General Hospital**

The Pennine Acute Hospitals NHS Trust
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre**Leeds General Infirmary**

The Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre**St John's Hospital at Howden**

NHS Lothian
Howden Road West
Howden
Livingston
United Kingdom
EH54 6PP

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust

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Sponsor type

Hospital/treatment centre

Website

<https://www.bradfordresearch.nhs.uk/>

ROR

<https://ror.org/05gekvn04>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) Programme Grant for Applied Research (PGfAR, reference: RP-PG-0615-20019)

Results and Publications

Publication and dissemination plan

The study results will be published in a peer reviewed journal, and as a part of the Programme Grant final report. Results will also be disseminated at stroke conferences and to the Consumer Research Advisory Group (CRAG) and wherever possible to other consumer conferences. A lay summary of the results will be placed on the AUECRs website to allow dissemination to the public, professionals and participants.

The publication policy for this study will follow the publication policy agreed by the Programme Management Group.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the work undertaken relates to feasibility only, this may include different approaches to data collection during implementation of the study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No