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Evaluation of benefits of the CAREGIVERSPRO-MMD platform giving support and assistance to people living with dementia and their primary caregiver

Submission date
31/01/2017

Recruitment status
No longer recruiting

Registration date
06/02/2017

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of the brain and its abilities, including memory loss and difficulties with thinking, problem-solving or language. There are 46.8 million people living with some form of dementia worldwide for which there is currently no treatment or effective strategy that can halt or reverse their decline. As Europe's population is aging, and longevity is the main risk factor for developing dementia, long-term care for older citizens will represent an increasing financial cost for society. There are currently 19 million people living with dementia in Europe, and this figure is expected to reach 31.5 million by 2050. To manage this transition, health policies of the EU and its member states are focused on enhancing elderly people’s longevity and preventing their dependency. This has the double aim of increasing their quality of life while reducing costs and increasing the effectiveness of healthcare. That is why this study aims to test the web platform “CAREGIVERSPRO-MMD”, which is accessible from computers, phones and tablets, and designed specifically for caregivers and people living with mild cognitive impairment or mild to moderate dementia. It provides services to improve the quality of life of those living with cognitive impairment or dementia as well as that of their caregivers, thus supporting them to live in the community for as long as possible.

Who can participate?
Patients aged 50 and over living with mild cognitive impairment or (mild to moderate) dementia and their caregivers, aged 18 and over

What does the study involve?
Participants are randomly allocated into two groups. One group is given access to the platform and the other group is not. During the following 18 months, the following aspects are assessed: the patient’s health (general health, brain functioning, activities of daily living, quality of life, adherence to drug treatment and other illnesses), social aspects (cohesion, social support, success in relationships, self-esteem, purpose and optimism), and economic aspects (cost-

effectiveness of the use of the platform) and the degree of satisfaction and usability of the platform.

What are the possible benefits and risks of participating?
Using the CAREGIVERSPRO-MMD platform is expected to improve the quality of life of people living with mild cognitive impairment or dementia, and reduce the level of burden experienced by the caregiver. There is no risk because CAREGIVERSPRO-MMD is a platform based on a social network for the monitoring and support of its users. Therefore, no risk to the user's health is expected

Where is the study run from?
1. University of Hull (UK)
2. Cooss Marche Onlus (Italy)
3. Bages University Foundation (Spain)
4. Rouen University Hospital (France)

When is the study starting and how long is it expected to run for?
January 2017 to October 2018

Who is funding the study?
Horizon 2020 (Belgium)

Who is the main contact?
Dr Xavier Girones
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Study website
http://caregiversprommd-project.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
690211

Study information

Scientific Title
Multicentre pilot study to determine the benefits of CAREGIVERSPRO-MMD platform use based on the information and communications technology (ICT), dedicated to the support and assistance of dyads living with neurocognitive diseases including persons living with mild cognitive impairment or mild to moderate dementia and their primary caregivers

Acronym
CAREGIVERSPRO-MMD

Study objectives
The dyad (formed by the person living with mild cognitive impairment (MCI) or mild to moderate dementia (PLWD) and their primary caregiver) and the social and health circle which is structured around it (family, friends, other dyads, health personnel, researchers), generates a lot of information regarding social and health concerns to improve living conditions and assessing the progression of the dyad. The existence of a platform based on Information and Communications Technology (ICT), capable of channelling all information generated and encouraging the search for solutions to specific problems, equipped with sensitive health monitoring tools and the possibility of putting all the different people living with mild cognitive impairment or dementia (mild to moderate) into direct contact; both the dyad as well as medical professionals or other dyads in the same situation; will improve the quality of care, control and monitoring of illness, resulting at the same time in a better diagnosis and an improvement in the subjective quality of life and health of its members.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board Fundació La Unió, 07/12/2016, ref: CEIC 16/87

Study design
Prospective randomised multicenter controlled parallel longitudinal study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
The patient information sheet is included in the clinical study protocol document (Page 95: information document template, page 99: informed consent model) http://caregiversprommd-project.eu/wp-content/uploads/Pilot-Operation-Manual.pdf

Health condition(s) or problem(s) studied
Mild cognitive impairment or dementia (mild to moderate)

Interventions
Dyads (people living with mild cognitive impairment or dementia (mild to moderate) and their primary caregivers) are randomised into two groups:
1. A group using the CAREGIVERSPRO-MMD platform
2. A control group without access to the platform

The CAREGIVERSPRO-MMD platform is an online resource based on web technology accessible by computer, mobile and tablet, dedicated to provide both monitoring and assistance for people with mild cognitive impairment or people living with dementia. Its structure, as a social network, and its evaluation capacity with multiple questionnaires (dedicated to MCI/PLWD and their caregivers) allows them to share detailed information on the status and progress of the illness (e. g., cognitive status, medication usage, mood). This personalisation leads users to access a range of information tailored to each situation, illness and assistance with the aim of improving the subjective quality of life of both the MCI/PLWD, carer and their immediate circle.

Measurements will be recorded at baseline (0) and at 3, 6, 9, 12, 15 and 18 months after.

Intervention Type
Other

Primary outcome measure
People living with mild cognitive impairment or dementia:
Quality of life, measured with the DEMQoL scale at baseline, 6, 12 and 18 months

Primary caregivers:
Perceived burden, measured with the ZBI scale at baseline, 6, 12 and 18 months

Secondary outcome measures
People living with mild cognitive impairment or dementia:
1. Treatment adherence, measured with the MMAS-8 scale at baseline, 6, 12 and 18 months with telephone calls at 3, 9 and 15 months
2. Activities of daily living, measured with the IADL scale at baseline, 6, 12 and 18 months
3. Cognitive-clinical symptoms, measured the MMSE scale at baseline, 6, 12 and 18 months
4. Activities of daily living, measured with the BADL scale at baseline, 6, 12 and 18 months
5. Behavioural-psychological symptoms, measured with the GDS scale at baseline, 6, 12 and 18 months
6. Behavioural-psychological symptoms, measured with the NPI scale at baseline, 6, 12 and 18 months

Primary caregivers:
1. Treatment adherence, measured with the MMAS-8 scale at baseline, 6, 12 and 18 months with telephone calls at 3, 9 and 15 months
2. Subjective quality of life, measured with the SF-36v2 scale at baseline, 6, 12 and 18 months
3. Behavioural-psychological symptoms, measured with the GDS scale at baseline, 6, 12 and 18 months
4. Behavioural-psychological symptoms, measured with the STAI scale at baseline, 6, 12 and 18 months
5. Perceived social support, measured with the MSPSS scale at baseline, 6, 12 and 18 months with telephone calls at 3, 9 and 15 months
6. Perceived success in relationships, measured with the FS scale at baseline, 6, 12 and 18 months with telephone calls at 3, 9 and 15 months

Dyads:
1. Quality of the caregiving relationship, measured with the DAS scale at baseline, 6, 12 and 18 months

Overall study start date
01/01/2017

Completion date
31/10/2018

Eligibility

Key inclusion criteria
People living with mild cognitive impairment or dementia:
1. People, aged 50 and over, living in the community, who are able to give informed consent (or the legal tutor)
2. Diagnosed with mild cognitive impairment (MCI) according to Petersen criteria or mild to moderate dementia diagnosed according on DSM-IV criteria (Diagnostic and Statistical Manual, 4th edition)
3. Having a Clinical Dementia Rating (CDR) of 0.5 for MCI, 1-2 for mild to moderate dementia
4. Having a Mini-Mental Exam score (MMSE) between 30 and 25 (inclusive) for MCI, and between 24 and 10 (inclusive) for dementia
5. Having a primary caregiver, familiar (or not), informal (or not) identified and also included in the study
6. Be willing to use Information Technology and Communications (ICT) according to the investigator criteria

Primary caregivers:
1. People, aged 18 years and over, with no diagnosis or no evidence of mild cognitive impairment or mild to moderate dementia (according DSM-IV criteria), who are able to give informed consent and with an intention to complete the study
2. Primary caregivers, informal (or not), familiar (or not), of person with mild cognitive impairment or mild to moderate dementia
3. People with Internet access and basic knowledge and skills in managing internet and social networks, or keen to learn, according to the investigator criteria
4. Having a Geriatric Depression Scale (GDS-Yesavage - 15 items) score less than 11 at the time of entry into the trial indicating no severe depressive symptoms

5. Having no specific conditions (evaluated by the investigator) reducing their physical abilities below the norm for their age that would limit or impair CAREGIVERSPRO-MMD platform use
6. Be willing to use Information Technology and Communications (ICT) according to the investigator criteria

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1204

Key exclusion criteria
People with mild cognitive impairment and people living with dementia:
1. Terminal or severe illness with survival prognosis less than 18 months
2. Having delusions, hallucinations, behavioural disturbances, that may interfere with the use of Information and Communications Technology (ICT) tools
3. Relevant sensory problems (visual or hearing impairment) or motor disability (such as paralysis of upper limb or disabling arthritis or disabling tremor, etc) evaluated by the investigator that would interfere with the use of Information and Communications Technology (ICT) tools
4. Not speaking the language of the country where the pilot is being conducted

Primary caregivers:
1. Terminal or severe illness with survival prognosis less than 18 months
2. Relevant sensory problems (visual or hearing impairment) or motor disability (such as paralysis of upper limb or disabling arthritis or disabling tremor, etc) evaluated by the investigator that would interfere with the use of Information and Communications Technology (ICT) tools
3. Not speaking the language of the country where the pilot is being conducted

Date of first enrolment
01/01/2017

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

France

Italy

Spain

United Kingdom

Study participating centre
University of Hull
Cottingham Road
Hull
United Kingdom
HU6 7RX

Study participating centre
Cooss Marche Onlus
Scpa Via Saffi, 4
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Italy
60121

Study participating centre
Bages University Foundation (FUB)
Av. Universitària, 4-6
Manresa
Spain
08242

Study participating centre
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1 rue de Germont
Rouen
France
76031

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/03mb6wj31

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
All partners will be involved in the dissemination of information about the partnership and project findings in forms that all partners can understand and use. This dissemination includes multiple audiences (e.g., community members, policy makers, local health professionals) and multiple formats (e.g., radio, newspapers, presentations at professional meetings, handbooks, policy position papers, scientific journal articles), with all partners involved as co-authors and co-presenters as their interests and circumstances allow.

1. Development of scientific papers and posters for dissemination of results
2. Presentation in seminars, conferences and scientific meetings related to the topic

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The data management plan can be found at: http://caregiversprommd-project.eu/wp-content/uploads/Data-Management-Plan-first-version-.pdf
This is a document that describes the different processes regarding data management, storage and exploitation that have to be agreed and adopted by every member of the CAREGIVERSPRO-MMD Consortium. Over the course of the project this document will be reviewed and updated. Additional information on the data structure or the methodology, a change in responsibility for a task or in the budget, may be included in future versions of the Data Management Plan.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	training methods	01/02/2021	27/11/2020	Yes	No
Other publications	User engagement, usability and usefulness	01/12/2020	27/10/2022	Yes	No
Other publications	Users' experiences, perceptions and support needs	01/01/2022	27/10/2022	Yes	No