ISRCTN18158500 https://doi.org/10.1186/ISRCTN18158500

Preliminary evaluation of a family-focused psychoeducational programme for stroke survivors and their family caregivers

Submission date
08/10/2022

Recruitment status
No longer recruiting

Registration date
10/10/2022

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is the first and second leading cause of death in China and worldwide, which can bring about a variety of physical and psychosocial disturbances for both stroke survivors and their family caregivers. A psychoeducational intervention seems to be an effective approach for them to improve their physical and psychosocial outcomes. Psychoeducation is an evidence-based intervention for patients and their loved ones that provides information and support to better understand and cope with illness. This study aims to develop and evaluate an appropriate theory-based family-focused approach to psychoeducational intervention to help improve psychosocial and physical health outcomes.

Who can participate?
People with stroke and their family caregivers, aged 18 years and over

What does the study involve?
Participants are randomly allocated to receive the family-focused psychoeducational intervention or usual care only.

What are the possible benefits and risks of participating?
It is expected that participants who receive this programme may improve their coping skills for disease management, which may improve functional and psychosocial outcomes accordingly. As this is a psychosocial and educational intervention, participants have few opportunities to suffer side effects or other risks

Where is the study run from?
The Chinese University of Hong Kong (Hong Kong)

When is the study starting and how long is it expected to run for?
November 2020 to February 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Huanyu Mou, mouhuanyu@link.cuhk.edu.hk

Contact information

Type(s)
Principal investigator

Contact name
Ms Huanyu Mou

Contact details
Room 702, 7/F, Esther Lee Building
The Chinese University of Hong Kong
Shatin, N.T.
Hong Kong
Hong Kong
-
+852 (0)63321157
mouhuanyu@link.cuhk.edu.hk

Additional identifiers

Study information

Scientific Title
Effectiveness of a family-focused dyadic psychoeducational intervention (FDPEI) for stroke survivors and family caregivers on functional and psychosocial health outcomes

Study objectives
The overall aim of this study is to determine the feasibility, acceptability and effectiveness of a family-focused dyadic psychoeducational intervention (FDPEI) programme for stroke dyads (i.e., stroke survivors and their family caregivers).
The study hypotheses are:
1. The family-focused dyadic psychoeducational intervention programme is feasible for stroke family dyads.
2. The family-focused dyadic psychoeducational intervention programme is acceptable for stroke family dyads.
3. The family-focused dyadic psychoeducational intervention programme can have significant effects on stroke dyads' functional and psychosocial health outcomes immediately post-intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 02/11/2020, Joint CUHK-NTEC Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; +852 (0)3505 3824; crec2@cuhk.edu.hk), ref: 2020.489-T

Primary study design
Interventional

Study design
Assessor-blinded two-arm (parallel-group) pilot-controlled trial with randomised allocation of study subjects and pre-test and post-test evaluative design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
The programme will be conducted via a hybrid approach in two parts: structured face-to-face education when survivors are in hospital or rehabilitation facilities; and telephone follow-up counselling after survivor discharge. The intervention will be initiated after survivors become stable in the hospital. The randomisation method is block randomisation with a block size of four.

Face-to-face education
This part will be conducted when patients in hospital or rehabilitation facilities (prior to the survivor's discharge), which consists of three sessions, namely, 1) overview of fundamental knowledge related to stroke; 2) adaptation for caring and being cared for in basic activities of daily life; and (3) psychological adjustment and stress management. An information booklet will be designed in accordance with the intervention protocol. Every session will be delivered in 1 hour. There are 2 or 3 days between two sessions, as a result, family dyads could have time to understand the intervention contents.

Telephone follow-up counselling
After the survivor's discharge, the follow-up family counselling will be conducted by the intervener via telephone contact weekly for 4 weeks. During each contact, the intervener encourages family dyads to express their encountered problems or stressful experience in their daily lives. The arising problems or issues (e.g. wrong caregiving behaviour, uncomfortable health status, or stressful feelings) will be appraised and discussed, and advice is given where needed. The counselling part is structured but not standardised, as it aims to respond to family dyads' individualised needs, which varied widely and cannot always be predicted.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility, measured by:
1.1. Recruitment rates (calculated as the percentage of the participants being enrolled /randomised divided by those who are eligible for study participation at baseline)
1.2. Attrition rates (calculated as the percentage of those participants not able to complete the study or the outcome assessment immediately post-intervention)

1.3. Adherence to interventions of the participants (measured as the percentage of participants attending ≥60% of the intervention sessions, i.e. ≥2 of 3 sessions in part I and ≥3 of 4 calls in part II)
2. Acceptability, open-ended questions, including the appropriateness of the intervention and the experiences of participating in the FDPEI, measured immediately post-intervention

Key secondary outcome(s)
1. Stroke survivors' functioning, measured by Stroke Impact Scale 3.0, at pre- and post-test
2. Caregiver burden, measured by Caregiver Burden Inventory, at pre- and post-test
3. Caregivers' competence, measured by Caregiving Competence Scale, at pre- and post-test
4. Dyads' coping, measured by Family Crisis Oriented Personal Evaluation Scale, at pre- and post-test
5. Dyads' depressive symptoms, measured by Patient Health Questionnaire-9, at pre- and post-test
6. Dyads' anxiety symptoms, measured by Generalised Anxiety Scale-7, at pre- and post-test
7. Dyads' family functioning, measured by general functioning of McMaster Family Assessment Device, at pre- and post-test
8. Dyadic relationship, measured by Mutuality Scale, at pre- and post-test

Completion date
27/02/2021

Eligibility

Key inclusion criteria
Stroke survivors:
1. Being firstly diagnosed with stroke within one month, aged 18 years or above
2. Being able to understand the intervention and communicate with the researcher
3. Given informed consent to participate in this study
4. Having a main family caregiver (i.e., another member of the dyad) as the family dyad in this study

Family caregivers:
1. The main family members who are responsible to take major care of the stroke survivors
2. Aged 18 years or above
3. Able to understand the study and intervention and communicate with the researcher
4. Given informed consent to participate in this study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
40

Key exclusion criteria
Stroke survivors:
1. Less than 6 months life expectancy, or other comorbidities in higher priority than their stroke rehabilitation
2. Having moderate or severe cognitive deficits
3. Been engaging in any other research and/or bio-psychosocial intervention
4. High independence in daily activity performance

Family caregivers :
1. History of major mental illness such as mood and psychotic disorders
2. Visual (blindness), auditory (deafness) and/or cognitive impairments
3. Engaging in other stroke care research and/or psychosocial or physical intervention

Date of first enrolment
07/12/2020

Date of final enrolment
18/01/2021

Locations

Countries of recruitment
China

Study participating centre
Shandong Provincial Hospital
No. 324, Five West Seven Road
Huaiyin Region
Jinan
China
250021

Study participating centre
Shandong Provincial Third Hospital Rehabilitation Facility
No. 12, Wuyingshanzhong Road, Tianqiao Region
Jinan, Shandong
Jinan
China
250031

Sponsor information

Organisation
Chinese University of Hong Kong

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the principle of informed consent which indicated that the participants' personal data will not be public.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/12/2022	30/03/2023	Yes	No