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Caregiver Connect: An mHealth-based intervention for supporting immigrant family caregivers to persons with dementia at home

Submission date 13/06/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 27/06/2023	**Overall study status** Ongoing	
Last Edited 30/01/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The number of persons with dementia (PWD) is estimated to be 250,000 in Sweden and 14 million in India by the year 2050. In Sweden, PWD increasingly live in their own homes. Family caregiving can lead to stress, poor health and poor quality of life. In Sweden, in 2017, only 5% of the municipalities offered any kind of support to family caregivers (FCs) whose native language was other than Swedish. The main research question in this project is whether a mHealth-based intervention given by community workers improves the caregiving competence of non-European immigrant FCs of PWD living at home and is effective at reducing caregiver stress and depressive symptoms and improving quality of life. This study will include participants from municipalities in Sweden. They will be randomly put into an intervention group and a control group.

Who can participate?
Adult FCs of PWD living at home who are recipients of the intervention and social care professionals (SCPs) who will deliver the intervention

What does the study involve?
The intervention will be delivered through a mobile application (app) in 10 sessions covering specific subjects to enhance the caregiving competence of FCs, e.g., introduction to dementia, being a caregiver, mental strategies, mindset, activities, diet, sleep and where to find resources in the community.
The outcomes of the study are caregiving competence, caregiver stress, depressive symptoms and quality of life. The outcomes will be measured at baseline, after completion of the 10-week-long intervention in the intervention group and after another 10-week intervention in the control group. In-depth interviews will be performed with SCPs and FCs after the intervention to understand their experiences of the ease of use and practicality of the app and the relevance of the intervention. The usage of different features of the app will be measured.

What are the possible benefits and risks of participating?
The project aims to reduce stress, and depressive symptoms, and increase caregiver competence

and quality of life of FCs taking care of persons with dementia at home by increasing the understanding of the illness and its related symptoms. It will also equip them with strategies on how to deal with the challenges of caregiving. The intervention is person-centered through direct interaction with the SCP. As the intervention is delivered by mobile application and can be used whenever the user chooses to, regardless of time and place, it offers flexibility.

It is possible that the intervention can affect the FCs negatively by improving their understanding of the disease and its progression, leading the caregiver to feel more stressed about their responsibilities. This risk can be lowered through guidance by the SCP who will be implementing the intervention.

Sometimes, when the FC tries to communicate with SCPs by text messages, it can trigger suspicion among the PWD cared for. This risk is lessened by the fact that the FC can choose a time of his/her convenience to communicate with the SCP so as not to affect the relationship within the family.

Where is the study run from?
Karolinska Institute (Sweden)

When is the study starting and how long it is expected to run for?
March 2023 to February 2026

Who is funding the study?
Swedish Research Council for Health, Working Life and Welfare (Sweden)

Who is the main contact?
Dr Zarina Nahar Kabir, zarina.kabir@ki.se (Sweden)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
m-Health based intervention by community workers to support family caregivers to persons with dementia living at home in Sweden

Acronym
CARE-2-CONNECT-Sweden

Study objectives
A mHealth-based intervention given by community workers will improve the caregiving competence of non-European immigrant family caregivers of persons with dementia living at home which in turn will reduce caregiver stress and depressive symptoms, and improve quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/08/2023, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46104750800; registrator@etikprovning.se), ref: 2023-02911-01

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Internet/virtual

Study type(s)
Prevention, 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
Strengthening caregiving competence thereby reducing stress, and depressive symptoms and improving the quality of life of non-European immigrant family caregivers of persons with dementia

Interventions

This randomized controlled study will include a waitlist control group. Participants from municipalities in Sweden with high immigrant density will randomly be assigned to the intervention group (n=44) and the waitlist control group (n=44).

Participants in the study will include:
1. Family caregivers (FCs) of persons with dementia (PWD) living at home and are recipients of the intervention
2. Social care professionals (SCP) who will deliver the intervention

The intervention will be delivered through a mobile application (app) in 10 sessions on specific subjects to enhance the caregiving competence of FCs, e.g., introduction to dementia, being a caregiver, mental strategies, mindset, activities, diet, sleep and where to find resources in the community.

Outcomes will be measured quantitatively at baseline, after completion of a 10-week intervention in the intervention group and after another 10-week intervention in the control group. In-depth interviews will be performed with SCPs and FCs after the intervention to understand their experiences with the ease of use and practicality of the app. Analytics information logged on the backend system will be used to assess the usage of different features of the app.

Intervention Type
Behavioural

Primary outcome measure
Caregiving competence measured using a questionnaire developed by the project team at baseline and 10 weeks after the intervention (in intervention and control groups)

Secondary outcome measures
1. Caregiver stress, depressive symptoms and quality of life measured using the Zarit Burden Index-12, Patient Health Questionnaire-9 and Carer QoL, respectively at baseline and 10 weeks after the intervention in both intervention and control groups
2. Ease of use/practicality of the App measured using in-depth interviews directly after the intervention in the intervention group
3. Usage of different features measured using analytics information logged on the backend system at the end of the study

Overall study start date
01/03/2023

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Adults who are of non-European immigrant background in Sweden
2. Have provided care to a person with dementia living at home for at least six months
3. Possess a smartphone or tablet
4. Have access to the Internet at his/her own cost
5. Able to read and write Swedish

Participant type(s)
Carer, Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44 in intervention group and 44 in control group

Key exclusion criteria
1. Family caregivers aged less than 18 years
2. Family caregivers suffering from conditions that impede communication

Date of first enrolment
01/03/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institute
Dept of Neurobiology, Care Sciences and Society
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Sponsor information

Organisation
Swedish Research Council for Health Working Life and Welfare

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Sponsor type
Government

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ROR
https://ror.org/02d290r06

Funder(s)

Funder type
Government

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

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

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan

The data sets generated during and/or analysed during the current study are not expected to be made available due to ethical considerations.

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		14/06/2024	17/06/2024	Yes	No