

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

Submission date 15/12/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/10/2024	Condition category Circulatory System	<input type="checkbox"/> 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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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 (Luojiating 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 available 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.

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**

Luojiaying Road

Chenzhou

China

423000

Study participating centre**Chenzhou Third People's People's Hospital**

Jiankang Road

Chenzhou

China

423000

Sponsor information**Organisation**

Xiangnan University

Sponsor details

Chenzhou Road, 889 hao

Chenzhou

China

423000

+86 2653023

xnygzx@163.com

Sponsor type

University/education

Website

<https://www.xnu.edu.cn>

ROR

<https://ror.org/05by9mg64>

Organisation

Universiti Sains Malaysia

Sponsor details

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Health Campus

Universiti Sains Malaysia 16150

Kubang Kerian

Kelantan

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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 journal

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