ISRCTN17968122 https://doi.org/10.1186/ISRCTN17968122

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

Submission date
13/12/2024

Recruitment status
No longer recruiting

Registration date
19/02/2025

Overall study status
Completed

Last Edited
19/02/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
Prof Elmar Graessel

Contact details
Schwabachanlage 6
Erlangen
Germany
91054
+49 9131 8534 810
elmar.graessel@fau.de

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective single-centre longitudinal interventional study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

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

Funder(s)

Funder type
Government

Funder Name
European Fund for Regional Developement (EFRD)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be availabe 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?
Results article		01/07/2022	17/12/2024	Yes	No
Other publications		31/12/2020	17/12/2024	Yes	No