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DemTab – Can a tablet app for people with dementia and carers improve care, treatment and management of dementia according to guidelines?

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
02/04/2019

Overall study status
Completed

Last Edited
04/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
In Germany, the majority of people with dementia (PwD) are treated on an outpatient basis, predominantly by general practitioners (GPs). However, outpatient care of PwD was repeatedly found to be unsustainable and deficient. While dementia guidelines give evidence-based treatment and care recommendations, these frequently lack adherence in care practice. Information and Communication Technologies may be a promising approach to improve guideline-based outpatient dementia care. The main objective of this study is the development and scientific evaluation of a tablet-based intervention that aims to improve outpatient dementia care by fostering guideline-based treatment. A two-arm cluster randomized controlled trial with an intervention group (tablet-based intervention) and a control group (treatment as usual plus information handbook), where clusters will be randomized at GP level, is planned. Patients will be recruited by GPs within the practice. The study's primary outcome is adherence to dementia guideline recommendations at follow up (9 months). Secondary outcomes include various health outcomes such as general health status, depression or quality of life. An estimated sample size of 20 GP practices with 102 PwD and their caregivers from Berlin and the surrounding area will be recruited. Primary and secondary outcomes will be analyzed by an Intention-to-treat Analysis and using mixed models. The present study is expected to provide evidence-based results on the usage and implementation of a tablet-based intervention with the aim to improve guideline-based dementia care in the primary care sector.

Background and study aims:
In Germany, the majority of people with dementia (PwD) are treated on an outpatient basis, mostly by general practitioners (GPs). However, outpatient care of PwD was repeatedly found to be unsustainable and ineffective. There are dementia guidelines that give evidence-based treatment and care recommendations, but GPs often do not consult or follow the guidelines. Technologies such as tablets may be a good way to improve guideline-based outpatient dementia care. The aim of this study is to develop and test a tablet-based guide to improve outpatient dementia care by encouraging guideline-based treatment.

Who can participate?
General practitioners, patients with dementia and their informal caregivers

What does the study involve?
GPs are randomly allocated to an intervention group (tablet-based intervention) or a control group (treatment as usual plus information handbook). PwD will be recruited by GPs within the practice. In the control group, PwD and their caregivers will receive usual treatment plus an information handbook, whereas in the intervention group, the study's participants will receive a tablet-based intervention that aims to promote guideline-based treatment and improve outpatient dementia care. At the start of the study and after 9 months, participants in both groups complete a range of questionnaires in order to assess how closely dementia guideline recommendations were followed, as well as the effects on the patients' and carers' health, such as general health status, depression or quality of life.

What are the possible benefits and risks of participating?
GPs can benefit from taking part in the study, as the tablet-based intervention might support GPs in providing the best care. Further, PwD and informal caregivers can benefit from the study, as the tablet-based app provides information and support on dementia management and may improve quality of outpatient dementia care. There are no risks involved with participating in this study.

Where is the study run from?
Charité- Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
April 2018 to April 2021

Who is funding the study?
German Innovation Fund

Who is the main contact?
1. Dr. Johanna Nordheim (scientific contact), johanna.nordheim@charite.de
2. Ms Sonia Lech (public contact), sonia.lech@charite.de

Study website
http://www.demtab.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01VSF17039

Study information

Scientific Title
DemTab – Tablet-based outpatient care for people with dementia: Guideline-based treatment planning, personalized disease management and network-based care. A cluster randomized controlled trial

Acronym
DemTab

Study hypothesis
A tablet-based Intervention can improve GPs' adherence to dementia guideline recommendations at follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 04/07/2019, Ethik Kommission der Charité – Universitätsmedizin Berlin (Charitéplatz 1, 10117 Berlin; +49 30 450 517 221; ethikkommission@charite.de), ref: EA1/085/19

Study design
Two-arm cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

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

Condition
Dementia

Interventions
Clusters will be randomized at GP level into an intervention group (tablet-based intervention) and a control group (treatment as usual plus information handbook). After randomization, in both groups, people with dementia (PwD) and informal caregivers will receive usual care during the study period. In the intervention group, PwD and caregivers will additionally receive a tablet-based intervention. In the control group, PwD and caregivers will additionally receive a handbook containing similar information as is available in the tablet intervention at the beginning of the trial.

Intervention Type
Behavioural

Primary outcome measure
Guideline adherence assessed using a checklist at baseline and at 9 months

Secondary outcome measures
Current secondary outcome measures as of 05/04/2022:
Secondary outcomes at PwD level measured at baseline and at 9 months:
1. Dementia-related quality of life measured using the QOL-AD questionnaire
2. Health status measured using the EQ-5D-5L measure
3. Behavioural symptoms measured using the Neuropsychiatric Inventory (NPI-PH)
4. Functional independence assessed using the Barthel Index for Activities of Daily Living (ADL)
5. Dementia stage assessed using the Functional Assessment Staging Test (FAST)

6. Depression measured using the Depression in Old Age Scale (DIA-S)
7. Medication intake assessed using lists obtained from the GP as well as from the PwD and caregiver

Secondary outcomes at informal caregiver level measured at baseline and at 9 months:
1. Depression measured using the Geriatric Depression Scale (GDS)
2. Caregiver burden measured using the Burden Scale for Family Caregivers (BSFC)
3. Health status measured using the Short Form (36) Health Survey (SF-36)

Secondary outcome for all participants (GPs, PwD, caregivers) measured at 9 months:
1. Evaluation of the tablet-based application using the Technikaffinitaet – Elektronische Geraete (TA-EG, Technology Affinity – Electronic Devices) questionnaire, Usability Scale and AttrakDiff mini questionnaire as well as a set of self-developed items

Previous secondary outcome measures:
Secondary outcomes at PwD level measured at baseline and at 9 months:
1. Dementia-related quality of life measured using the QOL-AD questionnaire
2. Health status measured using the EQ-5D-5L measure
3. Behavioural symptoms measured using the Neuropsychiatric Inventory (NPI-PH)
4. Cognition measured using the Mini-Mental State Examination (MMSE)
5. Functional independence assessed using the Barthel Index for Activities of Daily Living (ADL)
6. Dementia stage assessed using the Functional Assessment Staging Test (FAST)
7. Depression measured using the Depression in Old Age Scale (DIA-S)
8. Medication intake assessed using lists obtained from the GP as well as from the PwD and caregiver

Secondary outcomes at informal caregiver level measured at baseline and at 9 months:
1. Depression measured using the Geriatric Depression Scale (GDS)
2. Caregiver burden measured using the Burden Scale for Family Caregivers (BSFC)
3. Health status measured using the Short Form (36) Health Survey (SF-36)

Secondary outcome for all participants (GPs, PwD, caregivers) measured at 9 months:
1. Evaluation of the tablet-based application using the Technikaffinitaet – Elektronische Geraete (TA-EG, Technology Affinity – Electronic Devices) questionnaire, Usability Scale and AttrakDiff mini questionnaire as well as a set of self-developed items

Overall study start date
15/04/2018

Overall study end date
30/04/2021

Eligibility

Participant inclusion criteria
Current participant inclusion criteria as of 05/04/2022:
GPs:
1. Operates as a GP
2. Practice meets technical requirements (wifi connection available or can be installed)
3. Willing to participate in training
4. Signed cooperation agreement/informed consent to participate in the study

PwD:
5. Diagnosis of dementia: ICD-10 F00-F03, G30, G31.0 and G31.82
6. Living at home and receiving outpatient care or living in dementia shared homes (Demenz WG)
7. Signed informed consent to participate in the study (possibly through legal advisors)

Informal caregiver:
8. Signed informed consent to participate in the study

Previous participant inclusion criteria:
GPs:
1. Operates as a GP
2. Practice meets technical requirements (wifi connection available or can be installed)
3. Willing to participate in training
4. Signed cooperation agreement/informed consent to participate in the study

PwD:
5. Diagnosis of dementia: ICD-10 F00-F03, G30, G31.0 and G31.82
6. Living at home and receiving outpatient care
7. Informal caregiver available
8. Signed informed consent to participate in the study (possibly through legal advisors)

Informal caregiver:
9. Living with or regularly visiting PwD
10. Signed informed consent to participate in the study

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
GPs= 20, PwD and informal caregiver dyads= 102 (51 in the intervention group and 51 in the control group)

Total final enrolment
120

Participant exclusion criteria
GPs:
1. planned absence or closing of the practice longer than four weeks during the study period

PwD:
2. Other mental and behavioral disorders: ICD-10 Diagnosis F10-29 (except F10.1, F10.1, F17.1 or F17.2), F32.2 and F32.3
3. Planned hospital or rehabilitation stay longer than 4 weeks
4. Planned relocation to an inpatient care-facility or nursing home within the study period

Informal caregiver:
5. Planned absence longer than 8 weeks during the study period

Recruitment start date
01/05/2019

Recruitment end date
30/06/2020

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Medical Sociology and Rehabilitation Science, Charité - Universitätsmedizin
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Study participating centre
Technische Universität Berlin
Faculty IV Electrical Engineering and Computer Science
Quality and Usability Lab
Telekom Innovation Laboratories
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
German Innovation Fund

Results and Publications

Publication and dissemination plan
A scientific publication on the results of a requirement analysis is in preparation as of April 2019. A study protocol is in preparation as of April 2019. Results of the trial are planned to be published in a high-impact peer-reviewed journal after the study's end.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. For further questions regarding the data please contact Johanna. nordheim@charite.de (principal investigator) and Sonia.lech@charite.de (study coordinator).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/12/2021	20/12/2021	Yes	No
Results article		30/03/2021	07/04/2022	Yes	No
Results article		22/08/2019	07/04/2022	Yes	No
Results article		01/12/2023	04/12/2023	Yes	No