

A new concept of human-machine-interaction for the care of people with dementia in long-term care facilities

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| Submission date 13/12/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 19/02/2025 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/02/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

This research is looking at whether a robot is beneficial in group therapy for people with dementia. Before examining the effect of the robot, this study will examine whether the robot is accepted by the therapists, therapy attendees and their relatives.

Who can participate?

As the study is limited to the place where the robot is, only residents of the Wohnpark Elsa Fenske in Dresden, their informal caregivers and professional caregivers working there can participate. Participants need to be 18 years or older.

What does the study involve?

The residents will attend group therapy multiple times a week. The therapy is called MAKs and is usually administered by two trained therapists. At different times during the study, a social robot will be part of the therapy as well providing different functions to the therapist and attendees.

What are the possible benefits and risks of participating?

Group therapy is proven to benefit its attendees regarding their autonomy and cognition. The feedback from all participants will influence how the robot is developed further. All methods are non-invasive. The robot is certified to be used in public spaces and does not pose a risk to the participants.

Where is the study run from?

The study is a project between the Universitätsklinikum Erlangen, the University of Applied Science Dresden and the Cultus gGmbH in Dresden. All parts of the study are carried out in Dresden, Germany.

When is the study starting and how long is it expected to run for?

July 2017 to September 2022

Who is funding the study?

The European Union via the European Fund for Regional Development.

Who is the main contact?

Elmar Graessel, elmar.graessel@fau.de

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

100294374

Study information

Scientific Title

Care4All - Initial - A new concept of human-machine-interaction for the care of people with dementia

Acronym

Care4All

Study objectives

What changes due to the deployment of a social robot in a group therapy for people with dementia regarding the acceptance of the robot by professional caregivers, informal caregivers and therapy attendees?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/07/2018, Ethics Committee of the Friedrich-Alexander University Erlangen-Nuremberg (Ethik-Kommission der Friedrich-Alexander-Universität Erlangen-Nürnberg) (Krankenhausstr. 12, Erlangen, 91054, Germany; +49-9131-8522270; ethikkommission@fau.de), ref: 252_18 B

Study design

Prospective single-centre longitudinal interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Care home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Group therapy for residents of long-term care facility with mild to moderate dementia

Interventions

This is a prospective single-centre longitudinal interventional study on the deployment of a social robot in group therapy for people with dementia without a control group.

A social robot is deployed as a complement to the therapist in the psychosocial group therapy "MAKS" for a group of people with dementia in a long-term care facility. The functions of the robot are developed throughout the study and are designed to assist the therapist, e.g. taking attendance, reading news aloud, and singing karaoke with the attendees. The robot does not provide nursing care. The acceptance of the robot by professional and informal caregivers is assessed via questionnaires, and the acceptance by the therapy attendees is assessed using observational measures (Facial Action Coding System).

Intervention Type

Other

Primary outcome measure

1. Therapy attendees: Observed emotions are measured using the Facial Action Coding System (FACS) at baseline, 5, 12, 16, and 31 months after baseline
2. Professional Caregivers: Technology acceptance measured using the Unified Theory of Acceptance and Use of Technology (UTAUT) at 13 months after start of study

3. Informal Caregivers: Technology acceptance measured using UTAUT at 13 months after start of study

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/07/2017

Completion date

30/09/2022

Eligibility

Key inclusion criteria

Resident:

1. Mild to moderate dementia (Mini-Mental Status Examination score between 23 and 10)
2. Resident of long-term care facility
3. Consent to participate

Health professional:

1. Working at a long-term care facility
2. consent to participate

Carer:

1. Informal caregiver of the resident of the long-term care facility
2. Consent to participate

Participant type(s)

Health professional, Carer, Resident

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

172

Total final enrolment

172

Key exclusion criteria

Resident:

Unfit to participate in group setting

Health professional:
None

Carer:
None

Date of first enrolment
09/11/2017

Date of final enrolment
15/08/2021

Locations

Countries of recruitment
Germany

Study participating centre
Cultus gGmbH Dresden Wohnpark Elsa Fenske
Freiberger Str. 18
Dresden
Germany
01067

Sponsor information

Organisation
Hochschule für Technik und Wirtschaft Dresden – University of Applied Sciences

Sponsor details
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Sponsor type
University/education

Funder(s)

Funder type

Government

Funder Name

European Fund for Regional Developement (EFRD)

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal. Acceptance of social robot by people with dementia: Got bot? - Video analysis of a mobile service robot in psychosocial group therapy for people with dementia. Under review: BMC digital health

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Elmar Graessel, elmar.graessel@fau.de.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---------|--------------|------------|----------------|-----------------|
| Other publications | | 31/12/2020 | 17/12/2024 | Yes | No |
| Results article | | 01/07/2022 | 17/12/2024 | Yes | No |