ISRCTN46137262 https://doi.org/10.1186/ISRCTN46137262

Care of family caregivers of persons with dementia

Submission date
04/09/2019

Recruitment status
No longer recruiting

Registration date
10/10/2019

Overall study status
Ongoing

Last Edited
30/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 15/07/2020:
Background and study aims
In Sweden, most people with dementia (PWD) live in their own home and are cared for by family members. The health consequences of caregiving of PWD include stress, depressive symptoms, loneliness and poor self-rated health. The aim of this study is to assess the effectiveness of introducing a mobile application through the existing health care system in Sweden for reducing stress, depressive symptoms and loneliness, and improving quality of life of family caregivers of PWD.

Who can participate?
Adult family members who have provided care to a person with dementia living at home for at least six months, possess a smartphone or tablet, have access to the internet at his/her own cost and are able to read and write Swedish.

What does the study involve?
The study is conducted in the Stockholm and Västerbotten Regions in a sample of 78 family caregivers of PWD. The intervention is implemented by dementia nurses randomly selected in each of the study sites. The family caregivers are selected from the network of the selected dementia nurses. The intervention is a mobile application (app) on a smartphone/tablet through which the family caregivers, in groups of 8-10, can communicate with peers and a nurse, exchanging ideas how to deal with the PWD's behaviour and where family caregivers can get support in their neighborhood; discuss stressful events to get support from the nurse; conduct self-assessments of stress, depressive symptoms, loneliness, self-rated health, and quality of life; and nurses can make announcements to family caregivers. Data is collected through the app before and three time points after the 8-week long intervention to assess changes in the health outcomes of the family caregivers. In-depth interviews are done after the intervention to understand the experiences of family caregivers and dementia nurses regarding the ease of use and practicality of the app, especially in integrating in the existing healthcare system. Gender, socio-economic status, and lifestyle practices are taken into account in the collection and analysis of the data.

What are the possible benefits and risks of participating?
This intervention provides a platform for the rising digitally literate family caregivers of persons with dementia to alleviate stress and improve quality of life irrespective of distance to the nearest health center.

Where is the study run from?
The study will be conducted by two universities in Sweden, Karolinska Institute (lead centre) in Stockholm and Umeå University in Umeå

When is the study starting and how long is it expected to run for?
January 2019 to September 2025

Who is funding the study?
The study is financed by funding received from Kamprad Foundation and grants from Karolinska Institute.

Who is the main contact?
Dr Zarina Nahar Kabir
Zarina.kabir@ki.se

Previous plain English summary plan:
Background and study aims
In Sweden, most people with dementia (PWD) live in their own home and are cared for by family members. The health consequences of caregiving of PWD include stress, depressive symptoms, loneliness and poor self-rated health. The aim of this study is to assess the effectiveness of introducing a mobile application through the existing health care system in Sweden for reducing stress, depressive symptoms and loneliness, and improving quality of life of family caregivers of PWD.

Who can participate?
Adult family members who have provided care to a person with dementia living at home for at least six months, possess a smartphone or tablet, have access to the internet at his/her own cost and are able to read and write Swedish.

What does the study involve?
The study is conducted in the Stockholm and Östergötland Regions in a sample of 297 family caregivers of PWD. The intervention is implemented by dementia nurses randomly selected in each of the study sites. The family caregivers are selected from the network of the selected dementia nurses. The intervention is a mobile application (app) on a smartphone/tablet through which the family caregivers, in groups of 8-10, can communicate with peers and a nurse, exchanging ideas how to deal with the PWD’s behaviour and where family caregivers can get support in their neighborhood; discuss stressful events to get support from the nurse; conduct self-assessments of stress, depressive symptoms, loneliness, self-rated health, and quality of life; and nurses can make announcements to family caregivers. Data is collected through the app before and three time points after the 8-week long intervention to assess changes in the health outcomes of the family caregivers. In-depth interviews are done after the intervention to understand the experiences of family caregivers and dementia nurses regarding the ease of use and practicality of the app, especially in integrating in the existing healthcare system. Gender, socio-economic status, and lifestyle practices are taken into account in the collection and analysis of the data.

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Who is the main contact?
Dr Zarina Nahar Kabir
Zarina.kabir@ki.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Stav1

Study information

Scientific Title

Care of Family Caregivers of Persons with Dementia (CAFCA): mobile application to alleviate stress and improve quality of life

Acronym

CaFCa

Study objectives

The proposed project aims to assess the effectiveness of implementing a mobile application through existing health care system in Sweden in reducing stress and loneliness, and improving mental health and quality of life of family caregivers of persons with dementia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 25/05/2021:
Approved 23/04/2019, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; Tel: + 46 (0)10 4750800; Email: registrator@etikprovning.se), Dnr: 2019-01632; Dnr: 2020-06882

Previous ethics approval:
Approved 23/04/2019, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; Tel: + 46 (0)10 4750800; Email: registrator@etikprovning.se), Dnr: 2019-01632

Study design

Pragmatic intervention design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Quality of life

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

Stress, depressive symptoms, loneliness and quality of life of family caregivers of persons with dementia

Interventions

Using a pragmatic intervention design, this study will use pre- and post-intervention assessment to evaluate the effectiveness of the proposed intervention in a sample of 297 family caregivers (FC) of persons with dementia (PWD). The intervention will be implemented by approximately 30 healthcare professionals specialized in dementia care (HP) based in the municipalities in Sweden. The main thrust of the intervention is to provide professional support, with help of an interactive mobile app, to family members in their caregiving role for a PWD. Qualitative interviews with HPs and FCs form the groundwork of the development of the mobile app. By using the app on smartphone or tablet, the FC, in groups of 8-10, will communicate with peers and a HP exchanging ideas on how to deal with PWD's behavioural and cognitive changes, and where FCs can get support; discuss stressful events; access mindfulness exercises focused on themselves. Quantitative data will be collected through the app before and at three timepoints after the 8-weeks long intervention to assess changes in the health outcomes of the FCs. In-depth interviews will be conducted after the intervention to capture the experiences of FCs and HPs regarding the ease of use and practicality of the app.

Intervention Type

Mixed

Primary outcome measure

Caregiver stress is measured using Zarit Burden Interview questionnaire at baseline, directly after completion of the intervention, 4 weeks and 8 weeks after the intervention

Secondary outcome measures

1. Depressive symptoms assessed using a 9 items Patient Health Questionnaire
2. Loneliness assessed with a single item question
3. Quality of life assessed with Carer QoL7D

All assessments will be done at baseline, directly after completion of the intervention, 4 weeks and 8 weeks after the intervention

Overall study start date

01/01/2019

Completion date

30/09/2025

Eligibility

Key inclusion criteria

1. Adults who have provided care to a person with dementia living at home for at least six months
2. Possess a smartphone or tablet
3. Have access to the internet at his/her own cost
4. Able to read and write Swedish

Participant type(s)

Other

Age group
Adult

Sex
Both

Target number of participants
78

Total final enrolment
46

Key exclusion criteria
Caregivers aged less than 18 years and/or with severe physical or mental illness restricting their ability as caregivers

Date of first enrolment
15/09/2020

Date of final enrolment
23/11/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institute
Dept. Neurobiology, Care Sciences and Society,
Karolinska Institute,
Alfred Nobels Allé 23
Huddinge
Sweden
141 83

Study participating centre
Umeå University
Departement of Nursing
Umeå
Sweden
90187

Sponsor information

Organisation
Karolinska Institute

Sponsor details
Division of Nursing
Dept of Neurobiology, Care Sciences and Society
Alfred Nobels Allé 23, Plan C4
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+46 (0)852483697
zarina.kabir@ki.se

Sponsor type
University/education

Website
https://ki.se/

ROR
https://ror.org/056d84691

Funder(s)

Funder type
University/education

Funder Name
Kamprad Foundation

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Strategic Research Area Health Care Science: Karolinska Institute

Results and Publications

Publication and dissemination plan

The conventional publications in peer reviewed scientific journals will begin in the second year of the project after the first completed data collection phase. Publications are expected to continue after the formal completion of the project. Scientific outputs and learning from the research project will be used as pedagogic material in the education programmes in both undergraduate nursing programme and specialist nursing programme of Older People Nursing. Students of these nursing programmes will be encouraged to participate in the data collection and analysis for utilization in their project theses (Bachelor's and 'Magister'). Presentations in national and international conferences, seminars/webinars and workshops, and other professional and community forums will be made to reach the general audience. If potential lessons can be taken from the intervention on primary health care delivery, they will be disseminated to the relevant policy makers in the form of policy notes. Communication about the intervention project will also be done on social media and professional networks, e.g. Twitter, Facebook, ResearchGate, LinkedIn.

Intention to publish date

01/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the application for ethical approval of the study specified the researchers of the research team who would have access to the participant level data. The data will be stored at a secure server of the lead university, Karolinska Institute.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/08/2020	03/09/2020	Yes	No
Other publications	Qualitative results	25/06/2024	30/01/2025	Yes	No