

# ROSETTA Project; Guidance and Awareness Services for Independent Living

Published: 30-09-2010

Last updated: 04-05-2024

To help community dwelling people with progressive chronic disabilities, such as Alzheimer\*s Disease and Parkinson\*s Disease, to retain their autonomy and quality of life as much as possible and to support their informal caregivers by developing and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cognitive and attention disorders and disturbances
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34447

### Source

ToetsingOnline

### Brief title

ROSETTA

### Condition

- Cognitive and attention disorders and disturbances

### 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:** AAL regeling;ZonMW

## Intervention

**Keyword:** assistive technology, Dementia, experienced autonomy, quality of life

## Outcome measures

### Primary outcome

The primary outcome measure of the one group pretest-posttest study are user friendliness and usefulness of the ROSETTA system. For the assessment of user friendliness and usefulness of the system a semi-structured questionnaire (for persons with dementia and carers) will be developed, based on experiences with such a questionnaire in the COGKNOW project. This questionnaire will be shortened and further adapted based on the functionalities that will be available on the final prototype.

The primary outcome measure of the RCT concerns the impact of the system on the autonomy, quality of life of the elderly people with chronic disabilities and the burden, feelings of competence and quality of life of their informal carers.

The experienced autonomy will be assessed with a questionnaire developed by Meiland and Dröes (2006), based on the Mastery scale of Pearlin and Schooler (1978) and an adaptation of selected questions from the WHOQOL-100 (WHO, 1998).

To assess the quality of life of persons with dementia, the QoL-AD (Logsdon et al., 1999, 2002) will be administered. This instrument consists of 13 questions (e.g. on physical health, mood, memory, family, friends, life as a whole) and it can be used by people with dementia with MMSE scores as low as three.

To assess the burden and feelings of competence of informal carers, two questions on experienced burden will be administered and the Short Sense of

Competence Questionnaire (SSCQ; Vernooij-Dassen et. al. 1999) will be used. The quality of life of informal carers will be assessed with two items on the overall judgement of their quality of life (from the MDS-NPO).

### **Secondary outcome**

Delay of nursing home admission of the elderly persons with a chronic disease is the secondary outcome measure. Nursing home admission of participants will be recorded. The user-friendliness, usefulness and impact of the system on the domains of daily life that are mentioned before, will also be evaluated by qualitative open face-to-face interviews with persons with dementia and their carers, and diaries of the participants (with positive and negative experiences in using the system) will be studied.

Various patient, carer and context characteristics will be inventoried among informal caregivers. Among these are demographic characteristics, insight in the illness, style of caregiving, care needs and use of services.

## **Study description**

### **Background summary**

Titel: The ROSETTA Project; Guidance and Awareness Services for Independent Living

The European society is aging. Not only are there more elderly people, their mean age also will be higher. As a result, we will have more elderly people who will have more years to develop chronic diseases. It is expected that the capacity of care and support services will not rise accordingly, thus alternative solutions will have to be developed to meet the care and support needs of the elderly. Assistive technologies may provide such alternatives. In the ROSETTA project a technological assistive device will be developed together with potential end-users and domain experts. In this development we will focus mainly on the prevention, early detection and efficient management of treatable

psychosocial and physical consequences of chronic diseases that are accompanied by progressive cognitive decline and an increased risk of straying and falling during the advanced stages of the disease. Examples of such diseases are Alzheimer\*s disease, other dementias and Parkinson\*s disease.

## **Study objective**

To help community dwelling people with progressive chronic disabilities, such as Alzheimer\*s Disease and Parkinson\*s Disease, to retain their autonomy and quality of life as much as possible and to support their informal caregivers by developing and providing an ICT system that offers activity guidance and awareness services for independent living. The aim of this evaluation study is to assess the user-friendliness, usefulness and impact of the ROSETTA system on autonomy and quality of life of persons with dementia and on burden, feelings of competence and quality of life of their informal caregivers.

## **Study design**

A one-group pretest-post test design will be performed to investigate the user-friendliness and usefulness of the ROSETTA system.

A randomized controlled trial will be performed to study the impact of the system on the autonomy, quality of life and delay of nursing home admission of the elderly people with chronic disabilities and the burden, feelings of competence and quality of life of their informal caregivers. Randomization will occur with pre-stratification, consisting of four strata: persons with mild dementia and Parkinson\*s Disease, persons with mild dementia without Parkinson\*s Disease, persons with moderate to severe dementia with Parkinson\*s Disease, and persons with moderate to severe dementia with Parkinson\*s Disease. If possible, also living together or not with an informal caregiver will be taken into account After this stratification, in each stratum a block randomisation will be performed to assign persons to the experimental or control group.

## **Intervention**

The intervention consists of installation and use during eight to nine months of the ROSETTA system in people\*s own homes. The ROSETTA assistive technology consists of a video home terminal with touch screen, a mobile device, sensors, actuators and cameras, all integrated into a single system where messages and alarms are processed in a centralized, redundant hosted environment outside the home.

This ROSETTA system consists of three subsystems (that are integrated):

1) The UAS-AAPS (Unattended Autonomous Surveillance \* Advanced Awareness and Prevention Service). AAPS will be able to detect emergency situations and generate alarms to informal carers or care organisations. By using movement

sensors and cameras in the house, potential emergency situations will be detected. In emergency cases, a reminder will be pushed forward on the video home terminal and the person with dementia will be asked to confirm whether he is safe or not. When he is unsafe or when there is no response from the person with dementia, a connection between the health care centre and the speak-listen unit in the home of the person with dementia are automatically set up, enabling a health care professional to assess the situation and provide help if needed.

2) The EDS (Early Detection System) software will record the daily pattern of living of chronically ill elderly and any other residents (if a partner is present) for several weeks by analysing signals from the sensors in the house. After this period the software can:

- \* Generate graphs/indexes that offer a summary of the day-to-day pattern of living and reveal predominantly the slowly occurring changes in it.
- \* Automatically indicate whether there are significant changes in the day-to-day pattern of living.

The EDS will focus on sleep-wake rhythms, mobility inside and outside the house, meal preparations, personal hygiene and number of reminders and emergency alarms.

3) the EDN (the Elderly Day Navigator. the EDN will support the persons with mild to moderate severe dementia in their daily functioning in the areas of memory, social contact, daily activities and safety. This support will be provided on a video home terminal and/or a mobile device. To support with memory, the touch screen can provide reminders (for instance \*you have an appointment with the doctor at 10.00 a.m.), it shows a calendar with activities, and a digital clock is displayed. To support in social contact there is a picture dialling function on the screen with a photo address book. To support in activities, digital photos can be shown on the screen. And finally, to support in feelings of safety, there is a Help button, which enables easy telephone contact with a relative. If this relative does not answer the phone, the call may automatically be directed to another relative or to a health care organisation. Also, to support with safety, persons with dementia can be directed finding the way to their home with an outdoor navigation tool on the mobile device. The persons with dementia and/or informal carers may choose which functions of the EDN they want to be configured in the system in their homes. During the research project, functions may be activated and/or de-activated.

## **Study burden and risks**

The data collection consists of semi-structured interviews and standardised questionnaires that will be administered by trained interviewers among persons with dementia and their carers (at pretest and posttest, short interviews during the field test period). People from the experimental group will have the ROSETTA system installed in their homes and will be enabled to use it for 9 months. In this period users are asked to keep a diary with their experiences

in using the system. The usage of several functions will be logged. The ROSETTA system is intended to compensate for disabilities of persons with dementia and to timely detect potential emergency situations or deterioration in cognitive functioning. If this is the case, (informal) carers will be notified, which will allow for a more efficient casemanagement. We expect that the electronic device will enhance the objective and subjective safety. However, the researchers will stay alert for any additional burden or risks for the participants and avoid any disadvantageous situations. We expect that the risks for the participants are negligible.

## 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

Persons with mild to severe dementia with or without Parkinson's Disease and their informal

carers (

## Exclusion criteria

Living in an institutional setting

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2010
Enrollment:	40
Type:	Actual

## Ethics review

Approved WMO	
Date:	30-09-2010
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**

<b>Register</b>	<b>ID</b>
CCMO	NL32872.029.10