Geographic Information System (GIS) based intervention *Viamigo* for people with dementia and their informal caregivers: A single-arm trial to evaluate the feasibility and preliminary participant responses.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51706

Source
ToetsingOnline

Brief title
Viamigo for people with dementia and their informal caregivers

Condition

- Other condition
- Dementia and amnestic conditions

Synonym
caregivers, memory problems, mild to moderate dementia

Health condition

geen aandoeningen; familieleden van mensen met dementie

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Europese Unie: Marie Curie Innovative Training Network (ITN);H2020-MSCA-ITN-2018.

Intervention

Keyword: dementia, GPS, informal caregivers, social participation

Outcome measures

Primary outcome

The main study parameters are the feasibility of the Viamigo intervention for

people with dementia and their informal caregivers.

Secondary outcome

Secondary study parameters for people with dementia include out-of-home

mobility and social participation. Secondary study parameters for informal

caregivers include quality of life, caregiver burden, and gains in dementia

caregiving.

Study description

Background summary

People with dementia living in the community experience reduced out-of-home mobility and participate less in activities outside home. This results in reduced social participation outside home, which can negatively affect their health (e.g. leads to social isolation and increased risk of depressive symptoms). Technological interventions show promise in enhancing the social

participation of people with dementia. However, there is a lack of technological interventions that facilitate social participation outside home. While a growing body of evidence highlights the potential of Geographic Information Systems (GIS) in facilitating the out-of-home mobility of people with dementia and reducing informal caregivers* feelings of worry, very little attention is paid to the potential of GIS in enhancing the social participation of people with dementia. The GIS-based mobile application Viamigo aims to support the independent out-of-home mobility of the user and to reduce informal caregiver*s burden by teaching users a known individual route, which they can accomplish independently afterwards while being monitored by an informal caregiver. Although Viamigo was initially developed for persons with intellectual disabilities, it is expected that it can also support and improve out-of-home mobility and thereby the social participation of people with dementia.

Study objective

The main objective of this study is to evaluate the feasibility of the Viamigo intervention among people with dementia living in the community and their informal caregivers. The secondary objective of this study is to assess the first responses of people with dementia and informal caregivers to the Viamigo intervention.

Study design

This feasibility study includes a mixed methods single-arm pre-post design with a baseline assessment, a 3-month intervention period, and a post-intervention assessment.

Intervention

All eligible and consenting dyads will be asked to participate in the Viamigo intervention, consisting of three main components: (1) a face-to-face technology training session of 60 minutes, (2) a 3-month period of using the Viamigo intervention with support phone calls of approximately 5 minutes by the coordinating investigator once every two weeks, and (3) an evaluation phone call of 5-10 minutes.

Study burden and risks

People with dementia will be asked to fill in the same two questionnaires (approximately 20 minutes in total) during the baseline and post-intervention assessment. Additionally, they are asked to fill in a daily travel diary for one week at baseline, and the last week of the intervention period. Informal caregivers will be asked to fill in the same three questionnaires (approximately 25

minutes in total) during the baseline and post-intervention assessment and another 15-minutes questionnaire during the postintervention assessment. At the baseline meeting, persons with dementia and their informal caregivers will also be asked about demographic data (about 1 hour and 30 minutes). Additionally, a smaller sample of the dyads (10 dyads) will be asked to share their experiences using the Viamigo intervention in a semi-structured post-intervention interview of approximately 30 minutes.
Dyads will be asked whether they prefer to conduct the different assessments at home or another location (e.g. Maastricht University). By participating in the study, a participant with dementia might be more often exposed to potentially risky situations in his or her living environment (e.g. traffic). Participation in a technological intervention study can be time-consuming and demanding. One way to reduce the burden of the study is to give participants the freedom to use the Viamigo application at their own pace.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

People with dementia:
- Diagnosis of mild to moderate dementia as confirmed by a general practitioner or specialist;
- Living in the community (alone or with family/roommate(s)/friends);
- Availability of an informal family caregiver who is interested to take part in this study;
- Taking part in social activities outside home;
- Having an Android smartphone, as the Viamigo application to be used by the person with dementia is currently exclusively available for Android.

Informal caregivers:
- Informal caregiver of participant diagnosed with mild to moderate dementia;
- Aged 18+;
- Having at least weekly contact with the person with dementia;
- Having an Android or Apple smartphone and/or laptop.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- No informed consent given;
- Concurrent participation in any other interventional study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2023
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81938.068.22