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Telephone delivered intervention for family caregivers of persons with dementia in Malaysia

Submission date
20/09/2023

Recruitment status
No longer recruiting

Registration date
23/09/2023

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

Family caregivers of persons with dementia (PWD) are at heightened risk for emotional and mental health problems. While there are ample effective telephone-delivered approaches to address the negative effects of dementia caregiving practised in Western countries, they are lacking in Malaysia. This study assesses the efficacy of a telephone-delivered psychoeducational intervention given by occupational therapists on the reduction of caregiving burden, depressive and anxiety symptoms, and enhancement of caregiving self-efficacy and caregiver's quality of life in family caregivers of PWD.

Who can participate?

Family caregivers of PWD who are in a caregiving role for at least 4 hrs/day for >6 months and primary caregivers, aged 18 to 64 years old

What does the study involve?

This study develops an invaluable and novel model of psychoeducational intervention in a Malaysian context for family caregivers of persons with dementia. The psychoeducation intervention will be compared with the usual care currently available in psychiatric clinics. This usual care is clinic-based and does not address the specific needs of informal dementia caregivers in the community. However, the psychoeducational intervention based on cognitive behavioural therapy, developed according to the specific needs of the homebound dementia caregivers, is delivered by trained nurses or occupational therapists over the phone for 10 sessions. A total of 121 family caregivers (60 in each arm) will participate in this study. After recruitment, all are assessed for the baseline measurements. After baseline assessment, participants will be randomly allocated into intervention and control groups. The intervention group receives the psychoeducation intervention over 12 weeks and the control group receives the usual care that is available at the government hospitals. Each participant is expected to participate in the study including the baseline and post-intervention assessment for approximately 16 weeks (12 weeks for intervention ± 4 weeks for assessments).

What are the possible benefits and risks of participating?
Through participation in this research, participants should have the following benefits: any care-related stress and burden is expected to be reduced and thereby the quality of life and caregiving self-efficacy might be improved.

There are no potential risks with the proposed psychoeducation intervention in participants' lives as the psychoeducation intervention has already been proven beneficial in Western countries as well as in Hong Kong, Taiwan and Japan. The intervention itself may introduce more stress or anxiety as it affects the participant's schedule. However, a high dose of flexibility to adjust participants' time for delivering the intervention and good rapport will help to minimize those risks.

Where is the study run from?
As all procedure i.e., assessment and delivering intervention has been performed over the telephone, the participants can participate in the study from their home, hospital/clinic or workplace according to a convenient time and place. The nurses/occupational therapists deliver the intervention through the telephone from their clinic. The research assistants collect the data over the phone from their office/home (weekend).

When is the study starting and how long is it expected to run for?
September 2021 to September 2024

Who is funding the study?
Ministry of Higher Education, Malaysia (FRGS/1/2021/SKK04/UIAM/02/1/0)

Who is the main contact?
Prof Hashima E Nasreen, drnasreen@iium.edu.my

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FRGS21-210-0819

Study information

Scientific Title
Telephone delivered psychoeducational intervention to reduce of psychophysical burden among dementia caregivers in east and west coasts of Malaysia

Acronym
TPIFCPWD

Study objectives
Telephone delivered psychoeducational intervention will alleviate caregiving burden, depressive symptoms, and enhance caregiving self-efficacy and caregivers' quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/03/2022, Medical Research & Ethics Committee, Ministry of Health Malaysia (Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia) (No 1, Jalan Setia Murni U13/52, Seksyen U13, Setia Alam, Selangor, 40170 Shah Alam, Malaysia; +60333628888; mrecsec@moh.gov.my), ref: 22-00137-BUY

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Hospital, Telephone

Study type(s)
Efficacy

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
Reduction of caregiving burden, depression and anxiety, and improvement of quality of life and caregiving self-efficacy in family caregivers of persons with dementia.

Interventions
Participants are randomly assigned to intervention and control groups using a computerized randomization programme. The participants in the intervention group will receive the psychoeducation intervention. The psychoeducation intervention consists of 10 sessions that will be delivered by trained nurses/occupational therapists via the telephone over the period of 12 weeks. The sessions should be constructive and supportive towards everyday challenges faced by the caregivers while caring the dementia patients. Sessions may need to be divided into multiple smaller sessions depending on the accessibility and availability of both the health providers and caregivers.

The psychoeducation intervention is based on cognitive behavioural therapy and i-support for dementia (WHO 2019), which provides dementia education, and emotional support, directing caregivers to appropriate resources, encouraging caregivers to attend to their own physical, emotional and social needs, and teaching strategies to cope with the ongoing problems. The intervention does not provide any case management but serves as a question-answer hotline and provides psychotherapy over the telephone. The intervention will be implemented in three stages. The initial stage involves an introduction to the educational resource material and a description of what will happen during future follow-up calls. The psychoeducation component at this stage includes reviewing information about dementia, and common psychosocial, emotional and medical effects of caregiving, such as health, functioning, mood, thinking and family life. In the second stage, follow-up telephone contacts have been conducted to identify

any new problem encountered, to discuss positive or negative changes in caregivers or patients, to apply psychoeducational information for a particular situation, and to assist caregivers in solving the problems.

A therapist may choose the most appropriate intervention, such as supportive approaches (empathy, normalizing, provision of information, venting) or more active strategies (bibliotherapy, interpretation, positive reframing, problem-solving, task directive). The final call addresses issues of termination by allowing caregivers to anticipate psychoeducation telephone contacts coming to an end, and encouraging reliance on the support network established during the intervention.

Contrary, the control group receives the usual care provided by the State Health Department of the Ministry of Health, Malaysia.

Intervention Type
Behavioural

Primary outcome measure
Caregiving burden is measured using the Malay version of the Zarit Burden Interview and depressive and anxiety symptoms are measured by the Malay version of the Hospital Anxiety and Depression Scale at baseline and post-intervention (after 12 weeks)

Secondary outcome measures
1. Caregiving self-efficacy is measured using the Revised Scale for Caregiving Self-Efficacy at baseline and post-intervention (after 12 weeks of intervention)
2. Quality of life is measured using the Control, Autonomy, Self-realization and Pleasure-19 scale at baseline and post-intervention (after 12 weeks of intervention)

Overall study start date
07/09/2021

Completion date
06/09/2024

Eligibility

Key inclusion criteria
1. Family caregivers of persons with dementia who are in a caregiving role for at least 4 hrs/day for at least 6 months
2. Family caregivers aged 18 years old and above
3. Family caregivers able to read and write in Malay or English
4. Primary caregivers (if there is >1 caregiver)
5. Should have a smartphone

Participant type(s)
Health professional, Carer

Age group
Adult

Lower age limit

18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
121

Total final enrolment
121

Key exclusion criteria
1. Caregivers younger than 18 years old
2. Major acute medical illness
3. Any cognitive impairment
4. No access to a telephone

Date of first enrolment
08/04/2022

Date of final enrolment
10/03/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Kebangsaan Malaysia Medical Center
Jalan Yaacob Latif Kuala lumpur
Bandar Tun Razak
Wilayah Persekutuan
Kuala Lumpur
Malaysia
56000 Cheras

Study participating centre
Tengku Ampuan Afzan Hospital
Jalan Tanah Putih
Pahang
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Malaysia
25100

Study participating centre
Sultan Ahmad Shah Medical Centre @IIUM
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Sponsor information

Organisation
Ministry of Higher Education

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Sponsor type
Government

Website
https://www.mohe.gov.my

ROR
https://ror.org/02xvp8z16

Funder(s)

Funder type
Government

Funder Name
Ministry of Higher Education, Malaysia

Alternative Name(s)

MOHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in high-impact journal peer-reviewed journals.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and /or analysed during the current study are not expected to be available due to confidentiality issues but are available upon reasonable request from Prof Hashima E Nasreen, drnasreen@iium.edu.my.

Individual participant data will be available after de-identification. The individual participant data will be shared that underlie the results reported in the particular article after de-identification. These data will be available beginning 3 months and ending 5 years following article publication and will be shared with researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. The proposal should be directed to drnasreen@iium.edu.my. To gain access, the data requestor will need to sign a data access agreement. Data will be available at the university website.

Informed consent was obtained prior to interviewing the participants. When presenting or publishing the study results, participants' identities will not be revealed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	16/03/2022	22/09/2023	No	Yes
Protocol file			22/09/2023	No	No
Interim results article		05/08/2024	06/08/2024	Yes	No