Aus dem Institut für Medizinische Soziologie und
Rehabilitationswissenschaft
der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Demenz in der hausärztlichen Versorgung – Ergebnisse der
Durchführung einer cluster-randomisierten kontrollierten
Studie

Dementia in primary care – Results of the implementation of a
cluster randomized controlled trial

zur Erlangung des akademischen Grades
Doctor rerum medicinalium (Dr. rer. medic.)

vorgelegt der Medizinischen Fakultät
Charité – Universitätsmedizin Berlin

von

Sonia Lech

aus Wien

Datum der Promotion: 25.06.2023

Table of contents

List of tables

List of figures

List of abbreviations

DEGAM   German College of General Practitioners and Family Physicians

PCP   primary care physician

PwD   patients with dementia

RCT   randomized controlled trial

cRCT   cluster randomized controlled trial

SD   standard deviation

ICC   interclass correlation coefficient

IQR   interquartile range

Mdn   median

Abstract

Background: Dementia represents a major global health burden, affecting not only individuals but the society. In Germany, primary care physicians (PCPs) have a central role in the provision of dementia care. However, well-developed, and novel research approaches are urgently needed to improve primary health care for patients with dementia (PwD). The main aim of the present dissertation was to generate evidence from different stages of the implementation of the research project *DemTab: Tablet-based outpatient care of people with dementia* (DemTab Study). **Methods:** Based on the DemTab Study, a two-arm, cluster randomized controlled trial aiming at developing and evaluating a tablet-based intervention to improve guideline-based dementia care in primary care, three manuscripts were published as part of the dissertation. The manuscripts represent outcomes and evidence from three different stages of the implementation. **Results:** All three manuscripts provide valuable input to the field of dementia research as well as the implementation of research in primary care prior to the final evaluation of the effectiveness of an intervention. Results of *Manuscript I* included a detailed study protocol, which was published prior to the recruitment of study's participants. Results of *Manuscript II* indicated an overall PCPs recruitment rate of about 5%, with the most efficient strategy being recruitment though primary care research networks. Further, on average PCPs successfully recruited four PwD (range: 1 – 11 PwD). Results of *Manuscript III* indicated high levels of adherence to the German S3 Dementia Guideline among PCPs (71%). Further, a significant association between adherence to the German S3 Dementia Guideline and higher numbers of patients was found ($\gamma 10$ = - 5.58, *CI* = - 10.97, - 0.19, *p* = .04). However, no association between adherence to the German S3 Dementia Guideline and PwD's quality of life was found ($\gamma 10$ = -.86, *CI* = - 4.18, 2.47, *p* = .61). **Conclusion:** First, the present dissertation outlines that while study protocols represent an important tool to foster methodological standards of trial implementation, violations, particularly in dementia research, may occur. Second, present results highlight the potential of primary care research networks and the importance to include PCP's interests and perspectives when conducting research. Third, overall adherence to guideline recommendations is high among PCPs, although variations across specific recommendations are being observed. **Implications**: Future dementia research should consider more adaptable and pragmatic trials and PCP's interests, experiences, and perspectives should be included in all stages of research to

ensure successful recruitment and implementation. Finally, while PCPs overall adherence to the German S3 Dementia Guideline is observable, specific aspects of dementia care require more attention. Results of the present dissertation will be incorporated in the final evaluation of the trial.

Zusammenfassung

Hintergrund: Demenzerkrankungen stellen weltweit eine große gesundheitliche Belastung dar, die nicht nur den Einzelnen, sondern auch die Gesellschaft betrifft. In Deutschland spielen Hausärzt:innen (HA) eine zentrale Rolle in der Versorgung der Demenz. Um die hausärztliche Versorgung von Patient:innen mit Demenz (PmD) zu verbessern, werden jedoch dringend neue Forschungsansätze benötigt. Das Hauptziel der vorliegenden Dissertation war es, Ergebnisse und Erkenntnisse aus verschiedenen Phasen der Umsetzung des Forschungsprojektes *DemTab: Tabletbasierte ambulante Versorgung von Menschen mit Demenz* zu generieren: **Methoden:** Auf der Grundlage der DemTab-Studie, einer zweiarmigen, cluster-randomisierten kontrollierten Studie zur Entwicklung und Evaluierung einer tablet-basierten Intervention zur Verbesserung der leitlinienbasierten Demenzversorgung in der Primärversorgung, wurden im Rahmen der Dissertation drei Manuskripte veröffentlicht. Die Manuskripte stellen Ergebnisse aus drei verschiedenen Phasen der Implementierung der DemTab-Studie dar. **Ergebnisse:** *Manuskript I* enthielten ein detailliertes Studienprotokoll, welches vor der Rekrutierung von Studienteilnehmenden veröffentlicht wurde. Ergebnisse von *Manuskript II* zeigten eine HA Rekrutierungsrate von etwa 5 %, wobei die effizienteste Strategie die Rekrutierung über Forschungsnetzwerke in der Primärversorgung darstellte. Im Durchschnitt wurden pro Praxis vier PmD (Spanne: 1 - 11 MmD) erfolgreich rekrutiert. Ergebnisse von *Manuskript III* deuten auf eine hohe Adhärenz der S3-Leitlinie Demenzen durch HA (71 %). Außerdem wurde festgestellt, dass die Leitlinienadhärenz signifikant mit einer höheren Anzahl von Patient:innen assoziiert ist ($\gamma10$ = - 5,58, *CI* = - 10,97, - 0,19, *p* = .04). Jedoch wurde kein Zusammenhang zwischen der Leitlinienadhärenz und der Lebensqualität von PmD festgestellt ($\gamma10$ = -.86, *CI* = - 4.18, 2.47, *p* = .61). **Schlussfolgerung:** Erstens zeigt die vorliegende Dissertation, dass Studienprotokolle zwar ein wichtiges Instrument zur Förderung methodischer Standards bei der Durchführung von Studien darstellen, jedoch Verstöße, insbesondere in der Demenzforschung, beobachtbar sind. Zweitens unterstreichen die Ergebnisse der Rekrutierung das Potenzial von Forschungsnetzwerken in der Primärversorgung und die Bedeutung der Einbeziehung von HA bei der Durchführung von Forschung. Drittens ist die Befolgung der Leitlinienempfehlungen insgesamt hoch, auch wenn Unterschiede bei den einzelnen Empfehlungen zu beobachten sind. **Implikationen:** Künftige interventionelle Forschung in der Demenzversorgung sollte anpassungsfähigere und

pragmatischere Studiendesigns in Betracht ziehen. Darüber hinaus sollte die Forschung die Interessen, Erfahrungen und Perspektiven von HA einbeziehen und bestimmten Aspekten der Demenzversorgung sollte mehr Aufmerksamkeit geschenkt werden. Die Ergebnisse der vorliegenden Dissertation werden in die abschließende Auswertung der DemTab-Studie einfließen.

1   Introduction

1.1 Background

According to a recent report, over 55 million individuals worldwide live with dementia, a number that is estimated to rise up to 78 million people in 2030 and up to 139 million people in 2050 (World Health Organization, 2021). The number of people living with dementia doubles every five years (Cao et al., 2020). In Germany, the current number of people with dementia is estimated at 1.7 million, representing about 2% of the German population (Thyrian et al., 2020). "*Dementia is a syndrome, usually of a chronic or progressive nature, that leads to deterioration in cognitive function (i.e. the ability to process thought) beyond what might be expected from the usual consequences of biological ageing. Dementia affects memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgement.*" (World Health Organization, 2021). In addition, the syndrome is often accompanied by behavioral and psychological symptoms, also referred to as neuropsychiatric symptoms of dementia (Lyketsos et al., 2011). The global burden of dementia is vast. Besides the physical and psychological impact on patients with dementia (PwD) and their (in)formal caregivers, the social and economic impact lies on society as a whole (Nichols, 2019; World Health Organization, 2021). Globally, dementia represents a leading cause of disability, dependency, and death among older people (World Health Organization, 2021). Further, PwD depend upon a comprehensive scope of health care and social services (Eisele et al., 2010; Wang et al., 2021). However, access and navigation to health services can propose a major challenge for PwD and their informal caregivers, especially in home dwelling PwD (Smith et al., 2021).

1.2 The key role of primary care physicians

Past research has repeatedly acknowledged the central role of primary care physicians (PCPs) in dementia care (Kaduszkiewicz & van den Bussche, 2022; Pentzek et al., 2017; Prince et al., 2016; Thyrian & Hoffmann, 2012). For example, a recent systematic review of trials examining dementia care models delivered by PCPs reported positive impact of primary and community-based care on clinical outcomes and healthcare costs for dementia care (Frost et al., 2020). In Germany, PCPs have a pivotal part in the provision of diagnosis, treatment and care for dementia (Kaduszkiewicz & van

den Bussche, 2022; Leve et al., 2017; Pentzek et al., 2019; Thyrian & Hoffmann, 2012). For example, in our own study we found that home dwelling PwD consulted their PCP about two times in three months and about one third of PwD were diagnosed with dementia at their general practitioner (Lech et al., 2021a). However, past research has also found that PCPs report challenges in dementia care delivery (Kaduszkiewicz et al., 2008; Mansfield et al., 2018; Wang et al., 2020). For example, a postal survey conducted in Germany reported that 15% of PCPs showed negative attitudes towards the care of patients with dementia (Kaduszkiewicz et al., 2008). In addition, system related factors such as time constraints (Mansfield et al., 2018; Turner et al., 2004) or lack of cross-sectional collaboration between PCPs and other specialists (Franz et al., 2010) propose additional barriers in the delivery of optimal dementia care. In their most recent report, the World Health Organization proposes to foster development, delivery, and promotion of evidence-based risk reduction interventions in primary care (World Health Organization, 2021). The provision of evidence-based and person-centered care for dementia is essential. However, dementia remains often undetected, undiagnosed and under treated in primary care (Kaduszkiewicz et al., 2010; Prince et al., 2016). Thus, trainings of health care workers, such as PCPs in diagnosis, treatment, and care as well as on ethics of dementia are of great relevance (Bentley et al., 2019; Edwards et al., 2013). The improvement of ambulatory care for home dwelling PwD depends largely on the perspectives and prospect of PCPs. However, the involvement of PCPs in research proposes a considerable challenge (Krebs et al., 2021). In particular, the recruitment of PCPs has proven to be very challenging (Pit et al., 2014). Drawing on the key role of PCPs in the ambulatory care of dementia, novel approaches are urgently needed to support PCPs in their care provision and involve them in research to provide new insights on the role and the needs of PCPs in dementia care.

1.3 The role of evidence-based dementia care

Generally, for health care providers, evidence-based guidelines may propose a valuable contribution to optimal health care delivery. For example, they can provide an overview of relevant medical literature and offer a framework for diagnosis, treatment, care, and many other aspects of clinical practice (Lim et al., 2008). With regard to dementia care, adherence to guidelines may contribute to an improvement of care (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für

Neurologie, 2016; Jeschke et al., 2011) and patient health-related quality of life (Vickrey et al., 2006). For example, a recent interventional study from Australia among health professionals who participated in an intervention fostering dementia care, reported a significant increase in adherence to guideline recommendations (Laver et al., 2020). However, a systematic review concluded that educational interventions alone did not increase adherence to dementia guidelines among PCPs (Perry et al., 2011). Further, interventional studies fostering guideline-based dementia care in primary care, in particular for Germany, remain rare. Moreover, gaps between evidence-based guideline recommendations and clinical practice as well as challenges in implementation of guideline recommendations exist (Laver et al., 2020). In Germany, the German S3 Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) provided evidence-based recommendations for diagnostics, treatment, and care of dementia. Although the *German College of General Practitioners and Family Physicians* (DEGAM) did not participate in the development of the German S3 Dementia Guideline, a separate chapter on the role of PCPs in ambulatory dementia care was inserted by the DEGAM (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016). Generally, due to the essential role of PCPs in ambulatory dementia care, the inclusion of primary care perspectives in the development of guideline recommendations is highly recommended. Currently, the German S3 Dementia Guideline is being renewed (expecting a new version in 2022) with the DEGAM participating in the development of a new guideline. To sum up, while adherence to dementia guideline recommendations may improve primary dementia care, evidence on the knowledge, utilization, and perceived usefulness of the German S3 Dementia Guideline as well as the guideline's potential to improve dementia care in primary care in Germany remains rare. For a deeper understanding, research investigating the role of evidence-based dementia guidelines in primary care and examining potential gaps and barriers in the implementation of evidence-based guidelines in clinical practice is urgently needed.

Novel approaches using technologies propose a promising approach in health care that not only allow PwD to stay in their homes and their community, promote autonomy and social participation, but also improve guideline-based health care provision for PwD and their caregivers (Moyle, 2019). Based on empirical work, a recent systematic review aiming at PwD and their caregivers concluded that information and communications technologies improve quality of life for the elderly and their caregivers (Martínez-Alcalá et

al., 2016). Further, a study conducted in Germany, provided empirical evidence for the efficacy of a computer-based intervention-management system for PwD, informal caregivers and PCPs (Thyrian et al., 2017). The technology-based intervention of the aforementioned study rested on the German S3 Dementia Guideline (Eichler et al., 2014). In sum, past research has acknowledged the potentials of technology assisted health care for dementia. However, evidence-based, and affordable technologies in ambulatory dementia health care remain rare. In the context of population aging, novel approaches on how to successfully improve dementia care of home dwelling PwD are urgently needed. The research project *DemTab: Tablet-based outpatient care of people with dementia* (DemTab Study), a two-arm, cluster randomized controlled trial (cRCT) aimed at closing exactly this research gap by developing and empirically evaluating a tablet-based intervention striving for improving guideline-based treatment for home-dwelling PwD in primary care. The present dissertation is based on the DemTab Study.

1.4 Aim of the present dissertation

The key objective of the present dissertation is to generate and to reflect on scientific evidence and outputs acquired throughout different stages of the implementation of a research project, which aimed at improving primary dementia care in Germany (DemTab Study). Following methodological standards for the successful implementation and evaluation of a cRCT, as part of the dissertation, scientific outcomes were generated through out three different stages of the DemTab Study prior to the trial's main evaluation of primary and secondary outcomes. The present dissertation provides an overview of the implementation of all three stages: development of the study's design (Stage I), recruitment of participants (Stage II), and collection of cross-sectional baseline data of participants (Stage III). The author of the present dissertation was coordinating the DemTab Study. Further, the author was responsible for the development, the implementation, and the evaluation of the research project throughout all three stages. As part of the dissertation, three manuscripts from the three different stages of the DemTab Study were published. Figure 1 represents an overview of three different stages of the DemTab Study and their main objectives, as well as the published manuscripts within each stage and their main aims. Key results of the published manuscripts are being described in the *3. Results section* of the present dissertation.

The key objective of *Manuscript I* was to, prior to the trial's beginning, to develop and publish a study protocol (Lech et al., 2019). According to the current scientific standards, randomized clinical trials (RCTs) require a protocol that defines the study's rationale, methods, proposed analysis plan, and administration details (Tetzlaff et al., 2012). The great value of study protocols is well established (Chan et al., 2013; Jones & Abbasi, 2004; Summerskill et al., 2009). Study protocols represent a quality tool that forces researchers to establish and honor ethical standards for their trial, enables the scientific community to monitor protocol deviation, and facilitates the reflection upon potential biases of trail results (Tetzlaff et al., 2012). Moreover, often when submitting trial manuscripts, scientific journals require the submission of study protocols, and authors are asked to include the protocol in the peer review process (Tetzlaff et al., 2012). Therefore, in an early stage of the DemTab Study, prior to the recruitment of participants, a study protocol was published (*Manuscript I*).

The main objective of *Manuscript II* was to describe the recruitment process of the DemTab Study and to generate new evidence with regard to the effectiveness of different recruitment strategies for PCPs and PwD in primary care research (Lech et al., 2021a). Past research has previously acknowledged the difficulties of both, recruitment of PCPs and their patients into primary care research (Krebs et al., 2021; Leysen et al., 2019; Sahin et al., 2014). However, the effectiveness and comparison of different recruitment strategies in primary care in Germany remained unstudied. Hence, main findings of the recruitment process of the DemTab Study were published (*Manuscript II*). As past research on the recruitment of PCPs and their patients into dementia research in Germany was limited, *Manuscript II* was based on an explorative design and no hypothesis were tested. The main aim of *Manuscript II* was to provide a detailed description of recruitment rates and recruitment ratios obtained from the DemTab Study and no prior assumptions on the effectiveness of different strategies were made (Lech et al., 2021a).

The key objective of *Manuscript III* was to, based on cross-sectional baseline data obtained from the DemTab Study, describe the study's population, to investigate the role of evidence-based guidelines in the treatment of dementia in primary care, and to examine factors associated with PCP's adherence to guideline recommendations (Lech et al., 2021b). Past research has already studied barriers and facilitators of optimal dementia care delivery in primary care, mainly focusing on individual factors such as knowledge and educational trainings on dementia management (Krebs et al., 2021).

However, little is known on the role of guideline-based dementia care. Research questions such as: *Do PCPs know about the German S3 Dementia Guideline*? *Do PCPs use German S3 Dementia Guideline? Is the German S3 Dementia Guideline perceived as helpful by PCPs?*, as well as the adherence to current guideline recommendations among PCPs were addressed in *Manuscript III*. For this purpose, the associations between adherence to the German S3 Dementia Guideline and *individual factors* (age, years of experience as a PCP, frequency of utilization of the guideline, and perceived usefulness of the guideline) as well as *structural factors* (type of practice, total number of patients and total number of PwD seen by a participating PCP during last three months) were examined. First, we proposed *structural factors* to have a greater impact on adherence to the German S3 Dementia Guideline recommendations *than individual factors* (Hypothesis 1, Lech et al., 2021b). Second, adherence to the German S3 Dementia Guideline was proposed to be positively associated with PwD's self-reported quality of life (Hypothesis 2, Lech et al., 2021b).

.

Table 1 Overview of different stages of the DemTab Study and the corresponding manuscripts of the present dissertation

Stage	Aim of the stage	Outcome of the stage	Manuscript	Title of the manuscript	Aim of the manuscript
Stage I	Development of the study's design and methods	Conception of a study protocol	Manuscript I	Tablet-Based Outpatient Care for People With Dementia - The DemTab Study Protocol	Define and describe the rationale, methods, and organization of the study
Stage II	Recruitment of the study's participants	Evaluation of the recruitment of participants	Manuscript II	Recruiting general practitioners and patients with dementia into a cluster randomized controlled trial: strategies, barriers and facilitators	Describe the recruitment and analyze recruitment rates and ratios
Stage III	Collection of cross-sectional baseline data of the study	Evaluation of cross-sectional baseline data	Manuscript III	Dementia Care and the Role of Guideline Adherence in Primary Care: Cross-Sectional Findings From the DemTab Study	Describe the sample and analyze cross-sectional baseline data on adherence to dementia guideline

Note: Table 1 was created specifically for the dissertation and was not published elsewhere.

2   Methods

In this section, the study design and methodology of the DemTab Study will be briefly described. A more detailed description of the DemTab Study's methods is presented in the *3. Result* section. Specifically, the study design and methods for the DemTab Study have been published in *Manuscript I* (Lech et al., 2019), and the recruitment process and results of the recruitment have been published in *Manuscript II* (Lech et al., 2021a) of the present dissertation. A brief overview is presented in the following.

2.1 Study design

The DemTab Study was a cRCT investigating the effects of a tablet-based intervention on the improvement of dementia care in primary care. The study took place between April 2018 and June 2021. The research project was a cooperation between the Institute of Medical Sociology and Rehabilitation Science of the Charité – Universitätsmedizin Berlin and the Quality and Usability Lap of the Technische Universität Berlin and was funded by the Innovation Fund of the Federal Joint Committee (G-BA). The main study consisted of a two-arm cRCT with an intervention group and a control group. Study participants of the DemTab Study were PCPs, PwD and their informal caregivers from Berlin and the surrounding area. A cluster randomization design was chosen to minimize contamination effects across groups with clusters being randomized at the PCP level. Recruitment of study's participants was conducted in two steps: first PCPs and second PwD were recruited. For the recruitment of PCPs, different recruitment strategies were applied, including recruitment though cold calls, snowball sampling as well as in person practice visits. PwD were approached by participating PCPs in their practice. PCPs provided a brief overview of the DemTab Study and in case of participants interested, contact details of PwD and informal caregivers were forwarded to the research team who then approached PwD and informal caregivers and recruited them via phone. Based on sample calculation conducted prior to the trials beginning, a total sample size of N = 204 PwD was originally estimated (Lech et al., 2019). All participants signed an informant consent prior to the start of the intervention. Baseline data was collected at the beginning of the trial and follow-up data after nine months. At the time of the finalisation of the present dissertation, the follow up data of the DemTab Study was collected but not yet analysed. All PCPs received a financial compensation (100 EUR per successfully

recruited PwD) as well as a tablet computer. PwD and informal caregivers did not receive a financial compensation. However, at the end of the study a lucky draw was conducted where 25 tablets were drawn and distributed among participants. The DemTab Study was conducted according to the principles of Good Clinical Practice and the Declaration of Helsinki. Ethical approval was acquired by the ethics committee of the Charité – Universitätsmedizin Berlin (EA1/085/19). Further, the trial was registered with the ISRCTN registry (Trial registration number: ISRCTN15854413). A study protocol was published prior to the study's beginning (Lech et al., 2019).

2.2 Intervention

Based on previous research (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016; O'Sullivan et al., 2022) as well as interviews with PCPs and other actors from the ambulatory dementia care sector, which were conducted at the beginning of the DemTab Study, a tablet-based intervention (DemTab App) was developed. A publication on the development process and the evaluation of the interviews is currently being finalized. The main aim of the DemTab App was the improvement of guideline based primary care for home dwelling PwD. The intervention was carried out on a tablet. Both, PCPs and PwD (and their informal caregivers) received a tablet with internet access for the duration of the intervention (nine months). Prior to the start of the intervention, all participants of the intervention group received a training provided by the researcher's team as well as a handbook with a detailed description of the DemTab App. The intervention included multiple functions for all study participants and consisted of two different version of the DemTab App: one for PCPs and one for PwD and their informal caregivers. An overview of the functions of the DemTab App for PCPs can be obtained from Figure 1. For PCPs, the main function was a checklist, which was developed based on the German S3 Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) and aimed at supporting PCPs in the provision of guideline-based care of dementia. The checklist was presented to PCPs in their training as a conversational guideline, which should be used with each patient. Another function of the DemTab App was a tool for guideline-based prescription of anti-dementia drugs. Based on the dementia type and the level of cognitive impairment (Mini Mental Examination Score, MMES), this function provided PCPs, if necessary, with individual suggestions on suitable medication.

The recommendations were drawn from the German S3 Dementia Guideline. Another main function of the DemTab App was the development of an individual, virtual care plan and individual therapeutic measures and goals. The care plan was accessible for both, PCPs and PwD on their individual tablets. In addition to these functions, direct and indirect communication between PCPs, PwD and informal caregivers was fostered with the DemTab App. First, PCPs and PwD were able to send direct messages via the tablet. However, it is pointed out clearly, that direct messaging should not be used in times of emergency. Second, PwD were able to record (health) data on their tablet, which was presented on the PCP's tablet. Further, access to the German S3 Dementia Guideline as well as further information on dementia were provided. Finally, a daily planner provided an overview of open tasks and was directly linked to all functions. In addition, red push notifications (as can be seen in Figure 1) indicated open tasks.
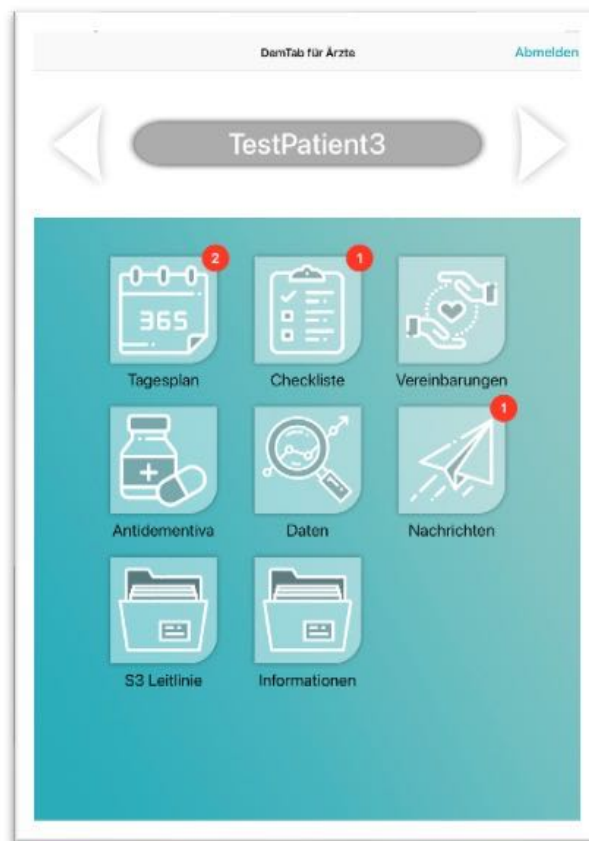

Figure 1 Overview of the DemTab App for PCPs

Note: Figure 1 was created specifically for the dissertation and was not published elsewhere.

In addition to the above-mentioned functions as part of the PCPs DemTab App, PwD were provided with a variety of games engaging in cognitive training and activities

of daily living, and biography work in their DemTab App. These games were specifically designed for older adults with cognitive and/or sensory impairment and included games among others as a quiz, a spelling game, and a game where objects of daily living need to be assigned to tasks. Further, PwD and their informal caregivers were also provided with information on dementia and dementia care. For example, access to an interactive location service (Bundesministerium für Familie, Senioren, Frauen und Jugend, 2019) to find nearby consulting points and treatment options for dementia (e.g., dementia-specific occupational therapy or day care facilities) and for their informal caregiver (counselling centers, self-help groups, or short-term nursing) was enabled. Finally, for informal caregivers and PwD guided audio-relaxation was included in the DemTab App.

2.3 Measures

Data of the DemTab Study was collected from all participants (i.e., PCPs, PwD, informal caregivers) prior to the intervention's beginning (baseline data) and after nine months (follow-up data) by a trained study nurse. For the baseline data the study nurse was blinded. Due to the study design (tablet-based intervention), a blinding for the follow up data was not possible. An overview of all study outcomes can be obtained from Table 2. At the time of the finalisation of the present dissertation, the follow up data of the DemTab Study was collected but not yet analysed.

2.3.1 Primary Outcome

The primary outcome of the DemTab Study was adherence to the German S3 Dementia Guideline. Adherence to the German S3 Dementia Guideline was measured with a 23-item and a 16-item checklist from both, PCPs and informal caregivers, respectively. The development of the checklists was based on the German S3 Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) and empirical research focusing on the role of guideline-based primary care (Downs et al., 2000; Murphy et al., 2014; Vickrey et al., 2006). The original checklists can be found in Lech et al. (2021a). The checklists assessed adherence to the S3 German Dementia Guideline in a dichotomous format with "yes" (=1) and "no" (=0). For the purpose of *Manuscript III* and the present dissertation, only PCPs guideline adherence was assessed. First, the final score of the PCP's checklist was calculated for each PwD as the proportion of guideline adherence and all responded

items ([sum of items answered as guideline adherent/sum of all answered items] X 100, Lech et al., 2021b). Second, the overall adherence to guideline (across all PwD) was calculated as the mean percentage of per-patient guideline adherence across all PCPs (Lech et al., 2021b). The internal consistency of PCPs checklist was Cronbach's α = .876.

2.3.2 Secondary Outcomes

Secondary outcomes for the DemTab Study were assessed by self-report and/or informant ratings in PwD, informal caregivers, and PCPs. Variables of interest included, among others, quality of life (Logsdon et al., 2002), neuropsychiatric symptoms (Cummings et al., 1994), depression (Gauggel & Birkner, 1999; Heidenblut & Zank, 2010), and general health status (Bullinger et al., 1995). However, for the purpose of the present dissertation, only data of PCPs and PwD were analyzed and reported. Generally, standardized assessments were chosen based on the suitability for PwD (e.g., quality of life was measured using the Quality of Life in Alzheimer's Disease assessment; Logsdon et al. (2002). For other, non-standardized assessments of variables, such as sociodemographic information (e.g., age, gender, education, care level) data was always intended to be obtained from PwD. If not possible, because PwD was unable to respond, or responses were ambiguous, the obtained information was verified with informal caregivers. For example, if a PwD seemed unsure regarding their year of birth, data collectors indented to verify this information. Data from PCPs was collected through a questionnaire sent via mail. Data from PwD and informal caregivers was originally collected in patient's home. However, due to the COVID-19 pandemic data collection had to be shifted to phone interviews but was proven to be feasible with the exclusion of the Mini Mental State Examination (MMSE), which was not feasible as a phone interview. For the baseline data collection this resulted in a total of n = 12 PwD phone assessments, for the follow-up all data was collected via phone.

Table 2 Overview of all variables of interest of the DemTab Study

Outcome/assessment	Participants of the DemTab Study		
	PCP	PwD	Informal Caregiver
Socio-demographic Information			
Age	x	x	x
Sex	x	x	x
Education	x	x	x
Care level		x	
Diagnosis		x	
Primary Outcome			
Adherence to the German S3 Dementia Guideline	x		x
Secondary Outcome			
Quality of Life			
Quality of Life in Alzheimer's Disease QOL-AD (Logsdon et al., 2002)		x	
Health status			
EQ-5D-5L (Herdman et al., 2011)		x	
Short Form (36) Health Survey (SF-36) (Bullinger et al., 1995)			x
Neuropsychiatric symptoms of dementia			
Neuropsychiatric Inventory Questionnaire (NPI-PH) (Cummings et al., 1994)		x	
Cognition			
Mini-Mental State Examination (Folstein et al., 1975)		x	
Activities and instrumental activities of daily living			
Barthel Index (Heuschmann et al., 2005)		x	
Functional Assessment Staging Test (FAST) (Sclan & Reisberg, 1992)		x	
Depression			
Depression in Old Age Scale (DIA-S) (Heidenblut & Zank, 2010)		x	
Geriatric Depression Scale (GDS) (Gauggel & Birkner, 1999)			x
Caregiver burden			
Burden Scale for Family Caregivers (BSFC) (Gräßel & Leutbecher, 2001)			x
Others			
Medication intake		x	
Technical Affinity (TA-EG) (Karrer et al., 2009)	x	x	x

Note: Table 2 is based on Table 1 (page 140) of Lech et al. (2019) and was modified for the present dissertation.

2.4 Statistical Analysis

For the purpose of *Manuscript II and Manuscript III* and the present dissertation, different statistical analysis were conducted. First, based on data on the recruitment of

PCPs and PwD (*Manuscript I)* as well as cross sectional baseline data obtained from PCPs and PwD via questionnaires (*Manuscript II)*, descriptive analyses (means, standard deviations, ranges for continuous variables, as well as frequencies for nominal and ordinal variables) were calculated. For *Manuscript I,* recruitment rates (number of successfully recruited PCPs divided by the number of PCPs contacted for recruitment) and recruitment ratios (number of successfully recruited PCPs in relation to the final PCP sample) for each recruitment round were calculated (Lech et al., 2021a). Due to the explorative design of *Manuscript II* no hypothesis were proposed nor tested. For *Manuscript II*, Linear Mixed Models (LMM) for continuous outcomes were applied to test Hypothesis 1 & 2. Hypothesis 1 proposed that structural factors such as type of practice, total number of patients, and total number of PwD seen by a participating PCP during the last three months would have a greater association with adherence to the German S3 Dementia Guideline than individual factors such as age, years of experience as a PCP, frequency of utilization of the guideline, and perceived usefulness of the guideline (Lech et al., 2021b). Hypothesis 2 proposed a positive association between adherence to the German S3 Dementia Guideline and PwD's self-reported quality of life. LMM allows for the nested structure (PCP clusters) of the present data. The IDs of participating PCPs were used as the clustering variable. In addition, an intraclass correlation coefficient (ICC) was calculated. Statistical analyses were conducted using the software IBM SPSS Statistics for Windows V.27.0 and all tests of significance were based on a $p < .05$ level and a 95% confidence interval.

3.   Results

All three manuscripts were based on the DemTab Study. *Manuscript I* represents the study protocol of the study. *Manuscript II* focuses on the recruitment of participants. *Manuscript III* describes the sample of the study and examines the role of guideline-based dementia care in primary care using cross-sectional data. In the following section, a brief summary of all three manuscripts and their main results is presented separately.

3.1 Manuscript I

Manuscript I entitled "*Tablet-Based Outpatient Care for People With Dementia - The DemTab Study Protocol*" was published in GeroPsych (Lech et al., 2019). The main aim of this manuscript was to provide a detailed study protocol including the DemTab Study's rationale, methods, analysis plan, and administration details of the trial. Transparent and adequate study protocols are of great value for a successful implementation of research and pave the way for compliance of scientific and ethical standards (Tetzlaff et al., 2012). Adherence to guidelines that aim to improve reporting of study protocols improve the quality of reporting of randomized controlled trials (Turner et al., 2011). Drawing on these scientific recommendations, the present study protocol was conducted in accordance with the SPIRIT guideline for reporting randomized trials (Chan et al., 2013) and the CONSORT 2010 statement: extension to cluster randomized trials (Campbell et al., 2012).

A main result of the protocol included a flow chart of the study design (see Figure 2). As indicated by the flow chart, first, recruitment of study participants (PCPs, PwD and informal caregivers) was conducted. PCPs were recruited applying a variety of different recruitment strategies. Once a PCP was successfully recruited, PwD were recruited within the practice. Results of the recruitment can be obtained from *Manuscript II*. A summary of the inclusion and exclusion criteria for all participants (PCPs, PwD, informal caregivers) can be obtained from Table 3. Randomization was conducted at PCPs level (cluster). All participants of the intervention group received a tablet-based intervention. Prior to the interventions beginning, participants of the intervention group received a training on the use of the tablet. Participants of the control group received care as usual as well as a handbook on dementia care at the beginning of the trial. The duration of the intervention period was nine months. Follow-up data was collected after the intervention period. Further, a sample-size calculation was calculated and presented in *Manuscript I.* Based

on a comparable study conducted by Vickrey et al. (2006), a power calculation using G*Power 3.1 with a type I error rate of alpha = 0.05, a statistical power of 1- β = 0.8, an intra-cluster correlation of ICC = 0.03, and a drop-out rate of 18% at follow-up yielded a minimum total sample size of N = 204 (Lech et al., 2019a).
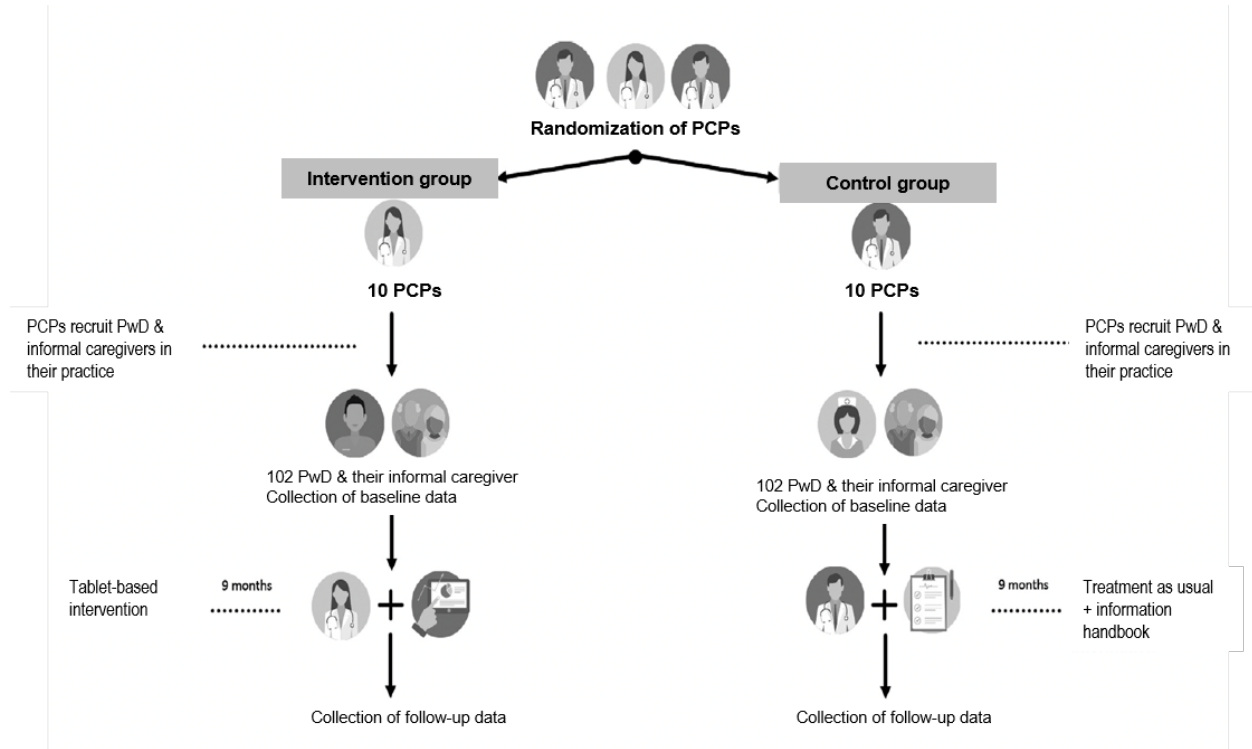
Figure 2 Original flow chart of the DemTab Study

Note: Figure 2 is based on Figure 1 (page 138) of Lech et al. (2019) and was modified for the present dissertation.

Table 3 Overview of all inclusion and exclusion criteria of the DemTab Study

	PCP	PwD	Informal caregiver
Inclusion criteria	operating PCP	dementia diagnosis (ICD-10: F00-F03, G30, G31.0 & G31.82)	living with or regularly visiting PwD
	internet connection available/installable	home-dwelling	signed informed consent
	participation in a training	informal caregiver present	

	signed cooperation agreement/informed consent	signed informed consent (possibly through legal advisors)	
Exclusion criteria	planned absence (4 weeks or longer)	other mental and behavioral disorders (ICD-10: F10-29 (except F10.1, F10.1, F17.1 & F17.2), F32.2 & F32.3) planned hospital or rehabilitation stay (4 weeks or longer) relocation to inpatient care-facility within study period	planned absence (8 weeks or longer)

Note: Table 3 was created specifically for the dissertation and was not published elsewhere.

3.2 Manuscript II

Manuscript II entitled "*Recruiting general practitioners and patients with dementia into a cluster randomized controlled trial: strategies, barriers and facilitators*" was published in *BMC Research Methods (*Lech et al., 2021a). The main objective of this manuscript was to describe the recruitment process and provide results on the enrollment of PCPs and PwD into the DemTab Study. As described in the introduction of the dissertation, previous research has already acknowledged some of the difficulties in engaging PCPs in research (Pit et al., 2014). However, little is known of effective recruitment strategies as well as factors that facilitate or hinder the successful recruitment of PCPs, especially in Germany. *Manuscript II* aimed at closing this gap.

Recruitment of participants into the DemTab Study was conducted in two steps. In a first step, PCPs from Berlin and the surrounding area were recruited. The recruitment of PCPs was carried out in three recruitment rounds. The first recruitment round included the publication of calls for participation and advertisements of the DemTab Study in related newsletters through different (primary care) networks, among others a call for participation in a newsletter published by research network of general practitioners in and around Berlin installed by the Institute of General Practice of the Charité – Universitätsmedizin Berlin. Further, in this round PCPs were recruited though recommendations of participating PCPS (snowball sampling). This recruitment round led

to several recommendations and referrals among PCPs (n = 17). In the second recruitment round, a random sample of 486 PCPs was selected from a database of the Statutory Health Insurance Physicians in Berlin (Kassenärztliche Vereinigung Berlin) and contacted via phone. In a third recruitment round, face-to-face recruitment of 116 PCPs in Berlin was conducted, where PCPs were visited on site in their practice. Overall, results of all three recruitment rounds can be obtained from Table 4. A total of N = 32 PCPs signed an informed consent. However, only N = 28 PCPs participated in the trial (n = 4 drop out). This proposes an overall recruitment rate of 4.6% (Lech et al., 2021a). As indicated in Table 4, in terms of absolute numbers, the most successful strategy was the second recruitment round (n = 18 PCPs). However, the recruitment rate, calculated as number of successfully participating PCPs divided by the number of contacted PCPs, was highest in the first recruitment round (n = 41.2%). In addition, all PCPS were asked about their reason to participate in the DemTab Study. The most frequent reasons for PCP's participation were *Improvement of patient's well-being* (n = 22, 79%) followed by *Interest in dementia research* (n = 18, 64%) (Lech et al., 2021a).

Table 4 Recruitment rates and ratios of PCPs

Recruitment round	Approached PCPs (N)	Successfully recruited PCPs (N)[a]	Drop out (N)	Recruitment rate (%)[b]	Recruitment ratio (%)[c]
First round	17	8	1	41.2	25.0
Second round	486	18	3	3.1	53.6
Third round	116	6	0	4.8	21.4

Note: [a] PCPs who signed informed consent. [b] Number of successfully participating PCPs (recruited PCPs minus drop-outs) divided by the number of approached. [c] Ratio of successfully participating PCPs (recruited PCPs minus drop-outs) and the final PCP sample (N = 28). Table 4 is based on Table 1 (page 6) of Lech et al. (2021a) and was modified for the present dissertation.

In a second step, once PCPs were successfully recruited and an informed consent was obtained, PCPs recruited their PwD. To facilitate a successful recruitment of PwD, PCPs were provided with information material and flyers of the DemTab Study. In addition, due to data regulations, PCPs were instructed to appeal to their PwD, present the DemTab Study and in case of interest, obtain permission for sharing contact details of PwD and/or informal caregivers with the research team. Once permission was obtained and contact details shared, the research team approached PwD and their informal

caregivers via phone and provided a detailed description of the study followed by the provision of study information and the informed consent as well as reply-paid envelope via mail. PwD were considered successfully recruited once a signed informed consent was sent back. Results of the recruitment of PwD can be obtained from Table 5. A total of N = 102 PwD were successfully recruited into the DemTab Study. On average, one PCP referred seven PwD (range: 1 – 17 PwD; mdn = 6) and successfully recruited four PwD (range: 1 – 11 PwD; mdn = 3) (Lech et al., 2021a).

Table 5 Overview of the recruitment of PwD

	PwD contacts provided by PCPs					PwD successfully recruited				
	n	*Range*	*Mean (SD)*	*Mdn*	*IQR*	*n*	*Range*	*Mean (SD)*	*Mdn*	*IQR*
Total	194	1-17	6.79 (3.91)	6.0	3.5	102	1-11	3.64 (2.53)	3.0	3.5
Intervention	124	2-17	8.13 (4.70)	7.0	8.0	67	1-11	4.47 (3.11)	3.0	5.0
Control	70	1-8	5.23 (1.92)	5.0	3.0	35	1-4	2.69 (1.11)	3.0	2.0

Note: N = 102 PwD. SD = Standard Deviation, Mdn = Median, IQR = Interquartile range. Table 5 is based on Table 3 (page 8) of Lech et al. (2021a) and was modified for the present dissertation.

3.3 Manuscript III

Manuscript III entitled "*Dementia Care and the Role of Guideline Adherence in Primary Care: Cross-Sectional Findings From the DemTab Study*" was published in *BMC Geriatrics (*Lech et al., 2021b). The main objective of the study was to describe the DemTab sample and to explore the role of the German S3 Dementia Guideline in primary care. As described in the introduction section, based on past literature, we expected stronger associations between adherence to the dementia guideline and structural factors (type of practice, total number of patients and total number of PwD seen by a participating PCP during the last three months) compared to individual factors (age, years of experience as a PCP, frequency of utilization of the guideline, and perceived usefulness of the guideline) (Hypothesis 1, Lech et al., 2021b). Further, we expected a positive association between guideline-adherence score and PwD's self-reported quality of life

(Hypothesis 2, Lech et al., 2021b). Figure 3 shows the final enrollment, allocation, and baseline data collection of the DemTab Study.
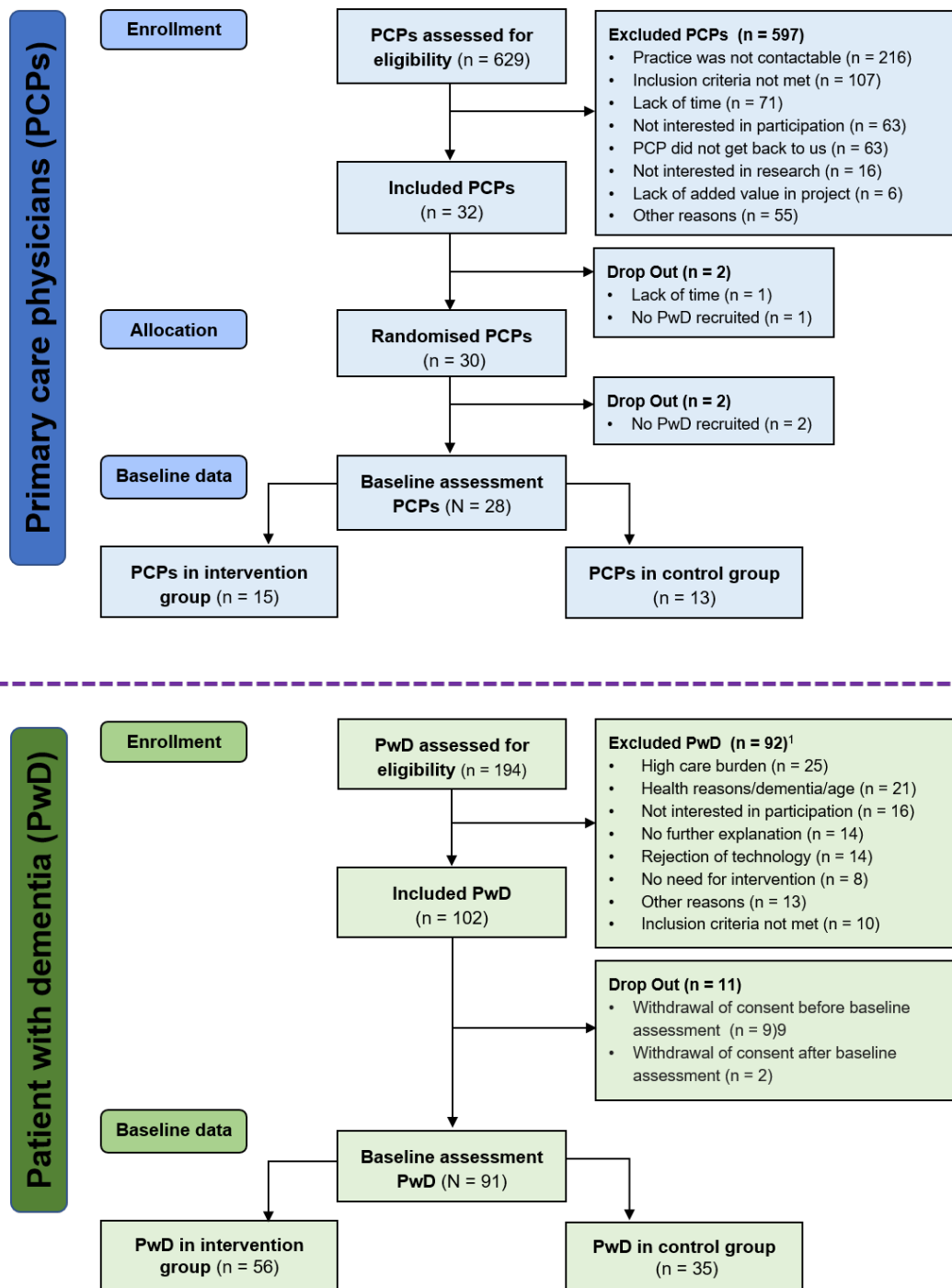
¹ N = 92 PwD were not included in the DemTab Study. A total of n = 111 reasons for non-participation where documented, as n = 20 PwD reported multiple reasons for non-participation.

Figure 3 Final flow chart of the DemTab Study

Note: Figure 3 was created specifically for the dissertation and was not published elsewhere.

Results of the analysis of cross-sectional baseline data (Lech et al., 2021b) are presented in the following paragraph. Participating PCPs were on average 50 years old (*SD* = 7.99, range: 38 – 67 years) and 61.0% were female. About 43.0% (n = 12) of PCPs reported working in a single-handed practice and a mean of 12 years (*SD* = 9.11, range: 1 – 29 years) of experience as a PCP. Further, PCPs treated on average of n = 1489 patients (*SD* = 656.03, range: 700 – 2990 patients) and n = 61 PwD (SD = 52.80, range: 9 – 200 PwD) during the last three months. In regard with frequency of utilization only 19.2% (n = 5) PCPs reported using the guideline often, 35.7% (n = 10) reported using it sometimes, 26.9% (n = 7) using it seldom and 15.4% (n = 4) never using the guideline. With regard to perceived usefulness, 20.8% (n = 5) of PCPs perceived the guideline as very helpful, 45.6% (n = 11) as partially helpful, and 33.3% (n = 8) as somewhat helpful. Main descriptive characteristics of PwD's baseline data can be obtained from Table 6. Results with regard to the role of guideline-based dementia care indicated an average overall adherence to guidelines of 71% (*SD* = 19.4, range: 25 – 100). However, adherence across specific recommendations varied from 19.2% to 95.3%, with lowest rated for discussion of palliative care (19.2%) and discussion of the current driving situation (49.2%, Lech et al., 2021b). Further, around 54% of the variance in adherence to the guideline was accounted by cluster (*ICC* = .536). With regard to Hypothesis 1, it was found, that only lower adherence was significantly associated with higher numbers of patients ($\gamma 10$ = -5.58, *CI* = -10.97, -0.19, *p* = .04, Lech et al., 2021b). No association between adherence to guideline and age*,* years of experience as a PCP, frequency of utilization of the guideline, perceived usefulness of the guideline, type of practice or number of PwD was found (Lech et al., 2021b). Further, Hypothesis 2 was rejected as no significant association between adherence to the guideline and PwD's quality of life was found ($\gamma 10$ = -.86, *CI* = -4.18, 2.47, *p* = .61, Lech et al., 2021b).

Table 6 Main descriptive characteristics of PwD

	n	%	M	SD	range
Age			80.5	6.3	63 - 94
Gender (female)	54	59.3			
Years of education			12.7	2.8	8 - 17
Living situation					
Alone	17	18.7			
With spouse/partner	53	58.2			
With another informal caregiver	6	6.6			
In outpatient facility	15	16.5			
Care level (yes)	71	64.6			
Care level 1	5	5.5			
Care level 2	20	22.0			
Care level 3	29	31.9			
Care level 4 or 5	17	18.7			
Type of dementia diagnosis					
Alzheimer's Disease	34	37.4			
Unspecified dementia	32	35.2			
Vascular dementia	17	18.7			
Other type of dementia diagnosis	7	7.7			
MMSE score			18.9	7.8	0 - 30
Severity of cognitive impairment					
Mild	38	51.4			
Moderate	27	36.5			
Severe	9	12.2			
QOL-AD			34.1	5.8	18 - 48

Note: N = 91, M = Mean, SD = Standard Deviation, MMSE = Mini Mental State Examination, QOL-AD = Quality of Life in Alzheimer's Disease questionnaire. Table 6 is based on Table 2 (page 6) of Lech et al. (2021b) and was modified for the present dissertation.

4.   Discussion

The key objective of the present dissertation was to generate evidence from three different stages of the implementation of a two-arm cRCT aiming at improving dementia care in primary care in Germany (DemTab Study). Three manuscripts were published as part of the dissertation, one for each implementation stage of the DemTab Study. *Manuscript I* provided a detailed study protocol of the DemTab Study. *Manuscript II* focused on the recruitment of PCPs and PwD and provided empirical evidence on recruitment rates and their efficacy. *Manuscript III,* based on cross-sectional baseline data obtained from the DemTab Study, provided a sample description of participants, and examines the role of guideline-based dementia care in primary care. Further, factors associated with adherence to the German S3 Dementia Guideline are examined in *Manuscript III.* All three manuscripts provide valuable input to the field of dementia research in primary care. In the following section main results from the three different stages of the DemTab Study will be highlighted and discussed.

4.1 Stage I: RCTs and study protocols

Manuscript I represents the DemTab Study protocol. The main aim of *Manuscript I* was to transparently describe important methodological details of the DemTab Study in accordance with scientific standards. The writing and publishing of study protocols, especially when conducting RCT, represent a scientific and ethical standard which is increasingly considered as crucial for good clinical practice (Tetzlaff et al., 2012; World Medical Association, 2009). In addition, a series of guidelines for the preparation of study protocols were developed to facilitate the drafting of high-quality protocols (Chan et al., 2013). In accordance with existing guidelines (Campbell et al., 2012; Chan et al., 2013), the DemTab Study published prior to the trial's beginning a study protocol in a peer reviewed journal to comply with current scientific standards. Further, during the implementation of the DemTab Study, the study protocol helped assure that our research is conducted in accordance with predefined assumptions and procedures. However, while study protocols endorse the quality of a trial, unexpected and sometime unavoidable events occur during the implementation of a trial, hindering the strict observance to a protocol. Generally, literature differentiates between protocol deviations and protocol violations (Bhatt, 2012): protocol deviation refers to non-serious violations with no significant consequences (e.g., missing a data collection window due to participants brief

absence) while protocol violations reduce the quality of data, make signed informed consent incorrect or threaten participants safety, rights, or welfare. Examples for protocol violations include, among other, inclusion/exclusion criteria are not met, incorrect or missing data assessments or unreported serious adverse events (Bhatt, 2012). The COVID-19 pandemic affected the implementation of the DemTab Study and led to a number of violations, in particular the recruitment in Stage II of the DemTab Study. Problems in the recruitment during the pandemic resulted in the extension of the originally determined inclusion and exclusion criteria. First, as reported in the study protocol, we planned to only include informal caregivers who regularly visited their PwD. Due to the COVID-19 pandemic, for participants living solely (n = 17) regular visits from informal caregivers were restricted, leading to violations of the protocol. Less frequent visits of informal caregivers may have affected the usage of the tablet-based intervention, especially for PwD with major cognitive impairment. However, as most of included PwD lived together with their informal caregivers, we believe this violation of the protocol is of small relevance. Second, in the protocol we reported to include informal caregivers such as family members or close friends of PwD. However, as many of the recruited PCPs worked together with ambulatory dementia shared homes (in Germany so called Demenz WG, n = 8), we decided to extend this inclusion criteria and included PwD living in shared dementia homes and their caregivers in our study. As the main aim of the DemTab Study was to improve ambulatory primary care of dementia and in Germany, shared dementia homes fall under the ambulatory care sector, we believe the impact of this violation is marginal. Third, another impact of the pandemic was with regard to the assessments of cognitive functioning. As described in the study protocol, the assessment of cognitive functioning was conducted with the MMSE. However, as previously described, the in-person assessment of data was changed to phone assessment due to the pandemic. The execution of the MMSE over phone was not feasible. However, this only affected 12 PwD and the MMSE was not a primary outcome of the DemTab Study, thus we believe this violation did not have a major impact on the study results. In spite of various attempts to improve the recruitment of participants, including the adaptation of inclusion as exclusion criteria, the originally estimated sample size of N = 204 could not be reached. This represents a major limitation of the DemTab Study and will affect the interpretation of the results of the evaluation of the tablet-based intervention. While the deviation and violation of study protocols propose a serious problem in RCT (Tripepi et al., 2020), adaptive clinical trials (Mahajan & Gupta, 2010) or pragmatic trials (Ford & Norrie, 2016; Loudon

et al., 2015), which allow for more flexibility and methodological adaptation during a trial such as modifications of eligibility criteria and study protocols, are found to be a more promising approach for translatable dementia research (Baier et al., 2018; Gilmore-Bykovskyi, 2018; Mitchell et al., 2020). In sum, while study protocols are a valuable tool to ensure quality of trials, research, especially dementia research, cannot always act in accordance with the protocol. The present study has shown that violations of the protocol occur during the implementation of a clinical trial. However, it is of great importance to document violations, transparently communicate, and acknowledge violations of study protocol when interpreting results. The author of the present dissertation has regularly updated the DemTab study's registry and has documented all deviations (https://www.isrctn.com/ISRCTN15854413).

4.2 Stage II: Recruitment in primary care research

The main contributions of *Manuscript II* are twofold. First, to describe and empirically evaluate different recruitment strategies. The most effective recruitment strategy in terms of the recruitment rate was the first recruitment round, in particular the strategy to recruiting PCPs via primary care research network. Second, the main aim was to acquire better knowledge for barriers and facilitators of recruitment in primary care. A key facilitator of a successful recruitment was PCPs reporting a similar research interest in the topic. However, as described in *Manuscript II,* recruitment of PCPs and their PwD was challenging. Regardless of the additional negative impact of the COVID-19 pandemic on the recruitment of the DemTab Study, difficulties in the recruitment of PCPs into primary care research were found in previous research (Krebs et al., 2021; Leysen et al., 2019). In addition, the overall response rate of the DemTab Study represented almost 5% which is comparable to previous research (Parkinson et al., 2015). However, the successful engagement and recruitment of PCPs remains an obstacle in the implementation of research. Two main conclusions can be drawn from *Manuscript II.* First, the recruitment of PCPs through primary care research networks represented the most successful strategy. The key role of primary care research networks in development and implementation of primary care research has been acknowledge numerous times (Ngune et al., 2012; Robitaille et al., 2014). Moreover, in Germany, the Initiative of German Practice-Based Research Networks (DESAM-ForNet), a research network uniting regional research networks across Germany, aims to meet the challenge of recruitment

in primary care and to develop sustainable concepts to successfully conduct research together with PCPs. Second, the interest and practical relevance of research topics for PCPs propose a main driver in their decision to participate. This finding is in line with previous research which has acknowledged, that addressing specific topics of interest for participants facilitates the recruitment (Bell-Syer et al., 2011; Treweek et al., 2018). For example, Ferrand Devouge et al. (2019) reported as one of two main conditions for PCP's participation the personally rated relevance of the study topic for clinical practice. In Germany, care provision, especially of older adults, takes place to a large extent in primary care. It is therefore highly relevant to pursue future research in the general practice setting. A sustainable way of engaging with primary care physicians and their patients is inevitable. Both findings outline the great importance of including PCPs and primary care networks in all stages of primary care research. This should include early stages such as the proposal writing for a research project, but also the planning of the study, as well as recruitment, implementation, and evaluation of a research project. The DemTab Study aimed at involving PCPs from an early stage and therefore was conducted during the beginning of the trial interviews and a workshop with PCPs in order to gain a better understanding of the needs and key factors for a good dementia care provision in primary care. However, future research should include scientific and practical perspectives of PCPs in an early stage of the research project such as the writing of a research proposal or the development of the project to ensure a successful implementation. Collaborations with primary care research institutes and networks should be made a priority.

4.3 Stage III: Cross-sectional data on the role of the German S3 Dementia Guideline

Based on cross-sectional baseline data obtained in the DemTab Study, *Manuscript III* of the present dissertation provided a sample description of the study's population and examined the role of evidence-based guideline in the ambulatory care of dementia. The main contributions of *Manuscript III* are threefold. First, this is one of the first studies to examine the role of evidenfce-based German S3 Dementia Guideline in primary care using descriptive statistics as well as multivariate analysis in Germany. Results indicated high levels of adherence to the German S3 Dementia Guideline among PCPs. Second, results revealed that the number of patient visits was negatively associated with adherence to guideline-based recommendation. Third, adherence to the guideline

recommendation was not associated with higher quality of life on PwD. Future studies and interventions concerning guideline-based dementia care in primary care should examine the role of structural factors such as number of patients or time per patient in the delivery of dementia care. Systematically developed, evidence-based guidelines may serve as an important measure for securing and improving the individually appropriate medical care of the population (Ollenschläger, 2015) as they offer an evidence-based framework for diagnosis, treatment, and care. For dementia, the German S3 Dementia Guideline proposes a major action for quality assurance and improvement of dementia care (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016; Jeschke et al., 2011). However, only a few studies have examined the role of guideline-based dementia care in primary care. *Manuscript III* indicated a relatively high adherence to the German S3 Dementia Guideline among PCPs. This finding is not in line with previous research. Past research reported low levels of guideline adherence among PCPs leading to few interventional studies aiming at improving adherence to guideline recommendations (Thyrian et al., 2017; Trautmann & Beesdo-Baum, 2017; Vickrey et al., 2006). However, some of these studies assessed adherence to guidelines based on medical record data, avoiding potential subjective bias of PCPs, while the DemTab Study assessed adherence to the German S3 Dementia Guideline from using self-reported checklists. Further, *Manuscript III* only assessed PCPs reported adherence to guideline recommendations. As previous studies indicate lack of concordance between PCP's and patient's reports on health data (Schneider et al., 2013), data on adherence to guideline recommendations obtained from informal caregivers should be analyzed as part of the final evaluation of the DemTab Study. Further, adherence to specific guideline recommendations varied widely, with the lowest adherence for recommendations on palliative care and assessment of fitness to drive. The importance of both aspects in primary care have been previously discussed (Leve et al., 2021; Pentzek et al., 2015; van der Steen et al., 2014). Further findings of *Manuscript III* included a significant negative association between guideline adherence and number of patients treated in a practice, but no association between guideline-adherence and patients related quality of life. These findings are partially in line with previous research. While the positive impact of time per patient on quality of health care has been discussed numerous times (Irving et al., 2017), a systematic review of clinical trials did not find sufficient empirical evidence of a link between longer consultations and quality of care (Wilson & Childs, 2006). However, in a cross-sectional data among PCPs from Germany,

PCPs strongly believed that their dementia care provision would improve with more time for PwD and their informal caregivers (Thyrian & Hoffmann, 2012). Generally, drawing on data from Germany showing an average consultation length of less than eight minutes (Irving et al., 2017), it appears reasonable to suspect that a great number of patients being treated in a practice is negatively associated with consultation time which also has a negative impact on adherence to guideline recommendation. In particular, present data shows that PCPs report that lack of time and length of the German S3 Dementia Guideline are main barriers of the guideline's implementation in daily practice. However, the present study did not assess length of consultation per patient nor the amount of all the patient's visits within the last three months. Thus, we recommend future research to explore the association between time for care provision, adherence to guidelines and quality of care in more detail.

In sum, future research is urgently needed to examine the benefits, risks, and barriers of implementation of guideline adherence in the primary care setting. Especially in terms of personalized care provision, it is of great importance to focus on an individual care plan, taking into account the patients and their health problems as a whole, rather than the strict following of guideline recommendations. PCPs, as a primary contact point for a variety of health-related problems, especially for older adults, aiming at a holistic and individualized view on their patient, may have various reasons for not following specific guideline recommendation in case of a given patient. Thus, even if evidence-based guidelines may foster health care quality in primary care, future research should developed study designs where not following a specific guideline recommendation does not unquestionably signal lack of quality of care. As the German S3 Dementia Guideline is currently under development, it is highly recommended to include the perspectives of PCPs, researchers, and practitioners from primary care in the development of the new guideline.

4.4 Strengths and weaknesses of the studies

The main strength of the present dissertation lies in the generation of empirical outputs and evidence across different stages of the implementation of a cRCT prior to the final evaluation of the effectiveness of the trial. The strength lies in the concurrent evaluation of different aspects of the execution of the DemTab Study, a trial aiming at improving the primary health care situation of PwD and their informal caregivers. The

three stages included the development of the study design (Stage I), recruitment of participants (Stage II) and collection of cross-sectional baseline data (Stage III). Based on these different stages, three scientific outputs were published in three different, peer reviewed journals. Specifically, two of those manuscripts were published in leading international journals, which according to their impact factor, are among the top 25 percent of the journals within their area (Journal Citation Reports SCIE, SSC). Further, the author of the present dissertation coordinated the DemTab Study and took the main lead on all three manuscripts. In addition, *Manuscript III* is, to this date, the first study which empirically evaluated the role of guideline-based dementia care in primary care with a checklist developed based on the German S3 Dementia Guideline recommendations. Second, due to the study design (cRCT), high internal validity of the DemTab Study was aspired: a study protocol was written and published prior to the trial's beginning (*Manuscript I)*, participants were selected randomly, an experimental manipulation (intervention) was undertaken, and randomization was conducted on PCPs level in order to avoid contamination effects. These factors all help improving internal validity of clinical trials (Bothwell et al., 2016) and represent a major strength of the present dissertation. In terms of external validity, the DemTab Study represents a trial that was conducted in real-life primary care setting. The implementation of the study and the intervention were intended as near on daily practice as possible.

However, several limitations of the DemTab Study must be outlined. First, while it is of great importance to gain a better understanding on how to involve PCPs in research and to examine different recruitment strategies and their success rates (*Manuscript II*), it is crucial to refer to the limits of the generalizability of the present sample. Participants of the DemTab Study were partially recruited through convenience sampling, limiting the generalizability due to potential bias. Generally, convenience sampling may lead to an under-representation of subgroups compared to the general population (Bornstein et al., 2013). In addition, participating PCPs, PwD, and their caregivers selected themselves into the DemTab Study, leading to a higher risk of a self-selection bias, as the decision to participate in a study may be associated with traits that influence outcomes (Ellenberg, 1994). Further, self-selection is found to affect the validity of cross-sectional and longitudinal data (Keiding & Louis, 2016). Therefore, the generalization of PwD of the present study could be limited, as PwD were recruited for a technology based interventional study, and the willingness to participate in a technology-based intervention might be associated with greater cognitive and health status compared to the general

dementia population. With regard to PCPs, although digitalization in the health sector is increasing and health care providers are more than ever willing to incorporate new technologies in their care provision, past research has acknowledged that PCPs are found to be reluctant to new technologies (Wälivaara et al., 2011; Webb et al., 2018). In sum, the external validity of the study population (Pearl & Bareinboim, 2022) of the present study is limited and this limitation must be taken into account when interpreting results. Second, while *Manuscript III* is the first study in Germany examining the role of guideline-based dementia care with a checklist developed based on the German S3 Dementia Guideline recommendations, using a self-developed measure instead of a standardized and validated assessment has its limitations. Because up to this date, there is no standardized assessment on adherence to the German S3 Dementia Guideline, a checklist was developed for the purpose of the DemTab Study. As described in detail in the *2 Methods* section of the present dissertation, a variety of obstacles were raised with regard to the assessment of the primary outcome of the DemTab Study. For example, originally the checklist planned to include a "not applicable" category. Due to PCP's inconsistencies in the selection of this category, the category was eliminated retrospectively and recoded into missing data. Although the comparison of means and correlations across scoring methods with and without the category "not applicable" did not affirm significant differences between model outcomes, the category "not applicable" may be of great value for the evaluation and final scores (Lech et al., 2021b). For example, an individual specific recommendation of the German S3 Dementia Guideline may simply not be applicable for an individual. The current scoring method does not account for that. This limitation must be taken into account when interpreting the present guideline adherence score. Further, PCP's guideline adherence in the DemTab Study was assessed with self-report. Self-reported data is at higher risk to be unreliable, an occurrence that is referred to as the self-reporting bias (Althubaiti, 2016). Self-report bias may arise from social desirability or from recall difficulties (Althubaiti, 2016). This limitation must be kept in mind when interpreting results of the DemTab Study. Although self-reports represent a common assessment method in health research, future research should assess guideline adherence with more objective assessments, such as medical records. Finally, Hypothesis 1 and 2 of *Manuscript III* were tested using cross-sectional data. While our hypotheses were correlational only, and thus, can be answered appropriately using cross-sectional data, causal relationships cannot be drawn based on the results. For example, while there is theoretical and empirical background to assume

that higher number of patients cause lower levels of guideline adherences, the potential causal direction remains unclear (Flanders et al., 1992). Future research should examine multidirectional associations between adherence to dementia guideline recommendations and health outcomes using different study designs and longitudinal data.

4.5 Implications for future research and clinical practice

The main implications of the present dissertation with regard to future research are manifold. First, although study protocols represent a powerful tool to foster scientific and ethical standards in the implementation of RCT, violations of study protocols are sometime unavoidable, especially in dementia research. Pragmatic study designs with more flexibility throughout the trial's implementation may propose a promising approach in dementia research (Mitchell et al., 2020). Present results of barriers in the recruitment of study participants, in particular with regard to inclusion and exclusion criteria, imply a need for more flexible and adjustable – yet still internally valid - study designs and protocols in dementia research (Gilmore-Bykovskyi, 2018; Pallmann et al., 2018). Adaptive designs are found to be potentially more ethical and informative, to make economical use of resources, and may require fewer study participants (Pallmann et al., 2018). Future research should balance between different study designs in order to ensure a successful implementation of a trial. Second, present results indicate the central role of PCPs in dementia care and primary care research on how to improve dementia care in primary care is of great value. However, present results indicate a need for participatory approaches in the realization of primary care research. Recruitment of PCPs and their PwD proposed a major challenge of the DemTab Study (Lech et al., 2021a). Further, results show the importance of inclusion of interests, perspectives, and experiences of PCPs in the design and implementation of primary care research. In the present study we have included PCP's experiences from an early stage, by conducting interviews and workshops with PCPs with regard to the development of the intervention. However, future research should include PCPs perspectives earlier during the planning stage of a research project, ideally when writing the research proposal. The participation of PCPs in the planning stage was already shown to improve research participation (Hummers-Pradier et al., 2014; Tong et al., 2018). Results of the present dissertation outlines this

approach and recommends future research to include PCP's perspective at an earlier stage.

The main implications of the present dissertation with regard to clinical practice are numerous. First, the present dissertation outlines the central role of PCPs in the diagnostics, treatment, and care provision of PwD and their informal caregivers. The central role of PCPs in dementia care provision should be acknowledged not only from research but also from different health and social care providers as well as from decision makers and other stakeholders. An effective dementia workforce is of great clinical importance (Surr et al., 2017), especially in ambulatory dementia care. Present results confirm the high frequency of PCPs visits among PwDs as well as the major role of PCPs in the diagnostics of dementia (Lech et al., 2021a) and are in line with public health recommendations on the necessity of national and international frameworks to foster dementia care in primary care (World Health Organization, 2021). Second, present results suggest that the overall adherence to German S3 Dementia Guideline is high (Lech et al., 2021a). However, adherence to specific recommendations varied widely. Present results indicate, that especially with regard to palliative care and fitness to drive, improvements are urgently needed. Trainings or educational programs to improve dementia care provision propose one strategy to support PCPs with dementia care. In addition to training offered for graduated PCPs, undergraduate medical education on dementia could be fostered in universities. Past research has repeatedly investigated evidence-based content for new university curricular on dementia care (Tullo & Allan, 2011). Both, trainings on dementia before and after graduation of PCPs may propose a promising approach to foster evidence-based dementia care. Finally, although results of the present dissertation show high levels of adherence to guideline, no association between guideline adherence and patient's quality of life was found (Lech et al., 2021a). While past research has proposed evidence-based guidelines as a mean to improve quality of care (Deutsche Gesellschaft für Psychiatrie und Psychotherapie, 2016; Vickrey et al., 2006), present results indicate, that adherence to German S3 Dementia Guideline was not related to quality of life for patients. Based on results of the present dissertation, evidence-based guidelines may not always indicate best quality of care for an individual. As pointed out in the German S3 Dementia Guideline by the DEGAM, a holistic view and individualized care for patients that addresses the primary needs of the patient's social and health situation is of great importance (Deutsche Gesellschaft für Psychiatrie und Psychotherapie, 2016). In that regard, not following a specific recommendation of the

guideline might mean lower adherence but may still propose better quality of care as patient preferences and context may have led to the choice of care. However, awareness about the guideline as well as knowledge on current evidence-based standards and recommendations remain essential for quality care provision. When it comes to lack of adherence to guideline recommendations, future research should incorporate measures of justified versus not justified lack of adherence. We believe that knowledge on evidence-based recommendation foster individualized care provision.

4.6 Outlook of the evaluation of the DemTab Study

To this date, the evaluation of the tablet-based intervention of the DemTab Study is still ongoing. The follow-up data of the DemTab Study was successfully collected, entered and missing data was replaced with multiple imputation (10 replicates) under the assumption that the mechanism of the missing values was Missing at Random (MAR). The author of the present dissertation is in charge of the statistical analysis with regard to the primary and secondary outcomes of the study. Primary and secondary outcomes of the intervention will be analyzed applying intention-to-treat analysis and Linear Mixed Models in order to account for the nested structure of the data. Further, subgroup analyses for differential effects (e.g., of age, gender, cognitive functioning, and care level) will be conducted as exploratory posthoc analyses. In addition, dyadic effects from PwD and informal caregiver (interdependence models) will be estimated. A manuscript on the results of the effectiveness of the DemTab intervention is planned and shall be published. Further, a congress abstract was submitted and accepted to the Annual Scientific Meeting of the Gerontological Society of America (GSA). To examine the particular role of informal caregiving in ambulatory care of dementia, a separate manuscript focusing on informal caregiving will be published by the DemTab research group.

5.   Conclusions

The present dissertation contributes to a more comprehensive understanding of dementia care in primary care and includes new evidence from different stages of the implementation of a two-arm cRCT (DemTab Study) aiming at improving dementia care in Germany. The dissertation discusses the importance and limitations of study protocols in dementia research, from both, a methodological as well as a practical perspective. It examines the effectiveness of different recruitment strategies in primary research for PCPs and PwD and analyzes cross-sectional baseline data on the current dementia care situation and the role of evidence-based guidelines in primary care. Limitations with regard to internal and external validity of the manuscripts were discussed as well as the causality of the data and generalizability and self-selection of the sample. Finally, implications for clinical practice and research were drawn from the present dissertation. The main clinical implications include the acknowledgment of the key role of PCPs in the diagnostic, treatment, and care of dementia in Germany, and trainings and education of PCPs in order to improve care provision. Further, while PCPs overall adherence to the German S3 Dementia Guideline is observable, specific aspects of dementia care require more attention. The main implications for future research include a need for participatory approaches in primary care research where PCP's perspectives and experiences are included in the development and implementation of primary care research. Further, we conclude that more adjustable study designs in dementia research are needed, which still maintain high internal validity but also allow for deviations and flexible adjustments within the implementation of trials.

Reference list

Althubaiti, A. (2016). Information bias in health research: definition, pitfalls, and adjustment methods. *Journal of multidisciplinary healthcare*, *9*, 211-217. https://doi.org/10.2147/JMDH.S104807

Baier, R. R., Mitchell, S. L., Jutkowitz, E., & Mor, V. (2018). Identifying and Supporting Nonpharmacological Dementia Interventions Ready for Pragmatic Trials: Results From an Expert Workshop. *J Am Med Dir Assoc*, *19*(7), 560-562. https://doi.org/10.1016/j.jamda.2018.02.011

Bell-Syer, S. E., Thorpe, L. N., Thomas, K., & Macpherson, H. (2011). GP Participation and Recruitment of Patients to RCTs: Lessons from Trials of Acupuncture and Exercise for Low Back Pain in Primary Care. *Evid Based Complement Alternat Med*, *2011*, 687349. https://doi.org/10.1093/ecam/nen044

Bentley, M. W., Kerr, R., Ginger, M., & Karagoz, J. (2019). Behavioural change in primary care professionals undertaking online education in dementia care in general practice. *Aust J Prim Health*. https://doi.org/10.1071/py18079

Bhatt, A. (2012). Protocol deviation and violation. *Perspectives in clinical research*, *3*(3), 117-117. https://doi.org/10.4103/2229-3485.100663

Bornstein, M. H., Jager, J., & Putnick, D. L. (2013). Sampling in Developmental Science: Situations, Shortcomings, Solutions, and Standards. *Developmental review : DR*, *33*(4), 357-370. https://doi.org/10.1016/j.dr.2013.08.003

Bothwell, L. E., Greene, J. A., Podolsky, S. H., & Jones, D. S. (2016). Assessing the Gold Standard--Lessons from the History of RCTs. *N Engl J Med*, *374*(22), 2175-2181. https://doi.org/10.1056/NEJMms1604593

Bullinger, M., Kirchberger, I., & Ware, J. (1995). Der deutsche SF-36 Health Survey Übersetzung und psychometrische Testung eines krankheitsübergreifenden Instruments zur Erfassung der gesundheitsbezogenen Lebensqualität [journal article]. *Zeitschrift für Gesundheitswissenschaften = Journal of public health*, *3*(1), 21. https://doi.org/10.1007/bf02959944

Bundesministerium für Familie, Senioren, Frauen und Jugend. Retrieved April from https://www.wegweiser-demenz.de/startseite.html

Campbell, M. K., Piaggio, G., Elbourne, D. R., & Altman, D. G. (2012). Consort 2010 statement: extension to cluster randomised trials. *BMJ : British Medical Journal*, *345*, e5661. https://doi.org/10.1136/bmj.e5661

Cao, Q., Tan, C. C., Xu, W., Hu, H., Cao, X. P., Dong, Q., Tan, L., & Yu, J. T. (2020). The Prevalence of Dementia: A Systematic Review and Meta-Analysis. *J Alzheimers Dis*, *73*(3), 1157-1166. https://doi.org/10.3233/jad-191092

Chan, A.-W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gøtzsche, P. C., Krleža-Jerić, K., Hróbjartsson, A., Mann, H., Dickersin, K., Berlin, J. A., Doré, C. J., Parulekar, W. R., Summerskill, W. S. M., Groves, T., Schulz, K. F., Sox, H. C., Rockhold, F. W., Rennie, D., & Moher, D. (2013). SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. *Annals of Internal Medicine*, *158*(3), 200-207. https://doi.org/10.7326/0003-4819-158-3-201302050-00583

Cummings, J. L., Mega, M., Gray, K., Rosenberg-Thompson, S., Carusi, D. A., & Gornbein, J. (1994). The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology*, *44*(12), 2308-2314. https://doi.org/10.1212/wnl.44.12.2308

Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde. (2016). S3-Leitlinie Demenzen [S3 Guideline Dementia]. Leitlinien für Diagnostik und Therapie in der Neurologie [Guidelines for Diagnostics and Therapy in Neurology]. (Langversion – Januar 2016). Retrieved from https://www.dgppn.de/_Resources/Persistent/ade50e44afc7eb8024e7f65ed3f44e995583c3a0/S3-LLDemenzen-240116.pdf

Downs, M., Cook, A., Rae, C., & Collins, K. E. (2000). Caring for patients with dementia: The GP perspective. *Aging & Mental Health*, *4*(4), 301-304. https://doi.org/10.1080/713649963

Edwards, R., Voss, S. E., & Iliffe, S. (2013). The development and evaluation of an educational intervention for primary care promoting person-centred responses to dementia. *Dementia*, *14*(4), 468-482. https://doi.org/10.1177/1471301213499768

Eichler, T., Thyrian, J. R., Fredrich, D., Köhler, L., Wucherer, D., Michalowsky, B., Dreier, A., & Hoffmann, W. (2014). The benefits of implementing a computerized intervention-management-system (IMS) on delivering integrated dementia care in the primary care setting. *Int Psychogeriatr*, *26*(8), 1377-1385. https://doi.org/10.1017/s1041610214000830

Eisele, M., Van Den Bussche, H., Koller, D., Wiese, B., Kaduszkiewicz, H., Maier, W., Glaeske, G., Steinmann, S., Wegscheider, K., & Schön, G. (2010). Utilization patterns of ambulatory medical care before and after the diagnosis of dementia in

Germany–results of a case-control study. *Dementia and geriatric cognitive disorders*, *29*(6), 475-483. https://doi.org/10.1159/000310350

Ellenberg, J. H. (1994). Selection bias in observational and experimental studies. *Statistics in medicine*, *13*(5-7), 557-567.

Ferrand Devouge, E., Biard, M., Beuzeboc, J., Tavolacci, M. P., & Schuers, M. (2019). Motivations and willingness of general practitioners in France to participate in primary care research as investigators. *Fam Pract*, *36*(5), 552-559. https://doi.org/10.1093/fampra/cmy126

Flanders, W. D., Lin, L., Pirkle, J. L., & Caudill, S. P. (1992). Assessing the Direction of Causality in Cross-sectional Studies. *American Journal of Epidemiology*, *135*(8), 926-935. https://doi.org/10.1093/oxfordjournals.aje.a116388

Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). "Mini-mental state": A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*, *12*(3), 189-198. https://doi.org/10.1016/0022-3956(75)90026-6

Ford, I., & Norrie, J. (2016). Pragmatic Trials. *New England Journal of Medicine*, *375*(5), 454-463. https://doi.org/10.1056/NEJMra1510059

Franz, C. E., Barker, J. C., Kim, K., Flores, Y., Jenkins, C., Kravitz, R. L., & Hinton, L. (2010). When help becomes a hindrance: mental health referral systems as barriers to care for primary care physicians treating patients with Alzheimer's disease. *The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry*, *18*(7), 576-585. https://doi.org/10.1097/jgp.0b013e3181a76df7

Frost, R., Walters, K., Aw, S., Brunskill, G., Wilcock, J., Robinson, L., Knapp, M., Dening, K. H., Allan, L., Manthorpe, J., Rait, G., & team, o. b. o. t. P. S. p. (2020). Effectiveness of different post-diagnostic dementia care models delivered by primary care: a systematic review. *British Journal of General Practice*, *70*(695), e434-e441. https://doi.org/10.3399/bjgp20X710165

Gauggel, S., & Birkner, B. (1999). Validität und Reliabilität einer deutschen Version der Geriatrischen Depressionsskala (GDS). [Validity and reliability of a German version of the Geriatric Depression Scale (GDS).]. *Zeitschrift für Klinische Psychologie*, *28*(1), 18-27. https://doi.org/10.1026//0084-5345.28.1.18

Gilmore-Bykovskyi, A. (2018). Commentary on Apathy as a Model for Investigating Behavioral and Psychological Symptoms in Dementia. *Journal of the American*

Geriatrics   Society,   *66   Suppl   1*(Suppl   1),   S13-S16.
https://doi.org/10.1111/jgs.15325

Gräßel, E., & Leutbecher, M. (2001). Häusliche Pflege-Skala HPS. *Zur Erfassung der Belastung bei betreuenden oder pflegenden Personen*, (2. ed). Ebersberg: Vless.

Heidenblut, S., & Zank, S. (2010). Entwicklung eines neuen Depressionsscreenings für den Einsatz in der Geriatrie [journal article]. *Zeitschrift für Gerontologie und Geriatrie*, *43*(3), 170-176. https://doi.org/10.1007/s00391-009-0067-z

Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L) [journal article]. *Quality of Life Research*, *20*(10), 1727-1736. https://doi.org/10.1007/s11136-011-9903-x

Heuschmann, P. U., Kolominsky-Rabas, P. L., Nolte, C. H., Hünermund, G., Ruf, H. U., Laumeier, I., Meyrer, R., Alberti, T., Rahmann, A., Kurth, T., & Berger, K. (2005). Untersuchung der Reliabilität der deutschen Version des Barthel-Index sowie Entwicklung einer postalischen und telefonischen Fassung für den Einsatz bei Schlaganfall-Patienten [The Reliability of the German Version of the Barthel-Index and the Development of a Postal and Telephone Version for the Application on Stroke   Patients].   *Fortschr   Neurol   Psychiatr*,   *73*(02),   74-82. https://doi.org/10.1055/s-2004-830172

Hummers-Pradier, E., Chenot, J., & Scherer, M. (2014). Sind Hausarztpraxen Forschungsinfrastruktur.   *Z   Allg   Med*,   *89*,   317-322. https://doi.org/10.3238/zfa.2014.0317-0322

Irving, G., Neves, A. L., Dambha-Miller, H., Oishi, A., Tagashira, H., Verho, A., & Holden, J. (2017). International variations in primary care physician consultation time: a systematic   review   of   67   countries.   *BMJ   Open*,   *7*(10),   e017902. https://doi.org/10.1136/bmjopen-2017-017902

Jeschke, E., Ostermann, T., Vollmar, H. C., Tabali, M., Schad, F., & Matthes, H. (2011). Prescribing patterns in dementia: a multicentre observational study in a German network   of   CAM   physicians.   *BMC   Neurology*,   *11*(1),   99. https://doi.org/10.1186/1471-2377-11-99

Jones, G., & Abbasi, K. (2004). Trial protocols at the BMJ. *BMJ*, *329*(7479), 1360. https://doi.org/10.1136/bmj.329.7479.1360

Kaduszkiewicz, H., & van den Bussche, H. (2022). Demenz. In J. Chenot & M. Scherer (Eds.), *Allgemeinmedizin* (pp. 567-579). Elsevier GmbH.

Kaduszkiewicz, H., Wiese, B., & van den Bussche, H. (2008). Self-reported competence, attitude and approach of physicians towards patients with dementia in ambulatory care: Results of a postal survey. *BMC Health Services Research*, *8*(1), 54. https://doi.org/10.1186/1472-6963-8-54

Kaduszkiewicz, H., Zimmermann, T., van Den Bussche, H., Bachmann, C., Wiese, B., Bickel, H., Mösch, E., Romberg, H. P., Jessen, F., Cvetanovska-Pllashniku, G., Maier, W., Riedel-Heller, S. G., Luppa, M., Sandholzer, H., Weyerer, S., Mayer, M., Hofmann, A., Fuchs, A., Abholz, H. H., & Pentzek, M. (2010). Do general practitioners recognize mild cognitive impairment in their patients? *The journal of nutrition, health & aging*, *14*(8), 697-702. https://doi.org/10.1007/s12603-010-0038-5

Karrer, K., Glaser, C., Clemens, C., & Bruder, C. (2009). *Technikaffinität erfassen – der Fragebogen TA-EG* (Vol. 29).

Keiding, N., & Louis, T. A. (2016). Perils and potentials of self-selected entry to epidemiological studies and surveys. *Journal of the Royal Statistical Society: Series A (Statistics in Society)*, *179*(2), 319-376.

Krebs, F., Lorenz, L., Nawabi, F., Lück, I., Bau, A.-M., Alayli, A., & Stock, S. (2021). Recruitment in Health Services Research—A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers. *International Journal of Environmental Research and Public Health*, *18*(19), 10521. https://www.mdpi.com/1660-4601/18/19/10521

Laver, K., Cations, M., Radisic, G., de la Perrelle, L., Woodman, R., Fitzgerald, J. A., Kurrle, S., Cameron, I. D., Whitehead, C., Thompson, J., Kaambwa, B., Hayes, K., & Crotty, M. (2020). Improving adherence to guideline recommendations in dementia care through establishing a quality improvement collaborative of agents of change: an interrupted time series study. *Implementation Science Communications*, *1*(1), 80. https://doi.org/10.1186/s43058-020-00073-x

Lech, S., O'Sullivan, J. L., Drewelies, J., Herrmann, W., Spang, R. P., Voigt-Antons, J. N., Nordheim, J., & Gellert, P. (2021b). Dementia care and the role of guideline adherence in primary care: cross-sectional findings from the DemTab study. *BMC Geriatrics*, *21*(1), 717. https://doi.org/10.1186/s12877-021-02650-8

Lech, S., O'Sullivan, J. L., Wellmann, L., Supplieth, J., Döpfmer, S., Gellert, P., Kuhlmey, A., & Nordheim, J. (2021a). Recruiting general practitioners and patients with dementia into a cluster randomised controlled trial: strategies, barriers and

facilitators. *BMC Medical Research Methodology*, *21*(1), 61. https://doi.org/10.1186/s12874-021-01253-6

Lech, S., O'Sullivan, J. L., Gellert, P., Voigt-Antons, J. N., Greinacher, R., & Nordheim, J. (2019). Tablet-Based Outpatient Care for People With Dementia. *GeroPsych*, *32*(3), 135-144. https://doi.org/10.1024/1662-9647/a000210

Leve, V., Ilse, K., Ufert, M., Wilm, S., & Pentzek, M. (2017). Driving and dementia : An issue for general practice?! *Z Gerontol Geriatr*, *50*(Suppl 2), 55-62. https://doi.org/10.1007/s00391-017-1234-2

Leve, V., Pentzek, M., Fuchs, A., Bickel, H., Weeg, D., Weyerer, S., Werle, J., König, H. H., Hajek, A., Lühmann, D., van den Bussche, H., Wiese, B., Oey, A., Heser, K., Wagner, M., Luppa, M., Röhr, S., Maier, W., Scherer, M., . . . Riedel-Heller, S. G. (2021). GPs' awareness of car driving among oldest patients: exploratory results from a primary care cohort. *BJGP Open*, *5*(2). https://doi.org/10.3399/bjgpo.2020.0145

Leysen, B., Van den Eynden, B., Janssens, A., & Wens, J. (2019). Recruiting general practitioners for palliative care research in primary care: real-life barriers explained. *BMC Family Practice*, *20*(1), 40. https://doi.org/10.1186/s12875-019-0930-y

Lim, W., Arnold, D. M., Bachanova, V., Haspel, R. L., Rosovsky, R. P., Shustov, A. R., & Crowther, M. A. (2008). Evidence-Based Guidelines—An Introduction. *Hematology*, *2008*(1), 26-30. https://doi.org/10.1182/asheducation-2008.1.26

Logsdon, R. G., Gibbons, L. E., McCurry, S. M., & Teri, L. (2002). Assessing quality of life in older adults with cognitive impairment. *Psychosom Med*, *64*(3), 510-519.

Loudon, K., Treweek, S., Sullivan, F., Donnan, P., Thorpe, K. E., & Zwarenstein, M. (2015). The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ : British Medical Journal*, *350*, h2147. https://doi.org/10.1136/bmj.h2147

Lyketsos, C. G., Carrillo, M. C., Ryan, J. M., Khachaturian, A. S., Trzepacz, P., Amatniek, J., Cedarbaum, J., Brashear, R., & Miller, D. S. (2011). Neuropsychiatric symptoms in Alzheimer's disease. *Alzheimer's & Dementia*, *7*(5), 532-539. https://doi.org/https://doi.org/10.1016/j.jalz.2011.05.2410

Mahajan, R., & Gupta, K. (2010). Adaptive design clinical trials: Methodology, challenges and prospect. *Indian journal of pharmacology*, *42*(4), 201-207. https://doi.org/10.4103/0253-7613.68417

Mansfield, E., Noble, N., Sanson-Fisher, R., Mazza, D., & Bryant, J. (2018). Primary Care Physicians' Perceived Barriers to Optimal Dementia Care: A Systematic Review. *The Gerontologist*, *59*(6), e697-e708. https://doi.org/10.1093/geront/gny067

Martínez-Alcalá, C. I., Pliego-Pastrana, P., Rosales-Lagarde, A., Lopez-Noguerola, J. S., & Molina-Trinidad, E. M. (2016). Information and Communication Technologies in the Care of the Elderly: Systematic Review of Applications Aimed at Patients With Dementia and Caregivers. *JMIR Rehabil Assist Technol*, *3*(1), e6. https://doi.org/10.2196/rehab.5226

Mitchell, S. L., Mor, V., Harrison, J., & McCarthy, E. P. (2020). Embedded Pragmatic Trials in Dementia Care: Realizing the Vision of the NIA IMPACT Collaboratory [https://doi.org/10.1111/jgs.16621]. *Journal of the American Geriatrics Society*, *68*(S2), S1-S7. https://doi.org/https://doi.org/10.1111/jgs.16621

Moyle, W. (2019). The promise of technology in the future of dementia care. *Nature Reviews Neurology*, *15*(6), 353-359. https://doi.org/10.1038/s41582-019-0188-y

Murphy, K., O'Connor, D. A., Browning, C. J., French, S. D., Michie, S., Francis, J. J., Russell, G. M., Workman, B., Flicker, L., & Eccles, M. P. (2014). Understanding diagnosis and management of dementia and guideline implementation in general practice: a qualitative study using the theoretical domains framework. *Implementation Science*, *9*(1), 1-13. https://doi.org/10.1186/1748-5908-9-31

Ngune, I., Jiwa, M., Dadich, A., Lotriet, J., & Sriram, D. (2012). Effective recruitment strategies in primary care research: a systematic review. *Qual Prim Care*, *20*(2), 115-123.

Nichols, E., Szoeke, C. E., Vollset, S. E., Abbasi, N., Abd-Allah, F., Abdela, J., ... & Murray, C. J. (2019). Global, regional, and national burden of Alzheimer's disease and other dementias, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Neurol*, *18*(1), 88-106. https://doi.org/10.1016/s1474-4422(18)30403-4

O'Sullivan, J. L., Lech, S., Gellert, P., Grittner, U., Voigt-Antons, J.-N., Möller, S., Kuhlmey, A., & Nordheim, J. (2022). A tablet-based intervention for activating nursing home residents with dementia: results from a cluster-randomized controlled trial. *International Psychogeriatrics*, *34*(2), 129-141. https://doi.org/10.1017/S1041610221000818

Pallmann, P., Bedding, A. W., Choodari-Oskooei, B., Dimairo, M., Flight, L., Hampson, L. V., Holmes, J., Mander, A. P., Odondi, L. o., Sydes, M. R., Villar, S. S., Wason, J.

M. S., Weir, C. J., Wheeler, G. M., Yap, C., & Jaki, T. (2018). Adaptive designs in clinical trials: why use them, and how to run and report them. *BMC Medicine*, *16*(1), 29. https://doi.org/10.1186/s12916-018-1017-7

Parkinson, A., Jorm, L., Douglas, K. A., Gee, A., Sargent, G. M., Lujic, S., & McRae, I. S. (2015). Recruiting general practitioners for surveys: reflections on the difficulties and some lessons learned. *Aust J Prim Health*, *21*(2), 254-258. https://doi.org/10.1071/py13129

Pearl, J., & Bareinboim, E. (2022). External Validity: From <i>Do</i>-Calculus to Transportability Across Populations. In *Probabilistic and Causal Inference: The Works of Judea Pearl* (Vol. 36, pp. 451–482). Association for Computing Machinery. https://doi.org/10.1145/3501714.3501741

Pentzek, M., Michel, J. V., Ufert, M., Vollmar, H. C., Wilm, S., & Leve, V. (2015). Fahrtauglichkeit bei Demenz – Theoretische Rahmung und Konzept einer Vorgehensempfehlung für die Hausarztpraxis. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*, *109*(2), 115-123. https://doi.org/https://doi.org/10.1016/j.zefq.2015.03.005

Pentzek, M., Vollmar, H. C., Wilm, S., & Leve, V. (2017). Putting dementia awareness into general practice [journal article]. *Zeitschrift für Gerontologie und Geriatrie*, *50*(2), 44-47. https://doi.org/10.1007/s00391-017-1206-6

Pentzek, M., Wagner, M., Abholz, H.-H., Bickel, H., Kaduszkiewicz, H., Wiese, B., Weyerer, S., König, H.-H., Scherer, M., Riedel-Heller, S. G., Maier, W., Koppara, A., & for the AgeCoDe Study, G. (2019). The value of the GP's clinical judgement in predicting dementia: a multicentre prospective cohort study among patients in general practice. *British Journal of General Practice*, *69*(688), e786. https://doi.org/10.3399/bjgp19X706037

Perry, M., Drašković, I., Lucassen, P., Vernooij-Dassen, M., van Achterberg, T., & Rikkert, M. O. (2011). Effects of educational interventions on primary dementia care: a systematic review. *International journal of geriatric psychiatry*, *26*(1), 1-11. https://doi.org/https://doi.org/10.1002/gps.2479

Pit, S. W., Vo, T., & Pyakurel, S. (2014). The effectiveness of recruitment strategies on general practitioner's survey response rates – a systematic review. *BMC Medical Research Methodology*, *14*(1), 76. https://doi.org/10.1186/1471-2288-14-76

Prince, M., Comas-Herrera, A., Knapp, M., Guerchet, M., & Karagiannidou, M. (2016). World Alzheimer report 2016: improving healthcare for people living with dementia:

coverage, quality and costs now and in the future. Retreived from: https://www.alzint.org/u/WorldAlzheimerReport2016.pdf

Robitaille, H., Légaré, F., & Tre, G. (2014). A Systematic Process for Recruiting Physician-Patient Dyads in Practice-based Research Networks (PBRNs). *The Journal of the American Board of Family Medicine*, *27*(6), 740. https://doi.org/10.3122/jabfm.2014.06.140035

Sahin, D., Yaffe, M. J., Sussman, T., & McCusker, J. (2014). A mixed studies literature review of family physicians' participation in research. *Fam Med*, *46*(7), 503-514.

Schneider, A., Wartner, E., Schumann, I., Hörlein, E., Henningsen, P., & Linde, K. (2013). The impact of psychosomatic co-morbidity on discordance with respect to reasons for encounter in general practice. *Journal of Psychosomatic Research*, *74*(1), 82-85. https://doi.org/https://doi.org/10.1016/j.jpsychores.2012.09.007

Sclan, S. G., & Reisberg, B. (1992). Functional Assessment Staging (FAST) in Alzheimer's Disease: Reliability, Validity, and Ordinality. *International Psychogeriatrics*, *4*(3), 55-69. https://www.cambridge.org/core/article/functional-assessment-staging-fast-in-alzheimers-disease-reliability-validity-and-ordinality/C586A7993E5C2DAD2FD986D45ADB9876

Smith, R., Martin, A., Wright, T., Hulbert, S., & Hatzidimitriadou, E. (2021). Integrated dementia care: A qualitative evidence synthesis of the experiences of people living with dementia, informal carers and healthcare professionals. *Archives of Gerontology and Geriatrics*, *97*, 104471. https://doi.org/https://doi.org/10.1016/j.archger.2021.104471

Summerskill, W., Collingridge, D., & Frankish, H. (2009). Protocols, probity, and publication. *The Lancet*, *373*(9668), 992. https://doi.org/10.1016/S0140-6736(09)60590-0

Surr, C. A., Gates, C., Irving, D., Oyebode, J., Smith, S. J., Parveen, S., Drury, M., & Dennison, A. (2017). Effective Dementia Education and Training for the Health and Social Care Workforce: A Systematic Review of the Literature. *Review of Educational Research*, *87*(5), 966-1002. https://doi.org/10.3102/0034654317723305

Tetzlaff, J. M., Chan, A.-W., Kitchen, J., Sampson, M., Tricco, A. C., & Moher, D. (2012). Guidelines for randomized clinical trial protocol content: a systematic review. *Systematic reviews*, *1*, 43-43. https://doi.org/10.1186/2046-4053-1-43

Thyrian, J. R., Boekholt, M., Hoffmann, W., Leiz, M., Monsees, J., Schmachtenberg, T., Schumacher-Schönert, F., & Stentzel, U. (2020). The prevalence of people with dementia in Germany-A nationwide analysis at the district level [Die Prävalenz an Demenz erkrankter Menschen in Deutschland – eine bundesweite Analyse auf Kreisebene]. *Der Nervenarzt*, *91*(11), 1058-1061. https://doi.org/10.1007/s00115-020-00923-y

Thyrian, J. R., Hertel, J., Wucherer, D., Eichler, T., Michalowsky, B., Dreier-Wolfgramm, A., Zwingmann, I., Kilimann, I., Teipel, S., & Hoffmann, W. (2017). Effectiveness and Safety of Dementia Care Management in Primary Care: A Randomized Clinical Trial. *JAMA Psychiatry*, *74*(10), 996-1004. https://doi.org/10.1001/jamapsychiatry.2017.2124

Thyrian, J. R., & Hoffmann, W. (2012). Dementia care and general physicians--a survey on prevalence, means, attitudes and recommendations. *Cent Eur J Public Health*, *20*(4), 270-275. https://doi.org/10.21101/cejph.a3751

Tong, S. F., Ng, C. J., Lee, V. K. M., Lee, P. Y., Ismail, I. Z., Khoo, E. M., Tahir, N. A., Idris, I., Ismail, M., & Abdullah, A. (2018). Decision making process and factors contributing to research participation among general practitioners: A grounded theory study. *PLoS One*, *13*(4), e0196379. https://doi.org/10.1371/journal.pone.0196379

Trautmann, S., & Beesdo-Baum, K. (2017). The Treatment of Depression in Primary Care. *Deutsches Arzteblatt international*, *114*(43), 721-728. https://doi.org/10.3238/arztebl.2017.0721

Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K., & Gardner, H. (2018). Strategies to improve recruitment to randomised trials. *Cochrane Database Syst Rev*, *2*(2), Mr000013. https://doi.org/10.1002/14651858.MR000013.pub6

Tripepi, G., Chesnaye, N. C., Dekker, F. W., Zoccali, C., & Jager, K. J. (2020). Intention to treat and per protocol analysis in clinical trials [https://doi.org/10.1111/nep.13709]. *Nephrology*, *25*(7), 513-517. https://doi.org/https://doi.org/10.1111/nep.13709

Tullo, E., & Allan, L. (2011). What should we be teaching medical students about dementia? *International Psychogeriatrics*, *23*(7), 1044-1050. https://doi.org/10.1017/S1041610211000536

Turner, L., Moher, D., Shamseer, L., Weeks, L., Peters, J., Plint, A., Altman, D. G., & Schulz, K. F. (2011). The influence of CONSORT on the quality of reporting of randomised controlled trials: an updated review. *Trials*, *12*(1), A47. https://doi.org/10.1186/1745-6215-12-S1-A47

Turner, S., Iliffe, S., Downs, M., Wilcock, J., Bryans, M., Levin, E., Keady, J., & O'Carroll, R. (2004). General practitioners' knowledge, confidence and attitudes in the diagnosis and management of dementia. *Age Ageing*, *33*(5), 461-467. https://doi.org/10.1093/ageing/afh140

van der Steen, J. T., Radbruch, L., Hertogh, C. M., de Boer, M. E., Hughes, J. C., Larkin, P., Francke, A. L., Jünger, S., Gove, D., Firth, P., Koopmans, R. T., & Volicer, L. (2014). White paper defining optimal palliative care in older people with dementia: a Delphi study and recommendations from the European Association for Palliative Care. *Palliat Med*, *28*(3), 197-209. https://doi.org/10.1177/0269216313493685

Vickrey, B., Mittman, B., Connor, K., Pearson, M., Della Penna, R., Ganiats, T., Demonte, R., Chodosh, J., Cui, X., Vassar, S., Duan, N., & Lee, M. (2006). The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial. *Annals of Internal Medicine*, *145*(10), 713-726. https://doi.org/10.7326/0003-4819-145-10-200611210-00004

Wälivaara, B. M., Andersson, S., & Axelsson, K. (2011). General practitioners' reasoning about using mobile distance-spanning technology in home care and in nursing home care. *Scand J Caring Sci*, *25*(1), 117-125. https://doi.org/10.1111/j.1471-6712.2010.00800.x

Wang, M., Xu, X., Huang, Y., Shao, S., Chen, X., Li, J., & Du, J. (2020). Knowledge, attitudes and skills of dementia care in general practice: a cross-sectional study in primary health settings in Beijing, China. *BMC Family Practice*, *21*(1), 89. https://doi.org/10.1186/s12875-020-01164-3

Wang, S., Yan, D., Temkin-Greener, H., & Cai, S. (2021). Nursing home admissions for persons with dementia: Role of home- and community-based services [https://doi.org/10.1111/1475-6773.13715]. *Health Services Research*, *56*(6), 1168-1178. https://doi.org/https://doi.org/10.1111/1475-6773.13715

Webb, M. J., Wadley, G., & Sanci, L. A. (2018). Experiences of General Practitioners and Practice Support Staff Using a Health and Lifestyle Screening App in Primary Health Care: Implementation Case Study. *JMIR Mhealth Uhealth*, *6*(4), e105. https://doi.org/10.2196/mhealth.8778

Wilson, A. D., & Childs, S. (2006). Effects of interventions aimed at changing the length of primary care physicians' consultation. *Cochrane Database Syst Rev*(1), Cd003540. https://doi.org/10.1002/14651858.CD003540.pub2

World Health Organization. (2021). *Global status report on the public health response to dementia*. Retrieved from: https://www.who.int/publications/i/item/9789240033245

World Medical Association. (2009). Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. *Jahrbuch für Wissenschaft und Ethik*, *14*(1), 233-238. https://doi.org/doi:10.1515/9783110208856.233

Statutory Declaration

"I, Sonia Lech, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic *Dementia in primary care – Results of the implementation of a cluster randomized controlled trial (Demenz in der hausärztlichen Versorgung – Ergebnisse der Durchführung einer cluster-randomisierten kontrollierten Studie)* independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

Furthermore, I declare that I have correctly marked all of the data, the analyses, and the conclusions generated from data obtained in collaboration with other persons, and that I have correctly marked my own contribution and the contributions of other persons (cf. declaration of contribution). I have correctly marked all texts or parts of texts that were generated in collaboration with other persons.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; http://www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me."

Date   Signature

Declaration of your own contribution to the publications

Sonia Lech contributed the following to the below listed publications:

Publication 1: Lech, S., O'Sullivan, J. L., Gellert, P., Voigt-Antons, J. N., Greinacher, R., & Nordheim, J., (2019). Tablet-Based Outpatient Care for People With Dementia, *GeroPsych*
Contribution (please set out in detail):
Prior to the DemTab Study's beginning the research team established the methods and the study design of the study. I took the lead of coordinating and protocolling this process. I conducted literature research without support, independently designed and filled Table 1, and designed the first draft of the study protocol. Prior to the submission, I registered the study with the internationally recognized study registry ISRCTN and took part in the writing of the ethical approval for the study and the submission to the ethics committee of the Charité – Universitätsmedizin. The selection of the target journals was done in consultation with my supervisor Dr. rer. medic. Johanna Nordheim. After the manuscript had been revised by co-authors, I took full responsibility for the preparation and submission of the manuscript, the correspondence with the editor as well as for the revisions and response letters.

Publication 2: Lech, S., O'Sullivan, J. L., Wellmann, L., Supplieth, J., Döpfmer, S., Gellert, P., Kuhlmey, A., & Nordheim, J., (2021a). Recruiting general practitioners and patients with dementia into a cluster randomized controlled trial: strategies, barriers and facilitators, *BMC Medical Research Methodology*
Contribution (please set out in detail):
I oversaw the selection of different recruitment strategies and participated in the recruitment of participants. Based on recruitment data collected during the DemTab Study, I independently conducted literature research on the recruitment of primary care physicians and their patients, formulated the central research questions, conducted the analysis of data and prepared the first final draft of the manuscript. Apart from Figure 2 all figures and tables of the manuscript were designed and filled by me. The whole process was supervised by my supervisor Dr. rer. medic. Johanna Nordheim. The first complete draft of the manuscript was prepared by me. After the manuscript had been revised by co-authors, I took care of addressing all comments and revising the manuscript. Further, I took the responsibility of researching potential journals. The selection of the target journal was done in consultation with my supervisor. The preparation and submission of the manuscript as well as the correspondence with the editor, the revisions and response letters were primarily my responsibility.

Publication 3: Lech, S., O'Sullivan, J. L., Drewelies, J., Herrmann, W., Spang, R. P., Voigt-Antons, J. N., Nordheim, J., & Gellert, P., (2021b). Dementia care and the role of guideline adherence in primary care: cross-sectional findings from the DemTab Study, *BMC Geriatrics*
Contribution (please set out in detail):
I oversaw the data collection process and supervised data collectors. Prior to the data collection, I was in charge of the selection of standardized and validated assessments. Based on the collected baseline data

and literature research, I independently formulated the central questions of the publication and operationalized the primary target variable as well as possible independent influencing variables. I independently processed the raw data set for my analyses and prepared it for the statistical analyses. These activities included labeling and categorizing variables as well as cleaning and organizing the data set. I independently researched suggestions for evaluation methods. I developed the final analysis concept under the supervision of Prof. Dr. Paul Gellert. I performed the calculations independently. I independently designed and filled all the tables and figures contained in the publication. The first complete draft of the manuscript was prepared by me. After the manuscript had been revised by co-authors, I took care revising the manuscript. After the manuscript had been finalized, it was proof-read by a native speaker. The selection of the target journal was done in consultation with my supervisor. The preparation and submission of the manuscript as well as the correspondence with the editor and the revisions and response letters were primarily my responsibility.

_____

Signature, date and stamp of first supervising university professor / lecturer

_____

Signature of doctoral candidate

Excerpt from Journal Summary List for Manuscript I

The journal *GeroPsych* is not listed in the Journal Summary List (ISi Web of KnowledgeSM). Therefore, for *Manuscript I* (Lech et al., 2019), no excerpt from the Journal Citation Report (Editions SCIE, SSCI) is provided. An alternative list was provided to the PhD committee separately (please, see Votum Informativum and attached documents).

Printing copy of Manuscript I

Full-Length Research Report

Tablet-Based Outpatient Care for People With Dementia

The DemTab Study Protocol

Sonia Lech[1], Julie L. O'Sullivan[1], Paul Gellert[1], Jan-Niklas Voigt-Antons[2,3], Robert Greinacher[2], and Johanna Nordheim[1]

[1]Institute for Medical Sociology and Rehabilitation Science, Charité – Universitätsmedizin Berlin, Germany
[2]Quality and Usability Lab, Technische Universität Berlin, Germany
[3]German Research Center for Artificial Intelligence (DFKI), Berlin, Germany

Abstract: Most people with dementia (PwD) are treated on an outpatient basis, predominantly by general practitioners (GPs). This article provides a detailed protocol of a study aimed at developing and evaluating a tablet-based intervention to improve outpatient dementia care by fostering guideline-based treatment. A cluster-randomized controlled trial with an intervention group (tablet-based intervention) and a control group (treatment as usual plus information handbook) will be conducted. Clusters will be randomized at GP level. Primary outcome is defined as adherence to dementia guideline recommendations after 9 months. Secondary outcomes include various health outcomes assessed in PwD (e.g., quality of life) and informal caregivers (e.g., caregiver burden). Outcomes will be analyzed by an intention-to-treat analysis and using mixed models.

Keywords: dementia, general practice, information and communication technology, guideline-based care, informal caregiver

Dementia has become a national and global public health priority. According to the World Alzheimer's Report, in 2015 46.8 million people worldwide were living with dementia. This number is estimated to increase to 74.7 million by 2030 and to 131.5 million by 2050 (Livingston et al., 2017; Prince et al., 2015). In Germany, according to estimates, in 2015 there were 1.6 million people with dementia (PwD) (Prince et al., 2015).

Dementia is a syndrome characterized by difficulties with memory, language, problem solving, and other cognitive skills that affect a person's capacity to perform everyday activities (Alzheimer's Association, 2017). It affects not only those living with dementia, but also their family and informal caregivers, the healthcare system, and society as a whole (Prince et al., 2015; Winblad et al., 2016; World Health Organization, 2012). Further, providing requisite treatment and care often challenges the skills and capacity of healthcare professionals (World Health Organization, 2012). In Germany, the majority of PwD are treated on an outpatient basis, predominantly by general practitioners (GPs) (Albrecht & Sander, 2015; Strohmaier et al., 2018). However, GPs are often challenged by dementia care and have acknowledged the need for further training and education in order to deliver optimal care (Foley, Boyle, Jennings, & Smithson, 2017; Koch & Iliffe, 2010; Mitchell, Meader, &

Pentzek, 2011; Olafsdottir, Foldevi, & Marcusson, 2001; Turner et al., 2004).

In Germany, the fundamental role of GPs in dementia care has been highlighted in many studies (Kaduszkiewicz, Wiese, & van den Bussche, 2008; Leve, Ilse, Ufert, Wilm, & Pentzek, 2017; Pentzek, Fuchs, Abholz, & Wollny, 2011; Pentzek et al., 2009; Pentzek, Vollmar, Wilm, & Leve, 2017; Thyrian & Hoffmann, 2012). For example, based on survey data from 321 German GPs, Thyrian and Hoffmann (2012) concluded, among other things, that dementia care is a relevant and prevalent topic for GPs. A different study conducted by Kaduszkiewicz et al. (2008) concluded that training the competences and general attitudes of GPs toward dementia care could be beneficial for both patients and their caregivers. The central role of GPs in optimal dementia care was highlighted in major national (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) and international (National Collaborating Centre for Mental Health, 2007) dementia care guidelines. The German Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) provides evidence-based recommendations on the prevention, diagnosis, therapy, and support of PwD and their caregivers. The guideline recommendations are based

on existing scientific evidence and are intended to improve the quality of treatment and care for PwD and their caregivers.

The development, dissemination, and implementation of dementia guidelines form a key strategy for quality assurance and improvement of dementia care (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016; Jeschke et al., 2011). Despite existing evidence that guideline recommendations can improve symptoms and delay institutionalization of PwD (Vickrey et al., 2006), these recommendations often lack adherence in care practice. Information and communication technologies (ICTs) may be a promising approach to improve guideline-based outpatient dementia care in GP practices. The German Center for Neurodegenerative Diseases (DZNE) conducted the research project DelpHi (Dementia: Life- and Person-Centered Help in Mecklenburg-Western Pomerania), aimed at implementing and evaluating an innovative system for PwD and their caregivers (Thyrian et al., 2012). The IT-based intervention developed in that study was based on the German Dementia Guideline and resulted in an improvement of quality of dementia primary care (Eichler et al., 2014). Further, in the same study, Thyrian et al. (2016) found that dementia care management in primary care was highly appreciated by GPs.

On the patient and caregiver side, Thyrian et al. (2017) provided evidence for the effectiveness of dementia care management and its potential to improve patient-related outcomes (reduction of behavioral and psychological symptoms) as well as caregiver-related outcomes (decrease of caregiver burden). The DelpHi study provided a variety of empirical evidence for the efficacy of computer-based intervention-management system in primary care of dementia for GPs, PwD, and their informal caregivers. In a follow-on project, the DZNE will investigate how caregivers can be better supported in providing homecare to PwD. Further, Schultz, Putze, and Kruse (2014) provided evidence that ICTs, such as tablet computers, could have great potential for supporting GPs in patient-centered and guideline-oriented treatment and for enabling PwD and informal caregivers in the implementation of effective therapeutic approaches in their home environment.

In summary, it has been shown that assistive and health technologies can be a valuable contribution in dementia care. Nevertheless, challenges may emerge (Meiland et al., 2017). For example, Livingston et al. (2017) stated that the application of ICTs has great potential to improve the quality of care by assisting healthcare professionals and informal caregivers, but the authors also point out that technology cannot replace human contact. This study serves to improve dementia care with a tablet-based intervention and by fostering guideline-based treatment and facilitating therapy delivery in primary care.

Objectives

This prospective study serves to improve dementia care in primary care. To this end, we designed a tablet-based intervention to optimize the primary care of PwD and will conduct a cluster-randomized controlled trial (cRCT) (with randomization at GP level) to investigate the effects of this tablet-based intervention on guideline adherence (primary outcome) and health-related patient and caregiver outcomes (secondary outcomes). The study will be conducted in Berlin and the surrounding area. Duration of the intervention is 9 months, commencing in June 2019. The study will be conducted according to the principles of Good Clinical Practice and the Declaration of Helsinki and was prospectively registered with ISRCTN registry (trial registration number: ISRCTN15854413).

The primary hypothesis proposes that guideline-based care for PwD increases among the tablet-based intervention group, compared to the control group not receiving the tablet-based intervention. The secondary hypotheses propose that the tablet-based intervention also positively affects various health outcomes of PwD and informal caregivers such as quality of life, depression, and caregiver burden (for a detailed description of the secondary outcomes see *Outcomes*). Further, we expect to identify barriers and develop strategies for a technology-based improvement of outpatient dementia care.

Study Design

The planned design of the study is depicted in Figure 1. A requirement analysis served as preliminary work in order to identify relevant treatment and care domains for the tablet-based intervention. Interviews with GPs as well as an expert workshop were conducted in order to obtain greater knowledge about the current dementia-care situation in primary care as well as to explore possible barriers and gaps in existing care. Results of the requirement analysis, together with an extended literature review of current empirical work on primary care and dementia, form the basis of the tablet-based intervention currently under development. A scientific publication of the results of the requirement analysis is in preparation.

The main study consists of a two-arm cRCT with an intervention group and a control group. Clusters will be randomized at the GP level. Patients will be recruited by GPs within their practice. After randomization, PwD and informal caregivers in both conditions will receive regular care during the study period. In the intervention group, PwD and informal
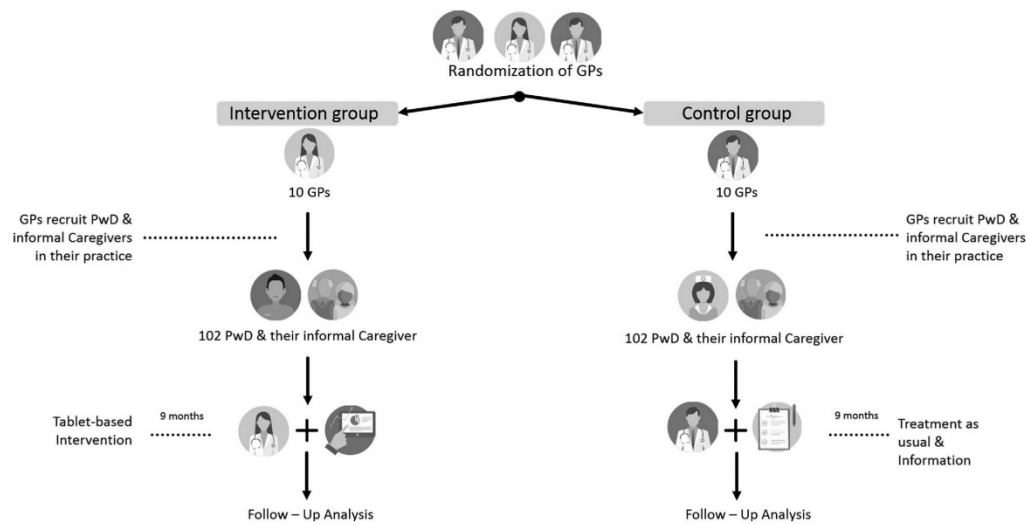
Figure 1. Flow chart of the study design.

caregivers will additionally receive a tablet-based intervention (for a detailed description of the intervention see *Intervention*). In the control group, PwD will receive standard healthcare by their GPs and additionally a paper information handbook on dementia at the beginning of the trial. Study variables will be assessed in both groups at baseline and after 9 months. We chose the period of 9 months mainly because of the German healthcare system, which is based on a quarterly billing system. Further, German health service research often reports within the quarterly billing system. Previous research reported the quarterly number of GP visits of PwD (Bohlken, Peiseler, & Kohlmann, 2015; Bussche et al., 2013). For example, Dreier and Hoffmann (2013) found that PwD visited their GPs 3.9 times on average per quarter (range: 0–20). We chose a period of three quarters (i.e., 9 months) to ensure that multiple visits to the GP take place during the intervention period.

Methods: Participants, Intervention, and Outcomes

Study Setting

The intervention will take place during consultation in GP practices and in the homes of PwD and their informal caregivers. Data of GPs will be collected in the practice, and the data of PwD and their informal caregivers will be collected in their homes.

Eligibility Criteria

Inclusion criteria for GPs are (1) operates as GP, (2) meets technical requirements (wifi connection available or installable), (3) participates in a training, and (4) signs a cooperation agreement/informed consent to participate in the study. Exclusion criteria include a planned absence or closing of the practice for longer than 4 weeks during the study period.

Inclusion criteria for PwD are (1) diagnosis of dementia obtained from a GP or medical specialist prior to the beginning of the trial (acc. to ICD-10 F00-F03, G30, G31.0 and G31.82), (2) living at home (outpatient care), (3) availability of an informal caregiver, and (4) signing an informed consent to participate in the study (if they are still legally authorized to sign), otherwise through a person holding the power of attorney. In most cases, the person holding the power of attorney will be the informal caregiver participating in the trial. However, if this is not the case, information about the legal guardian will be obtained from the PwD and/or the participating informal caregiver and/or the GP to ensure that informed consent is obtained from the legal guardian. In both cases, the PwD as well as the person holding the power of attorney will be informed verbally and in detail (using simple terms) about the study before receiving written information and giving informed consent.

Exclusion criteria include (1) other mental and behavioral disorders (acc. to ICD-10, F10-29, except for F10.1, F10.1, F17.1 or F17.2, as well as F32.2 and F32.3), (2) a planned hospital or rehabilitation stay longer than 4 weeks, and (3) a planned relocation to an inpatient care-facility or nursing home within the study period.

Inclusion criteria for informal caregivers are (1) living with or regularly visiting PwD and (2) signing an informed consent to participate in the study. Exclusion criteria includes a planned absence longer than 8 weeks during the study period.

Intervention

The tablet-based intervention comprises multiple functions and applications. GPs will receive one tablet, and each PwD and their informal caregiver will share a separate one. At the beginning of the trial, all study participants in the intervention group will receive extensive training concerning all components and functions as well as a handbook describing each application in depth. In addition, participants in the intervention group will be instructed to use the tablet-based intervention as often as possible during the 9 months. During the intervention period, the research team will be available for any inquiries and assistance needed in case of technical difficulties. Further, the research team can externally track the activity of each tablet and thus in case of rare usage send reminders (push notifications) to the tablet to ensure the implementation of the intervention. The following briefly describes the different functions and programs of the tablet-based intervention for (1) GPs and (2) PwD and their informal caregiver, respectively.

Intervention Components for GPs

During the study period, GPs are required to use the tablet applications in their treatment of study participants (PwD and informal caregivers). One of the main functions and intervention components is a checklist to support GPs in providing guideline-based treatment of dementia. This checklist resembles a conversation-guide and is based mainly on recommendations in the German Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016). Further, the checklist allows GPs to mark single elements as "discussed" after discussion with the patient during consultation. Once an element is marked, it automatically fades out, allowing GPs a better overview of topics already covered with the patient. Another function supports GPs, if necessary, in their prescription of suitable antidementia drugs. Based on preset filters (e.g., dementia severity), tailored individual and guideline-based treatment recommendations for antidementia drugs and dosages are delivered via tablet. For example, in adherence with

current dementia treatment guidelines, in the case of a PwD with a Mini Mental State Examination score (MMSE) of less than 10 points (= severe dementia), the treatment option of noncompetitive NMDA antagonist memantine is displayed for the GP. In addition, this feature provides the option of sending automatic reminders for correct medication intake and adjustment to GPs, but also to PwD and their informal caregivers. The third main function assists GPs in the joint development of a care plan and the determination of individual therapeutic measures and goals. This function enables GPs and their patients to reach a shared decision on the type and frequency of an established specific goal. For example, if a PwD is experiencing problems with a regular medication intake (e.g., because of memory impairment), the care plan can be used to establish a medication intake plan, by providing not only an overview of the established plan, but also by sending reminders on regular medication intake to be displayed on the study participant's tablet.

Further, the tablet-based intervention aims to improve direct and indirect communication and information exchange between GPs, PwD, and informal caregivers. Indirect communication refers to a variety of (health) information derived from the PwD, which is recorded by the PwD and/or their informal caregiver on their tablet and directly displayed on the GP's device. Direct communication refers to the option of sending direct messages between GP, PwD, and their informal caregiver in order to enhance communication and information exchange. For example, patients can enter their blood pressure values on their tablets. Their values are automatically displayed on the GP's tablet, thus enabling GPs to track blood pressure over time (indirect communication) and, in case of irregularities or anomalies, to act on it, for example, by sending a direct message to the patient and suggesting an adjustment to the medication or a new appointment (direct communication). Additionally, GPs are provided with a full electronic version of the German Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) as well as further information about outpatient dementia care on their tablet.

Intervention Components for PwD and Informal Caregivers

During the study period, the PwD and their informal caregivers are asked to use the tablet applications during their leisure time. Main available applications include serious games and programs specifically developed to engage, stimulate, and motivate PwD. Available games and programs were specifically designed for older and first-time tablet users with impaired cognitive, sensory and/or motor functioning and target the activation of cognitive and functional abilities as well as emotional self-regulation. Games

include cognitive training and stimulation (e.g., a quiz), games emphasizing activities of daily living (e.g., detecting objects from daily life such as a mug on a picture provided on the tablet), an interactive music program as well as a picture gallery for biography work. PwD can use the programs by themselves or engage with their informal caregiver and other family members or friends. In addition, both PwD and their informal caregiver can find a variety of information on dementia and dementia care on the tablet. Further, an interactive location service prepared by the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth (2019) is installed on the tablet and points out different consulting and support points as well as treatment options in the vicinity for both PwD (e.g., dementia-specific occupational therapy, daycare facilities) and for their informal caregiver (counselling points, self-help groups, short-term nursing). In addition, a communication platform enables indirect (documentation of health information) and direct (messaging) communication with the GP (for more details see Intervention Components for GPs above). As already mentioned, another main function of the tablet-based intervention includes a care plan to be developed together with the GP. The established care plan can be accessed by the PwD and their informal caregiver on their tablet and allows for regular notifications and reminders (e.g., about medication intake). Further, for informal caregivers (but also the PwD) a guided audio-relaxation technique (Reddemann, 2003) is available on the tablet and can be used throughout the study period.

Harms and Risk Assessment

No risks, disadvantages, or side effects are expected from the intervention. However, as part of quality assurance, any adverse events or other unintended effects of the intervention observed during the study period are collected, assessed, and reported.

Outcomes

The study's primary outcome is adherence to dementia guideline recommendations at follow-up (9 months). Based on the German Dementia Guideline (Deutsche Gesellschaft für Psychiatrie und Psychotherapie & Deutsche Gesellschaft für Neurologie, 2016) and other empirical work investigating the role of guideline-based primary care of dementia (Downs, Cook, Rae, & Collins, 2000; Murphy et al., 2014; Vickrey et al., 2006), we developed a checklist of 23 items and pilot tested them with three GPs in order to assess guideline adherence. These 23 recommendations fall into six domains: (1) diagnosis, (2)

primary care, (3) home and community care, (4) risk assessment, (5) care management, and (6) caregiver burden. All 23 items were dichotomous (*yes* or *no*). The means of percentages over all items and domains are calculated. Additionally, adherence to guideline recommendations are assessed by a caregiver survey. To this end, we developed a caregiver checklist with 19 items, similar to the checklist presented to GPs. Both checklists can be found in German (original) and English (simple translation) in the ESM 1.

Secondary outcomes are assessed by GPs, PwD, and informal caregivers and are measured at baseline and at 9 months. Secondary outcomes include various health outcomes such as quality of life (Logsdon, Gibbons, McCurry, & Teri, 2002), neuropsychiatric symptoms (Cummings et al., 1994), depression (Gauggel & Birkner, 1999; Heidenblut & Zank, 2010), and general health status (Bullinger, Kirchberger, & Ware, 1995), which are assessed by self-report or informant ratings (for a detailed description see Table 1). As far as possible, we selected self-reported standardized measurements suitable for PwD (e.g., quality of life will be measured using the Quality of Life in Alzheimer's Disease assessment; Logsdon et al., 2002). For all other self-reported items (e.g., sociodemographic information), we attempt to obtain data directly from the patient. However, if the PwD is no longer able to answer a question or the validity of the answer is questionable, provided answers/information are verified or obtained from the informal caregiver or the GP. For example, if PwD are unable to provide information on their age or seems unsure, a trained study nurse afterwards tries to best verify this missing information. With respect to autonomy and self-determination, we aim to involve and let the PwD participate and speak for themselves as much as possible. Hence, we set no cut-off values on the validity of responses, preferring rather to put a strong emphasis on a comprehensive training of our study nurses. Medication intake of PwD (type, dosage, dosage form and frequency) are obtained from medical records though the GP. Additionally, an evaluation of the tablet-based application is assessed by GPs, PwD, and informal caregivers of the intervention group.

Sample Size

The present sample-size calculations were based on a largely comparable research project conducted by Vickrey et al. (2006), which investigated the effectiveness of a dementia guideline-based disease management program. In a cRCT, Vickrey et al. (2006) measured dementia guideline adherence at baseline and follow-up by assessing the patient's medical records and the caregiver's survey. Based on a 78% (i.e., the actual statistical power under $1 - \beta = 0.8$

Table 1. Overview of main constructs and assessments for each study participant

	Participants of the study Self-rated (S), Informant (I) Assessment or medical record (R)		
Outcome/assessment	GP	PwD	Caregiver
Sociodemographic information			
Age	S	S (I)	S
Sex	S	S (I)	S
Education	S	S (I)	S
Care level		S (I)	
Diagnosis		R	
Primary outcome			
Guideline adherence	S		I
Secondary outcomes			
Quality of life			
Quality of Life in Alzheimer's Disease (Logsdon et al., 2002)		S (I)	
Health status			
EQ-5D-5L (Herdman et al., 2011)		S	
Short Form (36) Health Survey (Bullinger et al., 1995)			S
Behavioral symptoms			
Neuropsychiatric Inventory Questionnaire (Cummings et al., 1994)		I	
Cognition			
Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975)		S	
Activities and instrumental activities of daily living			
Barthel Index (Heuschmann et al., 2005)		I	
Instrumental activities of daily living (Lawton & Brody, 1969)		I	
Functional Assessment Staging Test (Sclan & Reisberg, 1992)		I	
Depression			
Depression in Old Age Scale (Heidenblut & Zank, 2010)		S	
Geriatric Depression Scale (Gauggel & Birkner, 1999)			S
Caregiver burden			
Burden Scale for Family Caregivers (Gräßel & Leutbecher, 2001)			S
Others			
Medication intake		R	
Technical Affinity (Karrer, Glaser, Clemens, & Bruder, 2009)	S	S	S

Note. S (I) = if a PwD is unable to provide information for this self-reported item, the information is obtained via informant assessment.

assumption) chance of detecting a statistically significant effect size Cohen's $d = 0.4$ between intervention and control group as well as taking into account an intracluster correlation coefficient of 0.03, Vickrey et al (2006) carried out the sample-size calculation. Because of the study design similarities, sample-size calculations for the present study were based on Vickrey et al. (2006). The power calculation for the present study with G*Power 3.1 yielded an estimated minimum sample size of $n = 71$ per group at a type I error rate of alpha = 0.05 and a statistical power of $1 - \beta = 0.8$. Taking into account the variance between 20 GPs (ICC = 0.03) and a drop-out rate of 18% at follow-up (as found by Vickrey et al., 2006), the final total sample size for the present study was calculated to be $N = 204$ or $n = 102$ in the intervention and $n = 102$ in the control group. Thus, a total of $N = 204$ PwD and $N = 204$ informal caregivers will be recruited.

Recruitment of GPs, Randomization, and Recruitment of PwD and Informal Caregivers

In a first step, we successfully recruited a total of 20 GP practices in Berlin and the surrounding area. We applied a variety of recruitment strategies to ensure a successful recruitment: (1) brief articles with project information and calls for study participation in various medical journals and newsletters; (2) 276 GPs randomly selected from Berlin

and contacted from a list of the Association of Statutory Health Insurance Physicians Berlin; (3) engaged the German Association of General Practitioners to accompany the recruitment process through contact mediation. GP recruitment commenced in November 2018 and was completed in May 2019.

In a second step, after completing the recruitment of 20 GPs, we will conduct the randomization at GP level. We chose a cluster randomization design in order to minimize the potential for contamination across groups. The GP practices are paired by patient volume: Within each pair, we will randomly assign one GP practice to the intervention and another GP practice to the control group using a computerized random-number generator operated by a study statistician. In a third step, in each GP practice, ten PwD and their informal caregivers are recruited by the GP. Because of the study design, study participants (GPs, PwD, and informal caregivers) as well as data collectors have knowledge of the group assignment, though GPs are blinded for data collection at baseline to ensure unbiased ascertainment of baseline data. GPs in both treatment conditions receive a financial compensation of 100 EUR for each PwD recruited and included in the trial. Furthermore, GPs in both intervention and control group are allowed to keep one tablet computer permanently. Participating PwD and informal caregivers do not receive any direct financial compensation, though all study participants are entered in a lucky draw and thus receive the opportunity to win a tablet computer.

Data Collection, Management, and Statistical Analysis

In both the intervention and the control group, standardized assessments will be carried out at baseline and after 9 months. There separate questionnaires are foreseen for each of the three target groups (GPs, PwD, and informal caregivers). The completion of a questionnaire should take up to a maximum of 1 hour per study participant and is to be carried out by a trained study nurse. When selecting the measuring instruments, attention was paid to the objectivity, reliability, and validity of the assessments. The questionnaires will be filled out in paper-pencil format and later transferred to a SPSS V.25 data mask. To ensure the accuracy of manual data entry, we will perform quality controls. Only the project team will have access to the data as defined in the data protection concept of the study (Version 0.9, 08.04.2019). In addition, data collected via tablet will be stored and processed by the cooperation partner Technische Universität Berlin, Quality and Usability Lab.

For sample description, among other things, age, sex, living situation (alone/not alone) as well as cognitive and func-

tional impairment, depression, and formal dementia diagnosis (ICD-10) will be analyzed. Primary and secondary outcomes of the intervention will be analyzed by an intention-to-treat analysis and mixed models at 9 months. These methods are suitable when using data with correlated residuals (cluster structure of GPs over measuring points). The choice of a dyadic approach (PwD and their informal caregiver) allows for calculation of dyadic effects from one participant to another (interdependence models). We will conduct subgroup analyzes for differential effects (e.g., of age, gender, cognitive functioning, and care level) in primary and secondary outcomes as exploratory posthoc analyses.

Ethics and Dissemination

Prior to the recruitment phase, the study was approved by the ethics committee of the Charité – Universitätsmedizin Berlin (EA1/085/19). Study participants receive comprehensive information material and detailed verbal information on the research project and the trial. Written informed consent is obtained from the GPs, the PwD (or, if the PwD is not authorized to sign anymore, the next of kin holding power of attorney or another legal guardian; see Inclusion criteria), and informal caregivers prior to data collection.

Discussion

The objective of this study protocol was to describe our planned study. The main objective of the study is to develop and evaluate a tablet-based intervention to improve outpatient dementia care by fostering guideline-based treatment. We expect the findings from this cRCT to provide evidence and new insights into the improvement of guideline-based outpatient dementia care using ICTs. The present study will be among the first targeting the improvement of guideline-based outpatient dementia care using ICTs. ICT devices such as tablets represent an affordable, accessible, and straightforward treatment option to facilitating guideline-based treatment on both the healthcare provider's and patient's part. Moreover, in this study we address people with dementia, a patient group representing the greatest global challenge to health and social care in the 21st century. However, several limitations must be outlined.

First, because of the study design, lack of blinding could possibly bias the actual treatment effect. Although randomization minimizes selection bias and confounding, blinding is important to avoid or reduce bias in the realization and interpretation of clinical trials. If study participants

are not blinded, knowledge of group assignment may influence their responses to subjective outcome measures (Karanicolas, Farrokhyar, & Bhandari, 2010). Blinding is not possible in the present study. However, this limitation will be addressed by blinding GPs and data collectors at baseline, and taking particular care to ensure that both groups, apart from the intervention, are treated as equally as possible. Second, a substantial part of the tablet-based intervention takes place in the PwD and their informal caregiver's home environment, so that conditions such as frequency and intensity of usage of the application, living situation, or the involvement of informal caregivers may be very heterogeneous between individuals. Unfortunately, this limitation lies largely beyond the researcher's control. However, we plan to address this limitation by (1) sending notifications and friendly reminders through the tablet during the study period to ensure a continuous usage of the tablet to the best of our ability; and (2) by statistically controlling for such variables when analyzing the data. Finally, to date a great number of the GPs (7 out of 20) were recruited from a research network of General Practitioners in and around Berlin. GPs who form part of this network are particularly interested in research on general practice. Thus, a selection bias of participating GPs must be kept in mind when interpreting results.

Conclusion and Future Research

The empirical evaluation of this innovative, technology-based approach for improving guideline-based outpatient dementia care will provide health policy makers and healthcare providers with new insights. Because the healthcare sector is increasingly confronted with technology-based approaches, empirical evaluations of technology-based interventions aiming to improve healthcare are crucial. Further, investigations of the value, benefit, and acceptance of ICT-based applications in healthcare are strongly required. The present study aims to contribute to this necessity, by providing evidence and new incentives on the improvement of guidelines-based outpatient dementia care using ICTs.

Electronic Supplementary Material (ESM)

The electronic supplementary material is available with the online version of the article at https://doi.org/10.1024/1662-9647/a000210

ESM 1. PDF. 23-item checklist for GPs in German

References

Albrecht, M., & Sander, M. (2015). *Demenzversorgung aus sektorenübergreifender Sicht, Patientenbezogene Auswertung von Daten aus der Gesetzlichen Krankenversicherung (BARMER GEK Krankenkasse) der Jahre 2008 bis 2010*. Retrieved from https://www.versorgungsatlas.de/fileadmin/ziva_docs/57/VA-57-2015-Kurzbericht-final.pdf

Alzheimer's Association. (2017). *2017 Alzheimer's disease facts and figures (1552–5260)*. Retrieved from http://www.sciencedirect.com/science/article/pii/S1552526017300511

Bohlken, J., Peiseler, G. J., & Kohlmann, T. (2015). Ambulante Demenzversorgung–Wer soll es machen? Eine Befragung von 400 Hausärzten [Service Provision for Dementia Patients in the Outpatient Setting – Who Should be Responsible? A Survey of 400 Primary Care Physicians]. *Aktuelle Neurologie, 42*(05), 256–259. https://doi.org/10.1055/s-0035-1550016

Bullinger, M., Kirchberger, I., & Ware, J. (1995). Der deutsche SF-36 Health Survey Übersetzung und psychometrische Testung eines krankheitsübergreifenden Instruments zur Erfassung der gesundheitsbezogenen Lebensqualität. *Zeitschrift für Gesundheitswissenschaften = Journal of public health, 3*(1), 21. https://doi.org/10.1007/BF02959944

Bussche, H. V. D., Wiese, B., Schön, G., Eisele, M., Koller, D., Steinmann, S., & Kaduszkiewicz, H. (2013). Die vertragsärztliche Versorgung von Patienten mit Demenz im Spiegel von Abrechnungsdaten einer GKV-Kasse. *Zeitschrift für Allgemeinmedizin, 89*, 55–60. https://doi.org/10.3238/zfa.2013.0055-0060

Cummings, J. L., Mega, M., Gray, K., Rosenberg-Thompson, S., Carusi, D. A., & Gornbein, J. (1994). The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology, 44*(12), 2308–2314. https://doi.org/10.1212/WNL.44.12.2308

Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde. (2016). *S3-Leitlinie Demenzen [S3 Guideline Dementia]. Leitlinien für Diagnostik und Therapie in der Neurologie [Guidelines for Diagnostics and Therapy in Neurology]*. (Langversion – Januar 2016). Retrieved from https://www.dgppn.de/_Resources/Persistent/ade50e44afc7eb8024e7f65ed3f44e995583c3a0/S3-LL-Demenzen-240116.pdf

Downs, M., Cook, A., Rae, C., & Collins, K. E. (2000). Caring for patients with dementia: The GP perspective. *Aging and Mental Health, 4*, 301–304. https://doi.org/10.1080/713649963

Dreier, A., & Hoffmann, W. (2013). Dementia Care Manager für Patienten mit Demenz. *Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz, 56*, 1398–1409. https://doi.org/10.1007/s00103-013-1796-0

Eichler, T., Thyrian, J. R., Fredrich, D., Köhler, L., Wucherer, D., Michalowsky, B., ... Hoffmann, W. (2014). The benefits of implementing a computerized Intervention Management System (IMS) on delivering integrated dementia care in the primary care setting. *International Psychogeriatrics, 26*, 1377–1385. https://doi.org/10.1017/S1041610214000830

Foley, T., Boyle, S., Jennings, A., & Smithson, W. H. (2017). "We're certainly not in our comfort zone": A qualitative study of GPs' dementia-care educational needs. *BMC Family Practice, 18*(1), 66. https://doi.org/10.1186/s12875-017-0639-8

Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). "Mini-mental state": A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research, 12*(3), 189–198. https://doi.org/10.1016/0022-3956(75)90026-6

Gauggel, S., & Birkner, B. (1999). Validität und Reliabilität einer deutschen Version der Geriatrischen Depressionsskala (GDS) [Validity and reliability of a German version of the Geriatric Depression Scale (GDS)]. *Zeitschrift für Klinische Psychologie, 28*(1), 18–27. https://doi.org/10.1026//0084-5345.28.1.18

Heidenblut, S., & Zank, S. (2010). Entwicklung eines neuen Depressionsscreenings für den Einsatz in der Geriatrie. *Zeitschrift für Gerontologie und Geriatrie, 43*(3), 170–176. https://doi.org/10.1007/s00391-009-0067-z

Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., ... Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D–5L). *Quality of Life Research, 20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Heuschmann, P. U., Kolominsky-Rabas, P. L., Nolte, C. H., Hünermund, G., Ruf, H. U., Laumeier, I., ... Berger, K. (2005). Untersuchung der Reliabilität der deutschen Version des Barthel-Index sowie Entwicklung einer postalischen und telefonischen Fassung für den Einsatz bei Schlaganfall-Patienten [The Reliability of the German Version of the Barthel-Index and the Development of a Postal and Telephone Version for the Application on Stroke Patients]. *Fortschritte der Neurologie-Psychiatrie, 73*(02), 74–82. https://doi.org/10.1055/s-2004-830172

Jeschke, E., Ostermann, T., Vollmar, H. C., Tabali, M., Schad, F., & Matthes, H. (2011). Prescribing patterns in dementia: A multicentre observational study in a German network of CAM physicians. *BMC Neurology, 11*(1), 99. https://doi.org/10.1186/1471-2377-11-99

Kaduszkiewicz, H., Wiese, B., & van den Bussche, H. (2008). Self-reported competence, attitude and approach of physicians toward patients with dementia in ambulatory care: Results of a postal survey. *BMC Health Services Research, 8*(1), 54. https://doi.org/10.1186/1472-6963-8-54

Karanicolas, P. J., Farrokhyar, F., & Bhandari, M. (2010). Practical tips for surgical research: Blinding: who, what, when, why, how? *Canadian Journal of Surgery, 53*, 345–348. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/20858381

Karrer, K., Glaser, C., Clemens, C., & Bruder, C. (2009). Technikaffinität erfassen–der Fragebogen TA-EG. *Der Mensch im Mittelpunkt technischer Systeme, 8*, 196–201.

Koch, T., & Iliffe, S., The E.-E. D. p. (2010). Rapid appraisal of barriers to the diagnosis and management of patients with dementia in primary care: A systematic review. *BMC Family Practice, 11*(1), 52. https://doi.org/10.1186/1471-2296-11-52

Lawton, M. P., & Brody, E. M. (1969). Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist, 9*(3), 179–186.

Leve, V., Ilse, K., Ufert, M., Wilm, S., & Pentzek, M. (2017). Driving and dementia: An issue for general practice? *Zeitschrift für Gerontologie und Geriatrie, 50*(Suppl 2), 55–62. https://doi.org/10.1007/s00391-017-1234-2

Logsdon, R. G., Gibbons, L. E., McCurry, S. M., & Teri, L. (2002). Assessing Quality of Life in Older Adults With Cognitive Impairment. *Psychosomatic Medicine, 64*(3), 510–519.

Livingston, G., Sommerlad, A., Orgeta, V., Costafreda, S. G., Huntley, J., Ames, D., ... Mukadam, N. (2017). Dementia prevention, intervention, and care. *The Lancet, 390*(10113), 2673–2734. https://doi.org/110.1016/S0140-6736(17)31363-6

Meiland, F., Innes, A., Mountain, G., Robinson, L., van der Roest, H., García-Casal, J. A., ... Franco-Martin, M. (2017). Technologies to support community-dwelling persons with dementia: A position paper on issues regarding development, usability, effectiveness and cost-effectiveness, deployment, and ethics. *JMIR Rehabilitation and Assistive Technologies, 4*(1), e1. https://doi.org/10.2196/rehab.6376

Mitchell, A. J., Meader, N., & Pentzek, M. (2011). Clinical recognition of dementia and cognitive impairment in primary care: A meta-analysis of physician accuracy. *Acta Psychiatrica Scandinavica, 124*, 165–183. https://doi.org/10.1111/j.1600-0447.2011.01730.x

Murphy, K., O'Connor, D. A., Browning, C. J., French, S. D., Michie, S., Francis, J. J., ... Green, S. E. (2014). Understanding diagnosis and management of dementia and guideline implementation in general practice: A qualitative study using the theoretical domains framework. *Implementation Science, 9*(1), 31. https://doi.org/10.1186/1748-5908-9-31

National Collaborating Centre for Mental Health. (2007). National Institute for Health and Clinical Excellence: Guidance. In *Dementia: A NICE-SCIE guideline on supporting people with dementia and their carers in health and social care*. Leicester, UK: British Psychological Society, The British Psychological Society & The Royal College of Psychiatrists.

Olafsdottir, M., Foldevi, M., & Marcusson, J. (2001). Dementia in primary care: Why the low detection rate? *Scandinavian Journal of Primary Health Care, 19*, 194–198. https://doi.org/10.1080/028134301316982469

Pentzek, M., Abholz, H. H., Ostapczuk, M., Altiner, A., Wollny, A., & Fuchs, A. (2009). Dementia knowledge among general practitioners: First results and psychometric properties of a new instrument. *International Psychogeriatrics, 21*, 1105–1115. https://doi.org/10.1017/s1041610209990500

Pentzek, M., Fuchs, A., Abholz, H.-H., & Wollny, A. (2011). Awareness of local dementia services among general practitioners with academic affiliation. *Aging Clinical and Experimental Research, 23*, 241–243. https://doi.org/10.1007/bf03337750

Pentzek, M., Vollmar, H. C., Wilm, S., & Leve, V. (2017). Putting dementia awareness into general practice. *Zeitschrift für Gerontologie und Geriatrie, 50*, 44–47. https://doi.org/10.1007/s00391-017-1206-6

Prince, M. J., Wimo, A., Guerchet, M. M., Ali, G. C., Wu, Y.-T., & Prina, M. (2015). *World Alzheimer report 2015 – The global impact of dementia*. London, UK: Alzheimer's Disease International.

Reddemann, L. (2003). *Imagination als heilsame Kraft. Hör-CD mit Übungen zur Aktivierung von Selbstheilungskräften* (Reihe Leben lernen Nr. 288). Stuttgart, Germany: Pfeiffer bei Klett-Cotta.

Schultz, T., Putze, F., & Kruse, A. (Eds.). (2014). *Technische Unterstuetzung fuer Menschen mit Demenz: Symposium 30.09.–01.10. 2013*. KIT Scientific Publishing.

Sclan, S., & Reisberg, B. (1992). Functional Assessment Staging (FAST) in Alzheimer's Disease: Reliability, Validity, and Ordinality. *International Psychogeriatrics, 4*(3), 55–69. https://doi.org/10.1017/S1041610292001157

Strohmaier, U., Keller, F., Kilimann, I., Michalowsky, B., Wucherer, D., Zwingmann, I., ... Thyrian, J. R. (2018). Patients with dementia in primary care: Who is referred to a neurologist/psychiatrist and what patient-oriented factors are associated with the visit? *Journal of Alzheimer's Disease (Preprint), 64*(3), 925–932. https://doi.org/10.3233/JAD-180196

Thyrian, J. R., Eichler, T., Pooch, A., Albuerne, K., Dreier, A., Michalowsky, B., ... Hoffmann, W. (2016). Systematic, early identification of dementia and dementia care management are highly appreciated by general physicians in primary care: Results within a cluster-randomized-controlled trial (DelpHi). *Journal of Multidisciplinary Healthcare, 9*, 183–190. https://doi.org/10.2147/jmdh.s96055

Thyrian, J. R., Fiß, T., Dreier, A., Böwing, G., Angelow, A., Lueke, S., ... Hoffmann, W. (2012). Life- and person-centred help in Mecklenburg-Western Pomerania, Germany (DelpHi): Study

protocol for a randomised controlled trial *Trials*, 56(1). https://doi.org/10.1186/1745-6215-13-56

Thyrian, J. R., Hertel, J., Wucherer, D., Eichler, T., Michalowsky, B., Dreier-Wolfgramm, A., ... Hoffmann, W. (2017). Effectiveness and safety of dementia care management in primary care: A randomized clinical trial. *JAMA Psychiatry, 74*, 996–1004. https://doi.org/10.1001/jamapsychiatry.2017.2124

Thyrian, J. R., & Hoffmann, W. (2012). Dementia care and general physicians: A survey on prevalence, means, attitudes and recommendations. *Central European Journal of Public Health, 20*, 270–275.

Turner, S., Iliffe, S., Downs, M., Wilcock, J., Bryans, M., Levin, E., ... O'Carroll, R. (2004). General practitioners' knowledge, confidence and attitudes in the diagnosis and management of dementia. *Age and Ageing, 33*, 461–467. https://doi.org/10.1093/ageing/afh140

Vickrey, B. G., Mittman, B. S., Connor, K. I., Pearson, M. L., Della Penna, R. D., Ganiats, T. G., ... Lee, M. (2006). The effect of a disease management intervention on quality and outcomes of dementia care: A randomized, controlled trial. *Annals of Internal Medicine, 145*, 713–726. https://doi.org/10.7326/0003-4819-145-10-200611210-00004

Winblad, B., Amouyel, P., Andrieu, S., Ballard, C., Brayne, C., Brodaty, H., ... Zetterberg, H. (2016). Defeating Alzheimer's disease and other dementias: A priority for European science and society. *The Lancet Neurology, 15*, 455–532. https://doi.org/10.1016/s1474-4422(16)00062-4

World Health Organization. (2012). *Dementia: A public health priority*. Geneva: Author. Retrieved from http://www.who.int/iris/handle/10665/75263

Sonia Lech
Institute for Medical Sociology and Rehabilitation Science
Charité – Universitätsmedizin Berlin
Charitéplatz 1
10117 Berlin
Germany
sonia.lech@charite.de

APPENDIX

23-item Checklist for GPs in German (Original)

Frage	ja	nein	Nicht zutreffend
Wurde ein geriatrisches Basisassessment durchgeführt?			
Welche der folgenden Untersuchungen wurden im Rahmen der Diagnostik durchgeführt:			

Körperliche und psychopathologische Untersuchung
    Labor-Diagnostik
    Differenzialdiagnostik
    Schweregradabschätzung/Kognitive Testung
    Verlaufsuntersuchung
    CCT/fMRT			

Wurde ein kognitives Screening in der Hausarztpraxis durchgeführt?			
Wurden weitere körperliche Beeinträchtigungen/Erkrankungen erfasst?			
Wurden weitere psychische Beeinträchtigungen/Erkrankungen erfasst?			
Wurden mit dem Patienten/Angehörigen psychische und Verhaltenssymptome der Demenz ausführlich besprochen?			
Wurde die gesamte aktuelle Medikamenteneinnahme erhoben und besprochen?			
Wurde eine medikamentöse Therapie der Demenz mit dem Patienten/Angehörigen besprochen?			
Wurden nicht-medikamentöse Therapieangebote der Demenz mit dem Patienten/Angehörigen besprochen?			
Wurden dem Patienten nichtmedikamentöse Therapien empfohlen oder verordnet? Wenn ja, welche_____			
Befindet sich der Patient aufgrund der Demenz in fachärztlicher Behandlung?			
Wurden mit dem Patienten/Angehörigen weitere Versorgungsangebote besprochen?			
Wurde der Patient/Angehöriger über niedrigschwellige Angebote informiert?			
Wurde ein Behandlungsplan zusammen mit dem Patienten/Angehörigen erstellt?			
Wurden mit dem Patienten/Angehörigen Alltagsgestaltung und -kompetenzen besprochen?			
Wurden mit dem Patienten/Angehörigen eigentherapeutische Maßnahmen besprochen?			
Wurden neu aufgetretene Risiken besprochen? (z.B. Selbst-, Fremdgefährdung)			
Wurde mit dem Patienten/Angehörigen die Fahrtauglichkeit besprochen?			
Wurde der Patient/Angehörige auf die Beantragung eines Pflegegrades angesprochen?			
Wurde der Patient/Angehörige auf rechtliche Vorsorgemaßnahmen angesprochen?			
Wurde über Palliativversorgung gesprochen?			
Wurde die Belastungssituation des Angehörigen ausführlich besprochen?			
Wurde der Angehörige über Entlastungs- und Beratungsangebote informiert?			

23-item Checklist for GPs in English (simple translation)

Question	yes	no	Not applicable
Was a basic geriatric assessment (geriatrisches Basisassessment) conducted?			
Which of the following examinations were conducted during the diagnostic process? Physical examination and psychopathological/psychiatric evaluation Laboratory tests Differential diagnostics Cognitive and neuropsychological tests Recent medical history CT/MRI scans			
Did the GP administer a cognitive screening test?			
Were further physical impairments/medical conditions assessed?			
Were further mental health impairments/psychiatric conditions assessed?			
Did the patient/family caregiver receive advice concerning psychological and behavioral symptoms of dementia?			
Was the entire current medication assessed and discussed?			
Were pharmacological treatment options for dementia discussed with the patient/family caregiver?			
Were non-pharmacological interventions for dementia discussed with the patient/family caregiver?			
Were non-pharmacological interventions for dementia recommended or prescribed? If yes, which intervention_____			
Is the patient currently being treated by a dementia specialist (i.e. neurologist, geriatric psychiatrist)?			
Were further care services for people with dementia discussed with the patient/family caregiver?			
Was the patient/family caregiver informed about local support services for people with dementia?			
Was a care plan developed with the patient/family caregiver?			
Were daily activities and how to maintain them discussed with the patient/family caregiver?			
Were self-help measures discussed with the patient/family caregiver?			
Were newly emerging risks assessed and discussed? (i.e. self-harm or harming others)			
Were driving skills or lack thereof discussed with the patient/family caregiver?			
Was the patient/family caregiver approached about an application for a care level from the German nursing care insurance (Pflegegrad)?			
Was the patient/family caregiver made aware of their rights and the availability of local advocacy services?			
Was palliative care discussed?			
Was the caregiver stress level discussed in detail with the family caregiver?			
Was the family caregiver informed about available resources and support offers for family carers?			

19-item Checklist for informal caregivers in German (Original)

Frage	ja	nein	Weiß nicht
Hat der Hausarzt den Studienteilnehmer aufgrund der Demenz zu einem Facharzt (Neurologe, Psychiater, Nervenarzt, Gedächtnissprechstunde) überwiesen?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer eine medikamentöse Therapie der Demenz besprochen?			
Hat der Hausarzt eine demenzspezifische, medikamentöse Therapie in den letzten 9 Monaten angepasst oder neu verordnet?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer mögliche medikamentöse Nebenwirkungen besprochen?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer nicht-medikamentöse Therapieangebote der Demenz besprochen?			
Hat der Hausarzt dem Studienteilnehmer eine nichtmedikamentöse Therapie verordnet oder empfohlen?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer psychische und Verhaltenssymptome der Demenz besprochen?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer weitere Versorgungsangebote besprochen? (z.B. Hilfsmittel, Tagespflege)			
Wurden Sie/der Studienteilnehmer über niedrigschwellige Angebote informiert? (z.B. Beratung, Gruppenangebote)			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen neu aufgetretene Risiken besprochen? (z.B. Selbst-, Fremdgefährdung)			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen Alltagsgestaltung und -kompetenzen besprochen?			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen eigentherapeutische Maßnahmen und Ziele besprochen?			
Wurde ein Behandlungsplan zusammen mit dem Hausarzt erstellt?			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen die Beantragung eines Pflegegrades besprochen?			
Hat der Hausarzt Ihre Belastungssituation erfasst?			
Hat der Hausarzt Sie über Entlastungs- und Beratungsangebote für Sie selbst informiert?			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen rechtliche Vorsorgemaßnahmen besprochen?			
Hat der Hausarzt mit dem Studienteilnehmer/Ihnen Palliativversorgung besprochen?			
Hat der Hausarzt mit Ihnen/dem Studienteilnehmer die Fahrtauglichkeit besprochen?			

19-item Checklist for informal caregivers in English (simple translation)

Question	yes	no	Don't know
Was the participant referred to a dementia specialist (i.e. neurologist, psychiatrist, memory clinic) by his or her GP?			
Did the GP discuss pharmacological treatment options with you and/or the participant?			
Was a dementia specific pharmacological therapy adjusted or newly prescribed within the past 9 months?			
Did the GP discuss possible adverse effects of pharmacological therapies with the participant?			
Did the GP discuss non-pharmacological treatment options with you and/or the participant?			
Did the GP recommend or prescribe a non-pharmacological intervention to you and/or the participant?			
Did the GP discuss psychological and behavioral symptoms of dementia with you and/or the participant?			
Did the GP discuss further care services (i.e. day care facilities, nursing aids) for people with dementia with you and/or the participant?			
Did the GP inform you and/or the participant about local support services for people with dementia?			
Did the GP discuss newly emerging risks (i.e. self-harm or harming others) with you and/or the participant?			
Did the GP talk to you and/or the participant about daily activities and how to maintain them?			
Did the GP discuss self-help measures and goals with you and/or the participant?			
Was a care plan developed with the GP?			
Did the GP approach you and/or the family caregiver about an application for a care level from the German nursing care insurance (Pflegegrad)?			
Did the GP assess your stress level?			
Did the GP inform you about available resources and support offers?			
Did the GP inform you and/or the participant about advocacy services?			
Did the GP discuss palliative care with you and/or the participant?			
Did the GP discuss driving skills or lack thereof with you and/or the participant?			

Excerpt from Journal Summary List for Manuscript II

In the field of Health Care Sciences and Services, the journal *"BMC Medical Research Methodology"* is ranked on the 24th place out of 102 journals. Thus, the journal is ranked within the top 25 percent (Q1), making it one of the leading top journals in the field.

Journal Data Filtered By: **Selected JCR Year: 2019** Selected Editions: SCIE,SSCI
Selected Categories: **"HEALTH CARE SCIENCES and SERVICES"**
Selected Category Scheme: WoS
Gesamtanzahl: 102 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	BMJ Quality & Safety	5,825	6.084	0.015370
2	Implementation Science	10,777	5.531	0.020190
3	ACADEMIC MEDICINE	17,605	5.354	0.028860
4	HEALTH AFFAIRS	17,516	5.331	0.047430
5	JOURNAL OF MEDICAL INTERNET RESEARCH	16,349	5.034	0.029410
6	JOURNAL OF CLINICAL EPIDEMIOLOGY	28,878	4.952	0.028410
7	VALUE IN HEALTH	10,040	4.748	0.017370
8	JOURNAL OF GENERAL INTERNAL MEDICINE	20,229	4.597	0.026960
9	MEDICAL EDUCATION	10,598	4.570	0.011180
10	Journal of Personalized Medicine	617	4.433	0.001950
11	JMIR mHealth and uHealth	4,226	4.313	0.010020
12	MILBANK QUARTERLY	3,822	4.195	0.004300
13	JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION	9,959	4.112	0.017380
14	International Journal of Health Policy and Management	1,463	3.821	0.004860
15	PALLIATIVE MEDICINE	5,413	3.739	0.008460
16	PHARMACOECONOMICS	5,150	3.563	0.009120
17	Internet Interventions-The Application of Information Technology in Mental and Behavioural Health	996	3.513	0.002720
18	HEALTH TECHNOLOGY ASSESSMENT	5,573	3.370	0.009440
19	Patient-Patient Centered Outcomes Research	1,204	3.226	0.003990

Selected JCR Year: 2019; Selected Categories: "HEALTH CARE SCIENCES and SERVICES"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
20	MEDICAL CARE RESEARCH AND REVIEW	2,459	3.212	0.003300
21	MEDICAL CARE	20,261	3.210	0.019020
22	JOURNAL OF PAIN AND SYMPTOM MANAGEMENT	10,897	3.077	0.014840
23	JOURNAL OF MEDICAL SYSTEMS	5,695	3.058	0.007050
24	BMC Medical Research Methodology	11,581	3.031	0.018590
24	Journal of Patient Safety	1,094	3.031	0.002310
26	INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS	5,368	3.025	0.007110
27	Journal of Managed Care & Specialty Pharmacy	1,667	3.021	0.005780
28	HEALTH EXPECTATIONS	3,600	3.008	0.008230
29	Health Informatics Journal	981	2.932	0.001530
30	JOURNAL OF HEALTH ECONOMICS	7,404	2.827	0.014020
31	QUALITY OF LIFE RESEARCH	14,492	2.773	0.018650
32	International Journal of Integrated Care	1,245	2.753	0.001750
33	HEALTH POLICY AND PLANNING	5,413	2.704	0.010540
34	BMJ Supportive & Palliative Care	1,309	2.681	0.003390
35	JOURNAL OF RURAL HEALTH	2,005	2.667	0.003100
36	MEDICAL TEACHER	8,633	2.654	0.009410
37	SUPPORTIVE CARE IN CANCER	12,842	2.635	0.021660
38	JOURNAL OF TELEMEDICINE AND TELECARE	2,703	2.616	0.003430
39	ADVANCES IN HEALTH SCIENCES EDUCATION	2,696	2.480	0.004210
40	Applied Health Economics and Health Policy	1,234	2.442	0.003140
41	Risk Management and Healthcare Policy	549	2.429	0.001530

Selected JCR Year: 2019; Selected Categories: "HEALTH CARE SCIENCES and SERVICES"

Printing copy of Manuscript II

RESEARCH ARTICLE   **Open Access**

Recruiting general practitioners and patients with dementia into a cluster randomised controlled trial: strategies, barriers and facilitators

Sonia Lech[1*] , Julie L. O'Sullivan[1], Leonard Wellmann[1], Juliana Supplieth[1], Susanne Döpfmer[2], Paul Gellert[1], Adelheid Kuhlmey[1] and Johanna Nordheim[1]

Abstract

Background: Recruitment of general practitioners (GPs) and their patients is reported as one of the most challenging steps when undertaking primary care research. The present paper describes the recruitment process of a cluster randomised controlled trial (cRCT) aiming to improve dementia care in the primary care setting.

Methods: Recruitment data was analysed descriptively using frequency tables to investigate comparisons of recruitment rates and results of different recruitment strategies as well as reasons for participation and non-participation of GPs, patients with dementia (PwD) and their caregivers.

Results: Over a period of 23 months, $N = 28$ GPs were successfully included in the cRCT. This represents an overall recruitment rate of 4.6%. The most efficient strategy in terms of high response and low labour-intensity involved the dissemination of calls for participation in a GP research network. Most frequently reported reasons for GP's participation were *Improvement of patient's well-being* ($n = 22$, 79%) followed by *Interest in dementia research* ($n = 18$, 64%). The most common reasons for non-participation were *Lack of time* ($n = 71$, 34%) followed by *Not interested in participation* ($n = 63$, 30%). On a patient level, $N = 102$ PwD were successfully recruited. On average, each GP referred about $n = 7$ PwD (range: 1–17; $mdn = 6$; IQR = 3.5) and successfully recruited about $n = 4$ PwD (range: 1–11; $mdn = 3$; IQR = 3.5).

Conclusion: First, our findings propose GP research networks as a promising strategy to promote recruitment and participation of GPs and their patients in research. Second, present findings highlight the importance of including GPs and their interests in specific research topics in early stages of research in order to ensure a successful recruitment. Finally, results do not support cold calls as a successful strategy in the recruitment of GPs.

Trial registration: The trial was prospectively registered with the ISRCTN registry (Trial registration number: ISRCTN15854413). Registered 01 April 2019.

Keywords: Primary care, Recruitment, Cluster randomised controlled trial, Dementia

* Correspondence: Sonia.lech@charite.de
[1]Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute of Medical Sociology and Rehabilitation Science, Charitéplatz 1, 10117 Berlin, Germany
Full list of author information is available at the end of the article

Background

General practitioners (GPs) play a paramount role in dementia care [1–6]. They are often the first point of contact for patients with dementia (PwD) and play a key part in both diagnosis [7–9] and management of the disease [1, 10–12]. Despite the central role of GPs in the care of dementia, primary care-based interventions to assist GPs and PwD remain rare. The involvement of GPs in research to improve dementia care remain crucial. However, the recruitment of GPs in health research poses a major obstacle and barriers of recruitment have been reported in various areas of health research [13–18]. Barriers to GP's recruitment and research participation were found to be manifold, including lack of time [13, 16, 17, 19, 20] and administrative burden [20, 21]. Further, in a systematic review poor communication by trial coordinators, difficulties of understanding research methods, concerns about possible harms for patients and feelings of being overwhelmed by too many research requests without being addressed as a real research partner were identified as barriers [22]. In Germany, despite an increasing awareness of the need for clinical trials in primary care there is no long tradition of involving GPs in research, and clinical trials in primary care are still under-represented [23]. In other countries, this tradition has existed significantly longer, as for example in the Netherlands, UK and the US [21, 23–25].

When it comes to primary care research, not only the recruitment of GPs proposes an obstacle, but also the recruitment of patients [22, 26–28]. For example, in the United Kingdom, less than one third of health studies in primary care reach their target number of patients, partly due to the overestimation of recruitable patients by GPs [27]. This frequently occurring case, also known as "*Lasagna's law*" [29], inevitably leads to challenges [30]. Despite necessary long-term commitments of GPs, the number of patients actually available for recruitment turns out to be many times lower than initially estimated. Recruitment of patients into randomised controlled trials (RCT) was proven to be particularly challenging [31]. RCTs require a sufficiently large number of participants and failure to reach patient recruitment targets often lead to insufficient statistical power or discontinuation of trials [30, 32]. Reasons for difficulties in the recruitment of patients within the primary care setting are manifold. For example, in a qualitative study investigating perceived barriers among GPs towards recruiting patients into RCTs lack of confidence in introducing research participation requests to their patients was found as one main reason [19]. Data protection regulations also make it particularly difficult to contact patients directly [33]. Particularly in studies with a limited funding period, extending periods of recruitment represent a major problem [34].

To sum up, recruitment of GPs and their patients is considered as one of the most challenging steps in health research and, although this difficulty has long been recognised as such, there is a lack of effective strategies to overcome it [14, 18, 31]. To date there is no comprehensive publication on the recruitment methods and facilitating and/or inhibiting factors in the recruitment of GPs and their patients with dementia into a RCT.

Aim of study

The present study aims to describe the recruitment process and the results of the recruitment of GPs recruited within the DemTab trial. The main focus of the present paper lies on the recruitment of GPs. In addition, the results of the recruitment of PwD and their caregivers are presented. The objective is to reflect on efforts and risks of different recruitment strategies applied in the present study. Furthermore, we investigate factors that have facilitated or hampered recruitment will be examined. We aim to contribute to a better understanding of barriers and facilitators of the recruitment of GPs and their patients.

Methods

Study design

To examine our research questions, data was used from the DemTab study, a two-arm cluster randomised controlled trial (cRCT) with the objective of the development and evaluation of a tablet-based intervention aiming to improve primary care for PwD and their caregivers[1] in Berlin and surrounding area. A study protocol of the DemTab study was published elsewhere [35]. The study was conducted and reported in accordance with the CONSORT guidelines for cRCT and ethical approval was obtained by the ethics committee of the Charité – Universitätsmedizin Berlin (EA1/085/19). The trial was prospectively registered with the ISRCTN registry (Trial registration number: ISRCTN15854413).

In the first part of the DemTab study a feasibility study was conducted. In order to collect perspectives and needs regarding the treatment of dementia in primary care and include these in the development of the intervention, interviews and a workshop with GPs and other important actors from the ambulatory care setting were carried out. A publication on the feasibility study is currently underway. Following the feasibility study, the intervention was developed and implemented.

---

[1]The target of the DemTab study included PwD who receive ambulatory care and their family or informal caregivers. However, in Germany dementia shared homes also count as ambulatory care. Therefore, we also included non-family caregivers from ambulatory care services such as dementia shared homes. We refer to family, non-family and caregivers as caregivers.

Intervention

The tablet-based intervention is composed of multiple functions and applications. The main functions include, for example, a checklist, similar to a conversation-guide which supports GPs in guideline-based care. Another function enables GPs to communicate via messages with PwD and their caregivers. GPs received each a tablet and PwD and their caregiver shared a separate one. Participants of the intervention group were provided (if necessary) with internet access. A training on the tablet-based intervention was conducted prior to the intervention's beginning to ensure participation, followed by a nine-month tablet-based intervention with the aim to improve guideline-based dementia care. Participants of the control group receive standard healthcare by their GPs and additionally an information handbook on dementia at the beginning of the trial. All participant are encouraged to use the tablet as often as desired – the usage of the tablet is voluntary and there are no further commitments in terms of frequency or quality of usage. The trial is currently ongoing. A more detailed description of study design, sampling methods, variables and procedures can be found in Lech et al. [35].

Participants and procedure

The recruitment process was comprised of two stages: first, GPs were recruited followed by the recruitment of PwD (and their caregivers). The original recruitment target of $N = 20$ for GPs and $N = 202$ for PwD and their caregivers was based on a sample size calculation using GPs ratings and proxy ratings of caregivers from medical record information as primary outcome [36]. Due to challenges in the recruitment of GPs and PwD the primarily estimated sample size could not be reached. Consequently, literature was reviewed de novo [36, 37]. When in 2017 a comparable cRCT from Germany evaluated a guideline-oriented intervention (Dementia Management Program) for PwD in primary care using a patient-related primary endpoint, a new power calculation at patient level was conducted based on the reported medium-sized effect of Cohen's $d = 0.5$ [37]. Based on that study, a new power calculation using the software G*Power 3.1 yielded an estimated new total sample size of $N = 102$ or $n = 52$ per group at a type I error rate of alpha = 0.05 and a statistical power of $1-\beta = 0.8$. These calculations take into account the variance between GPs (ICC = 0.03) and a drop-out rate of 18% at follow-up, as found by Vickrey et al. [36].

Inclusion criteria for GPs were defined as (1) currently operating as GP, (2) meeting technical requirements (internet connection), (3) willing to participate in a training, and (4) signed cooperation agreement. Exclusion criteria for GPs were a planned absence or closing of the practice for longer than 4 weeks during the study period. Further, GPs with a lack of PwD currently treated in practice were also not included. Inclusion criteria for PwD were defined as (1) diagnosis of dementia obtained prior to the beginning of the trial (acc. to ICD-10, F00-F03, G30, G31.0 and G31.82), (2) living at home (outpatient care), (3) availability of a caregiver, and (4) signed informed consent (if they are still legally authorised to sign, otherwise through a person holding the power of attorney). Exclusion criteria for PwD were (1) other mental and behavioural disorders (acc. to ICD-10, F10–29, except for F10.1, F17.1 or F17.2, as well as F32.2 and F32.3), (2) a planned hospital or rehabilitation stay longer than 4 weeks, and (3) a planned relocation to an inpatient care-facility or nursing home within the study period. Inclusion criteria for caregivers were defined as (1) living with or regularly visiting PwD and (2) signed informed consent. Exclusion criteria included a planned absence longer than 8 weeks during the study period.

Assessments of primary and secondary outcomes were conducted before the intervention (baseline) and after the intervention (post intervention) in both groups. Primary outcome is defined as adherence to dementia guideline recommendations after 9 months. Secondary outcomes include various health outcomes assessed in PwD (e.g., quality of life) and caregivers (e.g., caregiver burden). Randomisation was conducted at a GP level to avoid contamination across groups (cluster randomisation). At the end of the study, participating GPs from both treatment groups were to receive a financial compensation of 100 EUR for each PwD successfully recruited. Furthermore, all GPs were to receive a tablet computer permanently. Participating PwD and caregivers did not receive any direct financial compensation, though all study participants enter a lucky draw and receive the opportunity of winning a tablet.

Recruitment of GPs, PwD and their caregivers

Overall, in line with prior research and the Dillman's Total Design Approach [38, 39], recruitment strategies for GPs included personalised invitations and letters, comprehensive information material on the study rationale, goals and design, follow-up calls and endorsement from the research team via telephone, reply paid envelopes as well as a financial compensation in case of participation. In the present study, the recruitment of GPs was conducted in *three recruitment rounds*. The first and the second recruitment round were intended prior to the beginning of recruitment. The third recruitment round was added during the ongoing recruitment process to ensure the necessary sample size. Partially, recruitment of all rounds took place simultaneously. In the *first recruitment round*, calls for participation and advertisements of the DemTab study were published in a

variety of general practice related publications and newsletters through different networks. A main strategy was the dissemination of a call for participation in a regular newsletter of a research network of general practitioners in and around Berlin established by the Institute of General Practice of the Charité – Universitätsmedizin Berlin. Further, a total of three advertisements in general practice related publications was disseminated and four ads were published on Facebook pages related to dementia. The project and call for participation were presented at two trainings for GPs in Berlin. Further, advertisements through further GP networks (e.g. presentation of the DemTab study in quality circles of primary care) lead to recommendations and referrals of potentially interested GPs (snowball sampling). In the *second recruitment round*, a sample of GPs ($n = 486$) was randomly selected from a database of the Statutory Health Insurance Physicians in Berlin (KV Berlin). At first, GPs received personalised letters with comprehensive information material about the DemTab study followed by a phone call. The low initial response (none of the contacted GPs got back to the research team based on letters) resulted in directly contacting GPs via phone (cold calls), instead of sending out letters first. Additionally, rural areas in the vicinity of Berlin were included and contacted via cold calls. Finally, a *third recruitment round* included face-to-face recruitment of GPs in $n = 116$ general practices in Berlin. Practices were selected primarily on the basis of the official number of older people living in the district, starting with the districts with the highest numbers. Practices were visited between October 2019 and February 2020. An in-person meeting with GPs was intended and a package of information material on the DemTab study was distributed directly to GPs in their practice.

Inclusion of GPs and PwD

Generally, once GPs showed interest in participating, a cooperation agreement accompanied by a reply-paid envelope was provided. A signed cooperation agreement was considered as a successful inclusion. Further, included GPs filled out a baseline survey. In a second step, GPs were required to recruit PwD in their practice. For this purpose, GPs were provided with information material and leaflets in order to ensure a successful recruitment of their PwD. Once GPs obtained permission from PwD and/or caregivers, patient's contact details were shared with the research team. The research team then contacted PwD and/or caregivers via phone in order to provide a detailed description of the study for each participant. Once PwD and/or caregivers indicated interest in the participation over the phone, detailed study information and an informed consent form, accompanied by a reply-paid envelope was sent to their homes. A signed informed consent was considered as a successful

inclusion. Further, included PwD and their caregivers filled out a baseline survey.

Data analysis

Data on the recruitment of GPs and PwD was collected and documented by the research team. Baseline data was obtained from all successfully recruited participants. Documentation of the recruitment process of GPs includes data on (1) number of contacted GPs, (2) amount of successfully recruited GPs and (3) drop-out rates for each recruitment round. Further, recruitment rates (number of successfully participating GPs divided by the number of GPs contacted for recruitment) and recruitment ratios (number of successfully participating GPs in relation to the final GP sample) for each recruitment round were calculated. Data on reasons for participations was analysed based on a survey filled out by each successfully recruited GP (Item: "*Why did you choose to participate in this research study?*", response categories: "*Improvement of patient's wellbeing*", "*Interest in dementia research*", "*Improvement of patient's health*", "*General interest in research*", "*Better insights in new health technologies*", "*Assistance in patient management*", "*Assistance in dementia care*", "*Expense allowance*" and "*Other reasons*", multiple responses possible). Data on reasons for non-participation was collected from each GP who was successfully contacted but declined participation (Question: "Why did you choose not to participate in this research study?"). Responses provided were documented and coded ("*Lack of time*", "*Not interested in participation*", "*Not interested in research in general*"," *Did not see any added value in participation*", and "*Other reasons*", multiple responses possible).

Documentation of the recruitment of PwD includes data on (1) number contacts of PwD provided by GPs, (2) number of successfully recruited PwD within each GP practice and (3) data on drop-out rates. Further, recruitment rates (number of successfully participating PwD divided by the number of PwD contacted for recruitment) were calculated. Data on reasons for participations was analysed based on a survey filled out by each successfully recruited PwD and their caregiver (Item: "*Why did you choose to participate in this research study?*", response categories: "*Improvement of patient's wellbeing*", "*Interest in dementia research*", "*Improvement of patient's health*", "*Improvement of communication with GP*", "*Improvement of disease management*", "*Assistance and discharge due to technology*", "*Better insights in new health technologies*"," *Participation in a raffle of a Tablet computer*" and "*Other reasons*", multiple responses possible). Data on reasons for non-participation was collected via phone from each PwD/and or caregiver who declined participation (Question: "*Why did you choose not to participate in this*

research study?"). Responses provided were documented and coded (*"High care burden", "Health reasons/advanced dementia/age", "Not interested in participation", "No further explanation", "Technology-related rejection", "No need for intervention"* and *"Other reasons"*, multiple responses possible). Data was analysed descriptively using frequency tables to explore comparisons of recruitment rates and recruitment ratios as well as results of recruitment strategies. For the descriptive analysis SPSS version 25 was used. Efforts of different recruitment strategies was ranked based on researchers experience and perception.

Results

Recruitment of GPs

The recruitment of GPs was undertaken between June 2018 and March 2020 in the region of Berlin, Germany and surrounding areas. First, a total of $n = 32$ GPs was recruited (i.e., signed a cooperation agreement) into the study. However, due to early drop out during the recruitment phase, the final GP sample consisted of $N = 28$ GPs who successfully participated in the study. The recruitment process is summarised in Fig. 1. Results of all recruitment rounds separately are described in depth below.

First recruitment round

In the first recruitment round, all efforts resulted in $n = 11$ interested GPs contacting the research team. Out of these $n = 11$ GPs who contacted us, a total of $n = 7$ GPs was successfully recruited into the study. This proposes a recruitment rate of almost 64%. Out of $n = 11$ who contacted us, more than a half of GPs ($n = 6$) contacted us based on the newsletter of the GP research network. Out of these $n = 6$ GPs a total of $n = 5$ GPs were successfully recruited into the study (83%). Further, $n = 6$ GPs were contacted through snowball sampling, only $n = 1$ was successfully recruited (17%). To sum up, from

a total of $n = 17$ eligible GPs in the first recruitment round, $n = 8$ GPs were successfully recruited into the study. However, $n = 1$ was not able to recruit any PwD and therefore was coded as a drop out after randomisation. This results in $n = 7$ GPs successfully participating in the study. Overall, the recruitment rate for the first recruitment round accounts for approximately 41% ($n = 7$). GPs recruited in this round represent 25% ($n = 7$) of the final GP sample.

Second recruitment round

In the second recruitment round $n = 486$ GPs (out of a total of $N \approx 2000$ GPs) from all of the 23 districts in Berlin were randomly drawn from a database (KV Berlin). The first $n = 276$ GPs were contacted via mail and phone, followed by $n = 210$ GPs who were contacted only via phone. Out of all GPs contacted in this round ($n = 486$), only $n = 271$ were successfully reached. In total, this strategy resulted in $n = 18$ GPs included in the study. However, $n = 3$ ($n = 2$ before randomisation, $n = 1$ after randomisation) GPs dropped out leading to $n = 15$ successfully participating GPs. This proposes a recruitment rate of about 3% ($n = 15$). GPs recruited in this round represent 54% ($n = 15$) of the total GP sample.

Third recruitment round

In the third recruitment round GPs were visited directly in their practice. Based on the highest proportion of elderlies per district, GPs from nine of the 23 districts of the city Berlin were randomly chosen and $n = 116$ practices were visited on site. Out of all GPs visited in this round ($n = 116$), only $n = 80$ were successfully reached. A total of $n = 6$ GPs successfully recruited in this recruitment round. This proposes a recruitment rate of 5% ($n = 6$). GPs recruited in this round represent about 21% ($n = 6$) of the final GP sample. An overview of all recruitment rates and recruitment ratios can be obtained from Table 1. Figure 2 aims to visualise the efficiency
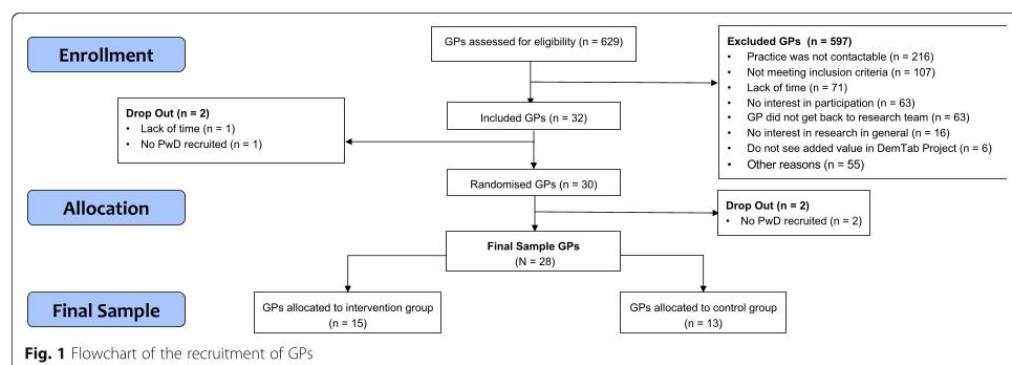

Fig. 1 Flowchart of the recruitment of GPs

Table 1 Overview of recruitment rates and recruitment ratios per round of GPs

GP Recruitment round	Contaced GPs (N)	GPs recruited (N)[a]	Drop Out (N)	Recruitment rate (%)[b]	Recruitment ratio (%)[c]
First recruitment round	17	8	1	41.2	25.0
Second recruitment round	486	18	3	3.1	53.6
Third recruitment round	116	6	0	5.2	21.4

Note. [a] includes GPs who signed informed consent. [b] Recruitment rate was calculated as number of successfully participating GPs (recruited GPs minus drop-outs) divided by the number of GPs contacted for recruitment. [c] Recruitment ratio was calculated based on the ratio of successfully participating GPs (recruited GPs minus drop-outs) and the final GP sample (*N* = 28)

(proportion of recruitment rate and effort of recruitment) of the different recruitment strategies and rounds of the present study.

Reasons given for participation and non-participation of GPs

The most commonly mentioned reason for participation was *Improvement of patient's well-being* (*n* = 22, 79%) followed by *Interest in dementia research* (*n* = 18, 64%). Further, across all recruitment rounds, *N* = 107 GPs (34%) were successfully reached but did not meet inclusion criteria. The most frequent inclusion criteria not met was because of *Few eligible PwD* (*n* = 40, 37%) and certain *Disease specialisations of the practice* (e.g. on diabetes) (*n* = 22, 21%). In a total of *n* = 211 cases GPs were successfully reached but denied participation. Out of *n* = 211 GPs who denied participation, reasons for non-participation were inquired via phone and documented. The most common reason for non-participation was *Lack of time* (*n* = 71, 34%), followed by *Not interested in participation* (*n* = 63, 30%). Reasons for participation and non-participation given by GPs can be obtained from Table 2.
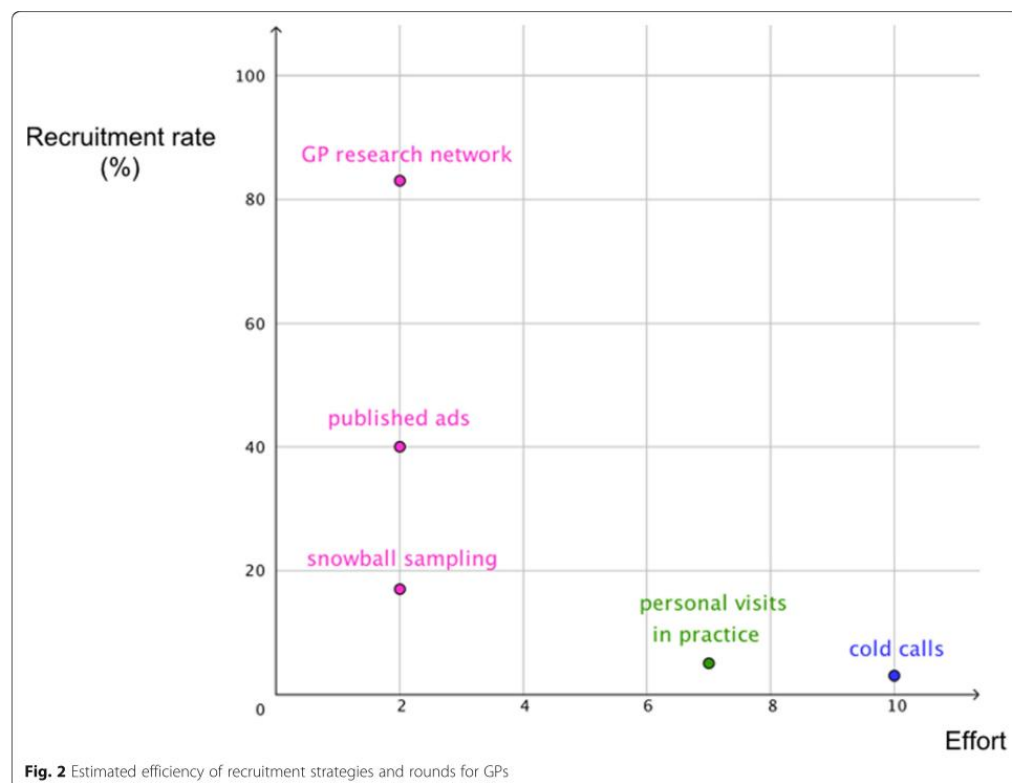

Fig. 2 Estimated efficiency of recruitment strategies and rounds for GPs

Table 2 Summary of reasons for participation and non-participation provided by GPs

	Number of GPs	Proportion %
Reasons for participation[a]		
Improvement of patient's wellbeing	22	78.6
Interest in dementia research	18	64.3
Improvement of patient's health	17	60.7
General interest in research	15	53.6
Better insights in new health technologies	12	42.9
Assistance in patient management	12	42.9
Assistance in dementia care	12	42.9
Expense allowance	2	7.4
Other reasons	8	28.6
Reasons for non-participation[b]		
Lack of time	71	33.7
Not interested in participation	63	29.9
Not interested in research in general	16	7.6
Did not see any added value in participation	6	2.8
Other reasons	55	26.1

Note. [a] $N = 28$ GPs, [b] $n = 211$ GPs

Recruitment of PwD and their caregivers

The recruitment of PwD and their caregivers was conducted between May 2019 and July 2020. A total of $n = 194$ contact details of PwD were provided by all $N = 28$ GPs. Figure 3 shows a flow chart of recruitment of PwD.

A total of $N = 102$ PwD were successfully recruited into the study. Overview of the recruitment descriptive statistics can be obtained from Table 3. On average, each GP referred about $n = 7$ PwD (range: 1–17; $mdn = 6$; IQR = 3.5), out of which on average about $n = 4$ PwD (range: 1–11; $mdn = 3$; IQR = 3.5) were successfully recruited. The overall recruitment rate for PwD was 54%.

Reasons given for participation and non-participation by PwD and/or caregivers

The most commonly mentioned reason for participation was *Improvement of patient's well-being* ($n = 73$, 82%) followed by *Interest in dementia research* ($n = 69$, 78%). Out of $n = 194$ PwD contact information provided by GPs, $n = 9$ PwD did not meet the inclusion criteria. Further, $n = 82$ PwD denied participation. Reasons for non-participation were inquired from PwD and/or caregivers and documented. The most common reason for non-participation provided was *High care burden* ($n = 25$, 22%) followed by *Health reasons/advanced dementia/age* ($n = 21$, 19%). Reasons for participation and non-participation given by caregivers of PwD can be obtained from Table 4.

Discussion

Recruitment of GPs and their patients is reported as one of the most difficult tasks in the implementation of primary care research. The key objective of the present paper was to describe the recruitment process and provide result of the enrolment of GPs and their PwD of a cRCT aiming to examine the effect of a tablet-based intervention. Recruitment was organised in two parts: first GPs were recruited, followed by the recruitment of PwD and their caregivers within each cluster.

Recruitment of GPs

Of all GPs who were eligible for participation almost 5 % responded to take part in the study, which is comparable to previous research [40, 41]. For example,
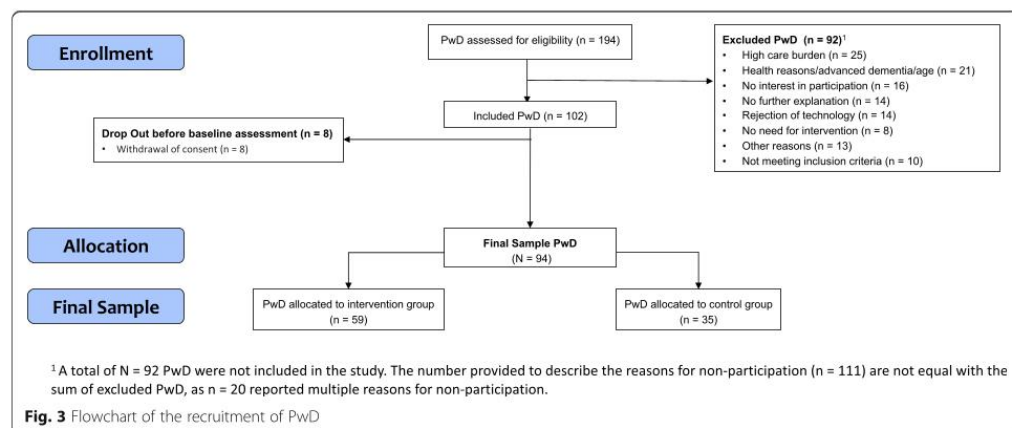

Reasons for non-participation (n = 111) are not equal with the sum of excluded PwD, as n = 20 reported multiple reasons for non-participation.

Fig. 3 Flowchart of the recruitment of PwD

Table 3 Overview of descriptive statistics of the recruitment of PwD

	Patients contacts provided by GPs					Patients successfully recruited into the study				
	n	Range	Mean (SD)	Median	IQR	n	Range	Mean (SD)	Median	IQR
Total	194	1–17	6.79 (3.91)	6.0	3.5	102	1–11	3.64 (2.53)	3.0	3.5
Intervention	124	2–17	8.13 (4.70)	7.0	8.0	67	1–11	4.47 (3.11)	3.0	5.0
Control	70	1–8	5.23 (1.92)	5.0	3.0	35	1–4	2.69 (1.11)	3.0	2.0

Note. N = 102 PwD. *SD* Standard Deviation, *IQR* Interquartile range

Williamson et al. [42] reported an initial overall response rate of 4.1% in their study. Further, the original target of recruiting *n* = 20 GPs was accomplished. However, similarly to other studies, recruiting time and resources had to be extended [34, 43]. A variety of recruitment rounds and strategies were applied in order to maximise successful recruitment. Recruitment efforts and success rates differed across strategies. The most efficient strategy in terms of absolute numbers was the second recruitment round. However, this strategy was proven to be extremely labour-intensive as it included cold calls of GPs in their practice. Initially, it was planned to send out information material and leaflets with calls for participation via mail to each practice. However, none of the GPs that were contacted via mail ever responded. This finding has been already reported in previous

Table 4 Summary of reasons for participation and non-participation provided by caregivers

	Number of caregivers	Proportion %
Reason for participation[a]		
Improvement of patient's wellbeing	73	82.0
Interest in dementia research	69	77.5
Improvement of patient's health	65	73.0
Improvement of communication with GP	58	65.1
Improvement of disease management	41	46.1
Assistance and discharge due to technology	35	39.3
Better insights in new health technologies	31	34.8
Participation in a raffle of a tablet computer	16	18.0
Other reasons	13	14.6
Reason for non-participation[b]		
High care burden	25	22.5
Health reasons/advanced dementia/age	21	18.9
No interest in participation	16	14.4
No further explanation	14	12.6
Technology-related rejection	14	12.6
No need for intervention	8	7.2
Other reasons	13	11.7

Note. [a] *n* = 89 caregivers, [b] *n* = 82 PwD and/or caregivers

research [40, 44]. Thus, follow-up calls were initiated and indicated a better response which is why a decision was made to forgo contacting GPs via mail and directly contact them via phone. This experience is in line with previous research. For example, Parkinson et al. [40] found in a sample of non-responding GPs that the vast majority had not seen the invitation which was sent via mail, suggesting it had not been passed on by administrative staff. Despite it being more fruitful, cold calls lead to new challenges. First, most GPs in Germany are only available during patient consultation hours. Consequently, a variety of GPs were occupied and therefore often not reachable. Second, once a primary care practice was successfully reached, the phone was answered almost exclusively by non-GP staff (e.g., receptionists, doctor's assistance or practice nurses). The present experience has shown that many times non-GP staff were occupied with daily work and due to practice structures not able and/or interested in passing on study information or requests for recalls to GPs. Further, engaging and rapport building with non-GP staff emerged as difficult. This hurdle is in line with previous work examining the role of non-GP staff in recruitment processes [6, 40, 42, 45], acknowledging the increasingly busy work environment in general practices [17, 23, 45]. To sum up, in the present study cold-calling GPs was found to be challenging, ineffective, extremely labour-intensive and opposite of the collaborative structure of primary care, all observations in line with previous research. However, in terms of the external validity and generalisability of study results, cold calls enable a random and systematical recruitment of GPs. If possible, future research should assess the labour-intensity and costs individually for each study in order to plan and budget accordingly. As shown in Fig. 2, the most efficient strategy in terms of high response and low labour-intensity was proved to be the first round, especially the dissemination of calls for participation in a GP research network. More than half of GPs recruited in this recruitment round were recruited via the GP research network. This is in line with previous research and the current trend to establish national research network for GPs [23, 26, 40, 46]. Further, whereas the representativeness of GPs from research networks may be limited, patients of these practices are found to be representative [47]. In the present study,

recruitment within a GP network was not only fruitful, but also did not require any financial and human resources. Based on the present finding and previous research, we strongly encourage the promotion and advertisement of GP networks. In Germany, the recent initiative (*Initiative of German Practice-Based Research Networks – DESAM-ForNet*; https://www.desam-fornet.de/ initiative-deutscher-forschungs praxennetze-desam-fornet/) aims to compose a wider research network by merging six regional research networks into one united German research network. GP networks might not only support with the recruitment of GPs into trials but represent potential for the provision of trainings for GPs who are interested in research methods and participation as well as recruitment of patients within their practice. In GP networks, GPs are seen as a research partner and not only as a provider of eligible patients. Their view on the relevance and feasibility of a research project at the planning stage of a project has the potential to improve the acceptability and thus participation of GPs in research [48–50]. With regard to snowball sampling, successfully recruited GPs of the present study were provided with additional recruitment material and asked to invite GP colleagues to participate in the study. This strategy has led to numerous referrals of potentially interested GPs, unfortunately only one was successfully included. However, previous research has recommended physician-to-physician recruiting as a promising recruitment strategy for primary care [51, 52]. Thus, future research may consider physician-to-physician recruitment. In terms of personal visits of GPs in their practice, based on present findings and previous research [51, 53, 54] we believe that well planned visits and a flexibility to individual practice styles may propose an effective recruitment strategy. In the present study, during our visit in GPs practices we provided GPs with a small package including information material on the study, flyers for patients, a required cooperation agreement in case of interest in participation as well as a reply-paid envelope. However, previous research has reported little or no effect of information leaflets and flyers on successful recruitment [53, 55].

Across all recruitment rounds, analysis of reported reasons of participation revealed that the *Improvement of patient's well-being* as well as a certain *Interest in the research topic* were main reasons for participation. Findings that practitioner's interest in the research topic facilitates recruitment is in line with previous studies [16, 56–58]. For example, a recent study conducted by Ferrand Devouge et al. [20] found that the relevance of a research topic for clinical practice was one main reason for participation. Our finding outlines the great importance of incorporating the role and views of GPs from an early stage on. However, the DemTab study was aiming

to involve primary care perspectives from the onset of the study. Thus, interviews and a workshop with GPs were conducted prior to the intervention's beginning in order to collect and analyse different perspectives and needs of dementia primary care and include these in the development of the study. However, the participation and involvement of GPs should commence at an earlier stage of research, namely in the development and design of research questions and project proposals. The present findings highlight the key role of GPs interest in certain research topic for their participation in research. In order to apply successful strategies for the recruitment of GPs that are congruent with the context of care delivery, it is highly instructive for future research to target active inclusion of GP's views and needs in the early stage of research, ideally at the stage of development of research projects and proposal writing. The most common reason for non-participation was *Lack of time*. This finding is in line with previous research acknowledging time constraints and time-related difficulties for participation in primary care research [13, 16, 17, 19, 20]. In order for GPs to participate in research and development of new care models, structural barriers such as lack of time due to everyday business in general practices have to be.

Recruitment of PwD

Recruitment of PwD emerged as challenging. Due to the cluster structure of the study and lack of PwD within one practice, recruitment of GPs had to be expanded. Even though we were able to recruit $N = 28$ GPs, only $N = 194$ contact details of PwD were forwarded by GPs. Consistent with previous research [22, 27, 59], in the present study the recruitment of patients into a cRCT through GPs has shown to be difficult and unsuccessful, as it did not result in the accomplishment of the primarily estimated sample size ($N = 204$). A variety of reasons can be drawn from the present study that may have contributed to a poor recruitment of PwD. First, at the beginning of the trial, most of GPs were too optimistic about eligible PwD in their practice. Later, GPs reported that it was much more challenging to recruit patients than expected. This phenomenon was already described by past research with the "*Lasagna's law*" [29] and is in line with previous research [42, 60]. However, in the present study, on average, one GP referred seven PwD (*mdn* = 6). A study conducted by Page et al. [31] reported a median of two patients per GP recruited into a trial. Further, our experience indicates that time constraints at GP level may have contributed to poor recruitment. Despite of continuous follow-up calls and reminders, it was often pointed out, that GPs did not have time or forgot to recruit PwD. This observation is also in line with previous research [16, 30, 31, 61].

However, the present study examined a technology-based intervention for GPs, PwD and their caregivers. Despite of lack of interest in technology not being a main reason for non-participation in the present study, it may be that a technology-based approach for the improvement of care for the elderly population meets no particular interest. This assumption is in line with previous empirical work, examining attitudes and beliefs towards technology based (health) devices [28, 62] and may propose a reason for the poor recruitment of PwD and their caregivers. The main reason for non-participation of PwD and/or caregivers included *High care burden* followed by *Health reasons/advanced dementia/age*. Previous research has already acknowledged poor health status and old age as predictors for refusal of participation in health research [63–65]. For example, Jacomb et al. [66] found that cognitive impairment predicted refusal of research participation. Future research should operate towards the identification of effective strategies to overcome recruitment barriers of older patients and patients with dementia in order to successfully include these groups in research and public health approaches aiming to improve health care. In terms of reasons for participation given by caregivers of PwD the most common reasons mentioned were *Improvement of patient's well-being*, followed by *Interest in dementia research*. Personal benefits have been already acknowledged as important drivers for participation in research [67, 68].

Limitations

The results of the present study have to be considered in light of certain limitations. First of all, the study's objective was the evaluation of a tablet-based intervention which limits the present results in terms of generalisability. Even though interest in and willingness to use technological based tools for the improvement of care are growing, practitioners are often found to be hesitant to new technologies [69–72]. Building on the present finding, that interest in a research topic plays a key role in the recruitment success of GPs, it may be that recruitment of GPs, PwD and their caregivers has proven complicated due to a technology-based intervention. For example, on a patient level, Foster et al. [28] found that a great proportion of patients rejected their participation in two linked randomised controlled telehealth trials because of a lack of ability to engage with telehealth or a lack of perceived need for it. However, in order to address and prevent structural and personal barriers of technology usage, GPs, PwD and their caregivers of the present study were provided with internet access, received a training and a handbook on the tablet usage prior to the beginning of the intervention. Further, analysis of reasons for non-participation did not reveal any

major indication for technology related lack of interest in the study. Only 12.6% of PwD/and or caregivers declined participation due to technology related reasons. However, present findings have to be interpreted in the context of technology-based intervention studies. Especially, as the target population of the present study was elderly patient diagnosed with dementia. This limitation has to be taken into consideration when interpreting the present results. Second, an unbalanced sample size between control and intervention group has to be taken into account. In order to minimise the risk of recruiting a selective sample of patients, GPs were not informed about allocation for as long as possible. Due to the design and flow of study, as well as the challenges emerging during recruitment of PwD, in the course of the trial GPs were informed about their allocation, in some cases during the ongoing recruitment process of PwD. In order to avoid bias, GPs were asked to not inform PwD about the allocation of the practice. Further, the study nurse was blinded until after the baseline assessment. However, the average number of referrals slightly differed between groups: in the intervention group GPs referred on average $n = 8$ PwD, whereas in the control group $n = 5$ PwD were referred on average. Although we did not see large differences across intervention arms in recruitment rates (median of successfully recruited PwD equals three for both groups), there might be a risk of bias in terms that it may have been easier for GPs to motivate and recruit PwD into the intervention group.

Practical implications

Based on the present findings, the following recommendations for the recruitment of GPs and their patients in primary care research in Germany can be drawn:

- *Cold calls remain labour-intensive and due to structural barriers in every day primary care practice unsuccessful, particularly for research projects dealing with low human and financial resources*
- *Primary Care Research Networks represent a valuable contribution to primary care research:*
    - Establishment of GP research networks
    - Trainings for GPs on research, participation and successful recruitment of patients
    - Dissemination of research projects and calls for participation among research interested GPs
- *The key role of research topics and their practical relevance for GPs*
    - Involvement of GPs in the research process from the early stage on:
        - Participation in the development of research questions

▪ Participation in the writing of research proposals

Conclusions

Barriers to GP recruitment identified in the present study were similar to those reported in previous research. To optimise recruitment of GPs in RCTs, research networks of GPs were found to be most efficient in terms of high response and low labour-intensity. Further, findings outline the great importance of involving GPs in early stage of research. Finally, results do not support cold calls as a successful strategy in the recruitment of GPs. Regarding recruitment of PwD and their caregivers, expectations of patient's well-being improvement and interest in research topic were the most common reasons for participation.

Abbreviations
cRCT: Cluster randomised controlled trial; GP: General practitioner; ICC: Interclass correlation coefficient; IQR: Interquartile range; Mdn: Median; PwD: Patients with dementia; RCT: Randomised controlled trial; SD: Standard deviation; UK: United Kingdom; US: United States of America

Authors' contributions
SL was primary contributor to data analysis, data interpretation and manuscript drafting. JLO, SD and LW assisted with the writing and interpretation of findings. JS primary oversaw and coordinated the recruitment of participant as well as its documentation and reporting. PG supervised the analysis. JN, PG and AK designed and led the DemTab study in which the present study was embedded. All authors contributed to the present study and critically revised and approved the final manuscript.

Authors' information
Not applicable.

Availability of data and materials
Data is stored in a non-publicly available repository. Data are however available from the corresponding author on request.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained by the ethics committee of the Charité – Universitätsmedizin Berlin (EA1/085/19). Written informed consent was obtained from all participants or legal guardians prior to data collection.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute of Medical Sociology and Rehabilitation Science, Charitéplatz 1, 10117 Berlin, Germany. [2]Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute of General Practice, Berlin, Germany.

References
1. Bally KW, Krones T, Jox RJ. Advance care planning for people with dementia: the role of general practitioners. Gerontology. 2020;66(1):40–6. https://doi.org/10.1159/000500809.
2. Leve V, Ilse K, Ufert M, Wilm S, Pentzek M. Driving and dementia : an issue for general practice?! Z Gerontol Geriatr. 2017;50(Suppl 2):55–62. https://doi.org/10.1007/s00391-017-1234-2.
3. Pentzek M, Vollmar HC, Wilm S, Leve V. Putting dementia awareness into general practice. Z Gerontol Geriatr. 2017;50(2):44–7. https://doi.org/10.1007/s00391-017-1206-6.
4. Thyrian JR, Fiß T, Dreier A, Böwing G, Angelow A, Lueke S, et al. Life- and person-centred help in Mecklenburg-Western Pomerania, Germany (DelpHi): study protocol for a randomised controlled trial. Trials. 2012;13(1):56. https://doi.org/10.1186/1745-6215-13-56.
5. Thyrian JR. Menschen mit Demenz in der primärärztlichen Versorgung. Z Gerontol Geriatr. 2017;50(2):32–8. https://doi.org/10.1007/s00391-017-1223-5.
6. Tan ACW, Clemson L, Mackenzie L, Sherrington C, Roberts C, Tiedemann A, et al. Strategies for recruitment in general practice settings: the iSOLVE fall prevention pragmatic cluster randomised controlled trial. BMC Med Res Methodol. 2019;19(1):236. https://doi.org/10.1186/s12874-019-0869-7.
7. Murphy K, O'Connor DA, Browning CJ, French SD, Michie S, Francis JJ, et al. Understanding diagnosis and management of dementia and guideline implementation in general practice: a qualitative study using the theoretical domains framework. Implement Sci. 2014;9(1):31. https://doi.org/10.1186/1748-5908-9-31.
8. Prins A, Hemke F, Pols J, van Charante EPM. Diagnosing dementia in Dutch general practice: a qualitative study of GPs' practices and views. Br J Gen Pract. 2016;66(647):e416–e22. https://doi.org/10.3399/bjgp16X685237.
9. Iliffe S, Robinson L, Brayne C, Goodman C, Rait G, Manthorpe J, et al. Primary care and dementia: 1. Diagnosis, screening and disclosure. Int J Geriatr Psychiatry. 2009;24(9):895–901. https://doi.org/10.1002/gps.2204.
10. Villars H, Oustric S, Andrieu S, Baeyens JP, Bernabei R, Brodaty H, et al. The primary care physician and Alzheimer's disease: an international position paper. J Nutr Health Aging. 2010;14(2):110–20. https://doi.org/10.1007/s12603-010-0022-0.
11. Balsinha C, Gonçalves-Pereira M, Iliffe S, Freitas JA, Grave J. Health-care delivery for older people with dementia in primary care. In: de Mendonça Lima CA, Ivbijaro G, editors. Primary care mental health in older people: a global perspective. Cham: Springer International Publishing; 2019. p. 311–29. https://doi.org/10.1007/978-3-030-10814-4_23.
12. Tilburgs B, Vernooij-Dassen M, Koopmans R, van Gennip H, Engels Y, Perry M. Barriers and facilitators for GPs in dementia advance care planning: a systematic integrative review. PLoS One. 2018;13(6):e0198535. https://doi.org/10.1371/journal.pone.0198535.
13. Huibers MJ, Bleijenberg G, Beurskens AJ, Kant IJ, Knottnerus JA, van der Windt DA, et al. An alternative trial design to overcome validity and recruitment problems in primary care research. Fam Pract. 2004;21(2):213–8. https://doi.org/10.1093/fampra/cmh219.
14. Sahin D, Yaffe MJ, Sussman T, McCusker J. A mixed studies literature review of family physicians' participation in research. Fam Med. 2014;46(7):503–14.
15. Voorhees JR, Xierali IM, Bazemore AW, Phillips RL, Jaén CR, Puffer JC. A small percentage of family physicians report time devoted to research. J Am Board Fam Med. 2013;26(1):7–8. https://doi.org/10.3122/jabfm.2013.01.120125.
16. Johnston S, Liddy C, Hogg W, Donskov M, Russell G, Gyorfi-Dyke E. Barriers and facilitators to recruitment of physicians and practices for primary care health services research at one Centre. BMC Med Res Methodol. 2010;10(1):109. https://doi.org/10.1186/1471-2288-10-109.
17. Leathem CS, Cupples ME, Byrne MC, O'Malley M, Houlihan A, Murphy AW, et al. Identifying strategies to maximise recruitment and retention of

practices and patients in a multicentre randomised controlled trial of an intervention to optimise secondary prevention for coronary heart disease in primary care. BMC Med Res Methodol. 2009;9(1):40. https://doi.org/10.1186/1471-2288-9-40.

18. Rosemann T, Szecsenyi J. General practitioners' attitudes towards research in primary care: qualitative results of a cross sectional study. BMC Fam Pract. 2004;5(1):31. https://doi.org/10.1186/1471-2296-5-31.

19. Mason V, Shaw A, Wiles N, Mulligan J, Peters T, Sharp D, et al. GPs' experiences of primary care mental health research: a qualitative study of the barriers to recruitment. Fam Pract. 2007;24(5):518–25. https://doi.org/10.1093/fampra/cmm047.

20. Ferrand Devouge E, Biard M, Beuzeboc J, Tavolacci M-P, Schuers M. Motivations and willingness of general practitioners in France to participate in primary care research as investigators. Fam Pract. 2019;36(5):552–9. https://doi.org/10.1093/fampra/cmy126.

21. Loskutova NY, Smail C, Ajayi K, Pace WD, Fox CH. Recruiting primary care practices for practice-based research: a case study of a group-randomized study (TRANSLATE CKD) recruitment process. Fam Pract. 2017;35(1):111–6.

22. Fletcher B, Gheorghe A, Moore D, Wilson S, Damery S. Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. BMJ Open. 2012;2(1):e000496. https://doi.org/10.1136/bmjopen-2011-000496.

23. Hummers-Pradier E, Bleidorn J, Schmiemann G, Joos S, Becker A, Altiner A, et al. General practice-based clinical trials in Germany - a problem analysis. Trials. 2012;13(1):205. https://doi.org/10.1186/1745-6215-13-205.

24. Jowett S, Macleod J, Wilson S, Hobbs F. Research in primary care: extent of involvement and perceived determinants among practitioners from one English region. Br J Gen Pract. 2000;50(454):387–9.

25. Felsen CB, Shaw EK, Ferrante JM, Lacroix LJ, Crabtree BF. Strategies for in-person recruitment: lessons learned from a New Jersey primary care research network (NJPCRN) study. J Am Board Fam Med. 2010;23(4):523–33. https://doi.org/10.3122/jabfm.2010.04.090096.

26. Ngune I, Jiwa M, Dadich A, Lotriet J, Sriram D. Effective recruitment strategies in primary care research: a systematic review. Qual Prim Care. 2012;20(2):115–23.

27. Bower P, Wallace P, Ward E, Graffy J, Miller J, Delaney B, et al. Improving recruitment to health research in primary care. Fam Pract. 2009;26(5):391–7. https://doi.org/10.1093/fampra/cmp037.

28. Foster A, Horspool KA, Edwards L, Thomas CL, Salisbury C, Montgomery AA, et al. Who does not participate in telehealth trials and why? A cross-sectional survey. Trials. 2015;16(1):258. https://doi.org/10.1186/s13063-015-0773-3.

29. Gorringe J. Initial preparation for clinical trials. Princ Pract Clin Trials Edinburgh Livingstone. 1970;4146:38.

30. van der Wouden JC, Blankenstein AH, Huibers MJH, van der Windt DAWM, Stalman WAB, Verhagen AP. Survey among 78 studies showed that Lasagna's law holds in Dutch primary care research. J Clin Epidemiol. 2007; 60(8):819–24. https://doi.org/10.1016/j.jclinepi.2006.11.010.

31. Page MJ, French SD, McKenzie JE, O'Connor DA, Green SE. Recruitment difficulties in a primary care cluster randomised trial: investigating factors contributing to general practitioners' recruitment of patients. BMC Med Res Methodol. 2011;11(1):35. https://doi.org/10.1186/1471-2288-11-35.

32. van der Gaag WH, van den Berg R, Koes BW, Bohnen AM, Hazen LM, Peul WC, et al. Discontinuation of a randomised controlled trial in general practice due to unsuccessful patient recruitment. BJGP Open. 2017;1(3). https://doi.org/10.3399/bjgpopen17X101085.

33. Taylor MJ, Whitton T. Public interest, Health Research and data protection law: establishing a legitimate trade-off between individual control and research access to health data. Laws. 2020;9(1):6. https://doi.org/10.3390/laws9010006.

34. Sully BGO, Julious SA, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. Trials. 2013;14(1):166. https://doi.org/10.1186/1745-6215-14-166.

35. Lech S, O'Sullivan JL, Gellert P, Voigt-Antons JN, Greinacher R, Nordheim J. Tablet-based outpatient Care for People with Dementia. GeroPsych. 2019; 32(3):135–44. https://doi.org/10.1024/1662-9647/a000210.

36. Vickrey BG, Mittman BS, Connor KI, Pearson ML, Della Penna RD, Ganiats TG, et al. The effect of a disease management intervention on quality and outcomes of dementia care. Ann Intern Med. 2006;145(10):713–26. https://doi.org/10.7326/0003-4819-145-10-200611210-00004.

37. Thyrian JR, Hertel J, Wucherer D, Eichler T, Michalowsky B, Dreier-Wolfgramm A, et al. Effectiveness and safety of dementia Care Management in Primary Care: a randomized clinical trial. JAMA Psychiatry. 2017;74(10): 996–1004. https://doi.org/10.1001/jamapsychiatry.2017.2124.

38. Dillman DA. Mail and telephone surveys: the total design method. New York: Wiley; 1978.

39. Dillman DA, Smyth JD, Christian LM. Internet, phone, mail, and mixed-mode surveys: the tailored design method (4th ed.). Hoboken Wiley; 2014.

40. Parkinson A, Jorm L, Douglas KA, Gee A, Sargent GM, Lujic S, et al. Recruiting general practitioners for surveys: reflections on the difficulties and some lessons learned. Aust J Prim Health. 2015;21(2):254–8. https://doi.org/10.1071/PY13129.

41. Gerlach FM, Beyer M, Erler A, Gensichen J, Hoffmann B, Petersen JJ, et al. Rekrutierung von Hausarztpraxen für Forschungsprojekte - Erfahrungen aus fünf allgemeinmedizinischen Studien. Z Allg Med. 2012;88(4):173–81.

42. Williamson MK, Pirkis J, Pfaff JJ, Tyson O, Sim M, Kerse N, et al. Recruiting and retaining GPs and patients in intervention studies: the DEPS-GP project as a case study. BMC Med Res Methodol. 2007;7(1):42. https://doi.org/10.1186/1471-2288-7-42.

43. McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials. 2006;7(1):9. https://doi.org/10.1186/1745-6215-7-9.

44. Crouch S, Robinson P, Pitts M. A comparison of general practitioner response rates to electronic and postal surveys in the setting of the national STI prevention program. Aust N Z J Public Health. 2011;35(2):187–9. https://doi.org/10.1111/j.1753-6405.2011.00687.x.

45. Thorpe C, Ryan B, McLean SL, Burt A, Stewart M, Brown JB, et al. How to obtain excellent response rates when surveying physicians. Fam Pract. 2009; 26(1):65–8. https://doi.org/10.1093/fampra/cmn097.

46. Howard RL, Avery AJ, Bissell P. Description of a multifaceted strategy for recruiting general practitioners and community pharmacists to talk about medication errors. Int J Pharm Pract. 2006;14(3):205–9.

47. Dapp U, Dirksen-Fischer M, Rieger-Ndakorerwa G, Fertmann R, Stender K-P, Golgert S, et al. Vergleichbarkeit von Studien epidemiologischer Alternsforschung. Bundesgesundheitsbl Gesundheitsforsch Gesundheitsschutz. 2016;59(5):662–78. https://doi.org/10.1007/s00103-016-2342-7.

48. Hummers-Pradier E, Chenot J-F, Scherer M. Sind Hausarztpraxen Forschungsinfrastruktur? Z Allg Med. 2017;93:317–22.

49. Peters-Klimm F, Freund T, Bentner M, Kiel M, Gutscher A, Szecsenyi J. Aus der Praxis und für die Praxis! Z Allg Med. 2013;89:183–8.

50. Tong SF, Ng CJ, Lee VKM, Lee PY, Ismail IZ, Khoo EM, et al. Decision making process and factors contributing to research participation among general practitioners: a grounded theory study. PLoS One. 2018;13(4):e0196379. https://doi.org/10.1371/journal.pone.0196379.

51. Goodyear-Smith F, York D, Petousis-Harris H, Turner N, Copp J, Kerse N, et al. Recruitment of practices in primary care research: the long and the short of it. Fam Pract. 2009;26(2):128–36. https://doi.org/10.1093/fampra/cmp015.

52. Ellis SD, Bertoni AG, Bonds DE, Clinch CR, Balasubramanyam A, Blackwell C, et al. Value of recruitment strategies used in a primary care practice-based trial. Contemp Clin Trials. 2007;28(3):258–67. https://doi.org/10.1016/j.cct.2006.08.009.

53. Bedson E, Bell D, Carr D, Carter B, Hughes D, Jorgensen A, et al. Folate Augmentation of Treatment--Evaluation for Depression (FolATED): randomised trial and economic evaluation. Health Technol Assess (Winchester, England). 2014;18(48):vii–viii 1–159.

54. Gardner HR, Treweek S, Gillies K. Using evidence when planning for trial recruitment: an international perspective from time-poor trialists. PLoS One. 2019;14(12):e0226081. https://doi.org/10.1371/journal.pone.0226081.

55. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev. 2018;2(2):Mr000013.

56. Bell-Syer SEM, Thorpe LN, Thomas K, Macpherson H. GP participation and recruitment of patients to RCTs: lessons from trials of acupuncture and exercise for low Back pain in primary care. Evid Based Complement Alternat Med. 2011;2011:687349.

57. Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, et al. Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. Health Technol Assess (Winchester, England). 2007;11(48):iii–ix–105.

58. Dormandy E, Kavalier F, Logan J, Harris H, Ishmael N, Marteau TM, et al. Maximising recruitment and retention of general practices in clinical trials: a case study. Br J Gen Pract. 2008;58(556):759–66. https://doi.org/10.3399/bjgp08X319666.

59. Bryant J, Powell J. Payment to healthcare professionals for patient recruitment to trials: a systematic review. BMJ. 2005;331(7529):1377–8. https://doi.org/10.1136/bmj.331.7529.1377.

60. Foy R, Parry J, Duggan A, Delaney B, Wilson S, Lewin-van den Broek N, et al. How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies. Fam Pract. 2003;20(1): 83–92. https://doi.org/10.1093/fampra/20.1.83.

61. Spaar A, Frey M, Turk A, Karrer W, Puhan MA. Recruitment barriers in a randomized controlled trial from the physicians' perspective: a postal survey. BMC Med Res Methodol. 2009;9(1):14. https://doi.org/10.1186/1471-2288-9-14.

62. O'Sullivan JL, Gellert P, Hesse B, Jordan L-M, Möller S, Voigt-Antons J-N, et al. Exploring attitudes of healthcare professionals towards ICT-based interventions for nursing home residents with dementia: a mixed-methods approach. Contemp Nurse. 2018;54(1):13–25. https://doi.org/10.1080/10376178.2017.1421087.

63. Chretien J-P, Chu LK, Smith TC, Smith B, Ryan MAK, the Millennium Cohort Study T. Demographic and occupational predictors of early response to a mailed invitation to enroll in a longitudinal health study. BMC Med Res Methodol. 2007;7(1):6.

64. Coste J, Quinquis L, Audureau E, Pouchot J. Non response, incomplete and inconsistent responses to self-administered health-related quality of life measures in the general population: patterns, determinants and impact on the validity of estimates — a population-based study in France using the MOS SF-36. Health Qual Life Outcomes. 2013;11(1):44.

65. Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI. Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. Cancer Detect Prev. 2006;30(1):24–33. https://doi.org/10.1016/j.cdp.2005.12.001.

66. Jacomb PA, Jorm AF, Korten AE, Christensen H, Henderson AS. Predictors of refusal to participate: a longitudinal health survey of the elderly in Australia. BMC Public Health. 2002;2(1):4. https://doi.org/10.1186/1471-2458-2-4.

67. Catt S, Langridge C, Fallowfield L, Talbot D, Jenkins V. Reasons given by patients for participating, or not, in phase 1 cancer trials. Eur J Cancer. 2011; 47(10):1490–7. https://doi.org/10.1016/j.ejca.2011.02.020.

68. Jenkins V, Farewell V, Farewell D, Darmanin J, Wagstaff J, Langridge C, et al. Drivers and barriers to patient participation in RCTs. Br J Cancer. 2013;108(7): 1402–7. https://doi.org/10.1038/bjc.2013.113.

69. Yarbrough AK, Smith TB. Technology acceptance among physicians: a new take on TAM. Med Care Res Rev. 2007;64(6):650–72. https://doi.org/10.1177/1077558707305942.

70. Richards H, King G, Reid M, Selvaraj S, McNicol I, Brebner E, et al. Remote working: survey of attitudes to eHealth of doctors and nurses in rural general practices in the United Kingdom. Fam Pract. 2005;22(1):2–7. https://doi.org/10.1093/fampra/cmh716.

71. Wälivaara B-M, Andersson S, Axelsson K. General practitioners' reasoning about using mobile distance-spanning technology in home care and in nursing home care. Scand J Caring Sci. 2011;25(1):117–25. https://doi.org/10.1111/j.1471-6712.2010.00800.x.

72. Webb MJ, Wadley G, Sanci LA. Experiences of general practitioners and practice support staff using a health and lifestyle screening app in primary health care: implementation case study. JMIR mHealth uHealth. 2018;6(4):e105. https://doi.org/10.2196/mhealth.8778.

Publisher's Note

Excerpt from Journal Summary List for Manuscript III

In the field of Gerontology, the journal "*BMC Geriatrics*" is ranked on the 6th place out of 36 journals. Thus, the journal is ranked within the top 25 percent (Q1), making it one of the leading top journals in the field.

Journal Data Filtered By: **Selected JCR Year: 2019** Selected Editions: SCIE,SSCI
Selected Categories: "GERONTOLOGY" Selected Category
Scheme: WoS
Gesamtanzahl: 36 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	JOURNALS OF GERONTOLOGY SERIES A-BIOLOGICAL SCIENCES AND MEDICAL SCIENCES	21,215	5.236	0.025410
2	JOURNAL OF THE AMERICAN GERIATRICS SOCIETY	33,158	4.180	0.034050
3	JOURNALS OF GERONTOLOGY SERIES B-PSYCHOLOGICAL SCIENCES AND SOCIAL SCIENCES	9,435	3.502	0.009930
4	AMERICAN JOURNAL OF GERIATRIC PSYCHIATRY	7,144	3.393	0.009920
5	GERONTOLOGIST	11,196	3.286	0.011530
6	BMC Geriatrics	6,492	3.077	0.015830
7	INTERNATIONAL PSYCHOGERIATRICS	7,341	2.940	0.009920
8	INTERNATIONAL JOURNAL OF GERIATRIC PSYCHIATRY	9,290	2.675	0.010310
9	AGING & MENTAL HEALTH	6,080	2.478	0.008140
10	European Journal of Ageing	1,248	2.413	0.001520
11	JOURNAL OF APPLIED GERONTOLOGY	1,664	2.144	0.002580
12	JOURNAL OF AGING AND HEALTH	3,109	2.136	0.004450
13	PSYCHOLOGY AND AGING	10,065	2.107	0.006280
14	Geriatrics & Gerontology International	3,866	2.022	0.008910
15	RESEARCH ON AGING	1,893	2.000	0.001940
16	Dementia-International Journal of Social Research and Practice	2,095	1.874	0.003010

Printing copy of Manuscript III

BMC Geriatrics

Dementia care and the role of guideline adherence in primary care: cross-sectional findings from the DemTab study

Sonia Lech[1,2]*, Julie L. O'Sullivan[1], Johanna Drewelies[3], Wolfram Herrmann[4], Robert P. Spang[5], Jan-Niklas Voigt-Antons[5,6], Johanna Nordheim[1] and Paul Gellert[1]

Abstract

Background: General practitioners (GPs) play a key role in the care of people with dementia (PwD). However, the role of the German Dementia Guideline in primary care remains unclear. The main objective of the present study was to examine the role of guideline-based dementia care in general practices.

Methods: A cross-sectional analysis of data obtained from the DemTab study was conducted. Descriptive analyses of sociodemographic and clinical characteristics for GPs ($N=28$) and PwD ($N=91$) were conducted. Adherence to the German Dementia Guideline of GPs was measured at the level of PwD. Linear Mixed Models were used to analyze the associations between adherence to the German Dementia Guideline and GP factors at individual (age, years of experience as a GP, frequency of utilization of guideline, perceived usefulness of guideline) and structural (type of practice, total number of patients seen by a participating GP, and total number of PwD seen by a participating GP) levels as well as between adherence to the German Dementia Guideline and PwD's quality of life.

Results: Self-reported overall adherence of GPs was on average 71% ($SD=19.4$, range: 25–100). Adherence to specific recommendations varied widely (from 19.2 to 95.3%) and the majority of GPs (79.1%) reported the guideline as only partially or somewhat helpful. Further, we found lower adherence to be significantly associated with higher numbers of patients ($\gamma 10=-5.58$, $CI=-10.97$, -0.19, $p=.04$). No association between adherence to the guideline and PwD's quality of life was found ($\gamma 10=-.86$, $CI=-4.18$, 2.47, $p=.61$).

Conclusion: The present study examined the role of adherence to the German Dementia Guideline recommendations in primary care. Overall, GPs reported high levels of adherence. However, major differences across guideline recommendations were found. Findings highlight the importance of guidelines for the provision of care. Dementia guidelines for GPs need to be better tailored and addressed. Further, structural changes such as more time for PwD may contribute to a sustainable change of dementia care in primary care.

Trial registration: The DemTab trial was prospectively registered with the ISRCTN registry (Trial registration number: ISRCTN15854413). Registered 01 April 2019.

Keywords: Dementia, Primary care, Adherence to dementia guideline

*Correspondence: Sonia.lech@charite.de
[1] Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Institute for Medical Sociology and Rehabilitation Science, Charitéplatz 1, 10117 Berlin, Germany
Full list of author information is available at the end of the article

Background

The current and imminent public health impact of dementia is vast. According to the World Alzheimer's Report published in 2015, 46.8 million people worldwide were estimated to live with dementia. Further, this

number is estimated to increase to 74.7 million by 2030 and 131.5 million by 2050 [1, 2]. Currently, about 1.7 million people with dementia (PwD) live in Germany, with a prevalence of 10% among older adults over the age of 65 [3, 4]. Dementia not only affects those living with dementia, but also their families and informal caregivers, the health care system, and society as a whole [5–7]. Consequently, policy makers and researchers are being urged to address dementia as a public health priority. In light of this, the World Health Organization (WHO) has called for national dementia strategies [6]. WHO's recommendations for national areas of action include, amongst others, the improvement of dementia care delivery. In Germany, general practitioners (GPs) play a pivotal role in the management and delivery of care for PwD [8–13]. For example, almost 99% of PwD living at home consult their GP at least once a year [14]. Despite empirical evidence reporting that GPs acknowledge dementia care as a relevant topic and show positive attitudes towards the care of PwD, GPs find many aspects of dementia care to be challenging [15]. The vast majority of previous research has focused on examining and improving primary care for dementia at an individual level of GPs. For example, research has primarily centered on providing knowledge training and education in diagnostics and dementia management [16–23]. However, structural factors such as time constraints per patient [17, 24], as well as lack of cross-sectional collaboration [25] and lack of social services support [17, 18] were frequently reported to negatively impact primary care delivery for dementia. It remains unclear which GP related factors impact dementia care delivery most.

Overall, evidence-based guidelines represent one public health tool that fosters optimal care delivery [26]. Following recommendations of evidence-based guidelines may contribute to an improvement of dementia care [27, 28] and patient health-related quality of life [29]. In Germany, the German Dementia Guideline (GDG) [28] provides evidence-based recommendations for treatment, care, and support of dementia. The GDG is an interdisciplinary guideline which is jointly issued by the German medical society for neurology, and the German medical society for psychiatry, psychotherapy, and psychosomatics. This comprehensive guideline comprises information on state-of-the-art diagnosis of Alzheimer's disease and other dementias as well as evidence-based recommendations for pharmacological and psychosocial treatment of dementia. Depending on dementia severity, recommendations are given for treatment of the core symptoms of dementia, including cognitive, functional, and behavioral symptoms. For example, the GDG recommends an intake of anti-dementia drugs dependent on type of dementia and severity of cognitive impairment. For individuals

diagnosed with Alzheimer's Disease and a mild to moderate cognitive impairment, the intake of Acetylcholinesterase inhibitors is recommended [28]. The guideline also includes information on caregiver burden and specific health risks for informal caregivers and provides recommendations on interventions for reducing their psychological burden. Regarding dementia treatment and care in the primary care setting, the guideline contains a specific chapter with information on the unique role of GPs which was added by the German College of General Practitioners and Family Physicians (DEGAM). The chapter outlines the importance of a holistic view and, in the best sense of participatory decision-making, recommends to prioritize the individual health status and health problems of patients.

While the implementation of and adherence to dementia guideline recommendations may improve dementia care, little is known about the knowledge and utilization of the GDG among GPs in Germany. However, the GDG was not specifically developed for general practice. In addition, the associations between adherence to dementia guidelines (AGDG) and GP and PwD related factors remain unclear. The present study aims to explore the role of using the GDG in recommendations in primary care. First, we aim at describing a newly developed checklist assessing adherence to the GDG. Second, we aim to examine the association between AGDG and GP factors at *individual levels* (age, years of experience as a GP, frequency of utilization of the GDG, and perceived usefulness of the GDG) as well as at *structural levels* (type of practice, total number of patients seen by a participating GP during last 3 months, and total number of PwD seen by a participating GP during last 3 months). Based on previous literature [29], the following hypothesis are proposed:

Hypothesis 1: Structural factors (type of practice, total number of patients seen by a participating GP during last 3 months, and total number of PwD seen by a participating GP during last 3 months) will have a greater impact on AGDG than individual factors (age, years of experience as a GP, frequency of utilization of the GDG, and perceived usefulness of the GDG).

Hypothesis 2: The AGDG score will be positively associated with PwD's self-reported quality of life.

Methods

Participants and recruitment

This paper uses baseline data obtained from the DemTab study, a cluster randomized controlled trial (cRCT) that investigated the effects of a tablet-based intervention on guideline adherence (primary outcome) and health related PwD and informal caregiver outcomes (secondary outcomes) in the primary care setting. The study

design and methods for the DemTab study have been published in detail elsewhere [30]. In summary, the target population of the DemTab study were GPs, PwD, and their informal caregivers from Berlin and the surrounding area and data was obtained from GPs, PwD and their informal caregivers. For the purpose of the present study, only baseline data from GPs and PwD were included. Eligible GPs were currently operating GPs who provided informed consent to participate in the study. Eligible PwD were community living patients with a dementia diagnosis (ICD-10 F00-F03, G30, G31.0 and G31.82), who were treated in outpatient care and provided a signed informed consent to participate in the study (if he/she is still authorized to sign) or otherwise through a person holding the power of attorney.
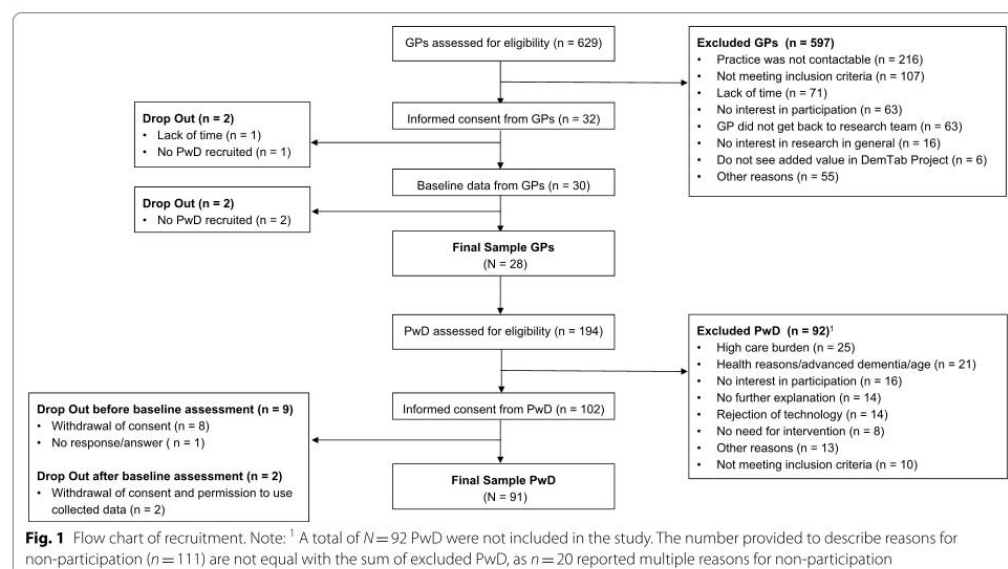
Study sample

Due to the cluster-randomized design, the study sample was determined in two steps. In the first step, GPs were recruited through a variety of sampling methods: 1) advertisements in general practice related publications and newsletters through different networks in and around Berlin; 2) via phone recruitment of GPs randomly drawn from a database of the Statutory Health Insurance Physicians in Berlin, and 3) face-to-face recruitment of GPs in their general practices in Berlin. In a second step, successfully recruited GPs recruited potentially eligible PwD from their practice. Overall, 629 GPs and 194 PwD were contacted for recruitment, of which 32 GPs and 102 PwD agreed to participate and signed an informed consent. On average, each GP referred about 7 PwD (range: 1–17; mdn = 6; IQR = 3.5) and successfully recruited about 4 PwD (range: 1–11; mdn = 3; IQR = 3.5). The final sample consisted of $N = 28$ GPs and $N = 91$ PwD. A flowchart is presented in Fig. 1. A thorough description of the recruitment process and responses rates can be found in Lech et al. [31].

Data collection

Baseline data were collected from July 2019 to July 2020. Data from GPs were obtained through a questionnaire sent via mail. Data collection from PwD was originally planned and in most cases obtained by trained study nurses in the patient's home. However, due to the coronavirus disease 2019 (COVID-19), data collection was aligned with new regulations and changed from face-to-face assessment to phone interviews ($n = 12$ PwD). The first assessment via phone was conducted on 30th March 2020. With the exception of the Mini Mental State Examination (MMSE), data collection via phone was uncomplicated and feasible. A follow up analysis revealed no differences in variables of PwD between data collected via face to face and data collected via phone interviews. However, due to the adjusted baseline data collection, it was not feasible to obtain data on the MMSE in a total of 11% of PwD ($n = 11$). Additional information on the

Fig. 1 Flow chart of recruitment. Note: [1] A total of $N = 92$ PwD were not included in the study. The number provided to describe reasons for non-participation ($n = 111$) are not equal with the sum of excluded PwD, as $n = 20$ reported multiple reasons for non-participation

health and care situation of each PwD was obtained from GPs via another questionnaire.

Measures

At baseline, variables of interest were collected using a self-report questionnaire. A detailed description of all variables and measures can be found elsewhere [30]. The DemTab study, with respect to autonomy and self-determination, aimed at involving and letting PwD speak for themselves as much as possible during data collection. Therefore, we mainly selected self-reported standardized measurements suitable for PwD. All further information (mainly sociodemographic information) was intended to be obtained from PwD directly. However, if the PwD was no longer able to provide answers or the validity of answers was questionable, a trained study nurse verified or obtained this information from the informal caregiver. For example, if a PwD was unable to provide information on their age or seemed unsure, the study nurse noted this during data collection and afterwards tried to verify the missing information with the caregiver. Study nurses always documented whether sociodemographic information was collected only from the PwD or also from the caregiver. In a total of 61.5% additional data on PwD was obtained from informal caregivers.

Measures of adherence to German dementia guideline

Adherence to the German Dementia Guideline (AGDG) was primarily assessed with a 23-item checklist. The checklist was developed based on the German Dementia Guideline [28] and other empirical work focusing on the role of guideline-based primary care [29, 32, 33]. AGDG was self-reported by each GP on patient's level (for each participating PwD). The checklist can be found in German (original) and English (simple translation) in Appendix 1. The original checklist was composed in a dichotomous format with "yes" and "no" as options, but also included the category "not applicable". However, when analyzing the data, it became evident that the category "not applicable" was selected inconsistently. Specifically, because we failed to define "not applicable" a priori, it was unclear how this category was used. Consequently, there were known inconsistencies. In order to analyze the impact of the category "not applicable" and reduce possible bias in the calculation of the final AGDG score, we conducted a set of analyses to compare different scorings (see Appendix 2; Table A1). *Scoring method 1:* "not applicable" was recoded into missing data. *Scoring method 2:* "not applicable" was recoded into "not guideline adherent" (= 0), *Scoring method 3:* items, where "not applicable" was plausible were recoded into "not guideline adherent" (= 0), all other "not applicable" were recoded into missing data. *Scoring method*

4: items, where "not applicable" was plausible were recoded into "guideline adherent" (= 1), all other "not applicable" were recoded into missing data. For each scoring method, means and final scores were calculated (see Appendix 2; Table A1). Comparisons of means and correlations across scoring methods did not reveal any significant differences (see Appendix 2; Table A2 and Table A3). Due to conceptual assumptions, *scoring method 1* was chosen for the calculation of the final score and "not applicable" was recoded as missing data. It is recommended for future research, when applying the present or any checklist for the assessment of guideline adherence, to define and include the category "not applicable" when appropriate, as this category may represent a valuable contribution. The final AGDG score for each PwD was calculated as the proportion of guideline adherence and all items answered ([sum of items answered as guideline adherent/sum of all answered items] × 100). The overall AGDG score was calculated as the mean percentage of per-patient guideline adherence across all GPs. The internal consistency of our scale for this data was Cronbachs's $\alpha = .876$.

In addition, we assessed other indicators measuring adherence to the GDG in primary care. First, *knowledge of the guideline* ("*Are you familiar with the dementia guideline?*"; yes/no), *utilization of the guideline* ("*Do you use the dementia guideline?*", yes/no), *frequency of utilization* ("*How often do you use the guideline?*"; always/often/sometimes/seldom/never) and *perceived usefulness of the guideline* ("*How useful do you find the guideline?*"; very/partially/somewhat/not helpful at all) were assessed from GPs. Further, *prescribed anti-dementia drug* (drug name), *type of dementia* (ICD-10 code) and *cognitive status* (MMSE) were compared based on guideline recommendations and a variable was computed (0 = not guideline adherent, 1 = guideline adherent, 2 = off-label use) to assess guideline adherence with regard to drug prescriptions.

Measures of GPs and PwD

Next, demographic and practice information was also collected for GPs. This information included *age* (years), *gender* (female/male/other), *years of experience* as a GP (years), *type of practice* (single/shared), *total number of patients seen by a participating GP during last 3 months* (NPAT) and *total number of PwD seen by a participating GP during last 3 months* (NPWD).

Finally, sociodemographic information of PwD were collected, including *age* (years), *gender* (female/male/other), *education* (years of education) and *living situation* (alone/with partner/with caregiver/in outpatient facility). Further, *level of care was measured according to the compulsory long-term care insurance in Germany*

(ranging from 1 = low level of care to 5 = high level of care) [34]. Information on *diagnostic procedure* ("*Who diagnosed the patient?*"; current GP/other GP/specialist/other facility), *type of dementia* (ICD-10 code) and *prescribed medications* were obtained via GPs. Dementia related assessments included the *Mini-Mental State Examination* (total score ranges from 0 to 30, higher scores indicating higher cognitive status) [35]. Quality of Life was assessed using the *Quality of Life in Alzheimer's Disease questionnaire (QOL-AD,* total score ranges from 13 to 52, higher scores indicating better quality of life) [36].

Statistical analysis

First, descriptive analyses (means, standard deviations and ranges for continuous variables, frequencies for nominal and ordinal variables) of sociodemographic and clinical characteristics for GPs and PwD as well as for AGDG were calculated. Second, to address Hypothesis 1 and Hypothesis 2, Linear Mixed Models (LMM) for continuous outcomes (covariance type = variance components, estimation = Maximum Likelihood) were applied to analyze the predictive values of independent variables (level 1) accounting for the nested structure (GPs, level 2). The ID of GPs was used as a clustering variable. In step 1, an intercept-only model (no level-one or level-two predictor was included in the model) was estimated to examine the variance associated between GP units and AGDG (base model). In order to describe dependencies due to the cluster structure of the data, an intraclass correlation coefficient (ICC) representing the ratio of the between-GP variance to the total variance was calculated. In step 2, a two-level random-intercept model, which allows for variation in intercepts across GPs was estimated, in order to account for the clustered structure of the data. In order to explore the association between individual and structural factors and AGDG (Hypothesis 1), the following predictors were included in this model: 1) individual factors: *age, years of experience as a GP, frequency of utilization of guideline* and *perceived usefulness of guideline,* and 2) structural factors: *type of practice, NPAT* and *NPWD.* In order to examine the association between PwD's quality of life and AGDG (Hypothesis 2), quality of life was included as a predictor variable in another model. All predictors were standardized. The likelihood ratio (LR) test was used to compare the difference between the two nested models. All statistical analyses were performed using IBM SPSS Statistics for Windows V.27.0 and RStudio (Version 1.4.1106). All tests of significance were based on a *p* < .05 level and confidence interval of 95%.

Results

Characteristics of GPs

Characteristics of participating GPs can be found in Table 1. Overall, 61.0% of participating GPs were female and on average 50 years old (*SD* = 7.99, range: 38–67), with a mean of about 12 years of experience as a GP (*SD* = 9.11, range: 1–29). Less than half of GPs (*n* = 12, 42.9%) were working in a single-handed practice. On average, GPs treated *N* = 1489 patients (*SD* = 656.03, range: 700–2990) and *N* = 61 PwD (*SD* = 52.80, range: 9–200) during the last 3 months.

Characteristics of PwD

Table 2 presents an overview of PwD's main characteristics. Overall, almost 60% (*n* = 54) of PwD were female, were on average 80 years old (*SD* = 6.3, range: 63–94), and reported an average of 12.6 years of education (*SD* = 3.3, range: 8–17). More than half of PwD lived together with their spouse or partner (*n* = 53; 58.2%). About 51% of PwD were in need of substantial care (care level 3 or higher). About half of PwD obtained their dementia diagnosis from a specialist (55.2%) and about a third (33.3%) from a GP. PwD visited their GP on average 2.8 times in the last 3 months (*SD* = 1.9, range: 0–11). The mean MMSE score was 18.9 (*SD* = 7.8, range: 0–30) and the majority of PwD (*n* = 38; 51.4%) were mildly cognitive impaired. More than one third of PwD (36.7%) reported the intake of an anti-dementia drug. The mean QOL-AD score was 34.1 (*SD* = 5.8, range: 18–48).

The role of the GDG in primary care

The overall mean AGDG score was 71.02 (*SD* = 19.4, range: 25–100). Table 3 shows frequencies for each recommendation of the GDG across all GPs and PwD.

The great majority of GPs reported following the guideline recommendations with regard to assessing a patient's entire current medication plan (95.3%), physical and psychopathological evaluations (94.3%),

Table 1 Main characteristics of GPs

Sociodemographic characteristics	N	%	M	SD	range
Age	28		49.9	8.0	38–67
Gender (female)	17	60.7			
Years of experience as a GP	28		11.8	9.1	1–29
Single-handed practice (yes)	12	42.9			
NPAT	28		1488.9	656.0	700–2990
NPWD	28		60.9	52.8	9–200

N = 28 GPs, *M* Mean, *SD* Standard Deviation, *NPAT* total number of patients seen by a participating GP during last 3 months, *NPWD* total number of PwD seen by a participating GP during last 3 months

Table 2 Main characteristics of PwD

Sociodemographic characteristics	n	%	M	SD	range
Age	91		80.5	6.3	63–94
Gender (female)	54	59.3			
Years of education	85		12.7	2.8	8–17
Living situation					
Alone	17	18.7			
With spouse/partner	53	58.2			
With another informal caregiver	6	6.6			
In outpatient facility	15	16.5			
Care level (yes)	71	64.6			
Care level 1	5	5.5			
Care level 2	20	22.0			
Care level 3	29	31.9			
Care level 4 or 5	17	18.7			
Dementia related assessments					
Diagnostic procedure					
Current GP	16	18.4			
Other GP	13	14.9			
Ambulatory specialist (psychiatrist, neurologist)	48	55.2			
Other facility	10	11.4			
Type of dementia diagnosis					
Alzheimer's Disease	34	37.4			
Unspecified dementia	32	35.2			
Vascular dementia	17	18.7			
Other type of dementia diagnosis	7	7.7			
MMSE score	74		18.9	7.8	0–30
Severity of cognitive impairment					
Mild	38	51.4			
Moderate	27	36.5			
Severe	9	12.2			
Intake of anti-dementia drugs (yes)	33	36.7			
QOL-AD	91		34.1	5.8	18–48

N = 91, *M* Mean, *SD* Standard Deviation, *MMSE* Mini Mental State Examination, *QOL-AD* Quality of Life in Alzheimer's Disease questionnaire

laboratory tests as part of the diagnostics procedure (94.3%), conducting a basic geriatric assessment (93.2%), and assessing psychological and behavioral symptoms of dementia (91.5%). Recommendations on discussing palliative care (19.2%) or the current driving situation (49.2%), as well as obtaining CT/MRI scans as part of the diagnostic procedure (54.1%), providing of information about local support services (54.8%) and prescribing non-pharmacological interventions (54.8%) were less frequently followed. Further, the great majority (*n* = 20; 71.4%) of GPs reported to be familiar with the GDG, but only 19.2% (*n* = 5) reported using it often. Further, 20.8% (*n* = 5) reported the GDG as very helpful and 45.8% (*n* = 11) found it to be partially helpful. Almost one third (*n* = 8; 28.6%) reported the length

of the GDG as a reason for not using the guideline. See Table 4 for a complete breakdown of attitudes toward the GDG. With regard to anti-dementia drug prescription, 10.3% of PwD were prescribed a drug that was not in line with guideline recommendations, and 44.8% were prescribed a drug that was considered as off-label use by the GDG.

Association between AGDG and factors on GP and PwD level

Results of the intercept-only model (base model) indicated there was statistically significant variation in the intercepts (ICC = .536), accounting for approximately 54% of the variance in AGDG and indicating a substantial clustering of observations within level 2 units. With regard to Hypothesis 1, the regression coefficient for NPAT showed a negative and significant predictive relationship between NPAT and AGDG ($\gamma 10 = -5.58$, $CI = -10.97, -0.19$, $p = .04$), indicating an association between higher number of patients and lower AGDG scores. Age ($\gamma 10 = -7.39$, $CI = -19.81, 5.03$, $p = .23$), *Years of experience as a GP* ($\gamma 10 = 7.92$, $CI = -5.03$, 20.86, $p = .22$), *frequency of utilization of GDG* ($\gamma 10 = -2.06$, $CI = -12.05, 7.93$, $p = .68$) and *perceived usefulness of GDG* ($\gamma 10 = 2.78$, $CI = -5.71, 11.29$, $p = .51$) as well as *type of practice* ($\gamma 10 = -2.54$, $CI = -7.73$, 2.65, $p = .33$) and *NPWD* ($\gamma 10 = -3.26$, $CI = -9.06$, 2.53, $p = .26$) were not significant in predicting AGDG. Further, results of the likelihood ratio test showed a significant increase of the fit by adding level 1 predictors ($\chi^2 = 155.6$, $df = 7$, $p < .001$). With regard to Hypothesis 2, the regression coefficient for QOL-AD shows no significant association between QOL-AD and AGDG score ($\gamma 10 = -.86$, $CI = -4.18, 2.47, p = .61$).

Discussion

The main objective of the present study was to examine the role of the German Dementia Guideline in primary care. The main objective of the present study was to examine the role of the German Dementia Guideline in primary care. Previous research has already acknowledged the central role of GPs in diagnostics, treatment and care of dementia. Generally, results of the present study underline the key role of GPs in dementia care. For example, in the present study, more than one third of PwD received their dementia diagnosis from a GP. This finding is in line with recent empirical data from Germany [37]. Further, findings of the present study indicate overall high levels of AGDG, although large differences can be observed across recommendations. With regard to Hypothesis 1, the total number of patients seen by a participating GP during the last 3 months was significantly and negatively associated with AGDG. With regard to

Table 3 Guideline adherence over all PwD on item level

Items of the checklist	n^a	Yes^b (%)
Was a basic geriatric assessment conducted?	88	93.2
Which of the following diagnostic examinations were conducted?		
Physical examination and psychopathological/psychiatric evaluation	89	94.3
Laboratory tests	88	94.3
Differential diagnostics	84	76.2
Cognitive and neuropsychological tests	84	78.6
Recent medical history	83	74.7
CT/MRI scans	81	72.8
Did the GP administer a cognitive screening test?	85	54.1
Were further physical impairments/medical conditions assessed?	90	87.8
Were further mental health impairments/psychiatric conditions assessed?	89	74.2
Did the PwD/family caregiver receive advice concerning psychological and behavioral symptoms of dementia?	82	91.5
Was the entire current medication assessed and discussed?	85	95.3
Were pharmacological treatment options for dementia discussed with the PwD/family caregiver?	81	65.4
Were non-pharmacological interventions for dementia discussed with the PwD/family caregiver?	84	72.6
Were non-pharmacological interventions recommended or prescribed?	84	54.8
Is the PwD currently being treated by a dementia specialist?	84	61.9
Were further care services for PwD discussed with the PwD/family caregiver?	84	64.3
Was the PwD/family caregiver informed about local support services for PwD?	75	54.7
Was a care plan developed with the PwD/family caregiver?	82	54.9
Were daily activities and how to maintain them discussed with the PwD/family caregiver?	82	79.3
Were self-help measures discussed with the PwD/family caregiver?	84	69.0
Were newly emerging risks assessed and discussed?	80	62.5
Were driving skills or lack thereof discussed with the PwD/family caregiver?	59	49.2
Was the PwD/family caregiver approached about an application for a care level from the German nursing care insurance?	79	79.7
Was the PwD/family caregiver made aware of their rights and the availability of local advocacy services?	81	67.9
Was palliative care discussed?	73	19.2
Was the caregiver stress level discussed in detail with the family caregiver?	81	74.1
Was the family caregiver informed about support offers for family caregivers?	79	87.1

$N = 28$ GP, Adherence to German Dementia Guideline was self-reported by each GP on patient's level (for each participating PwD), n^a = total number of PwD for whom adherence to the specific recommendation (item) was rated by the treating GP, Yes^b = percentage of PwD for whom treating GPs reported following a specific recommendation (=being adherent to guideline recommendation)

Hypothesis 2, quality of life was not significantly associated with AGDG.

Adherence to the German dementia guideline in primary care

For the purpose of this study, a checklist was developed to examine the role of adherence to the German Dementia Guideline. This checklist facilitates the assessment of AGDG for research (calculation of AGDG score) and may assist GPs in daily practice with treatment and care of dementia. With regard to the AGDG score, present findings indicate a relatively high overall guideline adherence among participating GPs. In contrast to our study, a study examining the effect of a disease management intervention on guideline adherence reported a much lower overall mean score of guideline adherence [29]. However, Vickrey et al. (2006) obtained information on guideline adherence by medical record review as well as by caregiver survey. The present study measured AGDG primarily with a self-report checklist. While the overall AGDG was relatively high, variability between recommendations were found. With regard to palliative care, past research has frequently acknowledged, that due to the progressive nature of dementia, advance care planning and palliative care is important, and GPs play a key role in the in-time planning [38–40]. In order to ensure and respect preferences and wishes of PwD, it is recommended to ascertain their views in an early stage of the disease, before ability to consider the future is limited [41]. As the majority of community dwelling PwD receive regular care from their GPs and GPs often have a long-standing relationship with their PwD, GPs are particularly suited to address palliative care [42]. In order to improve advanced and palliative care planning, we recommend

Table 4 GPs attitudes toward the German Dementia Guideline

Attitudes	n	%
Knowledge about guideline (yes)	20	71.4
Utilization of guideline (yes)	17	60.7
Frequency of utilization	26	
Often	5	19.2
Sometimes	10	35.7
Seldom	7	26.9
Never	4	15.4
Helpfulness of guideline	24	
Very	5	20.8
Partially	11	45.8
Somewhat	8	33.3
Not helpful at all	0	0
Reasons for non-utilization of guideline	*14*	
Length	8	28.6
Lack of relevance	4	14.3
Lack of knowledge	2	7.1

N = 28 GPs

that dementia guidelines should include guidance and recommendations on that matter. With regard to the present result on fitness to driving, the GDG specifically provides a section on dementia and driving and outlines the importance of evaluating current driving skills with the progression of dementia [28]. Previous research has acknowledged, that GPs play a key role in the assessment of fitness to drive in dementia, a topic of uncertainty and conflict for GPs [43]. A recent study found that GPs discussed fitness to drive with only 32.1% of potentially driving elderly patients [44]. Previous studies indicated that fitness to drive is severely impaired in moderate and severe dementia [45]. In sum, there is an urgent need to develop and provide training and guidance on performance of driving assessments for GPs so that they are able to perform such assessments with PwD [46].

With regard to the AGDG score, it is important to discuss the interpretation of the score. The aim of the present checklist was to examine and measure adherence to the GDG recommendations among GPs. Previous empirical work has acknowledged, that evidence-based guidelines may contribute to an improvement of care provision [26–28]. Building on this, a checklist was developed based on the recommendations of the current GDG. However, adherence to the GDG does not necessarily indicate best quality of care provided for individuals. As stated in the GDG recommendations of the DEGAM, a holistic view on PwD as well as provision of individualized medicine based on the current (health) needs of individuals is of great importance. With regard to the necessity of individualized treatment options especially for patients with multimorbidity, lower adherence to the recommendations still may propose better care provision for a given individual. However, awareness of evidence-based guidelines, knowledge about specific guideline recommendations and provision of care based on shared decision-making represent basic requirements for individualized care. We believe that the proposed checklist may serve as an overview of the most important aspects of dementia care with the aim to facilitate knowledge transfer, to support GPs in their decision-making and care provision and to allow GPs to assess and evaluate their adherence to specific guideline recommendations. Therefore, the checklist can be of great value, especially for practitioners. However, the present checklist does not take into account the provision of individualized care for PwD in primary care nor represent the quality of care provided by GPs. Especially in primary care, where GPs have many years of knowledge about their patients and their individual environments, (health) needs and preferences, deviations from specific guideline recommendations must be recognized in order to facilitate the provision of individualized treatment and optimal care. In addition to the AGDG score, we have analyzed data on anti-dementia drug intake with regard to guideline adherence. The GDG recommends intake of anti-dementia drugs dependent on type of dementia and severity of cognitive impairment. For example, for individuals diagnosed with Alzheimer's Disease and a mild to moderate cognitive impairment, the intake of Acetylcholinesterase inhibitors is recommended [28]. In the present sample, about 37% of PwD reported the intake of an anti-dementia drug, a finding in line with previous studies [47, 48]. For example, a study on medical treatment of PwD in Germany reported 25% of ambulatory PwD receiving an anti-dementia drug, and found that this number varied depending on whether PwD were seen by a GP and specialist or solely a GP (48% versus 24.5%, respectively) [49]. Past research has consistently reported a positive association between involvement of a GP/specialist and anti-dementia drug prescription [48, 50]. In the present study, about 10% of PwD reported the intake of an anti-dementia drug which was not in line with GDG recommendations, and almost half (44.5%) reported an intake of off-label drugs. With regard to medication, based on present findings, the prescription of anti-dementia drugs requires improvement. An anti-dementia drug treatment should be always based on individual assessments of risks and benefits [28, 47]. Key dementia care providers, especially GPs, should have knowledge on the latest guideline recommendations regarding anti-dementia drugs and their risks and benefits. Collaborative care models may improve anti-dementia drug prescriptions in ambulatory care for PwD. Our data shows that the majority of

PwD (62%) saw a specialist in addition to their GP. Collaborations between GPs and specialists (e.g., psychiatrist or neurologist) can improve the implementation of guideline recommendations with regard to anti-dementia drugs [47, 51–54].

Finally, nearly one third of GPs who participated in this study reported length of the GDG as a reason for non-utilization of the guideline and another third of GPs reported the guideline as only somewhat helpful. Given these findings, research should reconsider the current format of the GDG for GPs. More compiled and practical guidelines are needed. Further, it is of great importance to include perspectives and recommendations from general practice in the guideline development. Although the GDG acknowledged the important role of GPs in the care of PwD [28], the German College of General Practitioners and Family Physicians was hardly involved in the development of the guideline. The validity of the current GDG expired in February 2021. Thus, a new guideline is currently being developed. We highly recommend including the perspectives and experiences of GPs in the development and implementation of the new GDG.

Associations between AGDG and variables on GP and PwD level

It was of great interest to examine the associations between AGDG and factors on GPs and PwD level. With regard to individual and structural factors of GPs and AGDG, results of multilevel analyses revealed that only the total number of patients seen by a participating GP during the last 3 months were negatively associated with AGDG. This finding is partially in line with previous empirical work. While it is widely believed that more time per patient improves patient's health and quality of care [55–57], a systematic review of clinical trials found insufficient empirical evidence that patients benefit from longer consultations [58]. However, with regard to dementia, past research has recommended more time in primary care for PwD [12]. In Germany, a recent study found an average consultation length of 7.6 min [59]. It is reasonable to believe that GPs with larger patient loads have less time to spend with each patient, consequently resulting in less time to focus on and follow guideline recommendations. However, the observed effect should be interpreted with caution. The present study has no data on the frequency of visits for each patient nor the total number of hours GPs actually spend with their patients. Future research is needed in order to gain a better understanding of the role of a GPs patient load, time spent with each patient, and time spent on patient care, and its impact on guideline adherence.

With regard to the association between AGDG and PwD's quality of life, no significant association was found.

This finding is not consistent with previous research that examined the effects of a dementia guideline-based disease management program in a cRCT and found significant improvements in health-related quality of life in PwDs [29, 60]. Future research is required in order to gain a better understanding of the role of guideline-based dementia care in primary practices [61]. The present paper is based on baseline data collected within a cRCT that aims to evaluate the effect of a technology-based intervention on AGDG in primary care. We are currently conducting follow-up assessments with GPs and PwD and will be able to conduct a more in-depth examination of the association between AGDG and GP and PwD in the near future.

Limitations

This is the first study in Germany assessing adherence to the German Dementia Guideline in primary care with a checklist developed based on the GDG recommendations. However, there is a number of limitations that must be outlined. First, the present sample is drawn from a cRCT examining a tablet-based intervention for GPs, PwD, and their informal caregivers. The DemTab study is based on a convenience sample. Hence, in the present study GPs, PwD and their caregivers self-selected themselves into the DemTab study. The so-called self-selection may propose a higher risk of biased data. Participants' decision to participate may be correlated with traits that affect the study [62]. For example, the high guideline adherence found in our study may be because participating GPs were particularly engaged and interested in the study's topic. Further, as PwD agreed to use a technological device as part of the intervention, it may be that participating PwD were of greater health compared to a general sample of PwD. The self-selection bias is a known problem in research [63]. For example, Keiding & Louis (2016) argue that self-selection directly affects the validity of cross-sectional analyses and longitudinal trends [64]. This limitation must be taken into account when interpreting results. Based on the recruitment strategies of the present study, which were conducted in line with data protection laws, self-selection of PwD was hard to prevent, as contact information of patients was only forwarded by GPs once PwD agreed to it. However, the potential influences of self-selection for study participation were mitigated by strict inclusion and exclusion criteria. Only a subset of participants who wanted to participate in the study was selected for participation. Second, regarding the assessment of guideline adherence, the post hoc recoding of the category "not applicable" as missing data must be addressed. Even if comparisons of means and correlations across scoring methods did not reveal any significant differences, data

Künstliche Intelligenz GmbH (DFKI), Speech and Language Technology, Berlin, Germany.

References

1. Livingston G, Sommerlad A, Orgeta V, Costafreda SG, Huntley J, Ames D, et al. Dementia prevention, intervention, and care. Lancet. 2017;390(10113):2673–734.
2. Prince MJ, Wimo A, Guerchet MM, Ali GC, Wu YT, Prina M. World Alzheimer Report 2015 -The Global Impact of Dementia: An analysis of prevalence, incidence, cost and trends. Retrieved from https://www. alzint.org/u/WorldAlzheimerReport2015.pdf. 2015.
3. Deutsche Alzheimer Gesellschaft. Die Häufigkeit von Demenzerkrankungen; Informationsblatt 1. 2019.
4. Thyrian JR, Stentzel U. [Estimating the Number of People with Dementia in Germany in 2030 on County Level]. Psychiatrische Praxis. 2021;48(2):79–84. https://doi.org/10.1055/a-1228-4974.
5. Winblad B, Amouyel P, Andrieu S, Ballard C, Brayne C, Brodaty H, et al. Defeating Alzheimer's disease and other dementias: a priority for European science and society. Lancet Neurol. 2016;15(5):455–532.
6. World Health Organization. Dementia: a public health priority: World Health Organization; 2012.
7. Zeisel J, Bennett K, Fleming R. World Alzheimer report 2020: design, dignity, dementia: dementia-related design and the built environment; 2020.
8. Leve V, Ilse K, Ufert M, Wilm S, Pentzek M. Driving and dementia : an issue for general practice?! Zeitschrift fur Gerontol Geriatr. 2017;50(Suppl 2):55–62.
9. Pentzek M, Vollmar HC, Wilm S, Leve V. Putting dementia awareness into general practice. Zeitschrift fur Gerontol Geriatr. 2017;50(2):44–7.
10. Pentzek M, Fuchs A, Abholz H-H, Wollny A. Awareness of local dementia services among general practitioners with academic affiliation. Aging Clin Exp Res. 2011;23(3):241–3.
11. Pentzek M, Abholz HH, Ostapczuk M, Altiner A, Wollny A, Fuchs A. Dementia knowledge among general practitioners: first results and psychometric properties of a new instrument. Int Psychogeriatr. 2009;21(6):1105–15.
12. Thyrian JR, Hoffmann W. Dementia care and general physicians--a survey on prevalence, means, attitudes and recommendations. Cent Eur J Public Health. 2012;20(4):270–5.
13. Kaduszkiewicz H, Wiese B, van den Bussche H. Self-reported competence, attitude and approach of physicians towards patients with dementia in ambulatory care: results of a postal survey. BMC Health Serv Res. 2008;8:54.
14. Schwarzkopf L, Menn P, Leidl R, Wunder S, Mehlig H, Marx P, et al. Excess costs of dementia disorders and the role of age and gender - an analysis of German health and long-term care insurance claims data. BMC Health Serv Res. 2012;12(1):165.
15. Wang M, Xu X, Huang Y, Shao S, Chen X, Li J, et al. Knowledge, attitudes and skills of dementia care in general practice: a cross-sectional study in primary health settings in Beijing, China. BMC Fam Pract. 2020;21(1):89.
16. Foley T, Boyle S, Jennings A, Smithson WH. "We're certainly not in our comfort zone": a qualitative study of GPs' dementia-care educational needs. BMC Fam Pract. 2017;18(1):66.
17. Turner S, Iliffe S, Downs M, Wilcock J, Bryans M, Levin E, et al. General practitioners' knowledge, confidence and attitudes in the diagnosis and management of dementia. Age Ageing. 2004;33(5):461–7.
18. Koch T, Iliffe S. Rapid appraisal of barriers to the diagnosis and management of patients with dementia in primary care: a systematic review. BMC Fam Pract. 2010;11:52.
19. Mitchell AJ, Meader N, Pentzek M. Clinical recognition of dementia and cognitive impairment in primary care: a meta-analysis of physician accuracy. Acta Psychiatr Scand. 2011;124(3):165–83.
20. Olafsdottir M, Foldevi M, Marcusson J. Dementia in primary care: why the low detection rate? Scand J Prim Health Care. 2001;19(3):194–8.
21. Tang EYH, Birdi R, Robinson L. Attitudes to diagnosis and management in dementia care: views of future general practitioners. Int Psychogeriatr. 2018;30(3):425–30.
22. Stewart TV, Loskutova N, Galliher JM, Warshaw GA, Coombs LJ, Staton EW, et al. Practice patterns, beliefs, and perceived barriers to care regarding dementia: a report from the American Academy of Family Physicians (AAFP) National Research Network. J Am Board Fam Med. 2014;27(2):275–83.
23. Mukadam N, Cooper C, Kherani N, Livingston G. A systematic review of interventions to detect dementia or cognitive impairment. Int J Geriatr Psychiatry. 2015;30(1):32–45.
24. van den Dungen P, van Marwijk HW, van der Horst HE, Moll van Charante EP, Macneil Vroomen J, van de Ven PM, et al. The accuracy of family physicians' dementia diagnoses at different stages of dementia: a systematic review. Int J Geriatr Psychiatry. 2012;27(4):342–54.
25. Franz CE, Barker JC, Kim K, Flores Y, Jenkins C, Kravitz RL, Hinton L. When help becomes a hindrance: mental health referral systems as barriers to care for primary care physicians treating patients with Alzheimer's disease. Am J Geriatr Psychiatry. 2010;18(7):576–85.
26. World Health Organization. Delivering quality health services: a global imperative for universal health coverage. 2018.
27. Jeschke E, Ostermann T, Vollmar HC, Tabali M, Schad F, Matthes H. Prescribing patterns in dementia: a multicentre observational study in a German network of CAM physicians. BMC Neurol. 2011;11(1):99.
28. Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde, Deutsche Gesellschaft für Neurologie. S3 Leitlinie "Demenzen" (Langversion – Januar 2016). 2016.
29. Vickrey BG, Mittman BS, Connor KI, Pearson ML, Della Penna RD, Ganiats TG, Demonte RW Jr, Chodosh J, Cui X, Vassar S, Duan N, Lee M. The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial. Ann Intern Med. 2006;145(10):713–26.
30. Lech S, O'Sullivan JL, Gellert P, Voigt-Antons JN, Greinacher R, Nordheim J. Tablet-based outpatient care for people with dementia. GeroPsych. 2019;32(3):135–44.
31. Lech S, O'Sullivan JL, Wellmann L, Supplieth J, Döpfmer S, Gellert P, et al. Recruiting general practitioners and patients with dementia into a cluster randomised controlled trial: strategies, barriers and facilitators. BMC Med Res Methodol. 2021;21(1):61.
32. Downs M, Cook A, Rae C, Collins KE. Caring for patients with dementia: the GP perspective. Aging Ment Health. 2000;4(4):301–4.
33. Murphy K, O'Connor DA, Browning CJ, French SD, Michie S, Francis JJ, et al. Understanding diagnosis and management of dementia and guideline implementation in general practice: a qualitative study using the theoretical domains framework. Implement Sci. 2014;9(1):1–13.
34. Federal Ministry of Health. Peer review on "Germany's latest reforms of the 730 long-term care system": host country discussion paper - Germany. DG 731 employment, social affairs and inclusion: European Commission; 2018. https://ec.europa.eu/social/main.jsp?langId=en&catId= 89&newsId=9008. Accessed 22 Apr 2021
35. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12(3):189-98.
36. Logsdon RG, Gibbons LE, McCurry SM, Teri L. Assessing quality of life in older adults with cognitive impairment. Psychosom Med. 2002;64(3):510–9.
37. Eichler T, Thyrian JR, Hertel J, Köhler L, Wucherer D, Dreier A, et al. Rates of formal diagnosis in people screened positive for dementia in primary care: results of the DelpHi-trial. J Alzheimers Dis. 2014;42:451–8.
38. van der Steen JT, Radbruch L, Hertogh CMPM, de Boer ME, Hughes JC, Larkin P, et al. White paper defining optimal palliative care in older people with dementia: a Delphi study and recommendations from the European Association for Palliative Care. Palliat Med. 2013;28(3):197–209.
39. Evans N, Pasman HRW, Donker GA, Deliens L, Van den Block L, Onwuteaka-Philipsen B. End-of-life care in general practice: a cross-sectional, retrospective survey of 'cancer', 'organ failure' and 'old-age/dementia' patients. Palliat Med. 2014;28(7):965–75.
40. Tilburgs B, Vernooij-Dassen M, Koopmans R, van Gennip H, Engels Y, Perry M. Barriers and facilitators for GPs in dementia advance care planning: a systematic integrative review. PLoS One. 2018;13(6):e0198535.
41. Dening KH, Jones L, Sampson EL. Preferences for end-of-life care: a nominal group study of people with dementia and their family carers. Palliat Med. 2013;27(5):409–17.

42. Schers H, van den Hoogen H, Bor H, Grol R, van den Bosch W. Familiarity with a GP and patients' evaluations of care. A cross-sectional study. Fam Pract. 2005;22(1):15–9.

43. Pentzek M, Michel JV, Ufert M, Vollmar HC, Wilm S, Leve V. Fahrtauglichkeit bei Demenz–Theoretische Rahmung und Konzept einer Vorgehensempfehlung für die Hausarztpraxis. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen. 2015;109(2):115–23.

44. Leve V, Pentzek M, Fuchs A, Bickel H, Weeg D, Weyerer S, Werle J, König HH, Hajek A, Lühmann D, van den Bussche H, Wiese B, Oey A, Heser K, Wagner M, Luppa M, Röhr S, Maier W, Scherer M, Kaduszkiewicz H, … for the AgeCoDe/AgeQualiDe Study Group (2021). GPs' awareness of car driving among oldest patients: exploratory results from a primary care cohort. BJGP open. 2021;5(2):BJGPO.2020.0145.

45. Toepper M, Falkenstein M. Driving fitness in different forms of dementia: an update. J Am Geriatr Soc. 2019;67(10):2186–92.

46. Walsh L, Chacko E, Cheung G. The process of determining driving safety in people with dementia: a review of the literature and guidelines from 5 English speaking countries. Aust Psychiatry. 2019;27(5):480–5.

47. Wucherer D, Eichler T, Kilimann I, Hertel J, Michalowsky B, Thyrian JR, et al. Antidementia drug treatment in people screened positive for dementia in primary care. J Alzheimers Dis. 2015;44(3):1015–21.

48. Schütz LH, Boronat-Garrido X, Moser FA, Suhr R, Lahmann N. Dementia-specific drug treatment in home care settings: a German multicentre study. J Clin Nurs. 2019;28(5–6):862–9.

49. Bohlken J, Schulz M, Rapp MA, Bätzing-Feigenbaum J. Pharmacotherapy of dementia in Germany: results from a nationwide claims database. Eur Neuropsychopharmacol. 2015;25(12):2333–8.

50. Hoffmann F, van den Bussche H, Wiese B, Schön G, Koller D, Eisele M, et al. Impact of geriatric comorbidity and polypharmacy on cholinesterase inhibitors prescribing in dementia. BMC Psychiatry. 2011;11(1):1–8.

51. Schulz M, Bohlken J, Schulz M, Hering R, von Stillfried D, Bätzing-Freigenbaum J. Medikamentöse Behandlung von Patienten mit Demenz unter besonderer Berücksichti-gung regionaler Versorgungsunterschiede: Zentralinstitut für die kassenärztliche Versorgung in Deutschland; 2015.

52. Thyrian JR, Eichler T, Pooch A, Albuerne K, Dreier A, Michalowsky B, et al. Systematic, early identification of dementia and dementia care management are highly appreciated by general physicians in primary care–results within a cluster-randomized-controlled trial (DelpHi). J Multidiscip Healthc. 2016;9:183.

53. Schulz M, Bohlken J, Hering R, Bätzing-Feigenbaum J. Diagnostische und therapeutische Leistungsdichte von neu erkrankten, zu Hause lebenden Patienten mit Demenz: Versorgungsatlas-Bericht; 2014. Available online: http://www.versorgungsatlasde/themen/alle-analysen-nach-datum-sortiert

54. Laver K, Cations M, Radisic G, de la Perrelle L, Woodman R, Fitzgerald JA, et al. Improving adherence to guideline recommendations in dementia care through establishing a quality improvement collaborative of agents of change: an interrupted time series study. Implement Sci Commun. 2020;1(1):80.

55. Mercer SW, Fitzpatrick B, Guthrie B, Fenwick E, Grieve E, Lawson K, et al. The CARE Plus study - a whole-system intervention to improve quality of life of primary care patients with multimorbidity in areas of high socio-economic deprivation: exploratory cluster randomised controlled trial and cost-utility analysis. BMC Med. 2016;14(1):88.

56. Hutton C, Gunn J. Do longer consultations improve the management of psychological problems in general practice? A systematic literature review. BMC Health Serv Res. 2007;7:71.

57. Mercer SW, Fitzpatrick B, Gourlay G, Vojt G, McConnachie A, Watt GCM. More time for complex consultations in a high-deprivation practice is associated with increased patient enablement. Br J Gen Pract. 2007;57(545):960–6.

58. Wilson AD, Childs S. Effects of interventions aimed at changing the length of primary care physicians' consultation. Cochrane Database Syst Rev. 2006;(1):CD003540.

59. Irving G, Neves AL, Dambha-Miller H, Oishi A, Tagashira H, Verho A, et al. International variations in primary care physician consultation time: a systematic review of 67 countries. BMJ Open. 2017;7(10):e017902.

60. Pond D, Mate K, Stocks N, Gunn J, Disler P, Magin P, et al. Effectiveness of a peer-mediated educational intervention in improving general practitioner diagnostic assessment and management of dementia: a cluster randomised controlled trial. BMJ Open. 2018;8(8):e021125.

61. Joling KJ, van Eenoo L, Vetrano DL, Smaardijk VR, Declercq A, Onder G, et al. Quality indicators for community care for older people: a systematic review. PLoS One. 2018;13(1):e0190298.

62. Ellenberg JH. Selection bias in observational and experimental studies. Stat Med. 1994;13(5–7):557–67.

63. Bravo-Ureta BE, González-Flores M, Greene W, Solís D. Technology and technical efficiency change: evidence from a difference in differences selectivity corrected stochastic production frontier model. Am J Agric Econ. 2021;103(1):362–85.

64. Keiding N, Louis TA. Perils and potentials of self-selected entry to epidemiological studies and surveys. J R Stat Soc: Ser A (Statistics in Society). 2016;179(2):319–76.

65. Hoyt WT. Rater bias in psychological research: when is it a problem and what can we do about it? Psychol Methods. 2000;5(1):64.

66. Blumenthal-Barby JS, Krieger H. Cognitive biases and heuristics in medical decision making: a critical review using a systematic search strategy. Med Decis Mak. 2015;35(4):539–57.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Curriculum Vitae

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht."

Publication list

Publications in peer-reviewed journals

Lech, S., O'Sullivan, J.L., Romanescu, L., Nordheim, J., Gellert, P., Kuhlmey, A., & Yasar, S. (2022). Statin use in dementia - Review and comparison of guideline recommendations. *International Journal of Geriatric Psychiatry, 37*(1). https://doi.org/10.1002/gps.5653   **JIF: 3.485**

O'Sullivan, J.L., Schweighart, R., **Lech, S.,** Kessler, E.M., Tegeler-Nonnen, C., Teti, A., Nordheim, J., & Gellert, P. (2022). Concordance of self- and informant-rated depressive symptoms in nursing home residents with Dementia: cross-sectional findings. *BMC Psychiatry*, 22(1), 241. https://doi.org/10.1186/s12888-022-03876-5   **JIF: 3.630**

Herrmann, W. J., Oeser, P., Buspavanich, P., **Lech, S**., Berger, M., & Gellert, P. (2022). Loneliness and depressive symptoms differ by sexual orientation and gender identity during physical distancing measures in response to COVID-19 pandemic in Germany. *Applied Psychology: Health and Well-Being*, 1–17. https://doi.org/10.1111/aphw.12376   **JIF: 3.569**

Lech, S., O'Sullivan, J.L., Drewelies, J., Herrmann, W., Spang, R.P., Voigt-Antons, J.N., Nordheim, J., & Gellert, P. (2021). Dementia care and the role of guideline adherence in primary care: cross-sectional findings from the DemTab study. *BMC Geriatrics, 21*(1), 717. https://doi.org/10.1186/s12877-021-02650-8   **JIF: 3.921**

O'Sullivan, J.L., **Lech, S.,** Gellert, P., Grittner, U., Voigt-Antons, J.N., Möller, S., Kuhlmey, A., & Nordheim, J. (2021). A tablet-based intervention for activating nursing home residents with dementia: results from a cluster-randomized controlled trial. *International Psychogeriatrics, 34(2), 129-141*. https://doi.org/10.1017/S1041610221000818   **JIF: 3.878**

Buspavanich*, P., **Lech*, S**., Lermer, E., Fischer, M., Berger, M., Vilsmaier, T., ... & Batz, F. (2021). Well-being during COVID-19 pandemic: A comparison of individuals with minoritized sexual and gender identities and cis-heterosexual individuals. *PloS one*, *16*(6). https://doi.org/10.1371/journal.pone.0252356   **JIF: 3.240**

Gellert, P., **Lech, S.**, Kessler, E.M., Herrmann, W., Döpfmer, S., Balke, K., Oedekoven, M,. Kuhlmey, A., & Schnitzer, S. (2021). Perceived need for treatment and

non-utilization of outpatient psychotherapy in old age: two cohorts of a nationwide survey. *BMC Health Services Research,* 21(1), 442. https://doi.org/10.1186/s12913-021-06384-6

JIF: 2.655

Lech, S., O'Sullivan, J.L., Wellmann, L., Supplieth, J., Döpfmer, S., Gellert, P., & Kuhlmey, A., & Nordheim, J. (2021). Recruiting general practitioners and patients with dementia into a cluster randomised controlled trial: strategies, barriers and facilitators. *BMC Medical Research Methodology*, 21(1), 1-13. https://doi.org/10.1186/s12874-021-01253-6

JIF: 4.615

Lech, S., Schenk, L., De la Torre Castro, J., & Schindel, D (2021). A retrospective analysis of the health and social situation of homeless people in Berlin: study protocol. *Archives of Public Health, 79*(1), 28. https://doi.org/10.1186/s13690-021-00546-y

JIF: 2.589

Lech, S., O'Sullivan, J.L., Gellert, P., Voigt-Antons, J. N., Greinacher, R., & Nordheim, J. (2019). Tablet-based outpatient care for people with dementia. *GeroPsych 32*(3), 135–144. https://doi.org/10.1024/1662-9647/a000210

Manuscripts in review

Vathke, C., Kessler, E.M., O'Sullivan, J.L., Gellert, P. & **Lech, S.** (submitted). Motivation and psychotherapy in older adults with care needs and depression. *GeroPsych.*

Lech, S., Mümken, S., Kessler, E. M., & Gellert, P. (submitted). Life-space Mobility among home-living older Adults with Care Needs and clinical Depression. *International Journal of Geriatric Psychiatry.*

Marbin, D., Gutwinski, S., **Lech, S.**, Fürstenau, D., Kokwaro, L., Krüger, H., Schindel, D., & Schreiter, S. (submitted). Mobile phone, computer, internet, and social media use among users of psychiatric inpatient services in Berlin, Germany - A cross-sectional patient survey. JMIR Preprints. 27/04/2022:39075

Herrmann, W., Buspavanich, P., **Lech, S.,** Berger, Maximilian., & Gellert, P., (major revision). Veränderung hausärztlicher und psychotherapeutischer Versorgung in Deutschland während der ersten beiden COVID-19-Lockdowns 2020 und 2021: Zwei

Befragungswellen unter Berücksichtigung von Geschlechtsidentität und sexueller Orientierung. *Zeitschrift fuer Evidenz, Fortbildung und Qualitaet im Gesundheitswesen.*

Batz, F., Lermer, E., **Lech, S.,** O'Malley, G., Zenz-Spitzweg, D., Mahner, S., ... & Buspavanich, P. (submitted). Desire and motivation for parenthood during the COVID-19 pandemic: A comparison of cis-gender minoritized sexual identities with cis-heterosexual individuals living in Germany. BMC Public Health. 10.21203/rs.3.rs-1794441/v

Other publications

Lech, S., & Buspavanich, P. (2022, in press). Epidemiologie der Depression. In M. Adli & M. Hautzinger (Hrsg.), Praxishandbuchs Depression. ELSEVIER Verlag.

Schindel, D., **Lech, S.,** Radlbeck, D., Schlimper, G., & Schenk, L. Sozialpolitik: Wohnungslos und krank. *Deutsches Ärzteblatt 2021*,*118* (3), A96 A99.

https://www.aerzteblatt.de/archiv/217458/Sozialpolitik-Wohnungslos-und-krank

Conference Papers

Schindel, D., **Lech, S.,** & Schenk, L. (2022, März). Soziale Lage und Gesundheit wohnungsloser Menschen in Berlin-Mitte Einblicke in eine retrospektive Sekundärdatenanalyse [GIG Projekt]. „Runder Tisch" zur gesundheitlichen Versorgung wohnungsloser Menschen. Kongress Armut und Gesundheit, Berlin, DE. (Online).

Schindel, D., **Lech, S.,** & Schenk, L. (2022, März). Soziale Lage und Gesundheit wohnungsloser Menschen in Berlin-Mitte Einblicke in eine retrospektive Sekundärdatenanalyse [GIG Projekt]. Bundestagung 2022 der Bundesarbeits-gemeinschaft Wohnungslosenhilfe (BAG W). (UN)BEDINGT SYSTEMRELEVANT. Zahlen, Daten, Fakten über die Gesundheit wohnungsloser Menschen – aktuelle Forschungsprojekte stellen sich vor, Berlin, DE. (Online).

Schindel, D., **Lech, S.,** & Schenk, L. (2021, November). Soziale und gesundheitliche Lage Wohnungsloser in Berlin: Erste Ergebnisse einer retrospektiven Sekundärdatenanalyse (GIG Projekt). Dialogreihe „Gesundheitliche Chancengleichheit – Im Gespräch mit Wissenschaft und Praxis". Thema Wohnungs-/Obdachlosigkeit in Bezug

auf die Covid-19-Pandemie. HAGE - Hessische Arbeitsgemeinschaft für Gesundheitsförderung e.V., Frankfurt, DE. (Online).

Buspavanich, P., **Lech, S.,** Berger, M., Lermer, E., Fischer, M., Vilsmaier, T., Kaltofen, T., Keckstein, S., Mahner, S., Behr, J., Thaler, C.-J., Batz, F. (2021, November). *Auswirkungen der COVID-19 Pandemie auf die mentale Gesundheit von LGBTIQ* Menschen*. Vortrag auf dem Kongress der Deutschen Gesellschaft für Psychiatrie, Psychotherapie und Neurologie, Berlin, DE. (Online).

Schindel, D., **Lech, S.,** & Schenk, L. (2021, September). Soziale und gesundheitliche Lage Wohnungsloser in Berlin: Erste Ergebnisse einer retrospektiven Sekundärdatenanalyse (GIG Projekt). Jahrestagung Deutsche Gesellschaft für Medizinischen Soziologie, Hamburg, DE. (Online).

O'Sullivan, J.L., Schweighart, R., **Lech, S.,** Tegeler, C., Kesseler, E.-M., Voigt-Antons, J.-N., Teti, A., Nordheim, J. & Gellert, P. (2021, September). *Selbst- und fremdeingeschätzte depressive Symptome bei Pflegeheimbewohner*innen mit Demenz: Ergebnisse einer Querschnittsanalyse*. Gemeinsame Tagung der Sektionen III und IV der Deutschen Gesellschaft für Gerontologie, Siegen, DE. (Online).

Schenk, L., **Lech, S.,** Schindel, D. (2021, März). Gesundheit Wohnungsloser in Berlin - das GIG-Projekt. Kongress Armut und Gesundheit. Berlin, DE. (Online).

Lech, S., O'Sullivan, J.L., Voigt-Antons, J.-N., Greinacher, R., Gellert, P., Kuhlmey, A. & Nordheim, J. (2021, Februar). *Ambulante Versorgung von Menschen mit Demenz in Berlin und Umgebung - Querschnittsdaten aus der DemTab-Studie.* Vortrag auf dem 2. Charité-Versorgungsforschungskongress, Berlin, DE. (Online).

O'Sullivan, J.L., **Lech, S.,** Voigt-Antons, J.-N., Greinacher, R., Gellert, P., Kuhlmey, A. & Nordheim, J. (2020, November). *DemTab – Tabletgestützte ambulante Versorgung von Menschen mit Demenz: Leitlinienbasierte Behandlungsplanung, individuelles Krankheitsmanagement und Vernetzung*. Online-Symposium des Fachausschuss Alter und Technik der Deutschen Gesellschaft für Gerontologie und Geriatrie: COVID-19 als Brennglas: Was wir aus der Krise zum Thema Altern und Digitalisierung lernen können, Berlin, DE. (Online).

O'Sullivan, J.L., **Lech, S.,** Gellert, P., Voigt-Antons, J.-N., Greinacher, R., Möller, S., Kuhlmey, A. & Nordheim, J. (2020, Februar). *DemTab – Tablet-basierte ambulante Versorgung von Menschen mit Demenz: eine Cluster-randomisierte kontrollierte Studie.*

Vortrag auf der Jahrestagung des Instituts für Gerontologie der Universität Vechta, Vechta, DE.

Nordheim, J., O`Sullivan, J.L., **Lech, S.,** Voigt-Antons, J.-N., J., Gellert, P., Kuhlmey, A. (2019, September). *Informations- und Kommunikationstechnologien in der Versorgung von Menschen mit Demenz.* Vortrag auf Gemeinsame Fachtagung der Sektion III: Sozial- und verhaltenswissenschaftliche Gerontologie und der Sektion IV: Soziale Gerontologie und Altenarbeit der Deutschen Gesellschaft für Gerontologie und Geriatrie (DGGG), Berlin, DE.

Lech, S., Supplieth J., O`Sullivan, J.L., Voigt-Antons, J.-N., J., Gellert, P., Kuhlmey, A. & Nordheim, J. (2019, Mai). *Tablet-based Outpatient Care of People with Dementia: A Qualitative Feasibility Study.* Poster präsentiert auf dem International Association of Gerontology and Geriatrics European Region Congress, Gothenburg, SWE.

Lech, S., O`Sullivan, J.L., Voigt-Antons, J.-N., J., Gellert, P., Kuhlmey, A. & Nordheim, J. (2018, Oktober). *Tablet-based outpatient care for people with dementia: Guideline-based treatment planning, personalized disease management and network-based care.* Poster präsentiert auf dem 14th International Congress of the European Geriatric Medicine Society, Berlin, DE.

Lech, S., O`Sullivan, J.L., Gellert, P., Voigt-Antons, J.-N. & Nordheim, J. (2018, September). *Tabletgestützte ambulante Versorgung von Menschen mit Demenz.* Vortrag auf dem Kongress der Deutschen Gesellschaft für Gerontologie und Geriatrie, Köln, DE.

Woszidlo, A., & **Lech, S.** (2017, Mai). *Similarities and differences in older American and German couples' morale, negative affectivity, collaboration, health, and marital satisfaction.* Poster präsentiert auf dem Annual Meeting of the International Communication Association, San Diego, USA.

Lech, S., Woszidlo, A., & Gerstorf, D. (2015, Juli). *Can you control your health? Maybe your partner can: Examining the direct and indirect effects of perceived control, perceived stress and health problems among older German couples.* Poster präsentiert auf der International Association for Relationship Research Mini-Conference, Amsterdam, NL.

Acknowledgments