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The construction of supporting model for family caregivers of people with dementia - a preliminary study of barriers and needs

Submission date 15/12/2017	**Recruitment status** No longer recruiting	☐ Prospectively registered ☒ Protocol ☐ Statistical analysis plan
Registration date 18/01/2018	**Overall study status** Completed	☐ Results ☐ Individual participant data
Last Edited 02/04/2020	**Condition category** Mental and Behavioural Disorders	☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a broad category of brain diseases that cause a gradual decrease in the ability to think and remember. Due to the rapid increase of the aging population, there is a fast growing number of dementia patients in Taiwan. Many dementia patients are cared for at home, but there are few studies about the needs and barriers for family caregivers supporting people with dementia. The aim of this study is to explore the barriers and construct a supporting model in terms of needs for family caregivers of people with dementia.

Who can participate?
Group 1: primary family caregivers
Group 2: people diagnosed with dementia including Alzheimer's disease, vascular dementia and other types of dementia
Group 3: healthcare professionals including physicians, nurses, social workers and paid carers who are familiar with the disease and patients with dementia

What does the study involve?
The study divides into two phases. In phase I, participants are recruited from the outpatients of Neurology and Geriatrics Departments of a teaching hospital in Taichung to participate in interviews and to use a caring diary. At phase II, participants are selected from the above groups to participate in questionnaires. This study examines the barriers and needs of family caregivers of people with dementia in five areas: (1) knowledge of dementia and caring skills to cope with problem behaviours; (2) medication and comorbidity management; (3) family relationship and psychological support, (4) resources and benefits and (5) education and skills training. In the end, a supporting model of needs for family caregivers is constructed to provide healthcare professionals and family caregivers with more concise information and insights about the problems.

What are the possible benefits and risks of participating?
The healthcare professionals and the family caregivers may gain a deeper understanding of the barriers and needs of caring for a family with dementia. The risks of participating may result

from recalling negative memories or experiences of caregiving among the family caregivers during the interviews and writing the care diary. In this situation, participants are advised to leave the study and are directed to suitable counselling if they wish.

Where is the study run from?
China Medical University Hospital (China)

When is the study starting and how long is it expected to run for?
December 2017 to May 2018

Who is funding the study?
China Medical University Hospital (China)

Who is the main contact?
Dr Chia-Ming Yen
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
TRLS-D17-00988

Study information

Scientific Title
The construction of supporting model for family caregivers of people with dementia - a preliminary study of barriers and needs

Study objectives
There are 2 study hypotheses: firstly it is assumed that family caregivers of people with dementia suffer from barriers. Second, the needs and support from family caregivers of people with dementia are uncleared by healthcare professionals.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Research Ethics Committee, China Medical University & Hospital, 05/12/2017, ref: CMUH-REC1-142

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
The recruitment of participants is randomized in this study. There are two Phases of participant recruitment:

In phase I, healthcare professionals, for example, physicians, will be selected from the list of outpatient's timetable from Departments of Neurology, Psychiatry or Family Science in China Medical University Hospital. Other healthcare professionals will be then recruited by using snowball sampling from the same Hospital afterwards. Patients and family caregivers will be recruited through the introduction of physicians. An in-depth interview and caring diary will be adopted.

The participants are divided into three groups, Group 1 and 2 contain 10 participants respectively. Group 3 includes 18 participants. Participants from Group 1 are the primary family caregivers regardless of age and gender; Group 2 contains people who are diagnosed with dementia including Alzheimer's disease, vascular dementia and other types of dementia and regardless the stage of disease process. That is he or she is in his/her early, mild and server stages of dementia. Group 3 contains of 18 healthcare professionals including physicians, nurses, social workers and paid carers who are familiar with the disease and patients of dementia.

In phase II, 10 participants will be selected from the above groups to participate in Delphi questionnaires.

This study will systematically examine the barriers and needs of family caregivers of people with dementia in five domains:
1. Knowledge of dementia and caring skills to cope with problem behaviours
2. Medication and comorbidity management
3. Family relationship and psychological supports
4. Resources and benefits
5. Education and skills training

In the end, the supporting model of needs for family caregivers will be constructed which will be expected to provide healthcare professionals and family caregivers more concise information and insights about the problems.

Intervention Type
Other

Primary outcome(s)
interview results; qualitative interview results will be transcribed into text then the text will be analyzed. Thematic analysis will be used to analyze the text. Themes and subthemes will be cited from the text.

Key secondary outcome(s))
Delphi questionnaire results; the design of the Delphi questionnaire will be based on literature review and the themes and subthemes cited from interviews.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
The participants are divided into three groups:
Group 1 contains the primary family caregivers who live with the care recipient, regardless of age and gender
Group 2 contains people who are diagnosed with dementia. To have a complete picture from patients of dementia in terms of needs and supports in this study, people with any age and sex with a diagnosis of dementia (Alzheimer’s disease, vascular dementia or mixed Alzheimer’s and vascular dementia, or other types of dementia) who live in the community (excluding people in institutions receiving 24 hours of care). Also people at different stage of disease processes (people who are still able to express his/her views mainly) will be included
Group 3 contains healthcare professionals including neurologic or geriatric physicians, nurses, clinical psychologist, occupational therapist, social workers and paid carers

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Healthcare professional who never works with dementia patients
2. Primary family caregiver who does not live with the care recipient

Date of first enrolment
18/12/2017

Date of final enrolment

30/06/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Medical Center of Aging Research, China Medical University Hospital
Taiwan
40402

Sponsor information

Organisation
Medical Center of Aging Research, China Medical University Hospital

ROR
https://ror.org/00v408z34

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
China Medical University Hospital

Alternative Name(s)
CMUH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Chia-Ming Yen (ayen1001@gmail.com). The data will be possibly available around one year after the trial ends on 30/06/2018.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/01/2019	02/04/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes