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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55033

Source
ToetsingOnline

Brief title
RISE intervention

Condition

- Other condition
- Lifestyle issues

Synonym
Sedendary behavriour after stroke, sitting time after stroke

Health condition

Cardiovasculair, beroerte

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: SIA-RAAK Publiek (NWO)

Intervention

Keyword: Behaviour change intervention, Sedentary behaviour, Stroke

Outcome measures

Primary outcome

1. Preliminary effectiveness of the intervention on sedentary behaviour; total amount of sedentary time and the sedentary time fragmentation.

2. Feasibility of the intervention; compliance, satisfaction and safety.

Secondary outcome

Secondary study outcome:

1. Preliminary effectiveness of the intervention with PS on sedentary behaviour; total amount of sedentary time and the sedentary time fragmentation

2. Feasibility of the intervention with PS; compliance and safety

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.

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.

Study description

Background summary

People who have suffered a stroke are at high risk of functional decline, recurrent stroke and premature mortality. Therefore, secondary prevention is urgent. High amounts of sedentary behaviour, accumulated in prolonged bouts and low amounts of moderate to vigorous physical activity increase the risk of cardiovascular disease. In total 32% of the people with stroke have such a movement behaviour pattern called sedentary prolongers.
To support sedentary prolongers reduce and interrupt their sedentary time a behavioural change coaching intervention delivered by a physiotherapist, called the RISE intervention, was designed. It was designed using the behaviour change wheel in a co-design process with people with stroke, physiotherapist working with people with stroke and experts in the field of sedentary behaviour and stroke.

Study objective

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 dwelling sedentary prolongers with a first ever stroke. The secondary aim is to investigate 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. 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.

Study design

A prospective multiple baseline study. The design will include randomization to the intervention delivery with or without participatory support and the

duration of baseline measurements (either 4, 6, 8, 10, 12 or 14 days).

Intervention

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. A self-chosen person from their immediate social environment (e.g. their partner, close family member or friend) will participate in the RISE intervention including participatory support.

Study burden and risks

The burden and risk of participating in the RISE intervention are deemed low. The participants will receive a blended coaching intervention to reduce and interrupt their sedentary behavior. The blended intervention includes ten face-to-face sessions, wearing an activity monitor during the intervention period, and support from the smartphone application. During the intervention people will be encouraged to sit less and move more. The participant will participate in a baseline and a post intervention measurements. This includes wearing an activity monitor, questionnaires and performing the five meter walking test (only at baseline). Patient and stroke characteristics will be obtained from the medical records. After finishing the intervention participants will be asked to participate in a semi-structured interview to determine their experiences and satisfaction with the intervention. The goal of the intervention is to replace sedentary behavior by normal daily activities (light intensity physical activities), therefore the risk involved in participating is low. Additional the burden of the intervention is low since physiotherapist will visit the participant at home.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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.

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, hart 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	01-07-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-01-2021
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	09-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-09-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN10694741
CCMO	NL73036.041.20