A Tablet - Based Intervention for Activating Nursing Home Residents with Dementia: Results from a Cluster-Randomised Controlled Trial

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Abstract

Objectives: To investigate global and momentary effects of a tablet-based non-pharmacological intervention for nursing home residents living with dementia.

Design: Cluster-randomized controlled trial.

Setting: Ten nursing homes in Germany were randomly allocated to the tablet-based intervention (TBI, 5 units) or conventional activity sessions (CAS, 5 units).

Participants: N = 162 residents with dementia.

Intervention: Participants received regular TBI (n = 80) with stimulating activities developed to engage people with dementia or CAS (n = 82) for eight weeks.

Measurements: Apathy Evaluation Scale (AES-I, primary outcome), Quality of Life in Alzheimer's Disease scale, QUALIDEM scale, Neuropsychiatric Inventory, Geriatric Depression Scale and psychotropic medication (secondary outcomes). Momentary quality of life was assessed before and after each activity session. Participants and staff were blinded until collection of baseline data was completed. Data was analyzed with linear mixed-effects models.

Results: Levels of apathy decreased slightly in both groups (mean decrease in AES-I of .61 points, 95%CI: -3.54 to 2.33 for TBI and .36 points, 95%CI: -3.27 to 2.55 for CAS). Group difference in change of apathy was not statistically significant (B = .25; 95%CI: -3.89 to 4.38, p = .91). This corresponds to a standardized effect size (*Cohen's d*) of .02. A reduction of psychotropic medication was found for TBI compared to CAS. Further analyses revealed a post-intervention improvement in QUALIDEM scores across both groups and short-term improvements of momentary quality of life in the CAS group.

Conclusions: Our findings suggest that interventions involving tailored activities have a beneficial impact on global and momentary quality of life in nursing home residents with dementia. Although we found no clear advantage of TBI compared to CAS, tablet computers can support delivery of non-pharmacological interventions in nursing homes and facilitate regular assessments of fluctuating momentary states.

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Introduction

Dealing with dementia is currently one of the greatest challenges for health and social care (Winblad et al. 2016; Livingston et al. 2020). The prevalence of apathy in people living with dementia (PWD) is high, and not only is apathy the most common neuropsychiatric symptom in dementia (Brodaty and Burns 2012), but it is also accompanied by greater functional and cognitive decline (Robert et al. 2009) and

negatively associated with quality of life (Nijsten et al. 2019). Considering unsatisfactory pharmacological treatment options, there is a growing interest in non-pharmacological interventions for managing apathy in PWD (Zucchella et al. 2018; Theleritis et al. 2017). A variety of promising non-pharmacological interventions have been investigated, such as music therapy (Raglio et al. 2010; Holmes et al. 2006), activity interventions (Treusch et al. 2015), and environmental stimulation (Jao et al. 2019). However, studies in this field are heterogenous and there is a lack of standardized and systematic methodological approaches (Theleritis et al. 2018; Goris, Ansel, and Schutte 2016). Moreover, most studies on non-pharmacological interventions for PWD do not focus on apathy as a primary outcome (Theleritis et al. 2018).

A recent meta-analytic study confirmed that non-pharmacological interventions can generally improve activities of daily living and depression in nursing home residents living with moderate to severe dementia (Na et al. 2019). In light of these positive findings, evidence-based treatment guidelines have included recommendations for non-pharmacological interventions as primary treatment of both cognitive and non-cognitive symptoms in dementia (Pink et al. 2018; Dyer et al. 2018). However, considering the immense workload and limited resources in everyday nursing home settings, adequate delivery of guideline-based non-pharmacological interventions can be especially challenging in care facilities (Staedtler and Nunez 2015; Bennett et al. 2020).

Previous research has indicated that interventions for PWD are more effective when tailored to the specific needs of the targeted person (O'Connor et al. 2009). Information and Communication Technologies (ICT) such as tablet computers can be viewed as innovative tools for supporting delivery of non-pharmacological interventions (Hitch et al. 2017; Tyack and Camic 2017). ICT-based interventions can utilize adaptive algorithms, animated features and simplified interfaces to increase the individual fit of an intervention to a specific user (D'Onofrio et al. 2017) and may enhance beneficial effects of conventional interventions (Subramaniam and Woods 2016; Hung et al. 2018). However, there is a lack of controlled studies in this field (Van der Roest et al. 2017). ICT also allow new possibilities for assessing state variables in PWD. Ecological Momentary Assessments (EMA) focus on the PWD’s current state and are administered repeatedly over a certain period of time (Shiffman, Stone, and Hufford 2008). It has been argued that situational EMA may be more suited to assess fluctuations in mood or quality of life, as retrospective self-reports and questionnaires can prove challenging and may not capture subtle changes related to specific events and situations (Beerens et al. 2016; Schall et al. 2018).

The objective of the present study PflegeTab (*English translation: CareTab*) was to evaluate a novel ICT-based intervention for activating nursing home residents with dementia in a cluster-randomized controlled trial (cRCT). We hypothesized the multicomponent tablet-based intervention (TBI) would lead to a decrease in apathy (primary outcome) compared to an active control group receiving conventional individual activity sessions (CAS). Effects on secondary outcomes, quality of life, depressive and neuropsychiatric symptoms were also investigated. Further, we assessed effects of the intervention on momentary quality of life with EMA before and after each activity session.

Methods

Study design

The study was designed as a two-arm prospective longitudinal cRCT and carried out in ten nursing homes in Berlin, Germany from June 2016 to May 2017. Randomization was performed at nursing home level to avoid contamination across groups (cluster-randomization, parallel design) and stratified according to total number of residents per unit. A member of the research team randomly assigned the units in each stratum to the TBI or CAS (each five nursing homes) group using opaque sealed envelopes (1:1 randomization). Assessments of primary and secondary outcomes were conducted before the intervention and after eight weeks. EMA were recorded in both groups before and after each session throughout the intervention period. Study assessors, participants and staff members were blinded to the allocation until after the collection of baseline data. Effective blinding was not possible during the intervention, as TBI administers received tablet computers and training. The study was conducted and reported in accordance with CONSORT and approved by the Ethics Committee of the Medical University Berlin (EA1/013/16).

Participants and recruitment

All participants were long-term residents from the included nursing homes. Consent was first obtained from legal guardians, PWD were then asked to give consent. PWD and guardians were thoroughly informed about the trial and study information was provided in plain language writing. Inclusion criteria were *dementia diagnosis* or *cognitive impairment* meaning a Mini-Mental State Examination (MMSE) score of less than 24 points (Folstein, Folstein, and McHugh 1975). Exclusion criteria were *other mental and behavioral disorders* and *short-term residency* of less than four weeks.

Intervention

The multicomponent TBI comprised seven applications specifically developed for PWD. Based on results of a pilot study (Nordheim et al. 2015) the aims were (a) to stimulate cognitive and functional abilities and (b) to support emotional regulation. All components of the TBI were developed within a participatory and iterative framework including several pretests. Four applications (*Quiz, Spelling game, Show me, Move me*) targeted cognitive and functional abilities. Task difficulty was adapted based on task performance: exercises became more difficult as performance improved and vice versa (Cha et al. 2019). Three applications (*Interactive Cat, Picture Gallery*, *Color and Sound*) were designed to support emotional self-regulation. Task difficulty was not adapted for these applications, as they were mainly designed to enhance communication and well-being (figure 1).

Trained staff members guided participants throughout each TBI session and provided assistance whenever needed. Within each session, several activities were selected according to participants' current

preferences and needs. Instructions were provided both visually and auditory via tablet and participants also received motivational feedback. Staff members sat with participants throughout the entire session and were instructed to encourage and reinforce them. The main purpose of the intervention was to engage PWD in a stimulating activity and to provide a positive and enjoyable experience. Therefore, feedback was based on user interactions rather than user performance, meaning that every interaction with the tablet was rewarded, regardless if an action was carried out correctly or not.

Participants from the five CAS units received the same amount of individual activity sessions as participants in TBI facilities. No specifications were made about the nature of the activities, except that no ICT devices should be involved. Staff members documented the activities in a logbook.

Procedure

A two-hour training session was conducted on-site in each TBI facility. Additionally, a user manual was provided and a support-hotline was set up. Members of the occupational therapy staff were to engage participants in three 30-minute individual sessions per week, resulting in a planned goal criterion of 24 activity sessions per participant. Two trained research assistants visited each unit and collected informant and self-rated data. The intervention phase commenced for each participant as soon as their baseline data was fully collected. Post-assessments were then collected eight weeks later. Informant data on participants was assessed from care professionals who knew the participant well. None of the informants participated in the activity sessions. EMA were collected immediately before and after each individual activity session and recorded via tablet for TBI and on paper for CAS.

Measurements

The primary outcome *apathy* was assessed with the Apathy Evaluation Scale – Informant version (AES-I) (Marin, Biedrzycki, and Firinciogullari 1991) at baseline and after eight weeks. The AES-I consists of 18 items rated on a 4-point Likert scale. The total score ranges from 18-72; higher scores reflect higher levels of apathy. The subscale Apathy of the Neuropsychiatric Inventory – Nursing Home Version (NPI-NH) (Cummings et al. 1994) was used to determine convergent validity of the main outcome scale AES-I . Correlation between the NPI-NH subscale Apathy and the AES-I scores was moderate (*Spearman's r*=.52).

Informant reports of *global quality of life* were assessed with the QUALIDEM scale (Ettema et al. 2007) consisting of 37 items rated on a 4-point Likert scale with a total score ranging from 0-111. Self-rated quality of life was assessed with the Quality of Life in Alzheimer's Disease (QOL-AD) questionnaire (Logsdon et al. 2002). Participants are asked to rate 13 different aspects of their lives on a 4-point Likert scale resulting in a total score from 13-39. Higher scores reflect higher quality of life levels in both measures. An eight-item version of the QUALIDEM was used to conduct EMA of *momentary quality of life*. Psychometric properties of the QUALIDEM short version have been published elsewhere (Junge et al. 2020). *Neuropsychiatric symptoms* were measured with the informant-based NPI-

NH questionnaire (Cummings et al. 1994). NPI-NH evaluates 12 neuropsychiatric symptoms using standardized interview questions. Informants rate the frequency and severity of each symptom, resulting in a total NPI-NH score from 0-144. Higher scores represent more neuropsychiatric symptoms. We assessed the prescription of psychotropic medications as a further indicator of neuropsychiatric symptoms (Maust et al. 2017). Information on prescribed medication was derived from medical records and medication lists at the time of baseline assessment and again at post-assessment eight weeks later. Type of medication, current dosage and intake intervals were recorded. *Depressive symptoms* were measured using the Geriatric Depression Scale (GDS) (Yesavage and Sheikh 2008). GDS is a 15-item questionnaire in a yes/no format with total scores from 0-15. Higher total scores indicate a higher risk of depression. Further covariates were age, gender, functional status assessed with Barthel Index (BI) (Mahoney and Barthel 1965), and dementia stage measured with the Functional Assessment Staging (FAST) (Sclan and Reisberg 1992). FAST is comprised of 7 stages and 9 substages, which were transformed into a consecutive score ranging from 1-16 for further analysis. Higher scores represent higher dementia severity.

Sample size calculation

Sample size was estimated with G-Power (Version 3.1; test family: two-sample *t*-test) and based on expected differences in QOL-AD scores (Hoe et al. 2009). Previous research has suggested that effects of interventions on quality of life and apathy are comparable (Nijsten et al. 2019). The final estimate was N=240 PWD (i.e., 120 per group). This calculation was based on a significance level of 5% (two-sided), 80% power, a medium effect size of *Cohen's d*=.5, and an expected attrition rate of 20% (Hoe et al. 2009). Taking the nested structure of the data into account, we anticipated small intracluster correlations between nursing homes with an intraclass correlation coefficient =.005 (Adams et al. 2004).

Statistical analysis

Linear mixed-effects models (LMM) fit by Restricted Maximum Likelihood Estimation were applied using an Intention-To-Treat approach, including all available data regardless of loss to follow-up. When using LMM in incomplete data, power issues because of reduced sample size as well as bias in results due to selection of cases with more complete data might arise, therefore Multiple data Imputation (MI) was used (Jakobsen et al. 2017). Especially if the missing data mechanism is missing at random and the probability of missingness is related to observed characteristics, one cannot rule out bias. MI based on chained equations and predictive mean matching was performed at item-level for primary and secondary outcome measures and covariates, scale scores were then computed. We analyzed ten imputed datasets separately and combined the results following Rubin's rules (Rubin 2004). The number of scale scores including imputed data at item-level were: AES-I (n=28; 17%), QOL-AD (n=71; 44%), QUALIDEM (n=28; 17%), GDS (n=102; 64%), NPI-NH (n=28; 17%), FAST (n=31; 19%), MMSE (n=74, 46%). All individual scale

items, age, gender, group (TBI vs. CAS), years of education, nursing home and medication were used for the imputation process.

Change scores were computed by subtracting baseline scores from post-intervention scores. Baseline outcome measures were included as fixed covariates and a random intercept was added at nursing home-level to account for clustering of participants. *P*-values are reported for unadjusted models and additionally for models adjusted for age, gender, neuropsychiatric symptoms (NPI-NH) and dementia stage (FAST). Generalized estimating equations (GEEs) were used where more robust estimation methods lead to more stable models. For the purpose of a sensitivity check, differently specified LMM analyses were conducted based on a three-level hierarchy with the repeated measure time points nested in participants who were grouped in different nursing homes (random intercepts). Fixed factors were group (TBI vs. CAS), time (baseline vs. post-intervention) and a group x time interaction. Time was modelled as a repeated measure with an autoregressive covariance structure. LMM for analyzing momentary quality of life included the factor group (TBI vs. CAS) and covariates for pre-session EMA measurements (baseline EMA), age, gender, neuropsychiatric symptoms (NPI-NH) and dementia stage (FAST) and the time-varying covariate session. Clustering at nursing home level was accounted for (random intercept). No adjustment for multiple testing was applied for secondary hypotheses analyses. In this exploratory study interpretation of results of secondary hypotheses analyses is based on effect estimates and 95%CI and not on *p*-values.

All statistical analyses were performed using IBM SPSS software (IBM SPSS Statistics for Windows, Version 26.0. Armonk. NY: IBM Corp).

Results

Participant characteristics

A total of 203 residents were deemed eligible after initial screening, N=162 (80%) were included in the study. The most common reason for non-inclusion was failure to reach the legal guardian (figure 2).

Post-intervention data was collected from 134 (83%) of the 162 participants at baseline. On average, participants were aged 85 years (SD=7.1, range=53-100) and reported lower secondary education (mean=10.5 years of education, SD=4.2, range=0-19). The majority were women (74%) and in need of substantial care (53% w/care level 4 “most severe impairment”). The mean FAST score was 9.1 (SD=1.8, range=4-16), which reflects moderately severe dementia (FAST stage 6d). The overall mean AES-I score was 48.8 (SD=10.6, range=20-69). For a total of 61 participants (38%), substantial clinical apathy was reported at baseline with the Subscale Apathy of the NPI-NH (M=2.1, SD=3.1, range=0-12). An average intake of 2.0 psychotropic substances per day (SD=1.5, range=0-7) was reported. The average GDS score of 3.4 (SD=2.6, range=0-11) was below the clinical cut-off for depression of five points. Chi-square, Mann-Whitney-*U* and *t*-tests confirmed that cluster randomization was successful, as no differences were revealed between intervention and control group in most characteristics at baseline. Lower levels of

neuropsychiatric symptoms were reported for the TBI group at baseline (*U*=2536.50, *p*=.017). In subsequent adjusted LLM analyses, the NPI-NH score was controlled for. All descriptive analyses are based on original data (table 1).

Dose of the intervention and attrition rate

Overall, the majority of participants (85%) failed to reach the goal of 24 sessions over eight weeks. On average, the TBI group (n=80) received 12.7 sessions (SD=8.7, range=0-36) and completed 53% of the scheduled intervention sessions, whilst the CAS group (n=82) received 15.7 sessions (SD=7.1, range=0-30) and completed 66% of the scheduled intervention sessions. The most frequent CAS were memory training, life story work and physical activity (i.e. short walks). The sample-wide attrition rate was 17% (28 participants). Post-intervention data could not be collected from 24 PWD (30%) in the TBI group and 4 PWD (5%) in the CAS group. The most frequent reason for discontinuing the study was lack of motivation and mental overload in the TBI (13 participants) and death in the CAS group (3 participants).

Impact of the intervention on primary and secondary outcomes

Unadjusted LMM analysis showed no significant group differences in change of the primary outcome apathy (AES-I score) (B=.25; 95%CI: -3.89 to 4.38, *p*=.91). This corresponds to a standardized effect size (*Cohen's d*) of .02. Overall, the levels of apathy decreased slightly in both groups with an estimated mean decrease in AES-I scores of .61 points (95%CI: -3.54 to 2.33) in the TBI group and .36 points (95%CI: -3.27 to 2.55) in the CAS group. Baseline AES-I scores were negatively associated with change scores of AES-I. Higher AES-I scores at baseline were associated with a decrease in apathy rates whilst lower baseline scores were associated with an increase in apathy rates (association of baseline and post-intervention AES-I: B=-.43; 95%CI: -.57 to -.29, *p*<.001). Further exploratory analyses to test for a differential intervention effect between participants with and without clinically relevant apathy did not yield any different results.

No substantial group differences in change scores were revealed by the unadjusted models in secondary outcomes QOL-AD (B=.12; 95%CI: -1.23 to 1.47, *p*=.86), NPI-NH (B=-.91; 95%CI: -6.35 to 4.54, *p*=.74) and GDS (B=.003; 95%CI: -.74 to .73, *p*=.99). For the secondary outcome QUALIDEM, we saw a statistically non-significant group difference in QUALIDEM change scores (B=2.04; 95%CI: -.86 to 4.94, *p*=.17). Estimated average QUALIDEM scores increased by .81 points (95%CI: .71 to 4.99) in the TBI group compared to an increase of 2.85 points (95%CI: -1.02 to 2.64) in the CAS group. Furthermore, the analysis for psychotropic medication revealed a group difference (B=.42; 95%CI: .15 to .69, *p*<.01) in favor of a greater reduction in the TBI group. Estimated mean change scores showed an average reduction of .41 substances (95%CI: -.61 to -.22) in the TBI group compared to an average change of .01 substances (95%CI: -.17 to .19) in the CAS group. This effect remained stable in models adjusted for gender, age, and

dementia stage (FAST) and neuropsychiatric symptoms (NPI-NH) (B=.43; 95%CI: .11 to .76, *p*<.01). Table 2 shows the estimated post hoc means and group differences of primary and secondary outcome scores. There were no substantial differences in findings for any models with and without imputation.

For a sensitivity check, additional LMM analyses including a fixed factor for measurement timepoints (baseline vs. post-intervention) were conducted. Analyses revealed an overall post-intervention improvement of QUALIDEM scores (collapsed over groups) (B=3.36; 95%CI: .49 to 6.23, *p*=.022). Analyses based on imputed data also revealed a group x time interaction (B=-5.44; 95%CI: -10.05 to -.84, *p*=.021). Post-intervention improvement of informant rated quality of life was greater in the CAS group (EM=3.73; 95%CI: .97 to 6.49) than in the TBI group (EM=.68; 95%CI: -2.50 to 3.86). These findings on QUALIDEM remained stable in models adjusted for gender and baseline values of age, dementia stage (FAST) and neuropsychiatric symptoms (NPI-NH). The adjusted model for QUALIDEM revealed associations of QUALIDEM scores with NPI-NH scores and gender. Higher levels of quality of life were associated with less neuropsychiatric symptoms (B=-.53; 95%CI: -.63 to -.43, *p*=<.001) and female gender (B=3.76; 95%CI: .04 to 7.48, *p*=.048).

Ecological Momentary Assessments of Quality of Life

Over all sessions and participants, a total of 2264 pre-session EMA and 2150 post-session EMA were recorded. Sessions without post-session EMA recordings were omitted from further analyses. Across both groups, LMM analyses revealed a general post-session improvement of .32 points in mean EMA of quality of life (B=-.11; 95%CI: -.20 to -.01, *p*=.03). Further analyses with EMA change scores as outcomes and adjusted for EMA pre-session values revealed a group difference, the post-session improvement was greater for the CAS compared to the TBI group (B=.43; 95%CI: .30 to .56, *p*<.001). The LMM estimated change in the intervention group was .02 (95%CI = -.07 to .12) and .46 (95%CI = .37 to .54) in the CAS group (figure 3). This finding remained stable after adjusting for gender and baseline values of age, FAST, NPI-NH.

Discussion

This study investigated effects of a multicomponent tablet-based intervention for activating nursing home residents with dementia. We hypothesized that regular, guided and tailored TBI sessions would improve the primary outcome apathy, and secondary outcomes quality of life, neuropsychiatric and depressive symptoms, compared to CAS. However, we did not find a positive effect of TBI on apathy. Improvements in quality of life (measured with QUALIDEM) were observed in both groups and these were larger in the CAS compared to the TBI group. EMA recorded before and after each activity session also rendered short-term post-session benefits on quality of life in the CAS group. A reduction of psychotropic medication was found for TBI compared to CAS.

Although we expected the tailored TBI would increase engagement and reduce apathy, our findings do not support this notion. While it is clear that apathy plays an important role in dementia, research on the

impact of non-pharmacological interventions on apathy has yielded mixed results (Goris, Ansel, and Schutte 2016; Theleritis et al. 2018). Previous studies have also failed to detect clinically meaningful effects on apathy in the long term. Treusch et al. (2015) found an increase in apathy levels in a control group compared to a group with a weekly occupational and sport intervention. However, this effect faded twelve months after termination of the intervention, suggesting that long-term and on-going interventions are necessary to achieve a meaningful impact on apathy in PWD. Cohen-Mansfield (2018) observed increased engagement levels in nursing home residents with dementia during group activities compared to a control condition with unstructured time, while Raglio et al. (2010) reported beneficial effects of a music-based intervention. Future studies on ICT-based interventions should incorporate these activity types to gain more knowledge on effective strategies for reducing apathy in PWD. Moreover, considering our finding that higher levels of apathy at baseline were associated with a decrease in apathy, future studies that aim to address apathy in PWD should strive to include participants with high levels of apathy at baseline and define appropriate inclusion criteria prior to study entry (Cummings et al. 2015).

In line with previous findings, informant-rated quality of life improved in both groups (Ballard et al. 2018). However, the observed improvement was smaller for the TBI than the CAS group. In contrast, self-rated quality of life did not change markedly over the intervention period. This finding could be related to known challenges regarding self-reported outcomes in PWD (Robertson et al. 2017). We also observed improvements in momentary quality of life in the CAS group, whereas a ceiling effect was observed in the TBI group. Previous research has also reported situational improvements of quality of life in PWD (Schall et al. 2018).

A reduction of psychotropic medication was found in the TBI compared to CAS group. Although we did not expect this specific result, previous studies have reported similar findings. A cRCT conducted by Jøranson at al. (2016) reported a significant decrease in prescribed psychotropic medication related to a robot-assisted intervention for nursing home residents with severe dementia. Ballard et al. (2016) argue that effective non-pharmacological interventions should be implemented alongside antipsychotic review in order to reach sustainable benefits for PWD in nursing home care.

Possible reasons for the absence of group differences may be related to (1) design of the study, (2) implementation of the intervention and (3) content of the intervention.

All participants received substantial one-on-one time from occupational therapists, which may have led to benefits for participants in both groups. The activities conducted in the CAS group were chosen individually, essentially meaning that this group also received a tailored intervention. Evidence-based recommendations for cognitive interventions in dementia have established that control group activities should match those of intervention groups in duration, intensity and socio-physical environment (Ibanez et al. 2014). Therefore, we chose an active control group as opposed to a comparison group receiving treatment as usual. Methodological issues concerning active control group trials have been discussed elsewhere (Temple and Ellenberg 2000; Makuch and Johnson 1989). The absence of group differences within our study design could either mean that both treatments were equally effective (i.e., noninferiority),

or that no treatment had an effect. Previous research on individualized activity interventions for PWD has demonstrated that tailored interventions directed towards individual needs and abilities of PWD are associated with better clinical outcomes (Vernooij-Dassen et al. 2010; Ballard et al. 2018). Our finding that global quality of life, on average, marginally improved in both groups after eight weeks, combined with the ceiling effect in momentary quality of life in the TBI group and the improvement of momentary quality of life we observed in the CAS group, may suggest that in fact both groups received potentially effective treatments. Furthermore, there were considerable individual differences in change of quality of life around the mean change in our study and future studies should thus investigate which time-variant individual factors account for improved treatment effects.

Overall, only 59% of the intervention sessions were carried out. One important reason for the poor implementation was a lack of time and staff resources as well as high staff turnover rates in some of the participating units. Occupational stress in nursing home staff has been a much-researched topic (Costello et al. 2019). This unforeseen reduction of the intervention dose could have affected our results, as previous research has pointed out that the frequency and intensity of interventions are important factors (Kim and Park 2017). Conversely, the dose of the intervention exceeded the number of planned sessions in some participants. This too entails a methodological problem and could have impacted our findings. Previous studies have also reported inconsistent delivery of technology-based interventions (Godwin et al. 2013). We also found lower rates of delivered activity sessions for TBI units compared to CAS. Despite our efforts to boost acceptance, there may have been persistent ICT-related inhibitions in some of the participating staff. Perceived usefulness and perceived ease of use are pivotal factors for acceptance or rejection of new technologies in healthcare settings (Rahimi et al. 2018; Gagnon et al. 2012).

Finally, we must address the fact that 13 participants in the TBI group terminated the study because the TBI was too mentally challenging and stressful. Although reduced levels of cognitive functioning and inexperience of PWD were considered when designing the applications, we cannot rule out that the fact of simply being introduced to an unfamiliar device itself may have been overwhelming and excessively demanding for some participants. Hung et al. (2020) reported similar implementation barriers related to novel technologies.

Strengths and practical implications

Studies of non-pharmacological interventions have confirmed that changes in mood, cognition and behavior seldom persist in PWD after cessation of the intervention (Kim and Park 2017). This may be linked to the progressive nature of dementia, making it difficult to establish long-lasting and sustainable improvements in the absence of on-going interventions. It can also be methodologically challenging to quantify intervention effects on global outcomes such as apathy or quality of life. A strength of our study lies in the assessment of momentary quality of life in addition to conventional global outcome measures. This way, we were able to detect changes in both global and momentary states associated with the activity sessions. Even though short-term improvements may not impact global outcomes, temporary

benefits can be extremely meaningful for PWD and nursing home staff. Future studies should utilize situational EMA to investigate the effectiveness of on-going interventions in PWD.

It has been widely acknowledged that the prevalence of polypharmacy and inappropriate psychotropic medication are high in PWD (Jester et al. 2021). Our results indicate that non-pharmacological interventions may have the potential to reduce psychotropic drugs in nursing home residents with dementia. However, we specifically underline that this finding cannot be interpreted any further in the context of our study. It remains unclear if the reduced psychotropic medication can be attributed to less neuropsychiatric symptoms or other factors, as we did not find a corresponding decrease of NPI-NH scores in the TBI group. Further research is needed to investigate the possible impact of ICT-based interventions on prescription of psychotropic medications.

While interventions such as ours may not reduce costs or replace staff, they could absorb some of the workload for nursing home staff and enrich the repertoire of available activity options. ICT devices are small, easy to operate and pervasive in today's modern society. One single device can be used to engage numerous PWD, either simultaneously or individually. Therefore, we strongly recommend further research on meaningful ICT-based interventions for PWD.

Another strength of our study was that the activity sessions were executed by nursing home staff under 'real world' conditions, as recommended by Bennett et al. (2020). Future research on ICT-based interventions in nursing homes should consider barriers concerning workplace conditions, user acceptance and digital infrastructure. We recommend extensive staff training prior to introduction of novel interventions and close monitoring of on-going interventions to ensure a successful implementation and increase user acceptance of ICT-based interventions in nursing homes.

Limitations

Our study design does not allow an unambiguous interpretation of the results. Future studies should incorporate a third study arm to unravel effects associated with new interventions. Secondly, while baseline measurements were carried out by blinded study assessors, this approach was not feasible for the collection of EMA. EMA were conducted by the person who carried out the activity session, meaning that rater bias cannot be fully ruled out. This also may have amplified the ceiling effect observed in the TBI group. A third limitation stems from the fact that we were unable to collect self-reported data in some participants with higher dementia stages, resulting in higher proportions of missing data on self-report instruments. We cannot rule out inflated Type I error rates, since we did not adjust for multiple testing in the analyses of secondary hypotheses. *P*-values should be interpreted cautiously for secondary hypotheses. Finally, our study was underpowered which may have made it more difficult to detect a difference in our primary outcome.

Conclusion

Tablet computers can support delivery of non-pharmacological interventions in nursing homes and facilitate regular assessments of fluctuating momentary states in residents with dementia. Although the improvements in global quality of life observed in our study may not be specific to TBI, we believe they are related to the individualized and tailored activity sessions. We also found that EMA collected directly before and after activity sessions revealed subtle and short-term benefits. Non-pharmacological interventions could have a more meaningful impact on momentary states of nursing home residents with dementia than on their global conditions. These findings can be of high clinical relevance and underline the importance of individualized activity interventions in nursing home care. However, further research is needed to determine effective intervention components and unravel short- and long-term benefits of ICT-based interventions in PWD.

Abbreviations

95% CI: 95% confidence interval

AES-I: Apathy Evaluation Scale – Informant Version

BI: Barthel Index

CAS: conventional activity sessions

cRCT: cluster-randomised controlled trial

EMA: ecological momentary assessments

FAST: Functional Assessment Staging

GDS: Geriatric Depression Scale

GEE: generalized estimating equations

ICC: intraclass correlation coefficient

ICT: internet and communication technologies

ITT: intention-to-treat

LMM: linear mixed models

M: mean

MAR: missing at random

MMSE: Mini Mental State Examination

NPI: non-pharmacological interventions

NPI-NH: Neuropsychiatric Inventory - Nursing Home Version

PMM: predictive mean matching

PWD: people with dementia

QOL-AD: Quality of Life in Alzheimer's Disease

REML: restricted maximum likelihood estimation

SD: standard deviation

TAM: Technology Acceptance Model

TBI: tablet-based intervention

UTAUT: Unified Theory of Acceptance and Use of Technology

Declarations

Ethics approval and consent to participate

This study was approved by the local ethics committee of the Charité Medical University of Berlin (number EA1/013/16). Written informed consent was obtained from participants or legal guardians or prior to data collection.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analysed are stored in a non-publicly available repository and are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JLOS, PG, JNVA, SM, AK, and JN designed and conducted the study. JLOS, SL and JN conducted review of the literature. JLOS was the main contributor in writing the manuscript. SL and JN made substantial contributions to the manuscript. JLOS, UG and PG analysed the data, and all authors were involved in reviewing and interpreting the data. JLOS, SL, PG, UG, JNVA, SM, AK and JN critically revised the current manuscript for submission. All authors read and approved the final version of the manuscript.

Conflict of Interest

None.

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Tables

Table 1. Baseline characteristics for total cohort, TBI and CAS group, M (SD) or N (%), N = 162.

Characteristic	n	Total cohort (N = 162)	TBI (n = 80)	CAS (n = 82)	*p*
Demographics					
Age (years), M (SD)	162	85.0 (7.1)	85.4 (7.6)	84.6 (6.6)	ns
Female, n (%)	162	119 (74)	54 (68)	65 (79)	ns
Education (years), M (SD)	146	10.5 (4.2)	10.3 (4.2)	10.6 (4.2)	ns
Care level, n (%)	158				ns
Minor impairment		0 (0)	0 (0)	0 (0)	
Substantial impairment		2 (1)	2 (3)	0 (0)	
Serious impairment		51 (32)	24 (30)	27 (35)	
Most severe impairment		83 (53)	42 (53)	41 (53)	
Most severe impairment w/ special care needs		22 (14)	12 (15)	10 (13)	
Dementia-subtype, n (%)	154				ns
Alzheimer’s Disease		29 (19)	12 (15)	17 (23)	
Vascular Dementia		15 (10)	5 (6)	10 (13)	
Unspecified Dementia		77 (50)	44 (56)	33 (44)	
Mixed Dementia		17 (11)	10 (13)	7 (9)	
Others		16 (10)	8 (10)	8 (11)	
Functional Status					
BI score, M (SD)	161	53.6 (26.2)	54.1 (24.7)	53.1 (27.7)	ns
Dementia Stage					
FAST score, M (SD)	161	9.1 (1.8)	9.0 (1.9)	9.3 (1.7)	ns
Psychotropic Medication	161				
Antidementia agent present n (%)		41 (25)	20 (25)	21 (26)	ns
Neuroleptic agent present n (%)		89 (55)	39 (49)	50 (61)	ns
Apathy					
M (SD) AES-I	161	48.8 (10.6)	49.3 (9.8)	48.3 (11.4)	ns
Quality of Life					

M (SD) QOL-AD	128	28.8 (9.1)	28.3 (7.6)	29.2 (10.5)	ns
M (SD) QUALIDEM	161	77.4 (14.3)	79.5 (13.0)	75.3 (15.2)	ns
Neuropsychiatric Symptoms					
M (SD) NPI-NH	161	16.6 (16.3)	13.2 (12.6)	19.9 (18.6)	.017
M (SD) Psychotropic Medication	161	2.0 (1.5)	1.9 (1.7)	2.1 (1.4)	ns
Depressive Symptoms					
M (SD) GDS	127	3.4 (2.6)	3.6 (2.8)	3.1 (2.3)	ns

Note: TBI = tablet-based intervention, CAS = conventional activity sessions, M = Mean, SD = Standard Deviation, BI = Barthel Index, FAST = Functional Assessment Staging, AES-I = Apathy Evaluation Scale – Informant Version, QOL-AD = Quality of Life in Alzheimer's Disease, NPI-NH = Neuropsychiatric Inventory - Nursing Home Version, GDS = Geriatric Depression Scale, ns = non-significant. FAST stages (1-7) and substages (6a-e and 7a-f) were transformed into a consecutive score ranging from 1-16.

Table 2. Estimates of primary and secondary outcome post-intervention means for CAS and TBI group, adjusted for mean baseline values of particular outcome (N = 162).

Outcome	CAS (95% CI)	TBI (95% CI)	Group difference (CAS – TBI)	95% CI		*p*
AES-I[b]	48.51 (45.61-51.42)	48.27 (45.32-51.21)	.25	-3.89	4.38	.91
QOL-AD*[a]	34.15 (33.32-34.98)	34.03 (33.09-34.98)	.12	-1.23	1.47	.86
QUALIDEM*[a]	80.32 (78.18-82.45)	78.28 (76.45-80.10)	2.04	-.86	4.94	.17
NPI-NH[b]	16.46 (12.67-20.26)	17.37 (13.51-21.23)	-.91	-6.35	4.54	.74
GDS[a]	4.67 (4.03-5.32)	4.68 (4.32-5.03)	-.003	-.74	.73	.99
Psychotropic medication[a]	1.99 (1.81-2.17)	1.56 (1.37-1.76)	.42	.15	.69	< .01

Note: Group means and differences were estimated with generalized estimating equations[a] (GEE) and linear mixed models[b] (LMM). All models are adjusted for particular baseline measures. Clustering of measurements in nursing homes and participants were accounted for. Positive difference values indicate smaller means in the TBI group compared to the CAS group. * denotes measures where higher scores show improvements. TBI = tablet-based intervention, CAS = conventional activity sessions, 95% CI = 95% Confidence Interval, AES-I = Apathy Evaluation Scale – Informant Version, QOL-AD = Quality of Life in Alzheimer's Disease, NPI-NH = Neuropsychiatric Inventory - Nursing Home Version, GDS = Geriatric Depression Scale.

Supplementary File 2

Supplementary File 2 is not available in this version.

Figures

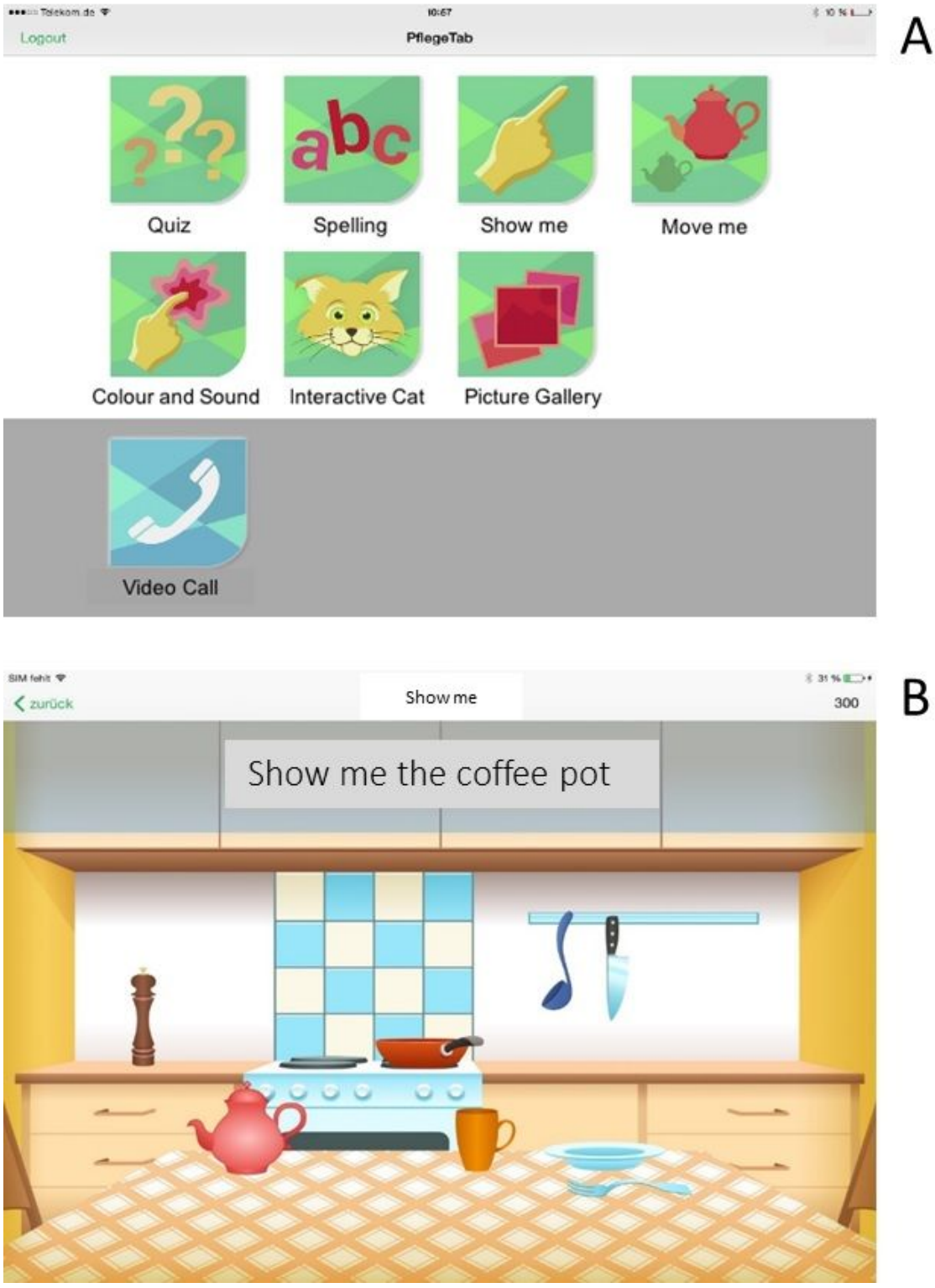

Figure 1

Panel A: PflegeTab launch screen with all seven applications for (a) stimulating cognitive and functional abilities (Quiz, Spelling, Show me, Move me) and (b) supporting emotional regulation (Interactive Cat, Color and Sound, Picture Gallery). Panel B: Task in the Move me application. The applications were designed especially for older and inexperienced tablet users. They were developed for the purpose of this research and are currently not available to the public. Interested researchers may contact us for a demo

version. The TBI was executed on Apple iPads version Air 2 (Model A1567) and the application was programmed in Swift. The copyright for the depicted images is owned by the authors.

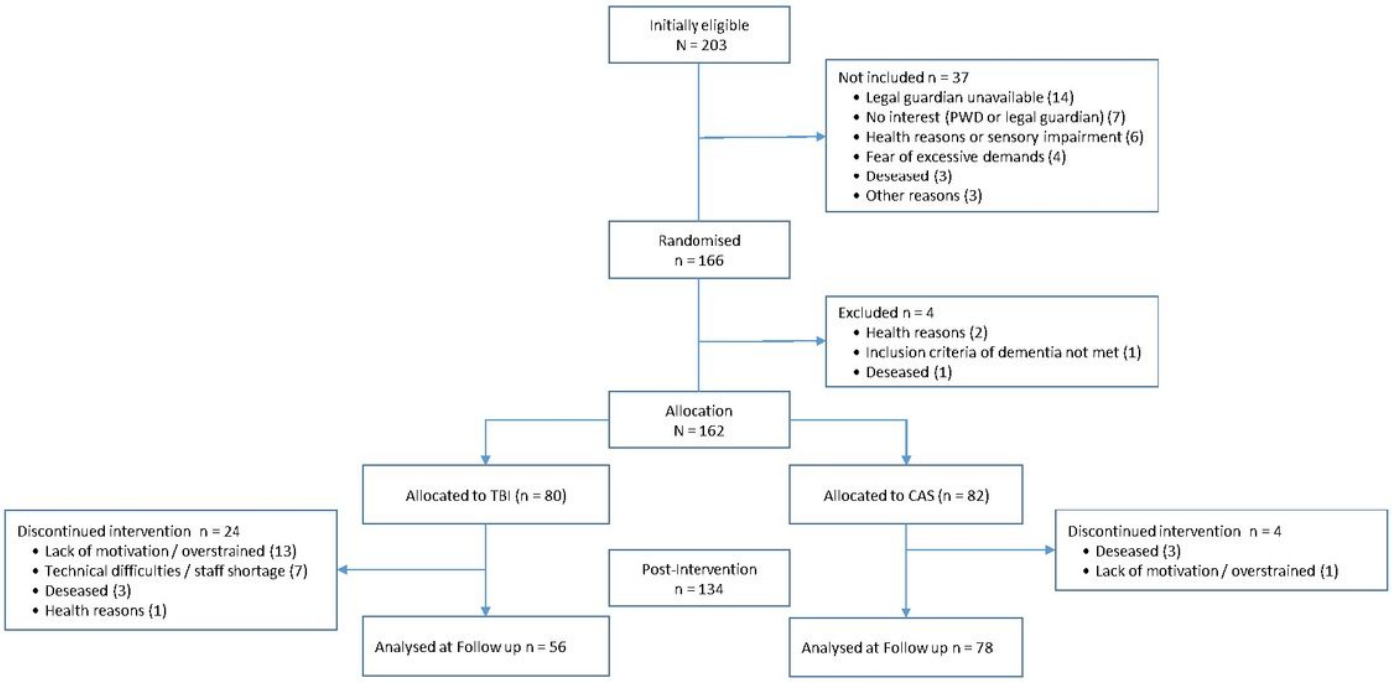

Figure 2

Flow chart of trial participants.

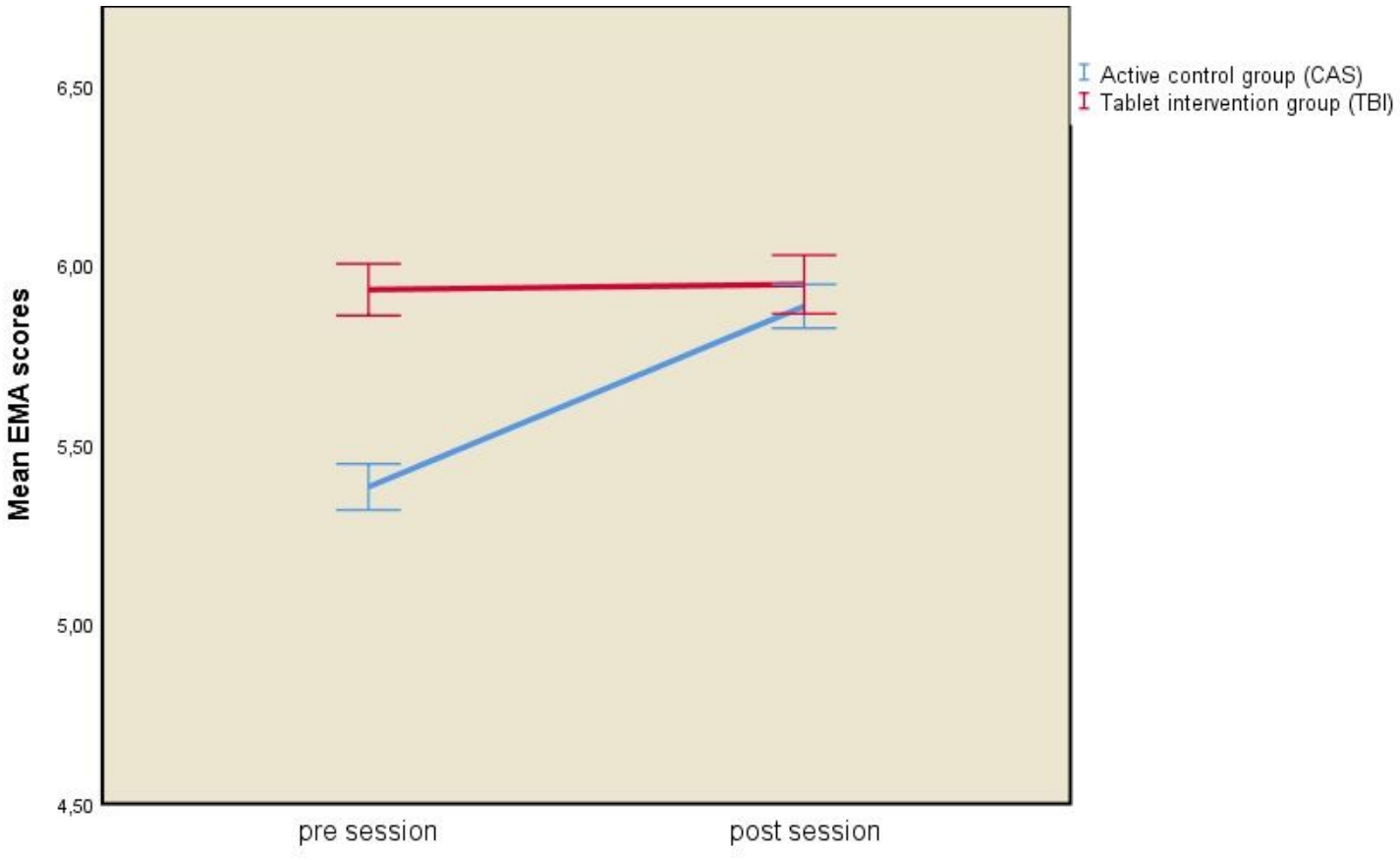

Figure 3

Overall observed means for pre and post-session EMA scores for TBI and CAS group. Note: Error bars represent standard deviations of observed mean EMA scores.

Supplementary Files

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- CONSORTChecklistPflegeTab.docx