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A psycho-educational intervention for family caregivers of patients with dementia using a mobile application

Submission date
18/01/2015

Recruitment status
No longer recruiting

Registration date
27/01/2015

Overall study status
Completed

Last Edited
28/01/2015

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
With the rapidly ageing population worldwide, it is expected that the number of people suffering from dementia will increase tremendously. Caring for patients with dementia is very demanding and stressful. It is known that, by providing caregivers with information on dementia and teaching skills, the stress and depression that can be experienced is reduced. Caregivers of patients with dementia often don't use the conventional services offered to them because they require a lot of work and can be seen as inconvenient but many strongly express the need for information, emotional and social support. There is therefore a strong need to develop a new approach to deliver the information and support to meet the needs of family caregivers. In time-pressed and caregiver-scarce Singapore, technology can play an important role in providing caregiver support and information. This study aims to develop a mobile application based psycho-education for family caregivers of patients with dementia in managing patients' challenging behaviours, and to examine the effect of this mobile application based psycho-education on burdens placed on caregivers, coping strategies, symptoms of depression, what they gain from caregiving, distress related to the challenging behaviours , and the frequency and severity of the challenging behaviours.

Who can participate?
Family caregivers who are age 21 and above and taking care of patients with dementia at home.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given routine support though outpatient and community services and the mobile application based psycho-education for 2 months. Those in group 2 (control group) are given just the standard routine care.

What are the possible benefits and risks of participating?
It is expected that the mobile application based psycho-education will improve the psychological well-being of the participants. The use of the mobile application is free of charge. Their participation will inform health professionals that whether this sort of intervention can be

effective in helping caregivers of patients with dementia in Singapore. There are no foreseeable risks involved in this study.

Where is the study run from?
Singapore General Hospital (Singapore)

When is study starting and how long is it expected to run for?
April 2015 to October 2016.

Who is funding the study?
1. SingHealth Foundation (Singapore)
2. Mitsui Sumitomo Insurance Welfare Foundation (Singapore)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SHF/HSR075/2013

Study information

Scientific Title
A psycho-educational intervention for family caregivers of patients with dementia using a mobile application: a randomized controlled trial

Study objectives
When compared with the routine care control group across two time points (immediately and 3-month post intervention), the intervention group will have significantly:
1. Lower levels of caregiver burden
2. Higher levels of coping strategies
3. Lower levels of depressive symptoms
4. Higher level of gain in caregiving
5. Lower levels of distress caused by behavioural and psychological symptoms of dementia (BPSD), and
6. Reduction in the frequency and severity of BPSD in patients with dementia (PWD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
SingHealth Centralised Institutional Review Board (CIRB), 22/04/2014, ref: 2014/137/A

Study design
A single-centre, two-group pretest and repeated posttests randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Dementia/Caregiver Support

Interventions
Participants will be randomly assigned to intervention or control group using sealed opaque sequential envelopes with codes from a blocked randomization list.
1. Control group: Participants receive routine outpatient services and community services.
2. Intervention group: Participants receive routine care plus the mobile application based psycho-education for 2 months.

Intervention Type
Behavioural

Primary outcome measure
1. The Zarit Burden Inventory (Zarit,1985) will be used to assessed the level of subjective and objective burden experienced by caregiver. This is a 22-item self-report inventory on a 5-piont Likert scale.
2. The Family Crisis Oriented Personal Evaluation Scales will be used to measure the family's coping strategies (McCubbin, 2001). This is a 30-item self-report scale on a 5-point Likert scale.

The measures will be administered at baseline, immediately post intervention and 3-month post intervention.

Secondary outcome measures
1. The modified version of the 11-item Centre for Epidemiologic Studies Depression Scale (Kohout, Berkman, Evans, & Cornoni-Huntley, 1993; Radloff, 1977) will be used to assess the caregiver depressive symptoms.
2. The Gain in Alzheimer care INstrument (GAIN) is a 10-item scale used to measure gains in dementia caregiving from the perspective of the family caregiver (Yap et al., 2010)
3. Neuropsychiatric Inventory Questionnaire (Cummings et al., 1994; Kaufer et al., 2000) is used to assess patient's severity of neuropsychiatric symptoms and caregiver's distress caused by the symptoms. It's a 12-item caregiver-rated scale.
4. The Revised Memory and Behaviour Problem Checklist (Teri et al., 1992) will be used to assess the frequency of behaviour problems in patients with dementia and the family caregiver's reactions to these behaviour problems. It's a 24-item caregiver self-reported scale.

The measures will be administered at baseline, immediately post intervention and 3-month post intervention.

Overall study start date
01/01/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Family caregivers of patients with dementia
2. Age 21 and above
3. Care for a patient with dementia, who has three or more behavioural problems at home as assessed by neuropsychiatric inventory questionnaire
4. Caregiving contact time>=10 hours per week
5. Own a smart phone (such as iPhone or Android phone) or tablet computer (such as iPad or Samsung Galaxy Note) and know how to use download applications from application distribution platforms (i.e. Apple AppStore or Google Play Store)
6. Able to read and write English

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
152

Key exclusion criteria
1. Family caregiver who is suffering from any mental illness such as depression or having major medical conditions such as cancer
2. Patient who is suffering from any psychiatric mental disorder or living in nursing home /sheltered home

Date of first enrolment
01/04/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Singapore

Study participating centre
Geriatric Medicine Clinic & Memory Clinic
Geriatric Medicine
Singapore General Hospital
Outram Road
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Sponsor information

Organisation
SingHealth Foundation

Sponsor details
Singapore Health Services Pte Ltd
31 Third Hospital Avenue
#03-03 Bowyer Block C
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Singapore
168753

Sponsor type

Other

Website
www.singhealth.com.sg

ROR
https://ror.org/04me94w47

Funder(s)

Funder type
Research organisation

Funder Name
SingHealth Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Singapore

Funder Name
Mitsui Sumitomo Insurance Welfare Foundation (Singapore)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration