ISRCTN23919537 https://doi.org/10.1186/ISRCTN23919537

Assessing the feasibility and effectiveness of a digital psychoeducational supportive program at improving health-related outcomes among family caregivers of stroke survivors

Submission date
10/01/2026

Recruitment status
No longer recruiting

Registration date
12/01/2026

Overall study status
Ongoing

Last Edited
12/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Stroke remains a major global health concern. Despite advances in stroke care and supportive services, many family caregivers continue to experience physical and psychological challenges, including stress, anxiety, depression, lack of self-efficacy and inadequate social support. These challenges highlight the need for targeted interventions to support caregivers and enhance their psychological well-being. Technology-based psychosocial interventions offer a promising approach,as they allow caregivers to access education and emotional support while continuing their caregiving roles. The design of the digital psychoeducational supportive program was developed based on the evidence from our systematic review and informed by findings from the qualitative study.

This study comprises both a pilot and a main randomly allocated and controlled (with a dummy treatment) study to evaluate a digital psychoeducational supportive program for family caregivers of stroke survivors (iSupportSTROKE). The objective of the pilot study is to assess the feasibility and initial effects of the program. The main study aims to examine the effectiveness of the program in reducing caregiver stress (primary outcomes), and improving anxiety, depression, physical health, caregiver self-efficacy, perceived social support, and psychological well-being among caregivers of stroke survivors.

Who can participate?
Family caregiver aged 18 years or older who are responsible for the daily care of a stroke survivor with an Activity of Daily Living (ADL) score of 11 or below and who provide the highest proportion of care hours among all caregivers.

What does the study involve?
Participants will be randomly assigned to one of the two groups: a) a wait-list control group (receive usual care during data collection period and will receive program at a later date), or b) a digital psychoeducational supportive program (intervention group: iSupportSTROKE program

plus usual care). Participants in the intervention group will receive the iSupportSTROKE program, which includes learning topics on the prevention of stroke-related complications, mindfulness in the caregiver's life, and several guided mindfulness practices aimed at alleviating physical and psychological commonly experienced by caregivers. Participants in the wait-list control group will receive the same intervention after the completion of the study period.

What are the possible benefits and risks for participating?
The intervention will be provided at no cost to all participants. Participation in this study involves minimal physical and psychological risk. Participants may experience an inconvenience of time commitment, as they are expected to spend about 5-7 hours completing the intervention. If, at any point in time, they feel uncomfortable with the study procedures and assessments, they are free to inform the study team, and they may take some rest. Additionally, participants are free to skip any questions in the self-assessment questionnaires that they feel uncomfortable or prefer not to answer.

Where is the study run from?
Primary health promoting hospitals (Thailand)

When is the study starting and how long is expected to run for?
January 2026 to December 2026

Who is funding the study?
PhD Staff Development Scholarship Program (Prince of Songkla University)

Who is the main contact?
Kanokwan Hounsri (PhD Candidate at Alice Lee Centre for Nursing Studies, National University of Singapore), e0948410@u.nus.edu

Contact information

Type(s)
Principal investigator

Contact name
Ms Kanokwan Hounsri

ORCID ID
https://orcid.org/0000-0002-0208-6739

Contact details
Kanokwan Hounsri
Faculty of Nursing, Prince of Songkla University
15 Karnjanavanich Road
Hatyai, Songkla
Thailand
90110
+66 95 0735202
e0948410@u.nus.edu

Type(s)
Scientific, Public

Contact name
Dr Piyanee Yobas

Contact details
Block MD6, Level 5
Alice Lee Centre for Nursing Studies, National University of Singapore
14 Medical Drive
Singapore
117599
+65 (0) 6516 7789
nurpk@nus.edu.sg

Additional identifiers

Study information

Scientific Title
The feasibility and effectiveness of a digital psychoeducational supportive program on health-related outcomes among family caregivers of stroke survivors: a randomised controlled trial

Acronym
iSupportSTROKE

Study objectives
This study involves a pilot randomised controlled trial (RCT) and the main RCT

Objective of the pilot RCT:
To assess the feasibility (recruitment, retention, attrition, response rate, and program engagement) and initial effects of the intervention on caregivers' health-related outcomes.

Objective of the main RCT:
1. To evaluate the effectiveness of the program on caregivers' health-related outcomes.
2. To explore family caregivers of stroke survivors' perceptions towards the iSupportSTROKE program.

Hypothesis of the main RCT of the study:
H1: In comparison with a wait-list control group, caregivers of stroke surviviors who complete the iSupportSTROKE program will report significantly lower levels of objective stress, subjective stress, depression, anxiety.
H2: In comparison with a wait-list control group, caregivers of stroke surviviors who complete the iSupportSTROKE program will report significantly higher levels of physical health, caregiver self-efficacy, perceived social support, and psychological well-being.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 21/10/2024, National University of Singapore (28 Medical Drive, Centre for Life Sciences (CeLS), CELS-01-03B, Singapore, 117456, Singapore; +65-65164311; irb@nus.edu.sg), ref: NUS-IRB-2024-660

2. Approved 17/01/2025, PSU Human Research Ethics Committee, Prince of Songkla University (15 Karnchanavanich Road, Hatyai, Songkla, 90110, Thailand; +66 7428-6955; psuhrec@gmail.com), ref: PSU-HREC 2024-073-1-1

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Improving physical and psychological problems and enhancing self-efficacy in caregivers of stroke survivors

Interventions
Before commencing participant recruitment, the researcher not involved in recruitment will generate block randomization sequence with a 1:1 allocation ratio. A set of random allocation sequences, ID 1-20 for the pilot RCT, and ID 1-140 for the main RCT will be prepared. Each sequential number indicating group assignment will be placed on a card and inserted in opaque sealed envelopes in advance. Subsequenty, the principal investigator will recruit the participants at the study sites and provide the sealed envelopes according to their enrolment sequence. Participants will be asked to open the envelope at the study site to reveal their group allocation.

Participants will be randomly assigned to one of the two groups: Wait-list control group or Intervention group
1. Wait-list control group:
Participants assigned to the wait-list control group will continue to receive usual care, which includes regular follow-up from health promoting hospitals. After the 6-week data collection period is completed, they will be invited to attend the iSupportSTROKE program. However, data during the intervention for the wait-list control group will not be collected.

2. Intervention group:
Participants assigned to the intervention group will be informed of the venue, intervention

schedule, and data collection procedures. They will be invited to attend a workshop on iSupportSTROKE mobile application user training one week before the program begins. The program consists of six weekly 45-minute sessions delivered using a hybrid approach, combining face-to-face sessions and the iSupportSTROKE mobile application. Face-to-face sessions will be conducted in weeks 1 and 6. During weeks 2-5, participants will engage in self-directed learning using the mobile application. Program content includes information specific to post-stroke care (e.g., prevention of post-stroke complications or post-stroke dementia, rehabilitation, nutrition and medication care), stress management for caregivers, and guided mindfulness relaxation practices. Participants will be asked to practice mindfulness at home around 10-15 minutes per day.

Intervention Type
Behavioural

Primary outcome(s)
1. Subjective stress measured using the stress subscales of the Thai-version Depression Anxiety Stress scale (DASS-21) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

2. Objective stress measured using peripheral skin temperature using stress thermometer and resting heart rate using pulse oximeter at before and after each of the six intervention sessions

Key secondary outcome(s)
1. Anxiety and Depression measured using the anxiety and depression subscales of the Thai version Depression Anxiety Stress Scale (DASS-21) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

2. Physical Health measured using the Thai version of the self-rated health (SRH) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

3. Caregiver Self-Efficacy measured using the Thai version of the Caregiver Self-Efficacy Scale (CSES) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

4. Perceived Social Support measured using the Thai version of the 12-item Multidimensional Scale of Perceived Social Support (MSPSS) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

5. Psychological Well-Being measured using the Thai version of the 18-item Psychological Well-Being Scale (PWB-S) at T0 (baseline), T1 (at the end of sessions 3; middle point of the intervention), T3 (at the end of sessions 6; endpoint of the intervention)

6. Participants' perceptions toward iSupportSTROKE program measured using focus group interviews at after the last of the six intervention sessions (only main RCT)

7. Program satisfaction measured using the Thai version of the Client Satisfaction Questionnaire (CSQ-8) at after the last of the six intervention sessions

8. Application usability measured using the Thai version of the System Usability Scale (SUS) at after the last of the six intervention sessions

9. For the pilot RCT, in addition to the above outcomes, the following will also be measured: 1) Recruitment rate 2) Retention rate 3) Attrition rate 4) Response rate 5) Program engagement 6) Program's perceived usefulness measured using a record form (program engagement), an open-ended questionnaire (perceived usefulness), and the reasons for exclusion, refusal to participate, and any records of incompletion or dropout, at throughout the recruitment and data collection process for reasons for exclusion, refusal to participate, and any records of incompletion or dropout, and after completion of the six intervention sessions for the program's perceived usefulness

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Family caregivers are eligible to participate if they:
1. Are primary caregivers of stroke survivors who have ADL equal to or less than 11
2. Provide the highest proportion of care hours among all caregivers
3. Aged 18 years old or older
4. Able to read and converse in Thai
5. Able to use smartphones in daily life
6. Have internet access

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Family caregivers will be excluded if they:
1. Are being paid
2. Have visual, hearing, or perceptual impairment that interferes with communication
3. Reported a doctor-diagnosed psychiatric illness

Date of first enrolment
16/01/2026

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
Singapore

Thailand

Study participating centre
Health promoting hospitals, Songkhla Provincial Administative Organization (Lead centre)
Songkhla Provincial Administrative Organization
900, Phawong Subdistrict
Songkhla
Thailand
90110

Study participating centre
Faculty of Nursing, Prince of Songkla University
15 Karnjanavanich Road
Hatyai
Thailand
90110

Study participating centre
Alice Lee Centre for Nursing Studies, National University of Singapore
Block MD6, Level 5
14 Medical Drive
Singapore
117599

Sponsor information

Organisation
National University of Singapore

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type

Funder Name
Prince of Songkla University

Alternative Name(s)
, Prince of Songkla University, Thailand, Prince of Songkla University | Hat Yai, Mahawitthayalai Songkhla Nakharin, PSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Thailand

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date