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Stroke education by emphasizing self-confidence to reduce risk factors and improve clinical outcomes for mild to moderate stroke patients

Submission date
04/01/2023

Recruitment status
No longer recruiting

Registration date
05/01/2023

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Circulatory System

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

Plain English summary of protocol
Background and study aims
Education of stroke patients is the key to decreasing the worldwide burden of stroke. Stroke patients seldom transform their "knowledge" into "activity" due to a disconnect between "knowing" and "doing." This gap is caused by stroke patients' poor self-efficacy and lack of self-care. This study aims to assess the potential for reducing stroke risk in patients with mild to moderate ischemic stroke through self-care and self-confidence-based education.

Who can participate?
Patients aged over 18 years at stroke onset who meet the mild-to-moderate stroke criteria

What does the study involve? (for participants)
All participants will be included in integrative discharge planning for ischemic stroke patients, which includes integrated education and discharge preparation. Patients and families will also be provided with ways to care for themselves and increase their confidence level for self-care. The study will be conducted from the time the patient goes home until 3 months after discharge

What are the possible benefits and risks of participating?
The advantage that will be obtained is increasing insight and self-confidence to care for yourself or a family affected by ischemic stroke. Patients will also receive an educational booklet that can be used as educational material for themselves and their families. There is no fatal risk that can arise when participating in this study.

Where is the study run from?
Cipto Mangunkusumo National Hospital (Indonesia)

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

Who is funding the study?
1. Directorate of Research & Development, University of Indonesia (Indonesia)
2. National Research and Innovation Agency (Indonesia)

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
KET-4/UN2.F1/ETIK/PPM.00.02/2022

Study information

Scientific Title
Exploring the self-efficacy and self-care based stroke care model for risk factor modification in mild to moderate stroke patients: a randomized controlled trial

Acronym
Self-Care and self-efficacy On Risk Education for Stroke (SCORES)

Study objectives
Self-efficacy-self-care-based stroke education can reduce the risk of stroke in patients with mild to moderate stroke compared to standard education only

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved January 2022, Faculty of Medicine Ethics Committee Universitas Indonesia (The Faculty of Medicine Ethics Committee, University of Indonesia - Cipto Mangunkusumo Hospital, Gedung Fakultas Kedokteran UI JI. Salemba Raya No.6, Jakarta 10430, PO Box 1358, Indonesia; +62 (0)213912477; humas@fk.ui.ac.id), ref: KET-4/UN2.F1/ETIK/PPM.00.02/2022

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Reduction of stroke risk factors through patient education based on self-care and self-efficacy

Interventions
The researchers enrol mild to moderate ischemic stroke patients during hospitalization in either the emergency department or the stroke unit at Cipto Mangunkusumo National Hospital. After informed consent is obtained, patients who fit the inclusion and exclusion criteria will be randomized to enhanced standard care or intervention following simple randomization procedures. A computer-generated list of random numbers is used to allocate the participants and was created by a statistician with no clinical involvement in the trial. The allocation sequence is concealed from the enrolling participants in sequentially numbered and sealed envelopes and placed in the researcher's ward at an approved location. The researcher in charge of carrying out the allocation then records each patient allocation. No sign is given to the patient or the patient's environment that could identify the patient's allocation group. Standard care for the

participant in the ward is also carried out by nurses who are different from nurses who provide education to avoid bias. The nurse who provides education never meets the patient before the discharge education plan.

All trial arms, regardless of randomization group, will receive a standard of care, a self-care assessment, a self-efficacy assessment, and a stroke risk assessment, including blood pressure measurements, anthropometric measures, and risk factor assessments. Information about patients: demographics, self-care level, self-efficacy level, stroke risk score, NIH Stroke Scale /Score (NIHSS), mRS, Barthel index, blood viscosity, hospital length of stay, and comorbidity will be obtained at baseline.

In addition to standard education, participants in the intervention group will receive stroke education based on self-care and self-efficacy. Self-care and self-efficacy education follows the Hypertension Self-Care Instrument, validated in the study population and carried out for patients and their caregivers before the patient is discharged. Education is given in Indonesian by a team of doctors and nurses who have received special training on related interventions. Participants in the intervention group will also receive an Indonesian language booklet about increasing self-care and self-efficacy in stroke care. Intervention patients will be given education before discharge and will be followed up 1 month and 3 months after discharge.

After being discharged, all patients will be followed up through in-person interviews. All participants will receive a card with the time, location, and contact information for a follow-up appointment at Stroke Subspecialty Cipto Mangunkusumo National Hospital, to occur within 1 month and 3 months of discharge. Data will be collected regarding assessments of self-care, self-efficacy, stroke risk, measurements of anthropometric indices, and neurological examination. All data will be collected in Indonesian through interviews with participants by doctors and nurses, using standardized data collection instruments and reviewing medical records. In order to control for the Hawthorne Effect, the study team will call all participants at 2 weeks post-discharge, including those randomized to usual enhanced care, to see how they are feeling and capture any outcome events.

Intervention Type
Other

Primary outcome(s)
1. Self-care and self-efficacy level is measured using the Hypertension Self-Care Instrument at baseline, 1 month, and 3 months after discharge
2. Stroke risk is measured using the Feigin Stroke Risk Score at baseline, 1 month, and 3 months after discharge

Key secondary outcome(s))
1. Blood viscosity measured using a micropapillary device at baseline, 1 month, and 3 months after discharge
2. Functional outcome measured using the modified Rankin Scale (mRS) score and Barthel index at baseline, 1 month, and 3 months after discharge
3. Element of risk factor for stroke measured using the Feigin Stroke Risk Score at baseline, 1 month, and 3 months after discharge

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Diagnosed with mild to moderate ischemic stroke based on a clinical definition of focal neurologic deficits consistent with the vascular territory of the brain
2. Aged over 18 years at onset of event
3. Lived around Jakarta during the research process
4. Discharge to home
5. Speaking Indonesian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Patients unable to give informed consent
2. Discharged to a long-term nursing home
3. Pre-stroke dementia history
4. Patients with end-stage cancer or other medical conditions resulting in mortality of less than 1 year

Date of first enrolment
10/01/2022

Date of final enrolment
10/01/2023

Locations

Countries of recruitment
Indonesia

Study participating centre

Cipto Mangunkusumo National Hospital
Pangeran Diponegoro No. 71
Jakarta
Indonesia
10430

Sponsor information

Organisation
University of Indonesia

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
University/education

Funder Name
Direktorat Riset and Pengembangan, Universitas Indonesia

Alternative Name(s)
Directorate of Research and Development, Directorate of Research and Development of the University of Indonesia, R&D Directorate, Directorate of Research and Community Engagements Universitas Indonesia, Directorate of Research and Community Engagement UI, Directorate for Research and Development - Universitas Indonesia, Direktorat Riset & Pengembangan, Risbang, Risbang UI, Directorate of Research and Community Engagement UI, Direktorat Riset dan Pengabdian Masyarakat UI, DRPM UI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Indonesia

Funder Name
Kementerian Riset dan Teknologi /Badan Riset dan Inovasi Nasional

Alternative Name(s)
Ministry of Research and Technology/National Research and Innovation Agency, Ministry of Research and Technology/National Research and Innovation Agency, Republic of Indonesia, Kementerian Riset dan Teknologi/Badan Riset dan Inovasi Nasional, Republik Indonesia, Kementerian Riset dan Teknologi / Badan Riset dan Inovasi Nasional, Kementerian Ristek / BRIN, Kementerian Riset Dan Teknologi Badan Riset Dan Inovasi Nasional, Kementerian Riset dan Teknologi RI / Badan Riset dan Inovasi Nasional RI, Kemenristek / BRIN, Ristek-BRIN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be 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?
Results article	results	11/05/2023	31/05/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			13/01/2023	No	No
Statistical Analysis Plan			13/01/2023	No	No