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Effectiveness of a Mobile App–Based (OASapp) Intervention Among Older Adults Stroke Survivors

Submission date
15/12/2022

Recruitment status
No longer recruiting

Registration date
20/12/2022

Overall study status
Completed

Last Edited
21/10/2024

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
Globally, stroke remained the second-leading cause of death after ischaemic heart disease and the third adult disability factor. Compliance with prescription medication is critical to prevent recurrence and other adverse outcomes of stroke after the first stroke has been controlled. However, medication adherence in stroke survivors is problematic. In line with recent changes in technology, smartphone applications (Apps) are increasingly being used to improve health in a number of areas. However, little is known about the use of Apps among elderly stroke survivors. The purpose of this study is to evaluate the effectiveness of a Mobile App–Based (OASapp) Intervention Among Older Adults Stroke Survivors on medication adherence, medicine beliefs, and health literacy on stroke and blood pressure.

Who can participate?
Older adults Stroke survivors who meet the inclusion-exclusion criteria

What does the study involve?
Participants will be randomly allocated to the intervention group (which received OASapp and standard carer) or control group (which received only standard carer). The intervention group will be provided with a detailed explanation of the OASapp in person by the project team leader and will be asked to utilize the app daily during a three-month period and receive one push notification each day at 19:00-21:00, with helpful self-care management tips. For the control group, they will not receive the app or any material included in the app during the study period. However, they will get access to the app after the 3-month trial.

What are the possible benefits and risks of participating?
This study's findings may give a whole picture of the effectiveness of the OASapp. It can also serve as an eye-opener for HCP, policy-makers, and the government, to increase availability of disease management techniques to endorse better stroke management. The utilization of mobile app technology improves barriers to healthcare access, improves patient medication

adherence, and increases patient exposure to self-care management techniques.
The risks involved in this study are minimal, which means they are equal to the risks you would encounter in everyday life.

Where is the study run from?
Three major general tertiary hospitals in Chenzhou, China: affiliated hospital of Xiangnan University, Chenzhou No. 1 People's Hospital, and Chenzhou Third People's Hospital.

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

Who is funding the study?
This work is supported by a special fund for young key teachers in Hunan Province, China (Xiangjiaotong (2021) 29) and the Hunan University Students' Innovation and Entrepreneurship Training Project (Xiangjiaotong (2022) 174 -4315).

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Linyan K2022-003-01, Yu2022033, Lunshen 2022-10

Study information

Scientific Title
Effectiveness of a Mobile App–Based (OASapp) Intervention Among Older Adults Stroke Survivors

Acronym
OASapp

Study objectives
The OASapp for older adults stroke survivors is effective in improving medication adherence, medicine belief, health literacy on stroke and reducing blood pressure

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 24/06/2022, Ethical committees of the Affiliated Hospital of Xiangnan University (Renmin Road, Chenzhou, Hunan province, China; +86 7352325232; no email provided), ref: Linyan K2022—003—01
2. Approved 09/06/2022, Ethical committees of Chenzhou No. 1 People's Hospital (Luojiajing Road, Chenzhou, Hunan province, China; +86 7352343039; no email provided), ref: Yu2022033
3. Approved 16/06/2022, Ethical committees of Chenzhou Third People's People's Hospital (Jiankang Road, Chenzhou, Hunan province, China; +86 7358889030; no email provided), ref: Lunshen 2022—10

Study design
A randomized open-label controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not avaible in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease in older adults stroke survivors

Interventions
Current interventions as of 09/05/2024:

Consented patients will undergo randomization in a 1:1 ratio to the intervention group or control group. The random allocation sequence will be computer generated in blocks of four by an independent researcher who is not involved in data collection. The total sample size is 80 (40 × 2 arms). The study will last three months.

For the intervention group, participants will be provided with a detailed explanation of the e-MAIMES in person by the project team leader and will be asked to utilize the app daily during a three-month period and receive one push notification each day at 19:00-21:00, with helpful self-care management tips.

For the control group, they will not receive the app or any material included in the app during the study period. However, they will get access to the app after the 3-month trial.

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Previous interventions:

Consented patients will undergo randomization in a 1:1 ratio to the intervention group or control group. The random allocation sequence will be computer generated in blocks of four by an independent researcher who is not involved in data collection. The total sample size is 84 (42 × 2 arms). The study will last three months.

For the intervention group, participants will be provided with a detailed explanation of the e-MAIMES in person by the project team leader and will be asked to utilize the app daily during a three-month period and receive one push notification each day at 19:00-21:00, with helpful self-care management tips.

For the control group, they will not receive the app or any material included in the app during the study period. However, they will get access to the app after the 3-month trial.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 16/08/2023:
Measured at baseline, 1 month and 3 months:
1. The general medication adherence scale (GMAS-C)
2. Blood pressure (mmHg) measured using a sphygmomanometer

Previous primary outcome measures:
Measured at baseline, 1 month and 3 months:
1. The general medication adherence scale (GMAS-C)
2. Beliefs about Medicines Questionnaire (BMQ)
3. Health literacy scale for stroke patients

Secondary outcome measures
Current secondary outcome measure as of 16/08/2023:
Beliefs about medication and health literacy measured using the Beliefs about Medicines Questionnaire (BMQ) for stroke patients at baseline and 3 months

Previous secondary outcome measure:
Blood pressure (mmHg) is measured (sphygmomanometer) at baseline, 1 month and 3 months.

Overall study start date
01/08/2021

Completion date
28/09/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 16/08/2023:
1. Aged 60 years or older
2. Have a history of stroke
3. Having a diagnosis of hypertension, either in the patient’s medical history or on admission to the hospital, defined as 140 mm Hg or higher for systolic blood pressure (SBP) and/or 90 mm Hg or higher for diastolic blood pressure by physicians

4. Taking at least one medication in the previous month such as (but not limited to) anti-platelets, statins, and anti-hypertensives to control risk factors for strokes
5. Having a smartphone and internet access to download App
6. More than a month since the last stroke episode
7. Modified Rankin Score of three or less
8. Able to read Chinese and communicate in Mandarin Chinese or the local Chenzhou dialect
9. Non-medication adherence (Patients with a total score of 26 according to the Chinese version of the General Medication Adherence Scale (GMAS-C))

Previous participant inclusion criteria:
1. Aged 60 years or older
2. Have a history of stroke
3. Having a diagnosis of hypertension, either in the patient's medical history or on admission to the hospital, defined as 140 mm Hg or higher for systolic blood pressure (SBP) and/or 90 mm Hg or higher for diastolic blood pressure by physicians
4. Taking at least one medication in the previous month such as (but not limited to) anti-platelets, statins, and anti-hypertensives to control risk factors for strokes
5. Having a smartphone and internet access to download App
6. More than a month since the last stroke episode
7. Modified Rankin Score of three or less
8. Able to read Chinese and communicate in Mandarin Chinese or the local Chenzhou dialect

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
80

Key exclusion criteria
1. The persons who had diagnosed with cognitive impairment (Mini-Mental State Examination score ≤17 [for illiterate] or ≤20 [individuals with 1–6 years of education] or ≤24 [individuals with 7 or more years of education])
2. Participating in another ongoing trial
3. Psychiatric illness or deafness, aphasia, or other language barriers
4. Secondary hypertension
5. Had participated in the Beta testing study

Date of first enrolment
20/01/2023

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
China

Study participating centre
Affiliated hospital of Xiangnan University
Renmin Road
Chenzhou
China
423000

Study participating centre
Chenzhou No. 1 People's Hospital
Luojiajing Road
Chenzhou
China
423000

Study participating centre
Chenzhou Third People's People's Hospital
Jiankang Road
Chenzhou
China
423000

Sponsor information

Organisation
Xiangnan University

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Sponsor type
University/education

Website
https://www.xnu.edu.cn

ROR
https://ror.org/05by9mg64

Organisation
Universiti Sains Malaysia

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Sponsor type
University/education

Website
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Funder(s)

Funder type
Government

Funder Name
Young key teachers in Hunan Province, China (Xiangjiaotong (2021) 29

Funder Name
Hunan University Students' Innovation and Entrepreneurship Training Project (Xiangjiaotong (2022) 174 -4315)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-review jounal

Intention to publish date
12/12/2024

Individual participant data (IPD) sharing plan
The data will available on request and published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/12/2022	No	Yes
Basic results			21/10/2024	No	No