ISRCTN10694741 https://doi.org/10.1186/ISRCTN10694741

RISE-Intervention for reducing sedentary behaviour after stroke

Submission date
12/04/2019

Recruitment status
No longer recruiting

Registration date
27/08/2020

Overall study status
Completed

Last Edited
03/09/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is one of the leading causes of death and disability worldwide. One in three of the people that survive the first stroke have a recurrent stroke or pass away within five years. Therefore secondary prevention aimed at reducing important risk factors such as high blood pressure, impaired glucose tolerance and unhealthy lifestyle (smoking and physical inactivity) is of vital importance.
The importance of physical activity after stroke is well known and integrated into usual care and treatment guidelines. Recent research has shown that high amounts of sedentary behaviour (time during the day spend sitting, lying or reclining) increase the risk of cardiovascular disease and death, even when someone spends sufficient amount of time in moderate to vigorous physical activities. Sedentary behaviour is most harmful if this is accumulated over 10 hours a day and in prolonged bouts and physical activity levels are low. For people with high amounts of sedentary behaviour accumulated in prolonged bouts an intervention to help people reduce their sedentary behaviour once they return home after having a stroke seem highly relevant.

A blended care intervention was developed using the behaviour change wheel and the CEHRES model. Elements will be eCoaching technologies, self-monitoring and face to face contact with a physiotherapist to support behavioural change. The intervention was developed in co-design with people with stroke, physiotherapist, physicians, technology experts and experts in the field of behavioural change and sedentary behaviour. The RISE intervention is 15 weeks and combines face to face coaching sessions by a physiotherapist with eCoaching by using an activity monitor and a m-health application. The aim of this study is to determine the preliminary effectiveness and the feasibility of the RISE intervention to reduce and interrupt sedentary behaviour in the first 6 months after discharge from hospital in community people with a first ever stroke. The secondary aim is to investigate the added value and feasibility of integrating participatory support within the RISE intervention. In participatory support (PS) a member of the participant's immediate social environment provides meaningful support. This member participates as a buddy in the intervention.

Who can participate?
Males and females aged over 18 who have suffered a first-ever stroke, who are independent in walking with or without a walking aid and have a sedentary and inactive movement pattern.

What does the study involve?
The study involves testing the preliminary effectiveness and feasibility of the RISE Intervention with and without PS. Participants will be randomized to either the RISE Intervention with PS or without PS after being included into the study. Participants will wear an activity monitor 4-14 days before, during and 4-14 days after the intervention to measure sedentary behaviour and physical activity. Also after the intervention participants will be asked to complete a questionnaire and to participate in an interview to determine the satisfaction with the intervention.

What are the possible benefits and risks of participating?
The possible benefit is that a reduction in sedentary behaviour might reduce the cardio metabolic risk factors like high blood pressure and glucose tolerance. This can prevent recurrent stroke, other cardiovascular diseases and mortality and decline in physical functions. The goal of the intervention is to replace sedentary behaviour by normal daily activities (light intensity physical activities), therefore the risk involved in participating is low.

Where is the study run from?
Department of Rehabilitation Physiotherapy Science and Sport, UMC Utrecht, Utrecht University, Netherlands

When is the study starting and how long is it expected to run for?
January 2021 to June 2022

Who is funding the study?
National Directorate for Practice-oriented Research SIA (Regieorgaan Praktijkgericht Onderzoek SIA), Netherlands

Who is the main contact?
1. Dr Wendy Hendrickx, W.Hendrickx@umcutrecht.nl (public)
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Preliminary effectiveness and feasibility of the RISE intervention to reduce and interrupt sedentary behaviour in community dwelling sedentary people after stroke

Acronym
RISE intervention

Study objectives
The RISE intervention is feasible and leads to a significant reduction of sedentary behaviour compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/07/2020 Medical Ethical Board of the University Medical Centre Utrecht (Heidelberglaan 100
3584CX, Utrecht, Netherlands; +31 88 75 56 376; info@metcutrecht.nl), ref: 20/250

Study design
Pilot randomized multiple baseline design trial

Primary study design
Interventional

Secondary study design
Randomized multiple baseline design

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
Participants will receive the RISE intervention, a blended movement behaviour change intervention that aims to support them to reduce and interrupt their sedentary time. The blended intervention is 15 weeks and combines face to face coaching sessions by a physiotherapist with eCoaching by using an activity monitor and a m-health application. Six of the 12 participants will be randomized to participate in the RISE intervention including participatory support (PS). In participatory support (PS) a member of the participant's immediate social environment provides meaningful support. This member participates as a buddy in the intervention. The participants buddy will get insight in relevant self-management information (e. g. why reducing sedentary time and increasing physical activity is important in people with stroke), the individual goals of the participant and how to provide meaningful support. By performing the same movement behavioural change tasks in reducing and interrupting sedentary behaviour as the participant, the buddy will be able to facilitate changes, provide encouragement support, increase enjoyment and provide greater accountability for a more active lifestyle. Participants will be randomized by an independent researcher to either the experimental group or the usual care group by a computer-generated random sequence table generated using SPSS. For both groups the outcome measures will be conducted in the same manner.

Intervention Type
Behavioural

Primary outcome measure
1. Preliminary effectiveness of the intervention on sedentary behaviour; total amount of sedentary time and the sedentary time fragmentation, assessed using the ActivPAL activity

monitor over the 15 week period
2. Feasibility of the intervention; compliance, satisfaction and safety, assessed using inclusion and adherence registration, semi-structured interviews and the System Usability Scale post-intervention

Secondary outcome measures
1. Preliminary effectiveness of the intervention with PS on sedentary behaviour; total amount of sedentary time and the sedentary time fragmentation, assessed using the ActivPAL activity monitor over the 15 week period
2. Feasibility of the intervention with PS; compliance and safety, assessed using inclusion and adherence registration semi-structured interviews and the System Usability Scale post-intervention
3. Preliminary effectiveness of the intervention on non-sedentary movement behaviour; the amount of light and moderate to vigorous physical activity, the step count and the time spent standing and/or walking. Assessed using the ActivPAL activity monitor over the 15 week period
4. Other study parameters: participant characteristics, sleep duration and quality, happiness, tiredness, stress, pain, time pressure, the inclusion rate, time consumption of the intervention and the study and the activity monitor data and the usage of the different parts of the app during the intervention period

Overall study start date
01/01/2020

Completion date
01/06/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/09/2021:
1. Aged 18 years or older
2. Stroke diagnosed in hospital within six months of the start of the RISE intervention
3. Able to walk independently, as defined by a functional ambulation categories score of at least 3
4. Sedentary prolonger; i.e. ≥9.5 hours of sedentary time per day and meeting at least one of the following criteria: >50% of the sedentary time is spent in bouts > 30 minutes and not reaching the physical activity guideline (150 minutes MVPA during the week)
5. Independent regarding activities of daily living pre-stroke, as defined by a Barthel Index score of >18
6. Discharged to the home-setting
7. Have someone who can participate as a bubby in the RISE intervention with PS
8. Given their written informed consent

Previous inclusion criteria as of 04/06/2021:
1. Aged 18 years or older
2. Stroke diagnosed in hospital within six months of the start of the RISE intervention
3. Able to walk independently, as defined by a functional ambulation categories score of at least 3
4. Sedentary prolonger; ≥9.5 hours of sedentary time per day, >50% of the sedentary time is spent in bouts > 30 minutes and not reaching the physical activity guideline (150 minutes MVPA during the week)

5. Independent regarding activities of daily living pre-stroke, as defined by a Barthel Index score of >18
6. Discharged to the home-setting
7. Have someone who can participate as a bubby in the RISE intervention with PS
8. Given their written informed consent

Previous inclusion criteria as of 23/02/2021:
1. Aged 18 years or older
2. First-ever stroke diagnosed in hospital within 6 months of the start of the RISE intervention
3. Able to walk independently, as defined by a functional ambulation categories score of at least 3
4. Sedentary prolonger; ≥9.5 hours of sedentary time per day, >50% of the sedentary time is spent in bouts > 30 minutes and not reaching the physical activity guideline (150 minutes MVPA during the week)
5. Independent regarding activities of daily living pre-stroke, as defined by a Barthel Index score of >18
6. Discharged to the home-setting
7. Have someone who can participate as a bubby in the RISE intervention with PS
8. Given their written informed consent

Previous inclusion criteria:
1. Aged 18 years or older
2. First ever stroke diagnosed in hospital in last 3 months
3. Able to walk independently, as defined by a functional ambulation categories score of at least 3
4. Sedentary prolonger; ≥9.5 hours of sedentary time per day, >50% of the sedentary time is spent in bouts > 30 minutes and not reaching the physical activity guideline (150 minutes MVPA during the week)
5. Independent regarding activities of daily living pre-stroke, as defined by a Barthel Index score of >18
6. Discharged to the home-setting
7. Have someone who can participate as a bubby in the RISE intervention with PS
8. Given their written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Total final enrolment
14

Key exclusion criteria
1. Insufficient knowledge of the Dutch language to understand the intervention content
2. Score <4 on the Utrecht Communication Assessment (UCO) to understand questionnaires and follow instructions
3. Severe comorbidities that prevent that person from safely reducing and interrupting their sedentary time (e.g. sever pulmonary diseases, heart failure or malignity's) as determined with the Physical Activity Readiness Questionnaire (PAR-Q)
4. Not receiving physiotherapy in any other setting then primary care

Date of first enrolment
01/09/2020

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Rehabilitation Physiotherapy Science and Sport, UMC Utrecht, Utrecht University
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Government

Funder Name
Nationaal Regieorgaan Praktijkgericht Onderzoek SIA

Alternative Name(s)
Nationaal Regieorgaan Praktijkgericht Onderzoek, National Board of Practice-Oriented Research SIA, National Board of Practice-Oriented Research, Regieorgaan SIA, NRPO-SIA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/08/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/07/2024	12/08/2024	Yes	No