COGKNOW- Helping people with mild dementia navigate their day

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Ethical review	Approved WMO
Status	Pending
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON29853

Source
ToetsingOnline

Brief title
COGKNOW

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's Disease, dementia syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: EU Sixth Framework Programme;Priority 2.5.11 eInclusion

Intervention

Keyword: experienced autonomy, Mild dementia, quality of life, technological solutions

Outcome measures

Primary outcome

The study is in the first place a product development project. This means that first an analysis will be made of the needs of teh participating persons with dementia and possible qualitative solutions.

The analysis will focus on the factors by which a person with mild dementia is affected or that affects the process of daily living (e.g. the (dis)abilities, patient characteristics, ways of coping, social and material contextual aspects, received support and care, unmet needs, quality of life aspects). On the basis of this analysis a device will be developed.

At the end of the first year and second year preliminary versions of the device will be tested with the users. The analysis will focus specifically on the user friendliness and practical/technical usability of the device.

At the end of the final test (in the third year) the impact of the developed system on actual and perceived autonomy and quality of life in the selected domains of daily life of the person with dementia will be investigated. The focus will be on memory, social contact, daily activities, feelings of safety.

Concrete questions will be, for example: does the device support the memory problems of the persons with dementia? Does it help them to communicate and stay in contact with their family and friends? Does it help them to execute, or participate in, activities they enjoy? Does it influence their mood and self-esteem positively and does it decrease their feelings of being isolated

and unsafe?

Secondary outcome

niet van toepassing

Study description

Background summary

With the increasing number of elderly in Europe in the coming decades the number of people with disabilitiess will also increase drastically. An increase is expected from 14% now to 20% in 2020. Dementia is a progressive chronic disease, from which about 5% of the people older than 65 years suffers and 40% of the 90-plus. The most prevalent type of dementia in the elderly is Alzheimer's Disease. It is expected that the number of people with dementia in Europe will redouble the coming 35 years. Due to this there will be long waiting lists for sheltered housing projects, homes for the elderly and nursing homes and other care facilities. The majority of people with dementia will have to "survive" in their own homes.
The studies carried out until now into the subjective needs of people with dementia indicate that the most frequently identified unmet needs by persons with dementia themselves are in the areas of information (on treatment, care and support, appointments), memory problems, and communication and psychological distress.
The COGKNOW proposal helps address these societal and indicvidual problems by investigating how technology can be used to improve the autonomy and the quality of life of elderly people, so that people with dementia can stay longer in their own homes with a better quality of life. It is to be expected that supportive measures that increase the autonomy and quality of life of the persons with dementia will not only help the patient but will also relieve the burden for the carer.

Study objective

The challenging aim of this three-year STREP project is to breakthrough with research that addresses the needs of those with dementia, particularly those with mild dementia in Europe. At about 2% of the elderly population, this comes to around 1,900,000 people. COGKNOW aims to develop technology that supports people with dementia in their daily life, more specific that helps them to remember, to maintain social contact, to perform daily life activities and to enhance their feelings of safety. The core technological objective is to research and prototype a successful, near-to-market, portable,

remotely-configurable, user-validated cognitive prosthetic device.

Study design

We will initially analyse the user needs, state of the art, healthcare models, technological infrastructures and existing standards in EU member states and use this information to guide the implementation of COGKNOW. The selection of tools (wearable systems, interfaces, network and platform, telecommunications solutions and portable/mobile units) and their integration will be based on
- their proven effectiveness and innovativeness in previous EU, and also
- based on the wish to integrate these services and systems to validate their use in combination. Thus building on previous European successes.
Implementation will be addressed in two complementary work packages. In the first instance the development of the cognitive prosthetic device to be used by the person and the associated home-based services will be addressed. Secondly, the overarching infrastructure will be developed.
Developments of these two components will provide a cognitive reminder paradigm which will extend upon previous developments and subsequently enhance the state-of-the-art. Such a solution will meet the project*s objectives of enhancing (actual and perceived) autonomy and quality of life of persons with dementia, especially in the selected aspects of daily living, i.e. remembering, maintaining social contacts, performing daily life activities and feeling safe.
Evaluation within the project will be supported via the results of three field tests performed in each year of the project at three differing sites (Ireland, The Netherlands and Sweden) and will be supported via Human Factor Analysis.

Intervention

The developed cognitive prosthetic device will be offered in three field tests (one field test very year), in three test sites to 5 persons with dementia, thus in total to 45 persons with dementia (3x3x5=45).
Workshops will be designed and carried out with the users (patients and (in)formal carers) in the different phases of the project to inventory the needs and wants of the users, and discuss possible qualitative solutions. By means of the workshops users will collaborate directly in the developmental process and can make comments on the performance, reliability, usefulness, safety factors, suitability or desirability of the developed service in each of the test phases.
All users are involved initially in a short information distribution explaining the purpose of the project and an informed consent procedure before they are invited to participate in the project.

Study burden and risks

The burden for patients and carers associated with participation in the project (a one hour workshop and two interviews of one hour per patient/carer during a

period of 8 months) is minimal and without risk in our opinion.
The system that will be developed in this project and that will be tested in the homes of people with dementia on user friendliness, usability and impact on the autonomy and quality of life aims to support the person with dementia in his/her daily life, to diminish problems that are a consequence of his/her disabilities and to improve their quality of life. By supporting them in their daily life it is expected that they run less risks in daily life than without the developed system.
However, during the project we will remain sensitive to instances where additional stresses might be placed on participants and avoid potentially harmfull events. The risks for this part of the project are for participants negligible small in our opinion.

Contacts

Public
Vrije Universiteit Medisch Centrum

Valeriusplein 9
1075 BG Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

Valeriusplein 9
1075 BG Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

People with mild dementia of the Alzheimer type ('late confusional stage' and 'early dementia stage' according to the Global Deterioration Scale of Reisberg) living in the community.
Informal carers of these people.

Exclusion criteria

Severe stages of dementia
Other mental impairments or brain diseases
Living in an institutional setting

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	technological device including: a remotely configurable reminding functionality;communication and in
Registration:	No

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL12562.029.06