

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

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|--|---|--|
| <b>Submission date</b><br>31/01/2017   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>06/02/2017 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>27/10/2022       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> 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

#### **Contact name**

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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

Ancona

Italy

60121

**Study participating centre**

**Bages University Foundation (FUB)**

Av. Universitària, 4-6

Manresa

Spain

08242

**Study participating centre**

**Rouen University Hospital**

1 rue de Germont

Rouen

France

76031

## **Sponsor information**

**Organisation**

Universitat Politècnica de Catalunya-BarcelonaTech (UPC)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

www.upc.edu

**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? |
|------------------------------------|---|--------------|------------|----------------|-----------------|
| <a href="#">Other publications</a> | training methods                                  | 01/02/2021   | 27/11/2020 | Yes            | No              |
| <a href="#">Other publications</a> | User engagement, usability and usefulness         | 01/12/2020   | 27/10/2022 | Yes            | No              |
| <a href="#">Other publications</a> | Users' experiences, perceptions and support needs | 01/01/2022   | 27/10/2022 | Yes            | No              |