

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

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## Research article

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# Abstract

**Background:** Non-pharmacological interventions (NPI) can improve cognitive and non-cognitive symptoms in nursing home residents living with dementia. However, delivery of suitable NPI can be challenging in everyday nursing home settings. Internet and communication technologies (ICT) may be promising tools for supporting NPI delivery in nursing homes.

**Methods:** A two-arm cluster-randomised controlled trial was conducted to investigate global and momentary effects of a novel ICT-based NPI for nursing home residents with dementia. Ten nursing homes were randomly allocated to the tablet-based intervention (TBI) or conventional activity sessions (CAS) group (each with five nursing homes) between April 2016 and May 2017. A total of N = 162 participants received either regular TBI (n = 80) or CAS (n = 82) over a period of eight weeks. Linear mixed models were used to analyse group differences regarding the primary outcome apathy (AES-I), and secondary outcomes quality of life (QOL-AD, QUALIDEM), neuropsychiatric (NPI-NH, psychotropic medication) and depressive symptoms (GDS). Ecological Momentary Assessments (EMA) of quality of life were also conducted in both groups before and after each activity session.

**Results:** No significant group difference in the change of apathy (AES-I score, primary outcome) was found post intervention (mean group difference: B = .19; 95% CI: -3.90 to 4.28,  $p = .93$ ). Regarding secondary outcomes, a reduction of psychotropic medication was found for TBI compared to CAS (B = .42; 95% CI: .15 to .69,  $p < .01$ ). Further analyses revealed a post-intervention improvement of informant-rated quality of life across both groups (B = 3.69; 95% CI: .68 to 6.69,  $p = .02$ ). Analysis of EMA also rendered short-term post-session improvements of quality of life in the CAS group (B = .43; 95% CI: .30 to .57,  $p < .001$ ).

**Conclusions:** These findings suggest that NPI involving individually tailored activities have a beneficial impact on quality of life in nursing home residents with dementia. Although we found no clear advantage of TBI compared to CAS, ICT have the potential to support NPI delivery and facilitate regular assessments of fluctuating momentary states in nursing home residents with dementia.

**Trial registration:** The trial was retrospectively registered with the ISRCTN registry (Trial registration number: ISRCTN98947160) on 01/09/2016 <http://www.isrctn.com/ISRCTN98947160>.

## Background

Dealing with dementia is one of the most pressing challenges for health and social care in the 21st century. (1, 2). According to the 2020 report of the *Lancet* Commission on dementia prevention, intervention, and care over 50 million people worldwide are currently living with dementia, and this number is expected to triple by 2050 (3). Dementia refers to a group of progressive neurological disorders characterized by multiple cognitive and behavioural symptoms. Those diagnosed with dementia experience a loss of memory function and a deterioration of functional abilities, causing growing dependence on family members and professional caregivers in order to manage daily life (4, 5).

A wide range of symptoms is associated with dementia, such as memory decline, apathy, agitation, and changes in personality and mood. The prevalence of apathy in PWD is high, and not only has apathy been reported as the most common non-cognitive symptom in dementia (6), but it is also known to be negatively associated with quality of life (7, 8). These findings illustrate the need for suitable interventions to reduce or maintain apathy levels in PWD (9). An etiological cure for dementia has yet to be discovered. Considering unsatisfactory findings on pharmacological treatment options, there is a growing interest in non-pharmacological interventions (NPI) for managing symptoms associated with dementia (10–14). According to Moniz-Cook et al. (13), NPI for dementia “encompass interventions involving interaction between people to improve psychological and/or social functioning, including well-being and cognition, interpersonal relationships and everyday functional abilities, such as activities and daily living skills”. A wide range of NPI belonging to various intervention categories and targeting different outcomes can be identified. Frequently applied NPI include reminiscence therapy, reality orientation, cognitive stimulation therapy, occupational therapy, music therapy, or psychological interventions. Olazarán et al. (12) conducted a comprehensive review of 1.313 studies (179 RCTs) belonging to 26 intervention categories and found evidence that certain types of NPI (cognitive training, cognitive stimulation, multicomponent interventions, ADL training, behavioural interventions, caregiver support and training) showed benefits for PWD. However, only two of the included studies investigated technology-based approaches, and both were intended for family caregivers and not for PWD. McDermott et al. (15) conducted a synthesis of 22 systematic reviews and found sufficient evidence that certain NPI (medium to long term multi-component exercise and group cognitive stimulation) showed consistent improvements on physical and cognitive functions, ADL, social interactions and quality of life. A recent meta-analytic study of RCTs also confirmed that NPI can improve activities of daily living (ADL) and depression in nursing home residents living with moderate to severe dementia (16). In light of these positive findings on benefits of NPI, evidence-based treatment guidelines have included recommendations for NPI as primary treatment of both cognitive and non-cognitive symptoms in dementia (17, 18). However, access to suitable NPI can be a challenge for many PWD and their caregivers. Considering the immense workload and limited resources in everyday nursing home settings, adequate delivery of guideline-based NPI to PWD can be especially challenging in care facilities (19). Accordingly, Molinari et al. (20) reported that only 12% of newly admitted nursing home residents in Florida, USA received NPI, while over 70% received at least one psychotropic medication.

Information and Communication Technology (ICT) devices such as tablet computers are affordable, widely available and offer a range of stimulating features, such as interactive communication or multimedia functions. This kind of technology has become increasingly popular in dementia care and could be an innovative tool for supporting NPI-delivery (21–25). Lazar, Thompson, & Demiris (26) found specific benefits of ICT for delivering reminiscence therapy, such as access to rich and engaging reminiscence material or opportunities to take part in social interactions. Lauriks et al. (27) reviewed the literature on ICT-based services for identified unmet needs of PWD and found that people with mild to moderate dementia were able to use simple ICT solutions designed for compensating disabilities, such as memory deficits or problems carrying out daily activities. Further benefits for PWD, such as enhanced

positive affect or confidence were also revealed. Recent studies show further potential benefits of ICT in dementia care, such as ICT-based caregiver interventions (28). Previous research has indicated that NPI for PWD are more effective when tailored to the specific needs and environment of the person targeted (29). ICT-based interventions can utilize adaptive algorithms, animated features and simplified interfaces designed specifically for cognitively impaired users in order to increase the individual fit of an intervention to a specific PWD (30, 31). Therefore, ICT-based delivery of adaptive NPI may have the potential to enhance beneficial effects of conventional interventions (32–34). Taken together, the available results show that ICT-based NPI could be an effective and innovative approach in dementia therapy delivery. However, there is a general lack of controlled studies in this field and more research is needed (35).

Besides offering multiple benefits regarding the delivery of suitable NPI to PWD, ICT also allow new possibilities for assessing state variables in PWD, such as daily fluctuations in mood or quality of life. Traditional measurement approaches in health and dementia research usually involve retrospective self-reports or informant ratings, which have been criticized for their lack of objectivity and ecological validity (36–39). Ecological Momentary Assessments (EMA) focus on the current state of a PWD and are administered repeatedly over a certain period of time (37). They usually consist of diaries, behavioural observations or brief questionnaires (40). By using technology-based measurement approaches to conduct EMA, researchers have the opportunity to repeatedly collect and analyse behavioural data from PWD within their natural settings. It has been argued that situational EMA may be more suited to assess psychological outcomes in PWD, as retrospective self-reports and questionnaires can prove challenging for cognitively impaired persons and may not capture subtle changes related to specific events and situations (41, 42).

The present study took place in Germany in the scope of the research project *PflegeTab* (engl. *CareTab*). The main goal of the project was to develop and evaluate the effects of a novel ICT-based NPI for nursing home residents with dementia. To this end, we conducted a cluster-randomised controlled trial (cRCT) with nursing home residents living with moderate to severe dementia. The tablet-based intervention (TBI) comprised multiple stimulating and motivating activities specifically developed to engage PWD. Our objective was to investigate whether the multicomponent TBI would lead to a decrease in apathy (primary outcome) compared to the 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 aimed to assess possible momentary effects of the intervention on quality of life with EMA conducted before and after each TBI and CAS session.

## Methods

### Study design

The *PflegeTab* study was designed as a two-arm prospective longitudinal cRCT. It took place from April 2016 to May 2017 and was carried out in ten nursing homes located in Berlin, Germany. The randomisation was performed at nursing home level to avoid contamination across groups (cluster-

randomisation, parallel design) and was stratified according to total number of residents in each unit. Within each of the five strata, a member of the research team randomly assigned the units to the intervention group (TBI, five nursing homes) and to the active control group (CAS, five nursing homes) using opaque sealed envelopes (1:1 randomisation). Assessments of primary and secondary outcomes were conducted before the intervention (baseline) and immediately after the eight-week intervention (post intervention). Additionally, EMA were continuously collected in both groups during the intervention phase. Study assessors, participants and staff members of each unit were left blinded to the allocation until the collection of baseline data was completed. Effective blinding was not possible during and after the intervention, as TBI administrators received tablet computers and training. The study was conducted and reported in accordance with the CONSORT guidelines for cRCT and was approved by the Ethics Committee of the Medical University of Berlin before enrolment of study participants (Charité – Universitätsmedizin Berlin; EA1/013/16). The trial was registered retrospectively during the recruitment phase with the ISRCTN registry (Trial registration number: ISRCTN98947160).

## Participants and recruitment

All participants were long-term residents from the included nursing homes. In nine participating facilities, all residents with dementia were screened for eligibility. The remaining facility had a special dementia unit, in this case only PWD from this unit were included in the further recruitment process. In a first step, legal guardians of potential participants were contacted via telephone. Comprehensive verbal and written information was provided to guardians about the research project and the trial. After consent was obtained from legal guardians, PWD were approached and also asked to give consent. In the few cases of PWD without legal guardians, PWD were approached directly by members of the study team. We took great care to ensure the recruitment procedure was conducted in a comprehensive manner appropriate for PWD. PWD and guardians were thoroughly informed about each part of the trial and all written study information was provided in plain language. Formal inclusion criteria for participants were defined as *dementia diagnosis*: ICD-10 F00-F03, G30, G31.0, G31.82 and/or *cognitive impairment*: Mini-Mental State Examination (MMSE)-score of less than 24 points. Exclusion criteria were *other mental and behavioural disorders*: ICD-10 Diagnosis F10-29 (except F10.1, F17.1, F17.2), and *short-term residency*: nursing home residency for less than four weeks at baseline.

## Intervention

### Intervention Group Nursing Homes

The multicomponent TBI comprised a total of seven basic applications specifically developed to engage PWD in stimulating and motivating activities. The TBI was designed (a) to target cognitive and functional abilities and (b) to support emotional regulation. These domains were selected based on the results of a pilot study (43) and existing research on suitable NPI for PWD. The individual components of the TBI

were developed within a participatory and iterative design framework. Each application was designed for older and inexperienced tablet users with impaired cognitive, sensory and/or motor functioning. Several pretests were conducted with PWD, family and formal caregivers. As far as possible, their requirements were implemented in the further design process. Four applications (*Quiz, Spelling game, Show me, Move me*) targeted cognitive and functional abilities. Task difficulty within these applications was adapted individually based on participant's task performance: exercises became more difficult as participant's performance improved and vice versa, for details see Cha et al. (44). Two further applications (*Interactive Cat, Colour and Sound game*) were designed to support emotional self-regulation. A *Picture Gallery* addressed both cognitive and emotional aspects within the scope of life story work. Task difficulty was not adapted for the applications *Interactive Cat, Colour and Sound game* and the *Picture Gallery*, as these were mainly designed to enhance communication and promote quality of life. An application for communication with family members by means of videoconferencing was also included.

A trained member of the occupational therapy staff accompanied each intervention session. Training workshops were conducted prior to the intervention period to ensure staff members could administer the TBI correctly. The occupational therapy staff members were instructed to guide participants throughout each session and provide assistance whenever needed. Within each TBI session, several activities were selected by the occupational therapists according to the participants' current preferences and needs. Instructions for each activity were provided both visually and auditory via tablet. After completing a task, participants also received motivational visual and auditory feedback via tablet. The main purpose of the intervention sessions was to engage PWD in a stimulating activity and to provide a positive and enjoyable experience. Therefore, the provided feedback was based on user interactions rather than user performance, meaning that every interaction with the tablet was rewarded, regardless of whether a user action was correct or not. To avoid unpleasant experiences, no direct error feedback was given. If a given response was not correct, the PWD were simply encouraged to try again. The TBI was executed on Apple iPads version Air 2 (Model A1567) and the *PflegeTab* application was programmed in Swift.

## Active Control Group Nursing Homes

According to the study protocol, participants from the five CAS nursing homes were to receive the same amount of individual CAS as participants from the five TBI facilities. A member of the occupational therapy staff also accompanied the individual CAS in this group. No further specifications were made about the nature of the activities, except that no ICT devices were to be involved. Staff members were asked to document the activities conducted in each session in a logbook.

## Procedure

Members of the occupational therapy staff in both the TBI and CAS group were instructed to engage participants in three 30-minute individual activity sessions per week over a period of eight weeks, resulting in a planned goal criterion of 24 activity sessions per participant. A two-hour staff training

session was conducted on-site in each TBI facility and a written manual with crucial information for the implementation was provided. Additionally, a support hotline was manned permanently during office hours in case any problems or malfunctions occurred. Two trained research assistants visited each TBI and CAS nursing home and collected informant and self-rated outcome data at baseline and after eight weeks on site. Informant data on participants was assessed from members of the nursing home staff (care professionals) who had worked with the participant on a regular basis and thus knew them well. None of the staff informants participated in the CAS or TBI sessions. Additionally, EMA were collected before and after each activity session. These brief assessments were conducted by the occupational therapist and recorded via tablet in the TBI group and on paper in the CAS group, respectively.

## Measurements

### Screening Variable: Cognitive Status

*Cognitive status* was measured using the MMSE (45). The MMSE is comprised of 30 questions on different aspects of mental functioning, such as orientation, memory, and ability to understand verbal instructions. Each correct answer is scored with one point resulting in a maximum score of 30 points. In the present study, internal consistency of the MMSE was excellent with *Cronbach's*  $\alpha = .91$ .

## Primary Outcome

### Apathy

The primary outcome *apathy* was rated by professional caregivers with the informant version of the Apathy Evaluation Scale (AES-I) (46) at baseline and after eight weeks. The AES-I consists of 18 items rated on a 4-point Likert scale ranging from 1 = not at all characteristic to 4 = very characteristic. A sum score is computed for each item; higher scores reflect higher levels of apathy. In the present study, internal consistency was excellent with *Cronbach's*  $\alpha = .91$ . The subscale Apathy of the Neuropsychiatric Inventory – Nursing Home Version (NPI-NH) (47) was used to determine the convergent validity of the main outcome scale AES-I (48). In terms of convergent validity, in our sample, correlations between the NPI-NH subscale Apathy and the AES-I scores were at moderate levels (*Spearman's*  $\rho = .52$ ).

## Secondary Outcomes

### Quality of Life

Informant reports of dementia-related *quality of life* were assessed with the QUALIDEM scale (49). QUALIDEM consists of 37 items belonging to nine subscales. All items are rated on a 4-point Likert scale

ranging from 0 = never to 3 = frequently. Scores are computed for each subscale. Although the original QUALIDEM does not include a total score, previous studies have created a comprehensive QUALIDEM score by summing the scores of the nine subscales, see (50) for an example. In accordance with this procedure, we also computed a total score for the QUALIDEM scale. Additionally, self-rated quality of life was measured with the Quality of Life in Alzheimer's Disease (QOL-AD) questionnaire (51) from PWD who were able to respond to the questions. Within the 13-item QOL-AD, participants are asked to rate different aspects of their lives on a 4-point Likert scale ranging from 1 = poor to 4 = excellent. The total score is the sum of all 13 items. Higher scores reflect higher quality of life levels in both measures. Internal consistency of both measures of quality of life was good with *Cronbach's a* = .83 for QOL-AD and *Cronbach's a* = .87 for QUALIDEM.

## Neuropsychiatric symptoms

The informant-based NPI-NH questionnaire was used to measure *neuropsychiatric symptoms* (47). The NPI-NH evaluates 12 neuropsychiatric symptoms commonly observed in PWD using standardized interview questions. Professional caregivers are asked to rate the frequency and severity of each neuropsychiatric symptom. Scores are computed for each symptom by multiplying severity (1 = mild – 3 = severe) by frequency (1 = rarely – 4 = very often). A total NPI-NH score is computed by adding up the individual symptom scores. Higher scores represent higher degrees of neuropsychiatric symptoms. In the present study, internal consistency of NPI-NH was *Cronbach's a* = .73. We assessed the intake of psychotropic medications as a further indicator of neuropsychiatric symptoms (52). The total number of psychotropic medications were recorded, as well as presence of antidementia agents (0 = not present, 1 = present) and neuroleptic agents (0 = not present, 1 = present).

## Depressive symptoms

*Depressive symptoms* were measured using the Geriatric Depression Scale (GDS). The GDS is a 15-item questionnaire in a yes/no format. Higher total scores indicate a higher risk of depression (53). In the present study sample, internal consistency of GDS was *Cronbach's a* = .68.

## Ecological Momentary Assessments of Quality of Life

We used an eight-item version of the QUALIDEM scale to conduct EMA of quality of life before and after each activity session. This short version consists of eight bipolar items based on items from the original QUALIDEM scale. The bipolar items belong to four QUALIDEM subscales (two items per scale) and address the following behaviours: body language, communication, happiness, anxiety, companionship, general satisfaction, restlessness, sadness. Each item was rated on a seven-point Likert scale by a staff informant immediately before and immediately after every single activity session in both the TBI and CAS group. Ratings of the QUALIDEM short version were associated with ratings on the original QUALIDEM scale and showed good internal consistency with *Cronbach's a* with values ranging from .88 to .93 across

sessions. Additional psychometric properties of the QUALIDEM short version have been published elsewhere (54).

Further covariates included the variables age, gender, functional status assessed with Barthel Index (BI) (55), and dementia stage measured with the Functional Assessment Screening Tool (FAST) (56).

## Sample size calculation

A sample size estimate was calculated with G-Power (Version 3.1; test family: two-sample t-test). Based on previous findings of Hoe et al. (57), the sample size calculation was conducted for expected differences in QOL-AD scores. Although the primary outcome in the present study was apathy, previous research suggests that the effects of NPI on quality of life and apathy are comparable (7, 8). Furthermore, the study by Hoe et al. was conducted under similar conditions to those in our study. The final sample size 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% (57). Taking the nested structure of the data into account (i.e., PWD clustered in ten nursing homes), we anticipated a small intracluster correlation between nursing homes with an intraclass correlation coefficient (ICC) of  $ICC = .005$  (58).

## Statistical analysis

Descriptive statistics of baseline data are reported as means, standard deviations and score ranges for continuous variables, and as absolute and relative frequencies for nominal or ordinal variables.

*Cronbach's a* was calculated to determine the internal consistency and reliability of the outcome scales at baseline. Nonparametric Spearman correlations were computed for preliminary analyses of relationships between the primary outcome apathy and other clinical study variables. We used an Intention-To-Treat (ITT) approach for analyses of primary and secondary outcomes, meaning that all available data was included in the analyses regardless of loss to post intervention follow-up while assuming dropouts were missing at random (MAR). Multiple data imputation based on chained equations was performed to account for missing data using ten imputed data sets. The predictive mean matching (PMM) procedure was applied to ensure that imputed values were plausible. With PMM, the imputed value always matches one of the observed values of a participant without missing and a similar estimated value from the imputation model as the participant with missing. A random seed number (123) was set to allow reproducibility. Imputation was performed at item-level for primary and secondary outcome measures and covariates, scale scores were then computed. The number of scale scores including imputed data at item-level for each outcome were: AES-I ( $n = 28$ ; 17%), QOL-AD ( $n = 71$ ; 44%), QUALIDEM ( $n = 28$ ; 17%), GDS ( $n = 102$ ; 64%), NPI-PH ( $n = 28$ ; 17%), MMSE ( $n = 74$ ; 46%) and FAST ( $n = 31$ ; 19%). The following variables were used for the imputation process: all individual scale items, age, gender, group (TBI vs. CAS), years of education, nursing home and medication.

Linear mixed-effects models (LMM) fit by Restricted Maximum Likelihood Estimation (REML) were applied to analyse group differences for the primary and secondary outcomes. Change scores served as dependent variables and were computed for each outcome by subtracting baseline scores from post intervention scores. Baseline outcome measures were included as fixed covariates in each model and a random intercept was added at nursing home-level to account for clustering of participants in ten nursing homes. *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 in some cases 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 (level 1) nested in participants (level 2) who were grouped in different nursing homes (level 3). Accordingly, nursing home-level random intercepts were also included in each model. Fixed factors in the unadjusted models included group (TBI vs. CAS), time (baseline vs. post intervention) and a group x time interaction term. Time was modelled as a repeated measure, an autoregressive covariance structure (AR1) was chosen to account for dependencies between both time points.

In LMM for analysing EMA of momentary quality of life measured before and after each individual activity session, the time-varying covariate session was added. Models for EMA also 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). Clustering at nursing home level was again accounted for (random intercept), resulting in three level models. All statistical analyses were performed using IBM SPSS statistics software (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp). No adjustment for multiple testing was applied since all secondary outcomes were analysed within an exploratory framework. Therefore, *p*-values have to be interpreted with caution for secondary analyses.

## Results

### Participant characteristics

A total of 203 residents from the ten participating nursing homes were deemed eligible after initial screening, N = 162 (80%) of these were included in the study. The most common reason for non-inclusion was failure to reach the legal guardian and thus no way of obtaining informed guardian consent. Figure 2 provides a participant flow chart.

Of the 162 participants at baseline, post-intervention data was collected from 134 (83%) after eight weeks. On average, participants were aged 85 years (SD = 7.1, range = 53 to 100 years) and they mostly reported lower secondary education (mean = 10.5 years of education, SD = 4.2, range = 0 to 19 years). The majority were women (74%) and in need of substantial care (53% w/care level 4 "most severe impairment"). The mean MMSE score was 13.6 (SD = 7.0, range = 0 to 29 points), which reflects a

moderate level of dementia. Accordingly, the mean FAST level was 9.2 “moderately severe dementia” (SD = 1.8, range = 4 to 16). For more than half of the participants (55%), regular intake of at least one neuroleptic drug was reported, 25% regularly received at least one antidementia agent. Table 1 presents an overview of participants’ main baseline characteristics. All descriptive and preliminary analyses are based on original data without imputation.

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

<b>Characteristic</b>	<b>n</b>	<b>Total cohort (N = 162)</b>	<b>TBI (n = 80)</b>	<b>CAS (n = 82)</b>
<b>Demographics</b>				
Age (years), M (SD)	162	85.0 (7.1)	85.4 (7.6)	84.6 (6.6)
Female, n (%)	162	119 (74)	54 (68)	65 (79)
Education (years), M (SD)	146	10.5 (4.2)	10.3 (4.2)	10.6 (4.2)
Care level, n (%)	158			
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			
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)
<b>Cognitive Status</b>				
MMSE score, M (SD)	121	13.6 (7.0)	13.5 (6.8)	13.8 (7.3)
<b>Functional Status</b>				
BI score, M (SD)	161	53.6 (26.2)	54.1 (24.7)	53.1 (27.7)
<b>Dementia Stage</b>				
FAST score, M (SD)	159	9.2 (1.8)	9.1 (1.8)	9.3 (1.7)
<b>Psychotropic Medication</b>				
Antidementia agent present n (%)		41 (25)	20 (25)	21 (26)
Neuroleptic agent present n (%)		89 (55)	39 (49)	50 (61)

## Descriptives of primary and secondary outcome measures

Reported baseline levels of apathy were high, with an overall mean AES-I score of 48.8 (SD = 10.6, range = 20 to 69 points). 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 to 12). AES-I scores at baseline were positively correlated with dementia stage (FAST, *Spearman's*  $\rho = .41$ ), apathy assessed with the Subscale Apathy of the NPI-NH (*Spearman's*  $\rho = .52$ ) and weakly with overall neuropsychiatric symptoms (NPI-NH, *Spearman's*  $\rho = .19$ ), and showed negative correlations with functional status (BI, *Spearman's*  $\rho = -.48$ ) and cognitive status (MMSE, *Spearman's*  $\rho = -.45$ ) and on a weak level with informant-reported quality of life (QUALIDEM, *Spearman's*  $\rho = -.12$ ).

An average intake of 2.0 psychotropic substances per day (SD = 1.5, range = 0 to 7) was reported. Regarding depressive symptoms, the average GDS score of 3.4 (SD = 2.6, range = 0 to 11) was below the clinical cut-off for depression of five points. Table 2 presents an overview of main outcome variables at baseline overall and for both study groups.

Table 2  
Baseline values for primary and secondary outcome measures for total cohort, TBI and CAS group, N = 162

Characteristic	n	Total cohort (N = 162)	TBI (n = 80)	CAS (n = 82)
Apathy				
M (SD) AES-I	161	48.8 (10.6)	49.3 (9.8)	48.3 (11.4)
Quality of Life				
M (SD) QOL-AD	128	28.8 (9.1)	28.3 (7.6)	29.2 (10.5)
M (SD) QUALIDEM	161	83.6 (15.1)	85.7 (13.6)	81.5 (16.2)
Neuropsychiatric Symptoms				
M (SD) NPI-NH	161	16.6 (16.3)	13.2 (12.6)	19.9 (18.6)
M (SD) Psychotropic Medication	161	2.0 (1.5)	1.9 (1.7)	2.1 (1.4)
Depressive Symptoms				
M (SD) GDS	127	3.4 (2.6)	3.6 (2.8)	3.1 (2.3)

## Dose of the intervention and attrition rate

Overall, the majority of participants (85%) failed to reach the goal criterion of 24 activity sessions over the study period of eight weeks. On average, the TBI group received 12.7 sessions (SD = 8.7, range = 0 to 36) while the CAS group received 15.7 sessions (SD = 7.1, range = 0 to 30), meaning that the nursing home staff carried out 53% of the scheduled intervention sessions in the TBI group and 65% of the scheduled activity sessions in the CAS group. CAS comprised diverse activities, the most frequently reported activities 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 group (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) ( $B = .19$ ; 95% CI: -3.90 to 4.28,  $p = .93$ ). Overall, the levels of apathy decreased slightly in both groups with an estimated mean decrease in AES-I scores of .54 points (95% CI: -3.45 to 2.38) in the TBI group and .34 points (95% CI: -3.21 to 2.53) 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:  $B = -.42$ ; 95% CI:  $-.57$  to  $-.29$ ,  $p < .001$ ). No substantial group differences in change scores were revealed by the unadjusted models for secondary outcomes QOL-AD ( $B = .11$ ; 95% CI: -1.31 to 1.53,  $p = .87$ ), NPI-NH ( $B = -.83$ ; 95% CI: -6.24 to 4.57,  $p = .76$ ) and GDS ( $B = .001$ ; 95% CI:  $-.76$  to  $.76$ ,  $p = .99$ ). For the secondary outcome QUALIDEM, we saw a statistically non-significant group difference in QUALIDEM change scores ( $B = 2.37$ ; 95% CI:  $-.63$  to 5.36,  $p = .12$ ). Estimated average QUALIDEM scores increased by .84 points (95% CI:  $-.86$  to 2.55) in the TBI group compared to an increase of 3.21 points (95% CI:  $.83$  to 5.59) in the CAS group. Furthermore, the analysis for psychotropic medication revealed a group difference ( $B = .42$ ; 95% CI:  $.15$  to  $.69$ ,  $p < .01$ ) in favour of a greater reduction in the TBI group. Estimated mean change scores showed an average reduction of .41 substances (95% CI:  $.65$  to  $.17$ ) in the TBI group compared to an average change of .01 substances (95% CI:  $-.23$  to  $.25$ ) in the CAS group. This effect remained stable in models adjusted for gender, age, dementia stage (FAST score) and neuropsychiatric symptoms (NPI-NH score) ( $B = .42$ ; 95% CI:  $.14$  to  $.72$ ,  $p < .01$ ). Table 3 shows the estimated post hoc means and group differences of primary and secondary outcome scores for both groups. There were no substantial differences in findings for any models with and without imputation.

Table 3

Estimates of primary and secondary outcome post intervention means for CAS and TBI group, estimated at mean baseline values of particular outcome, N = 162

Outcome	CAS (95% CI)	TBI (95% CI)	Group difference (CAS – TBI)	95% CI	<i>p</i>
AES-I <sup>b</sup>	48.53 (45.66–51.39)	48.33 (45.42–51.25)	.19	-3.90 4.28	.93
QOL-AD <sup>a</sup>	34.18 (33.32–35.05)	34.07 (33.12–35.03)	.11	-1.31 1.53	.87
QUALIDEM <sup>a</sup>	86.92 (84.54–89.31)	84.56 (82.86–86.26)	2.37	-.63 5.36	.12
NPI-NH <sup>b</sup>	16.45 (12.67–20.22)	17.28 (13.44–21.12)	-.83	-6.24 4.57	.76
GDS <sup>a</sup>	4.69 (4.03–5.34)	4.69 (4.29–5.09)	.001	-.76 .76	.99
Psychotropic medication <sup>a</sup>	1.99 (1.81–2.17)	1.56 (1.37–1.76)	.42	.15 .69	< .01

For the purpose of a sensitivity check, additional LMM analyses including a fixed factor for measurement timepoints (baseline vs. post intervention) were used. Analyses revealed an overall post intervention improvement of QUALIDEM scores (collapsed over groups) ( $B = 3.69$ ; 95% CI: .68 to 6.69,  $p = .016$ ). Analyses based on imputed data also revealed a group x time interaction ( $B = -5.97$ ; 95% CI: -10.33 to -1.61,  $p = .007$ ). Post intervention improvement of informant rated quality of life was greater in the CAS group (EM = 4.09; 95% CI: 1.14 to 7.03) than in the TBI group (EM = .67; 95% CI: -2.72 to 4.06). These findings on QUALIDEM remained stable in models adjusted for gender and baseline values of age, dementia stage (FAST score) and neuropsychiatric symptoms (NPI-NH score). The adjusted model for QUALIDEM also revealed a negative association of QUALIDEM scores with NPI-NH scores. Higher levels of quality of life were associated with less neuropsychiatric symptoms ( $B = -.57$ ; 95% CI: -.67 to -.46,  $p = < .001$ ).

## Ecological Momentary Assessments of Quality of Life

The collection of EMA before and after each intervention session was feasible in both the TBI and CAS group. Over all sessions and participants, a total of  $n = 2264$  pre-session EMA and  $n = 2150$  post-session EMA were recorded. The slight discrepancy was mostly attributed to time restraints and unforeseen events in the work environment of the staff members responsible for carrying out the intervention. 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 .57,  $p < .001$ ), see Table 4. The LMM estimated post-session mean was EM = 5.63 (95% CI = 5.54 to 5.73) in the intervention group and EM =

6.01 (95% CI = 5.99 to 6.12) in the CAS group. This finding remained stable after adjusting for gender and baseline values of age, FAST, NPI-NH. Figure 3 shows overall pre and post-session mean EMA scores for both groups.

Table 4

Estimated mean pre-post session change in EMA scores of momentary quality of life for CAS and TBI group, N = 147

Group	Mean change	95% CI		Group difference (TBI – CAS)	95% CI		<i>p</i>
TBI	.02 (.48)	-.08	.11	-.44	-.57	-.31	<.001
CAS	.46 (.05)	.37	.54				

## Discussion

The main aim of the present study was to test the effectiveness of a multicomponent tablet-based NPI developed specifically for activating nursing home residents with dementia. To this end, N = 162 PWD from ten nursing homes in Berlin, Germany participated in an eight-week cRCT receiving either TBI or CAS without ICT. We hypothesized that regular, guided and tailored TBI sessions would have beneficial effects on the primary outcome apathy, and on the secondary outcomes quality of life, neuropsychiatric and depressive symptoms, compared to CAS. Against our expectations, we did not find a positive effect of TBI on apathy. Improvements in quality of life (measured with QUALIDEM) were observed in both groups. However, improvements were larger (approximately 4 points) in the CAS group compared to the TBI group (approximately 1 point). EMA recorded before and after each activity session also rendered short-term post-session benefits on quality of life in the CAS group. Furthermore, a greater reduction of psychotropic medication was found in for TBI compared to CAS.

## Findings on Apathy

The levels and prevalence of apathy reported among participants of our study were similar to those reported in previous studies in nursing home residents with dementia (7, 9). Although we expected that the tailored TBI developed in our study would increase engagement and reduce apathy, our findings do not support this notion. We have no comprehensive alternative hypothesis why individual stimulating activity sessions were not effective in improving apathy over time. While it is clear that apathy plays an important role in dementia, research on the impact of NPI on apathy has yielded mixed results (59, 60). Previous studies on NPI in nursing home residents with dementia have also failed to detect clinically meaningful effects on apathy in the long term, although some have found effects during the intervention period. Treusch et al. (61) for example conducted a cRCT to investigate effects of a weekly occupational and sport intervention on apathy. While the authors found an increase in apathy levels in the control group after the intervention period of ten months compared to the intervention group, the effect had faded twelve months after termination of the intervention. This may suggest that long-term and on-going

interventions are necessary to achieve a meaningful impact on apathy in PWD. Cohen-Mansfield (62) 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. (63) reported beneficial effects of a music-based intervention. Unfortunately, neither group nor music-based activities were conducted in the TBI or CAS group within our study. The integration of group and/or customized music-based activities in the TBI may have yielded different results.

## **Findings on Quality of Life**

Informant-rated quality of life measured with the QUALIDEM questionnaire improved in both groups over the intervention period, albeit to a smaller extent in the TBI group than in the CAS group. This is in line with previous findings (64). Self-rated quality of life measured with the QOL-AD did not change markedly over the intervention period in both groups. However, this finding could be related to known challenges regarding self-reported outcomes in PWD (65). Crespo et al. (66) found that higher self-reported quality of life is related to low depression and better cognitive function, while higher informant-rated quality of life is mainly associated with better functional capacity and autonomy. We also saw post session improvements in momentary quality of life assessed immediately before and after each activity session in the CAS group. Previous research has reported similar findings on situational improvements of quality of life in PWD (42). A ceiling effect in momentary quality of life was observed in the TBI group. The levels of momentary quality of life in the TBI group were very high to begin with, and these high levels were maintained throughout the sessions.

## **Findings on Psychotropic Medication**

We found a reduction of psychotropic medication in the TBI group compared to the CAS group after the intervention period of eight weeks. Although we did not originally expect this specific result, previous research has reported similar findings. A cRCT conducted by Jøranson et al. (67) also reported a significant decrease in prescribed psychotropic medication related to a robot-assisted NPI for nursing home residents with severe dementia. Ballard et al. (68) recently demonstrated that although antipsychotic review alone can lead to a reduction of antipsychotic use in nursing home residents with dementia, greater benefits for PWD are achieved when antipsychotic review is combined with NPI. The authors argue that effective NPI should be implemented alongside antipsychotic review in order to reach sustainable benefits for PWD in nursing home care.

## **Absence of group differences**

Several reasons may account for the fact that our intervention did not result in any group differences in apathy or most of the other outcome variables. We will discuss possible explanations related to (1) design of the study, (2) implementation and dose of the intervention and (3) content of the intervention.

## ***Design of the study***

One reason we did not find any group differences in our study may be attributed to the fact that we chose an active control group as opposed to a comparison group receiving treatment as usual. Evidence-based recommendations for cognitive interventions in dementia have established that control group activities should match those of the intervention group in duration, intensity and socio-physical environment (69). With the aim of adhering to highest possible methodological standards, we incorporated this recommendation in our study design. Prior to our study, individual activity sessions were not usually carried out in the participating nursing homes. Thus, participants in both groups received substantial one-on-one time from occupational therapists during the study period. This may have led to benefits for participants in both study groups. Moreover, the activities conducted with participants in the CAS group were chosen individually in each session, according to their abilities and momentary interests. This means that the CAS group not only received individual activity sessions, but that they virtually also took part in a tailored intervention.

Methodological issues concerning active control group trials have been discussed elsewhere (70, 71). The fact that no differences were found between groups cannot be reliably interpreted within our study design, as the absence of group differences could either mean that both treatments were equally effective (i.e., noninferiority), or on the contrary that no treatment had an effect. However, our finding that global quality of life improved in both groups after eight weeks, combined with the high levels of momentary quality of life observed in both groups immediately after each activity session, suggests that in fact both groups received effective treatments. This finding is in line with previous research on individualized activity interventions for PWD. Previous research has shown that tailored interventions directed towards individual needs and abilities of PWD are associated with better clinical outcomes (29, 64, 72, 73). For example, a previous study conducted by van Haitsma et al. (74) employed a customized activity intervention that did not involve ICT, but focused on conventional activities most suited to the individual PWD. Their results show benefits of the tailored activity intervention compared to a standardized intervention for nursing home residents with dementia.

A second possible reason we did not find any significant post-intervention differences could have been the duration of the intervention. The present study is one of the few cRCTs to examine the potential of a TBI for nursing home residents with dementia. However, the chosen intervention period of eight weeks was rather short. In their recent meta-analysis and systematic review on the effectiveness of person-centered care on PWD, Kim & Park (75) concluded that the intervention duration plays a significant role. They found that while long-term interventions (> 3 months) had a significant impact on quality of life in PWD, short-term interventions (10 days to 3 months) did not. In their review of cognitive psychosocial interventions in PWD, Carrion et al. (76) reached the conclusion that interventions should be on-going in order to render long-term benefits.

## ***Implementation and dose of the intervention***

Although our cRCT was carefully planned and prepared, we encountered considerable unexpected barriers during the implementation phase. Overall, only 55% of the planned intervention sessions were carried out, and the goal criterion of 24 intervention sessions in eight weeks was missed in almost all participants. One important reason for the poor implementation was a lack of time and staff resources in the participating nursing homes. The activity sessions in our study were carried out by members of the occupational therapy staff of the participating nursing homes. We chose this approach to minimize external interference with the daily routines in the participating nursing homes, and to avoid having to confront study participants with strangers in the intervention sessions. Occupational stress in nursing home staff has been a much-researched and well documented topic over the past decades (77, 78). With the aim of reducing workload for the staff members involved in the study, all participating nursing homes were required to allocate additional personnel resources for the time of the intervention. Despite these efforts to secure a smooth implementation, we ascertained that the designated occupational therapists in most units did not have sufficient time to conduct the planned amount of activity sessions over the course of the intervention. High staff turnover rates in some of the participating units may have led to further detrimental effects. Altogether, the frequency of the activity sessions was much lower than originally planned. 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 (75).

Besides these general issues of limited time and staff resources that pertain to all studies conducted in nursing home settings, there were specific challenges in the five TBI units. The rate of delivered activity sessions was significantly lower in the TBI compared to the CAS group. This finding can most likely be explained by the technology (in)acceptance of the staff members responsible for carrying out the intervention and the digital infrastructure of the participating units. The important role of user acceptance for the successful implementation of new technologies in health care settings is well known (79, 80). Two of the most prominent theoretical frameworks in this field are the Technology Acceptance Model (TAM) and the Unified Theory of Acceptance and Use of Technology (UTAUT). According to both TAM and UTAUT, perceived usefulness and perceived ease of use are pivotal factors when it comes to user acceptance or rejection of a certain new technology in healthcare settings (23, 81). Previous studies on the acceptance of ICT in nursing homes have reported ambiguous attitudes of nursing home staff towards ICT. Sävenstedt et al. (82) conducted a qualitative study with professional caregivers and found a reluctance towards using this kind of technology with nursing home residents. In a mixed methods study, O'Sullivan et al. (83) found that whilst most professional caregivers reported positive attitudes towards ICT, there were also concerns regarding the specific usefulness of ICT-based interventions for PWD. For these reasons, we invested a great deal of effort to boost user acceptance. The usefulness of the ICT-based intervention was emphasized in the staff training workshops conducted prior to the study. A handbook containing detailed information on how and why to use the application as well as technical instructions for use was also provided. Finally, a support hotline was set up to provide assistance in case of any technical difficulties throughout the intervention. Despite these efforts, we suspect that there may have been persistent ICT-related inhibitions in some of the participating staff members.

Regarding the digital infrastructure, previous research on the availability of communication technologies in nursing homes has identified the lack of internet connections as an important barrier concerning the use of ICT in nursing homes (84, 85). Therefore, WIFI access points were set up in all the participating nursing homes prior to the intervention, to ensure that WIFI was available in at least one room of each facility. In most cases, this was the activity room of the dementia ward. However, this spatial confinement sometimes made it difficult to carry out the TBI, for example when participants with impaired mobility or fatigue were not able to reach the room with WIFI access. Although we took precautionary steps and equipped the study tablets with mobile internet, the mobile connection was unexpectedly poor in most buildings. Due to the architecture of the PflegeTab application database, a continuous internet connection was necessary to ensure correct functioning. Without internet access, the execution of the TBI was not possible, which may have led to further frustration in participants and staff members.

## ***Content of the intervention***

Finally, the absence of group differences may in part be related to the content of the TBI. As stated above, the rate of delivered activity sessions was lower in the TBI than in the CAS group. In this regard, we must address the fact that according to the nursing home staff, 13 participants in the TBI group terminated the study because the tablet activity sessions were allegedly too mentally challenging and stressful. Within the tailored tablet application, adaptive algorithms were employed to adjust task difficulty according to participants' individual abilities in four of the seven tablet activities. The other three tablet activities were primarily designed to enhance communication and well-being and did not involve any specific tasks for the user. Even though reduced levels of cognitive functioning and inexperience of PWD were considered when designing the application, 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 study participants. In their scoping review of the use of touchscreen devices in nursing home residents with dementia, Hung et al. (85) also reported implementation barriers related to the novelty of the technology.

Some potentially crucial components of the intervention could not be implemented as planned due to scheduling or logistic challenges. Although we provided the possibility to add personal photographs to the photo gallery to facilitate digital life story work (33) within the study, this feature was not used by any of the participating occupational therapists. Reported reasons included time constraints and organizational barriers retrieving the digital photos from relatives. We also implemented a feature for communication with family members by means of videoconferencing, unfortunately it proved extremely challenging to initiate any video calls with relatives during the study. Previous studies have also reported similar challenges concerning the use of videoconferencing in nursing homes (86, 87).

## **Strengths**

To our knowledge, our study was the first cRCT to investigate effects of an ICT-based intervention for activating nursing home residents with dementia. A strength of our study lies in the assessment of momentary quality of life before and after each activity session 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. Further strengths lie in our cRCT design and successful cluster randomization of participants across ten nursing homes. Overall, we adhered to higher methodological standards than most reported studies in this field. Finally, a strength of our study was the fact that the activity sessions were executed by nursing home staff under 'real world' conditions. Future research on ICT-based interventions in nursing home settings can learn valuable lessons on how to avoid and overcome implementation barriers in this field of research.

## **Limitations**

First of all, our study design does not allow an unambiguous interpretation of the results. Future studies should incorporate a third study arm in order to unravel effects associated with new interventions. Secondly, while pre and post measurements in our study were carried out by external research assistants, this approach was not feasible for the collection of EMA before and after the activity sessions. EMA were conducted by the same person who carried out the activity session, which means that rater bias cannot be fully ruled out. This may have also amplified the ceiling effect observed in the TBI group because raters were aware of their allocation to the treatment group. Finally, study assessors were not blinded to the allocation of participants, a factor that also may have affected our results. Although assessor effects are very unlikely, future trials should invoke independent and blinded raters for all study assessments.

## **Practical implications**

Individually tailored, long-term and continuous NPI seem necessary to stabilize and improve outcomes in nursing home residents with dementia. As family caregivers and healthcare professionals are faced with the growing challenge of providing adequate interventions for those affected by dementia, ICT devices should be considered as modern, versatile and cost-effective means of NPI delivery in nursing homes. However, further trials are needed in order to gauge the potential of ICT-based NPI in dementia.

It has been widely acknowledged that the prevalence of polypharmacy and inappropriate psychotropic medication are increasingly high in PWD (88). Although psychotropic drugs are frequently prescribed, they are associated with undesirable adverse effects in PWD (17). Our results indicate that NPI may have the potential to reduce the administration of 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 examine the role of ICT-based NPI and their possible impact on prescription of psychotropic medications.

Studies of NPI have repeatedly confirmed that changes in mood, cognition and behaviour seldom persist in PWD after cessation of the intervention (75, 76). This finding may be linked to the progressive course of dementia itself, 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. Intervention studies usually measure these

outcomes with established assessment scales, such as those used in our study. However, these measures can be insensitive to short-term changes and fluctuating states (39). Even though short-term improvements may not impact global outcomes, temporary benefits associated with NPI can be extremely meaningful for PWD and for nursing home staff. Therefore, we strongly recommend that future studies should employ EMA to investigate the momentary effectiveness of on-going interventions in PWD. In this regard, ICT can serve as useful tools for collecting and analysing EMA in nursing homes.

Future research on ICT-based NPI in real world nursing home settings should consider that barriers concerning workplace conditions, user acceptance and digital infrastructure can be difficult to overcome. We recommend extensive staff training prior to the introduction of novel NPIs and a close monitoring of on-going interventions to ensure a successful implementation and increase user acceptance of ICT-based interventions in nursing homes. The use of offline applications can help to overcome implementation barriers related to poor internet access.

## Conclusion

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. NPI 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 NPI 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.

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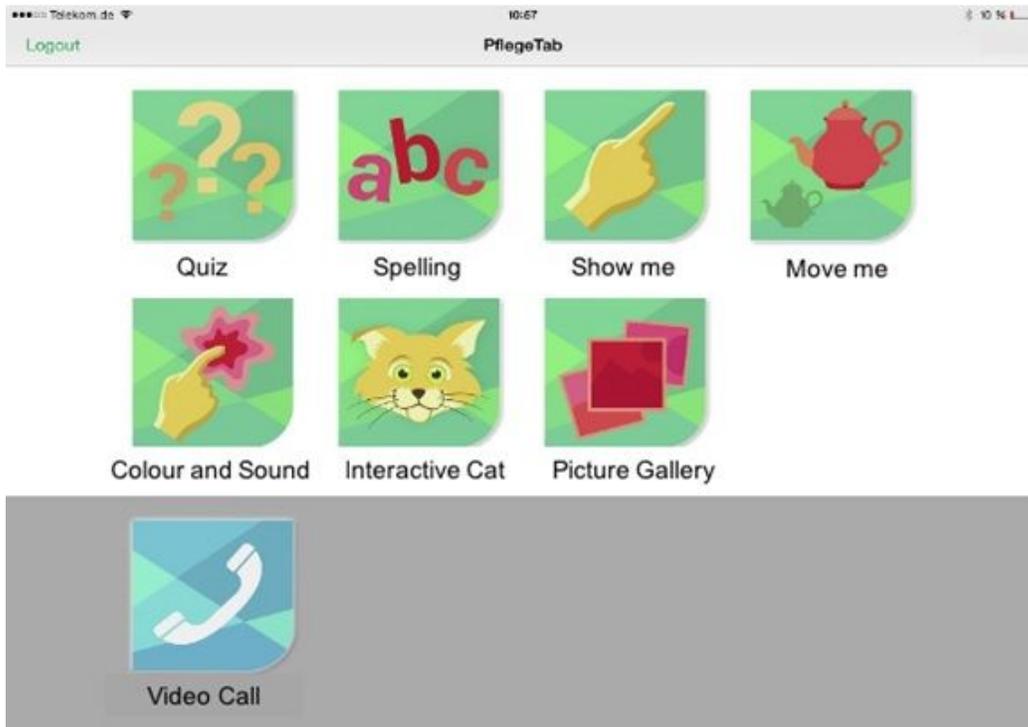
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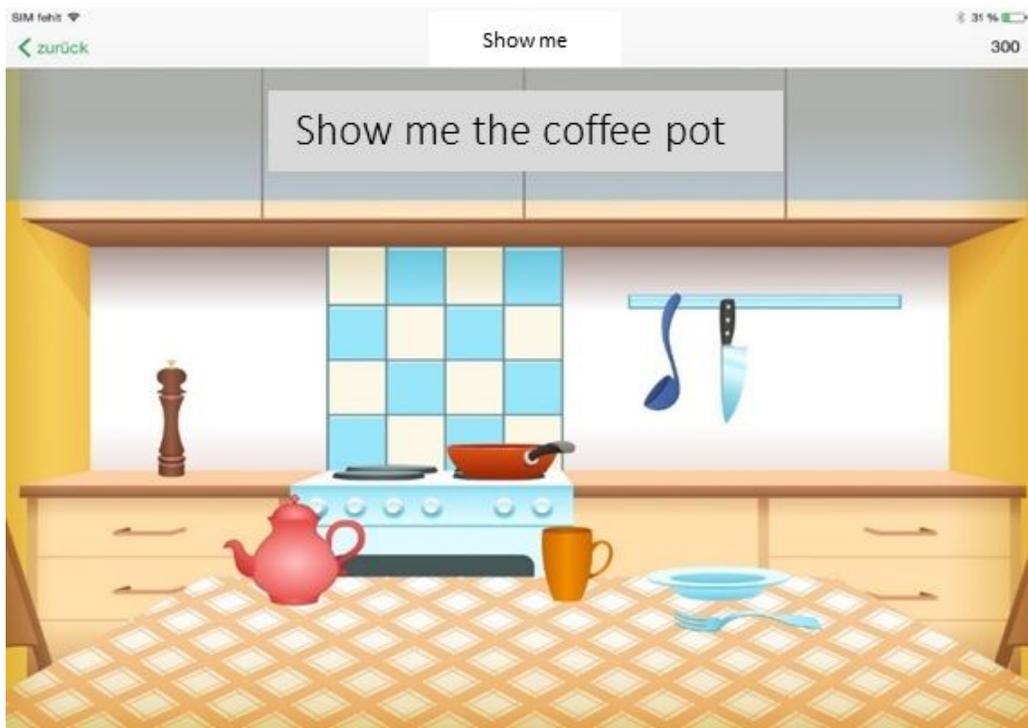
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## Figures



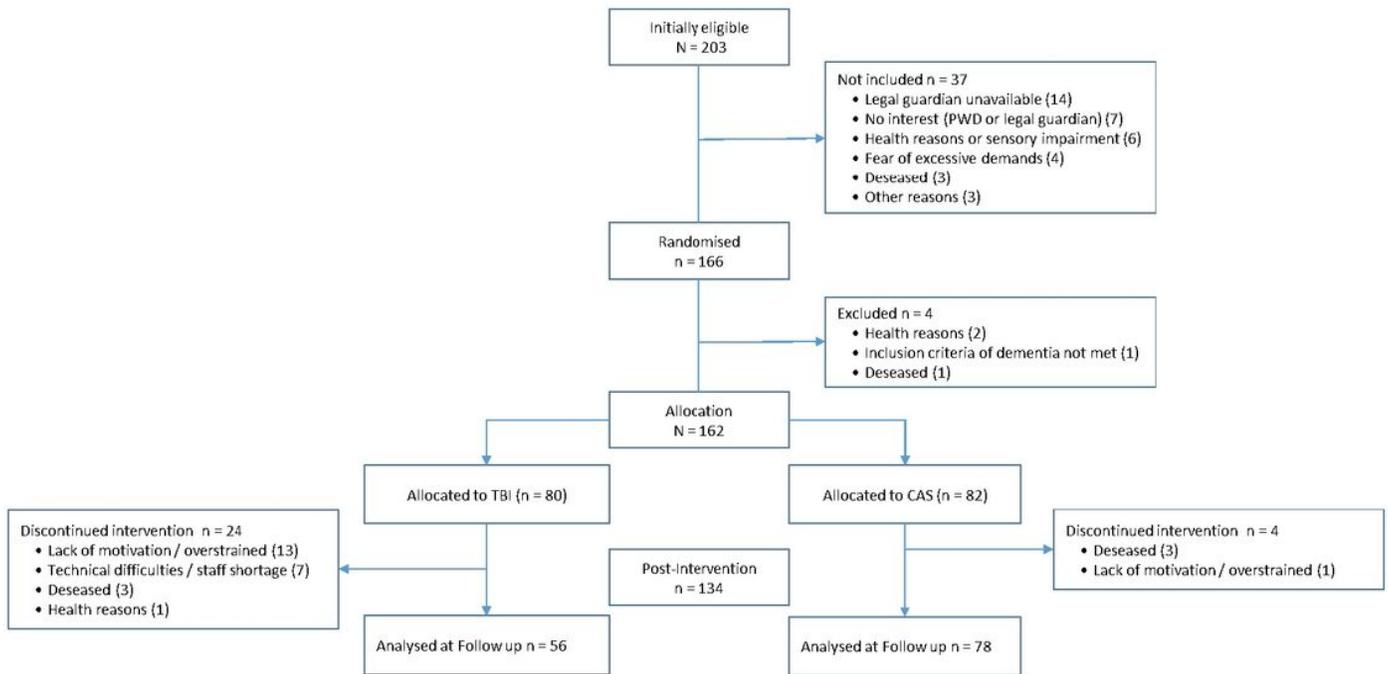
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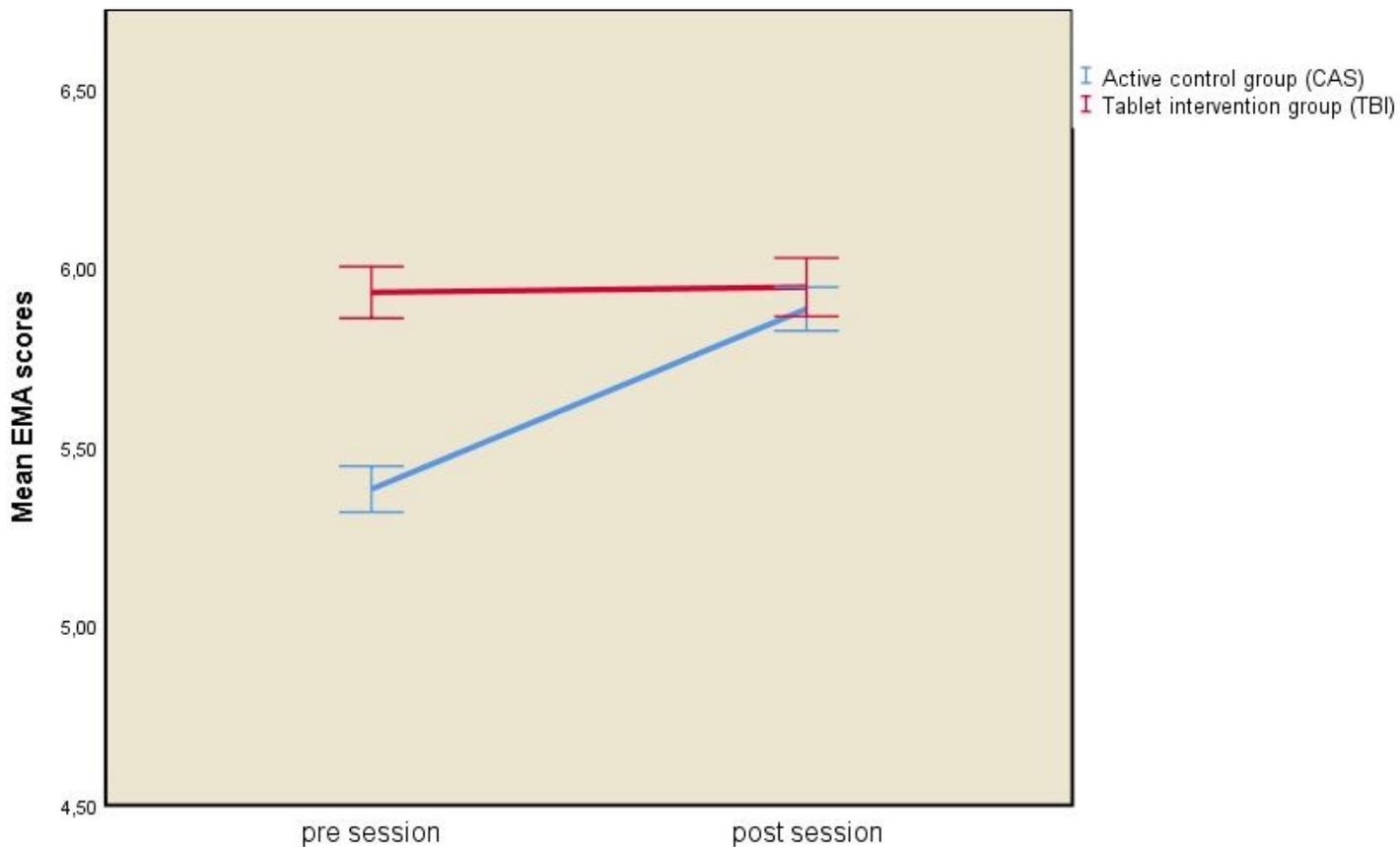
**Figure 1**

Panel A: PflegeTab launch screen with all seven applications for (a) targeting cognitive and functional abilities (Quiz, Spelling, Show me, Move me) and (b) supporting emotional regulation (Interactive Cat, Colour and Sound, Picture Gallery). The applications were developed within the project and designed especially for older and inexperienced tablet users. Panel B: Task in the Move me application. 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.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORTChecklistPflegeTab.docx](#)