ISRCTN50312942 https://doi.org/10.1186/ISRCTN50312942

Interventions and Implements for coping with the behavioral and psychological symptoms of dementia: perspectives from family caregivers

Submission date 29/04/2022	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/05/2022	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/05/2022	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

In Taiwan, it is estimated that one in every 12 persons aged 65 years and more and one in every 5 persons aged 80 years or more are diagnosed with dementia. Dementia is characterized by dysfunction or loss of memory, orientation, attention, language, judgement, and reasoning, and people living with dementia (PWD) become more dependent on their carers when the disease progresses. In Taiwan and globally, challenges are being faced because of the rapidly increased numbers of dementia recipients and family caregivers (FCGs) of PWD. It is estimated that in Taiwan, 6% of PWD are institutionalized, whereas 93% of PWD live at home and 55% are cared for by their family members, a percentage similar to that in Western countries. Behavioral and psychological symptoms of dementia (BPSD) such as agitation, aggression, calling out repeatedly, sleep disturbance, wandering and apathy affect up to 90% of PWD and are associated with poor outcomes such as distress in both the person with dementia and the carer. Caring for a FWD can be described as "challenging' when it causes distress to the person or the carers or family carers in particular. The aims of thisd study are to explore which behavioural and psychological symptoms of dementia (BPSD) affect the well-being of family care givers (FCGs) the most and how and in what ways could FCGs cope each of the problem behaviors. By the end, tailored interventions are developed to support FCGs in home settings to enhance the positive outcomes from caring for a person with dementia.

Who can participate?

Family caregivers of people living with dementia and their care recipients.

What does the study involve?

This study includes three phases. In phase I the effective BPSD guideline and strategies will be explored, collected, and edited into a handbook. The draft of the handbook would be approved by experts and used as the guideline for BPSD educational training programs. In phase II family caregivers (FCGs) and people living with dementia (PWD) are recruited from Chia-Yi and Tai-Chung in Taiwan respectively. Family caregivers who have experienced a negative caring experience possibly resulting from BPSD of the dementia care recipient, are recruited to participate in a 24-hour BPSD educational training program. The 24-hour BPSD educational training programs will be conducted for 3 months. Family caregivers are also interviewed before the start of training programs, followed by two interviews every 2 months before finishing their BPSD educational training. This would help the researcher to explore the initial caring attitudes and experiences of FCGs in home settings and to investigate whether those attitudes and caring experiences are changed into positive ones. In phase III the researcher and experts from the field will visit the FCGs and PWD at home. During the home visits, the home environment and interaction between caregiver and care recipient will be observed, asked and noted down to examine how and in what ways family caregivers deliver care to recipients in family settings.

What are the possible benefits and risks of participating?
The family caregivers in particular may not only benefit from gaining knowledge of dementia but also exchange ideas and experiences with others who join the BPSD educational training programs in terms of coping and management in home settings. During the home visits there is a risk that care recipients refuse or feel uncomfortable allowing 'strangers' (e.g., researchers and experts) to enter their house.

Where is the study run from?
National Health Research Institutes (Taiwan)

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

Who is funding the study?
National Health Research Institutes (Taiwan)

Who is the main contact?
Dr Chia-Ming Yen
cmyen@nhri.edu.tw

Contact information

Type(s)
Principal Investigator

Contact name
Dr Chia-Ming Yen

ORCID ID
http://orcid.org/0000-0002-9774-8634

Contact details
No.8, Syuefu West Road
Hu-wei Township, Yun-lin County
Taiwan
632
+886 (0)5 6325080
cmyen@nhri.edu.tw

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EC1110102

Study information

Scientific Title
From knowledge to practice: interventions and implementation for coping with behaviour problems in dementia care

Acronym
BPSD intervention: Family caregivers

Study objectives
This study explores which behavioral and psychological symptoms of dementia (BPSD) affect the well-being of family caregivers (FCGs) the most and how and in what ways to help FCGs manage these problem behaviors. This study develops tailored interventions to support FCGs in accordance with the reported BPSD from FCGs in home settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2022, Ethics Committee of National Health Research Institutes (No.35, Keyan Road, Zhunan, Miaoli County. Taiwan, Republic of China; +886 (0)37 206166 ext 38602, +886 (0) 37 58310; nirb@nhri.edu.tw), ref: EC1110102

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

Not available

Health condition(s) or problem(s) studied
BPSD interventions for family caregivers of people living with dementia

Interventions
This study includes three phases, each phase has its own design and criteria. In phase I the effective BPSD guideline and strategies will be explored, collected, and edited into a handbook. The draft of the handbook would be approved by experts and used as the guideline for BPSD educational training programs. In phase II 12 dyads of family caregivers (FCGs) and people living with dementia (PWD) are recruited from Chia-Yi and Tai-Chung in Taiwan respectively. Family caregivers who are experienced a negative caring experience possibly resulting from BPSD of the dementia care recipient, are recruited to participate in a 24-hour BPSD educational training program. The 24-hour BPSD educational training programs will be conducted for 3 months. Family caregivers are also interviewed before the start of training programs, followed by two interviews every 2 months before finishing their BPSD educational training. This would help the researcher to explore 1) the initial caring attitudes and experiences of FCGs in home settings and 2) to investigate whether those attitudes and caring experiences are changed into positive ones. In phase III the researcher and experts from the field will visit the dyads of FCGs and PWD at home. During the home visits, the home environment and interaction between caregiver and care recipient will be observed, asked and noted down to examine how and in what ways family caregivers deliver care to recipients in family settings.

Intervention Type
Behavioural

Primary outcome measure
1. Coping and skill management in the home setting evaluated by the researcher via interviews (self-report from the family caregivers) at baseline, 0, 3, 6 and 9 months
2. The interaction between caregivers and care recipients evaluated by the researcher and frontline workers (e.g. a neurologist or social worker) at three home visits in May, August and October 2022

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Family caregivers of people living with dementia and the care recipients

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
100

Key exclusion criteria
Early-onset dementia

Date of first enrolment
01/04/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Taiwan

Study participating centre
National Center for Geriatrics and Welfare Research, National Health Research Institutes
No. 8, Syue-Fu West Road, Hu-Wei Township
Yun-Lin County
Taiwan
632

Sponsor information

Organisation
National Health Research Institutes

Sponsor details
No.35 Keyan Road
Zhu-nan, Miao-li
Taiwan
350
+886 (0)37 246166
hsinlingyeh@nhri.edu.tw

Sponsor type
Research organisation

Website
https://www.nhri.edu.tw/eng/

ROR
https://ror.org/02r6fpx29

Funder(s)

Funder type
Government

Funder Name
National Health Research Institutes

Alternative Name(s)
NHRI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Taiwan

Funder Name
China Medical University, Taiwan

Alternative Name(s)
CMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Taiwan

Results and Publications

Publication and dissemination plan

One review article will look at the studies between 2000 and 2022, clinical trials and qualitative studies in particular on coping and management of BPSD among family caregivers of people living with dementia. The second manuscript is the protocol of the study. High-impact peer-reviewed journals are preferred.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

Not expected to be made available due to cultural norms.

IPD sharing plan summary

Not expected to be made available