ISRCTN31718066 https://doi.org/10.1186/ISRCTN31718066

Medication adherence and management of risk factors for secondary stroke prevention

Submission date
25/01/2023

Recruitment status
No longer recruiting

Registration date
09/02/2023

Overall study status
Completed

Last Edited
12/03/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The burden of stroke is increasing in India. One out of every four strokes is recurrent. The leading risk factors for stroke are high blood pressure, diabetes, high body mass index, smoking and air pollution. Secondary stroke prevention is important in preventing stroke recurrence. Adherence to medication is a key issue in treatment success and control of risk factors. Adherence to secondary preventive medications after a stroke is known to be suboptimal, especially in low- and middle-income countries. Evidence shows that establishing daily routines, periodic reminders, financial support to buy medicines and patient education can enhance medication adherence to prevent future strokes. The role of mobile phones in promoting adherence to medication and secondary prevention of stroke has not been extensively explored adequately. India is particularly suited for a mobile phone-based intervention given the widespread geographical connectivity, cheaper costs and the growing popularity of mobile phones. So this study aims:
1. To develop a smartphone-based app for medication adherence and secondary prevention of stroke among first-ever stroke survivors.
2. To test the feasibility of using a smartphone-based app to assess medication adherence, risk factor control and lifestyle modification for secondary stroke prevention
2. To compare the event rate between conventional and smartphone app-based follow-up.

Who can participate?
Patients aged over 18 years) who have had a stroke within 1 month and have one or more risk factors such as high blood pressure, diabetes, smoking and dyslipidemia (abnormal amount of fats in the blood)

What does the study involve?
Participants allocated to the intervention group will receive a mobile-app-based intervention for improving their stroke medication adherence and control of risk factors for secondary prevention post-stroke. The app aims to improve medication adherence, control vascular risk factors, and provide health education and physician involvement. The participants in the intervention group are made to update their monthly risk factor values of blood pressure and blood sugar. Based on their values they will receive messages on their control status and a physician intervention is planned when required. The patients will be followed up for 6 months,

including a direct visit to their treating neurologist in the 3rd and 6th months, and their risk factor values are measured (blood pressure, blood sugar, and lipid profile).

What are the possible benefits and risks of participating?
The participants may benefit by adhering to their stroke medication and monthly monitoring of risk factors and having better control of risk factors by timely consultation with a local physician for medication alteration and lifestyle modification. As such there are no potential risks to the participants.

Where is the study run from?
Sree Chitra Tirunal Institute of Medical Sciences & Technology (India)

When is the study starting and how long is it expected to run for?
November 2021 to February 2023

Who is funding the study?
World Stroke Organization (Switzerland)

Who is the main contact?
Dr P N Sylaja, sylajapn@hotmail.com

Contact information

Type(s)
Principal investigator

Contact name
Prof PN Sylaja

ORCID ID
https://orcid.org/0000-0003-4896-8275

Contact details
Department of Neurology
Sree Chitra Tirunal Institute of Medical Sciences & Technology
Thiruvananthapuram
India
695011
+91 (0)4712524482
sylajapn@sctimst.ac.in

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

V2 dt 10 January 2022

Study information

Scientific Title
Medication adherence and management of risk factors for secondary prevention of stroke using a smartphone-based application: a feasibility study

Acronym
MAMORs

Study objectives
The m-health app could improve medication adherence and risk factor control when compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2021, Sree Chitra Tirunal Institutional Ethics Committee (Medical College P.O, Thiruvananthapuram -11, India; +91 (0)471 2524689; iec@sctimst.ac.in), ref: SCT/IEC/1791 /DECEMBER/2021

Study design
Single-centre prospective two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Secondary prevention of stroke among stroke survivors

Interventions
Randomization will occur in a 1:1 ratio to either the smartphone group (intervention) or the usual care (control) group. Once the patient meets all study eligibility criteria and signs the consent form, randomization takes place centrally via REDCap software. The patient will not be blinded to procedures as the patient will be verbally informed by the investigator to what treatment group he/she has been assigned.

The subjects allocated to the intervention arm will receive a mobile-app-based intervention for improving their stroke medication adherence and control of risk factors for secondary prevention post-stroke. The app aims to improve medication adherence, control vascular risk factors, and provide health education and physician involvement. The participants in the intervention arm are made to update their monthly risk factor values of blood pressure and blood sugar. Based on their values they will receive messages on their control status and a physician intervention is planned when required.

The control group will receive usual care and health education on stroke, its type, symptoms, risk factors, lifestyle modification, and diets for secondary stroke prevention. They will be given a pamphlet along with their dates of monthly follow-up and visit dates.

The patients will be followed up for 6 months, including a direct visit to their treating neurologist in the 3rd and 6th months, and their risk factor values are measured (blood pressure, blood sugar, and lipid profile).

Intervention Type
Other

Primary outcome(s)
1. Medication adherence assessed using the Morisky Medication-Taking Adherence Scale (MMAS 4) at baseline, 3 and 6 months
2. Lifestyle and behavioral factors assessed using WHO STEPS instrument, physical activity questionnaire, and FADS questionnaire at baseline, 3 and 6 months
3. Control of vascular risk factors (fasting blood sugar, HbA1c, lipid profile and blood values) measured using standard techniques in the laboratory at baseline, 3 and 6 months

Key secondary outcome(s))
1. Vascular events (TIA/stroke/cardiac events/vascular deaths) measured using adverse events data updated within patient medical records at 6 months
2. Functional outcomes measured using the Modified Rankin Scale (mRS) at baseline, 3 and 6 months

Completion date
24/02/2023

Eligibility

Key inclusion criteria
1. Adult (aged >18 years) patients with onset of stroke within 1 month
2. Severity: Modified Rankin Scale (mRS) <5
3. Presence of one or more vascular risk factors such as hypertension, diabetes mellitus, smoking and dyslipidaemia
4. Patients who could fully understand the use of an Android-based smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
208

Key exclusion criteria
1. Patients with severe disability: mRS >4
2. Patients who do not consent
3. Severe cognitive impairment
4. Stroke survivor without a primary caregiver in patients with mRS 3 and 4

Date of first enrolment
06/06/2022

Date of final enrolment
09/09/2022

Locations

Countries of recruitment
India

Study participating centre
Sree Chitra Tirunal Institute of Medical Sciences and Technology
Medical College PO
Thiruvananthapuram
India
695011

Sponsor information

Organisation
World Stroke Organization

Funder(s)

Funder type
Research organisation

Funder Name
World Stroke Organization

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during and/ or analyzed during the current study will be available upon request from Dr P N Sylaja (sylajapn@hotmail.com, sylajapn@sctimst.ac.in).
The type of data that will be shared: All the collected data
Dates of availability: Until 5 years after the end of the trial
Whether consent from participants was required and obtained: Consent was required and was obtained
Comments on data anonymization: The name of the participants were anonymised
Any ethical or legal restrictions: No
Any additional comments: No

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/12/2022	02/02/2023	Yes	No
Basic results			12/03/2024	No	No