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PflegeTab - A tablet-based approach for improving the level of well-being and quality of life in people affected by dementia

Submission date
31/08/2016

Recruitment status
No longer recruiting

Registration date
01/09/2016

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. There are a range of different types of dementia, but the most common is Alzheimer's disease (AD). Around 65% of nursing home residents in Germany suffer from Alzheimer's disease and related disorders (ADRD). Therefore, psychosocial interventions (ways of supporting patients to overcome challenges and maintain good mental health) for dealing with ADRD related symptoms play an important role in residential care. Recent findings suggest that Information and Communication Technologies (ICTs) can be effective tools for supporting dementia care delivery. However, further in-depth research is needed to find out the specific benefits of ICTs in dementia care. The aim of this study is to investigate the effects of a tablet-computer-based program on quality of life and behavior in nursing home residents with dementia.

Who can participate?
Berlin nursing home residents with dementia.

What does the study involve?
Participating nursing homes are randomly allocated to one of two groups. Over a period of eight weeks, residents with ADRD in the first group take part in three supervised 30-minute tablet sessions per week which involve using tablet applications (apps) that target mental processes and functional abilities, while helping patients to control their emotions. Residents of nursing homes in the second group, complete the same sessions without the use of tablets. Sessions instead involve enjoyable activities such as drawing, singing, playing board games or taking short walks, with a trained caregiver. At the start of the study and then again after eight weeks, participants in both groups complete a range of questionnaires in order to assess their quality of life, thought processes and behavioural symptoms.

What are the possible benefits and risks of participating?
Participants can benefit from taking part in the sessions offered, as they may help to improve

their quality of life, thought processes and behavioural symptoms. There are no risks involved with participating in this study.

Where is the study run from?
Ten nursing homes located in Berlin (Germany)

When is the study starting and how long is it expected to run for?
February 2016 to March 2017

Who is funding the study?
GKV Spitzenverband (Germany)

Who is the main contact?
1. Dr Johanna Nordheim (scientific)
2. Ms Julie O'Sullivan (scientific)
3. Dr Jan-Niklas Antons (scientific)
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Study website
http://www.pflegetab.de

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Tablet-based intervention for Nursing Home Residents suffering from Alzheimer’s Disease and Related Disorders: A cluster-randomised controlled trial

Acronym
PflegeTab

Study objectives
A tablet-based psychosocial intervention can improve engagement, quality of life and behavioral symptoms in nursing home residents suffering from Alzheimer's disease and related disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Charité Universitätsmedizin Berlin, 25/02/2016, ref: EA1/013/16

Study design
Multi-centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (available in German)

Health condition(s) or problem(s) studied
Alzheimers disease and related disorders (dementia)

Interventions
Participants are randomised at nursing home level (cluster-randomisation) to one of two groups.

Intervention group: Over a period of 8 weeks, experimental group participants will engage in 3 supervised 30-minute tablet sessions per week using adaptive tablet-applications targeting cognitive and functional abilities and supporting emotional self-regulation. The applications were developed for the purpose of this study and run on a standard tablet device (iPad). A trained caregiver will guide and support the participants while they interact with the tablet.

Control group: Participants will receive an equal amount of individual activation sessions without tablets (3 sessions per week for a period of 8 weeks). During control group sessions, enjoyable activities such as drawing, singing, board games or short walks will be conducted. Control group sessions will also be accompanied by a trained caregiver.

All questionnaire data (primary and secondary outcomes) will be collected from participants at baseline and after an intervention period (tablet-based activation vs. individual activation without tablets) of 8 weeks. No further follow-ups are planned in this study.

Intervention Type
Behavioural

Primary outcome measure
Engagement is measured using the Adult Education Survey (AES) at baseline and after 8 weeks.

Secondary outcome measures

1. Dementia-related quality of life is measured using the QOL-AD questionnaire (patient) and the Qualidem scale (caregiver) at baseline and after 8 weeks
2. Behavioural symptoms are measured using the Neuropsychiatric Inventory – Nursing Home Version (NPI-NH) questionnaire at baseline and after 8 weeks
3. Cognition is measured using the Mini-Mental State Examination (MMSE) and the Alters-Konzentrations-Test (AKT) at baseline and after 8 weeks
4. Autonomy/iADL is measured using the Barthel Index and the Functional Assessment Staging Test (FAST) questionnaire at baseline and after 8 weeks
5. Depression is measured using the Geriatric Depression Scale (GDS) at baseline and after 8 weeks
6. Engagement is measured using behavioural data (number of solved tasks, number of mistouches, number of errors, etc.) assessed via tablet during each activation session (intervention group only)
7. Intensive longitudinal assessments are undertaken using a short version of the Qualidem scale administered before and after every single activation session in both intervention and control group

Overall study start date
01/02/2016

Completion date
15/04/2018

Eligibility

Key inclusion criteria
1. Nursing home residents diagnosed with dementia (MMST < 24)
2. Informed consent of participant (and legal guardian)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
N=240 (10 clusters w/24 participants each)

Key exclusion criteria
1. Other chronic psychiatric conditions
2. Resident for less than 4 weeks

Date of first enrolment
01/06/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Germany

Study participating centre
Charité Universitätsmedizin Berlin Insitut für Medinzinsche Soziologie
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13407

Study participating centre
Domicil Seniorenpflegeheim Feuerbachstraße GmbH
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12163

Study participating centre
Domicil Seniorenpflegeheim Gotlindestraße GmbH
Berlin
Germany
10365

Study participating centre
Domicil Seniorenpflegeheim Am Frankfurter Tor GmbH
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10249

Study participating centre
Domicil Seniorenpflegeheim Techowpromenade GmbH
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Domicil Seniorenpflegeheim Baumschulenweg GmbH
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Sponsor information

Organisation
GKV Spitzenverband

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Sponsor type
Government

Website
https://www.gkv-spitzenverband.de

ROR
https://ror.org/03psr2094

Funder(s)

Funder type
Government

Funder Name
GKV Spitzenverband

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/02/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	concordance of self- and informant-rated depressive symptoms	05/04/2022	07/04/2022	Yes	No

Other publications	validation of an eight-item version of the QUALIDEM	01/06/2020	28/10/2022	Yes	No