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

Submission date
09/07/2019

Recruitment status
No longer recruiting

Registration date
07/08/2019

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Circulatory System

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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
261159

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Scotland

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes