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(Digital) Mind-Body Intervention to Promote Health and Subjective Well-Being of Residents in Nursing Homes: A Cluster-Randomized Controlled Pilot Study

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Abstract:
Background: Nursing care insurance companies in Germany have the legal mandate to develop measures to strengthen the health resources of residents of nursing homes. The present study aimed to examine a mindfulness-informed mind-body intervention (on-site and app) adapted for residents in nursing homes regarding their effect on health-related parameters.
Methods: A pilot study (DRKS00030409) was carried out with three groups in twelve nursing homes (RCT). There was an on-site intervention in a group (O), an individual app application with technical support (A) and a passive control group (C). The participating residents (n_O=28; n_A=29; n_C=19) were cluster-randomized. Before, after, and three months after the intervention period (December 2022 - January 2023), among other things, subjective well-being (WHO-5, primary outcome) and mindfulness (KIMS-D, including four subscales) were assessed. Differences within and between study groups and participants with different participation intensity were tested. In addition, a sensitivity analysis was carried out with people who did not have severe cognitive impairments at all three survey times.
Results: Indications of differences were found in subjective well-being during the intervention period between the study groups of medium size. While a decrease was observed in the control group, there was no change in the intervention groups. When the intensity of participation was taken into account, the difference between the groups became clearer. In addition, the app group showed an increase in mindfulness (subscale Observing) immediately after the intervention compared to the control group.
Discussion: Although further studies with larger samples are needed, the results already indicate that the intervention improves the well-being and mindfulness of the target group. Individual support could explain the higher effectiveness in the app group. The influence of the Covid-19 pandemic and the season (winter) on effectiveness must also be examined.

Hintergrund: Pflegeversicherungen in Deutschland haben den gesetzlichen Auftrag, Maßnahmenvorschläge zur Stärkung von Gesundheitsressourcen der Bewohnenden in stationären Pflegeeinrichtungen zu entwickeln. Ziel der vorliegenden Studie war es, für diese Zielgruppe eine partizipativ angepasste achtsamkeitsinformierte Mind-Body-Maßnahme (Präsenz und App) hinsichtlich ihrer Wirkung auf gesundheitsbezogene Parameter zu untersuchen.
Methodik: Es wurde eine Pilotstudie (DRKS00030409) als RCT mit drei Gruppen in zwölf Pflegeeinrichtungen durchgeführt. Hierbei gab es eine Präsenz-Gruppe (O), eine Gruppe mit App-Einzelanwendung und technischer Unterstützung (A) und eine passive Kontrollgruppe (C). Die teilnehmenden Bewohnenden (n_O=28; n_A=29; n_C=19) wurden Cluster-randomisiert. Vor, nach und drei Monate nach dem Interventionszeitraum (Dezember 2022 - Januar 2023)

wurde mittels eines Fragebogens u.a. das subjektive Wohlbefinden (WHO-5, primäres Outcome) und Achtsamkeit (KIMS-D, inkl. vier Subskalen) erhoben. Es wurde auf Unterschiede innerhalb und zwischen den Studiengruppen und entsprechend der Teilnahmeintensität getestet. Außerdem wurde eine Sensitivitätsanalyse mit Personen durchgeführt, die keine kognitiven Einschränkungen aufwiesen (T0-T2).
Ergebnisse: Es gab einen Hinweis auf eine unterschiedliche Entwicklung des subjektiven Wohlbefindens während des Interventionszeitraums von mittlerer Größe. Während in der Kontrollgruppe eine Verschlechterung zu beobachten war, lag in den Interventionsgruppen keine Reduktion vor. Bei Berücksichtigung der Teilnahmeintensität wurde der Unterschied deutlicher. Außerdem zeigte die App-Gruppe direkt nach der Intervention eine Erhöhung der Achtsamkeit (Subskala Beobachten) im Vergleich zur Kontrollgruppe.
Diskussion: Weitere Studien mit größeren Stichproben sind erforderlich. Die vorliegenden Ergebnisse weisen jedoch darauf hin, dass die Interventionen das Wohlbefinden und die Achtsamkeit der Zielgruppe verbessert. Die höhere Wirksamkeit in der App-Gruppe könnte durch die Einzelbetreuung erklärt werden. Der Einfluss von Corona-Maßnahmen sowie der Jahreszeit (Winter) auf die Wirksamkeit sind zu prüfen.

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Background

Due to the ageing of societies and the increasing need for care, maintaining and promoting the health of those in need of care is gaining further relevance (1). In 2019, there were 877,200 places in full inpatient long-term care in Germany (2). Sixteen percent of people with a level of care requirements in Germany live in nursing homes (1). In order to comply to this relevance, long-term care insurances in Germany have the legal mandate to develop proposals for interventions to strengthen the health resources of residents of nursing homes (3). Comprehensive scientific evaluations of preventive interventions for residents of nursing homes according to SGB XI § 5 (The Eleventh Book of the German Social Code contains the law governing social care insurance in Germany.) recommend focusing on combined interventions from multiple areas of action (physical activity, violence prevention, cognitive resources, psychosocial health, nutrition) to achieve health-promoting effects (4).

Based on previous findings in health promotion for residents in nursing homes (4–6), the use of mind-body medicine (MBM), which is based on a connection between mind and body, appears promising (7). This concept includes, among other things, areas of action such as exercise and nutrition as well as training in mindfulness and self-care. Mind-body interventions typically integrate measures that promote mindfulness indirectly (mindfulness-informed interventions, MII) or directly (mindfulness-based interventions, MBI) (8). MII aim to improve specific parameters, such as physical flexibility through breathing exercises or yoga (9). MBI rather "focus on learning or improving mindfulness" (10) (e.g., through breathing meditation or body-scan exercises) (9).

Positive effects on stress reduction and health promotion through MBM have been shown in numerous studies (11, e.g. 12). Initial tests of MBI have also been carried out for the target group of seniors in the setting of nursing homes (4, 6). A study on the effectiveness of an MII for the target group of residents in nursing homes has shown that significant increases can be achieved with reference to physical health (subscale of SF-12) and depressive symptoms (GDS-12R). The authors conducted a non-randomized study without follow-up survey and emphasized the need for further adaptions of the course to the needs of seniors (5). Thus, further insights into the effectiveness of interventions for the target group are still needed.

The main aims of this pilot study were to develop a MBM-intervention for residents in nursing homes (13) and to explore the feasibility and effectiveness using qualitative (14) and quantitative methods. This paper describes the quantitative part of the pilot study and contains initial findings on the completetion rates, the effectiveness of the intervention and the expected effect sizes.

Methods

Study design

This pilot study is based on a cluster-randomized controlled study design (RCT). It was registered in the German Register of Clinical Studies (ID: DRKS00030409). Ethics vote (IRB) was obtained from the ethics committee of the University Witten/Herdecke (no. 233/2020).

Intervention

The basis for the participatory intervention development process (13) was the previously developed and evaluated MII health promotion course "BERN" (Behavior, Exercise, Relaxation, Nutrition). Exercises fostering skills in these areas (the BERN intervention) were adapted so that they were tailored to the resources of residents in nursing homes. BERN represents a typical MBM program (8, 15,

16). The participatory intervention development process involved multiple stakeholders (target group, their relatives, nurses and other experts from nursing homes, health insurance representatives and app developers) and is described in detail by Michaelsen et al. (13).

The result of the intervention development was an eight week group course (on-site) and an one-on-one app intervention (video instruction) with identical content (Online-Appendix 1). The on-site course took place in small groups (3-7 residents). A trainer (qualified therapist for health promotion; experienced with the target group) came to the facilities for around 50-60 minutes once a week and led the exercises of the week in person. The app intervention was completed using the tablets provided. The first exercise of each module was activated on a weekly basis. The next exercise was unlocked when the previous one was either completed or skipped. The entire previous module was unlocked at latest at the start of the new week, i.e., at the beginning of the next module. Exercises could be skipped or repeated. Progress was saved in the individual, non-password-protected profiles. It was not possible to interact with other participants or see other participants´ progress via the app. Project employees offered technical assistance on an individual basis twice a week for approximately 20 minutes each session in the residents' rooms.

Study population

Recruitment

In the first step of recruitment, nursing facilities in North Rhine-Westphalia (Germany) were contacted (N ≈ 250). Facility employees then identified suitable residents. Potential participants were invited to an information event led by project employees.

Inclusion and exclusion criteria

Social service employees in the facilities assessed the inclusion and exclusion criteria (external assessment). The minimum required age of participants was 70 years. Participants had to be physically and cognitively (Mini-Mental Status Test/MMST ≥20 at T0) capable of taking part in group activities, as they were required to follow group conversations, articulate themselves, and follow instructions. Furthermore, as a result of the participatory intervention development process, people with severe depression were excluded from participation: this assessment was made via accessing the relevant information in the resident´s file. There were no inclusion or exclusion criteria with regard to the length of time the persons had lived in the nursing home, level of care requirements or involvement of relatives.

Randomization

Twelve nursing homes took part in the research project. Facilities each were randomized to the on-site (O), app (A) and control (C) groups using the web program *Jerrydalal* by an independent researcher. The result of the randomization process was reported to the participants after T0.

Data collection

Three quantitative surveys (see Figure 1) were conducted in person individually by project employees in the nursing homes using tablets. The pre-survey (T0) took place immediately before the intervention period (Nov 2022). The post-survey (T1) was carried out immediately after the intervention period (Feb 2023), and the follow-up survey (T2) was carried out three months after the end of the intervention period (April 2023). The eight-week intervention were performed between T0 and T1. The survey was performed in German. All outcomes were coded uniformly so that a higher level could be interpreted as more advantageous. In addition, the trainer and the technical support documented the participation every week (see As- treated analysis).

[Figure 1]

The following socio-demographic information were collected: gender, age, marital status, highest general school qualification, highest professional degree, level of care requirements (1=independence slightly impaired to 5=severe impairment of independence; assessed by nursing care insurance) and move-in dates.

Primary outcome

Subjective well-being (17, 18) was measured by five items, for example: "In the last two weeks I have felt calm and relaxed". The items were rated on a six-point Likert scale ranging from (0) *at no time* to (5) *all the time* concerning the past two weeks. The score was: (0) *no well-being* to (100) *maximum well-being*.

Secondary outcomes

The Kentucky Inventory of Mindfulness Skills was used in its short form (19) to calculate an average score for the four fields of mindfulness (*observing*, *describing*, *acting with attention*, *accepting without judgment*) as well as an overall score ((1) *never or very rarely applies/*low mindfulness to (5) *very often or always applies/*high mindfulness).

Cognitive performance was assessed using the mini-mental status test (MMST) (20), which includes everyday questions and action-related tasks. One point was awarded for each correct answer. A maximum of 30 points (sum score) could be achieved

Two items of the Salience and Happiness Database (ESH) was included to measure the current state of happiness (G-1; 21) and life satisfaction (L-1; 22) ((0) *not at all happy or satisfied* to (10) *very happy or satisfied*; see also (23)).

The Geriatric Depression Scale in its short form GDS-8 (24) was used to assess mental health (dichotomous response scale; sum score: (0) *lowest mental health* to (8) *highest mental health*) .

The health-related quality of life was assessed with the first item of the SF-12 ((1) *bad* to (5) *excellent*) (25).

Stress warning signals (SWS) were identified with different items (binary coded: (1) *yes/applicable* (0) *no/not applicable*) of physical, emotional, cognitive, social and behavioral symptoms (if a SWS occurred: frequency (1) *very rare* to (10) *always*) (16).

Data analysis

The analysis was performed using *IBM* software *SPSS Statistics*. Pairwise case exclusion was carried out in the analyses. Only a few cases were missing. If a value was missing (WHO-5, KIMS-D, SWS), the single imputation method was used by adding the mean of the remaining answers of the (sub-)scale for the respective collection date.

First, a mean comparison was carried out between the three time points for each group (one-way repeated measures ANOVAs or Friedman test depending on the distribution), which indicated a temporal change (Online-Appendix 2a). If these comparisons were significant, we conducted pairwise comparisons (post hoc tests: Bonferroni or Dunn-Bonferroni) and estimated the effect size Hedges´ g for each pair (Online-Appendix 2b).

Second, change scores (ΔT1-T0, ΔT2-T0: positive sign indicates increase) were calculated for each group to test for differences between groups. Therefore, a mean comparison (one-factorial ANOVA or Welch-ANOVA depending on the variance given a normal distribution for all groups or Kruskal-Wallis test without normal distribution) was carried out between the three groups (study groups or participation intensity) (Online-Appendix 3a). If these comparisons were significant, we conducted pairwise comparisons (post hoc tests: Tukey-Kramer, Games-Howell or Dunn-Bonferroni) and estimated the effect size Hedges´ g for each pair (Online-Appendix 3b).

The significance level was set at $p<.05$. For the primary outcome, results with $p<.1$ or values close to this threshold were interpreted as indications. Here $|g|=.2-.49$ represents a small effect, $|g|=.5-.79$ for a medium effect and $|g|\geq.8$ for a large effect.

Intention-to-treat analysis (ITT)

The ITT aimed to examine the effects of the intervention by group according to cluster randomization. No participants were excluded.

As-treated analysis (AT)

The AT aimed to investigate whether people, regardless of the intervention group, with higher participation intensity (7-8 modules completed) differ from people with low participation intensity (0-6 modules completed) or people in the control group. All randomized participants were included.

Sensitivity analysis

During the study, it became apparent that some participant's cognitive performance decreased to the point below the limit defined in the inclusion criteria. The sensitivity analyses aimed to check how the results differ if only people with long-term sufficient cognitive performance were included. In this sense, the ITT and AT analyses were repeated with the subgroup that achieved at least 20 points on the cognitive performance test (MMST) at all three survey times.

Results

The results are presented below. Outcomes not mentioned did not yield any significant results (L-1, SF-12) or were evaluated descriptively (SWS).

Description of the sample

Study groups

85 residents were interviewed at T0, of which 76 residents met the inclusion criteria and were randomized (n_O=28; n_A=29; n_C=19). 73.7% of participants completed all three surveys (n=56) (see figure 2).

[Figure 2]

Completion rate

Overall, 70.2% (n=40) of the participants in the intervention groups completed the intervention, 59.6% (n=34; n_O=13; 46.4%; n_A=21; 72.4%) participated in 7-8 modules.

Sociodemographic data

The mean age was 85.66 years (SD: 6.62; range: 71–100). Most participants were widowed (n=51; 67.1%) and had children (n=63; 82.9%). Level of care requirements 2 to 5 were represented in the sample, with care level 3 being the most common (n=39; 51.3%) (see Table 1). A majority had an

equivalent qualification to a secondary or primary school qualification (n=49; 64.5%). Vocational training was most frequently cited as the highest level of training (n=33; 43.4%).

[Table 1]

Main analyses

Differences at T0

There were no differences at T0 except for the mindfulness subscale *Observing* (p=.006). The post hoc test showed that the on-site group differed significantly from the app group (p=.024) and from the control group (p=.028). The T0-mean was highest in the on-site group.

Intention-to-treat analysis

Primary outcome

There was an indication of a different development for subjective well-being (ΔT0-T1) of medium effect size (p=.112). In addition, there was a temporal change in the control group (p=.052). The associated post hoc test revealed a significant decrease between T0 and T1 (p=.03; |g|=.82) and indicated an increase between T1 and T2 (p=.073; |g|=.60). The intervention groups had no significant change over time (see Figure 3).

[Figure 3]

Secondary outcomes

The change scores ΔT0-T1 for mindfulness subscale *Observing* were different between the three study groups (p=.014). Participants with app access showed an increase in the mindfulness subscale *Observing* compared to the minimally decreased control group (p=.011; |g|=.91) and to the almost unchanged on-site group (p=.052; |g|=.72).

As- treated analysis

Primary outcome

When considering the intensity of participation, there was a significant difference between the three groups (ΔT0-T1, p=.036), particularly between participants with high participation intensity and those in the control group (p=.039; |g|=.78), whereas the values in the latter decreased between T0 and T1 as in the ITT analysis (see Figure 4).

[Figure 4]

Secondary outcomes

The development of mental health between T0 and T2 differed between the three groups (p=.027), particularly between participants with low (decrease) and high (increase) participation intensity (p=.010; |g|=.80).

Sensitivity analysis

Seven people (n_O=4; n_A=3) achieved less than 20 points on the MMST at minimum one survey point after T0. The results in the control group remain consistent because none of the participants met the exclusion criteria for the sensitivity analysis.

Differences at T0

Groups did not differ at T0 except for the mindfulness overall score (p=.029) and the subscale *Observing* (p=.028). The post hoc test showed for both results that the on-site group had significantly higher values than the app group (overall score: p=.024; subscale *Observing*: p=.029).

Intention-to-treat analysis

The sensitivity analysis showed some deviations from reported results of the main analysis. Differences of subjective well-being (ΔT0-T1) increased between the study groups. Further, there were minor deviations from the main analysis regarding the mindfulness subscale *Observing* (ΔT0-T1; p=.019). The increased app group differed significantly from the minimally decreased control group (p=.018; |g| =.93) and on-site group (p=.022; |g|=.80).

In addition, the three study groups exhibited a significant difference in mindfulness (overall score) (ΔT0-T1: *p*=.034, ΔT0-T2: *p*=.03). The post hoc tests revealed a significant difference between the on-site group (minimally decrease) and the app group (increase) (ΔT0-T1: p=.044; |g|=.774). The post hoc tests at ΔT0-T2 were not significant. Additionally, there was a temporal change regarding the mindfulness score (overall score) within the app group (*p*=.014). The post hoc test demonstrated a short term increase (ΔT0-T1: *p*=.035; |g|=.572).

As-treated analysis

Almost identical results were found in the sensitivity analysis based on the as-treated samples with regard to subjective well-being (ΔT0-T1; *p*=.038). The difference regarding mental health, however, was no longer visible.

In the sensitivity analyses, a difference in happiness was identified (ΔT0-T2; *p*=.03). Residents with a low participation intensity experienced a decrease and residents with a high participation intensity showed an increase in happiness (*p*=.008; |g|=1.039).

Discussion

We developed and evaluated a MII (on-site and app) for residents in nursing homes. The aim of the present RCT was to assess the influence of this intervention on subjective well-being and other health-related outcomes considering the study group (on-site, app, control), the participation intensity and the cognitive resources.

It can be summarized that the on-site and app intervention appear to “cushion” a decrease in subjective well-being that was observed in the control group. Subjective well-being in the control group worsened during the intervention period (|g|=.82). Additionally, the app group showed an increase in mindfulness (subscale *Observing*) during the intervention period in comparison to the control group (slight decrease; |g|=.91) and the on-site group (unchanged values; |g|=.72).

A high participation was associated with the maintenance or increase of health-relevant parameters. On the one hand, the difference in subjective well-being (ΔT0-T1) was identified between the control group and residents with a high participation intensity (|g|=.78). On the other hand, residents with low participation intensity showed a decrease in mental health over the entire study period (ΔT0-T2), while an increase was observed in the control group (|g|=.87) and group of high participation intensity (|g| =.80).

The discrepancies between the results of the main and sensitivity analyses suggest that the intervention was particularly more useful for individuals who possess a sufficient level of cognitive ability, as assessed by the MMST. The described beneficial effect of the app intervention regarding the mindfulness subscale *Observing* (ΔT0-T1), for example, seems to be particularly applicable for people without decreased cognitive abilities (sensitivity analysis: app and control group: |g|=.64; app and on-

site group: |g|=.77). In this sample, a high participation intensity was also associated with an increase in happiness, while participants with a low participation intensity experienced a decrease (|g|=1.04).

Lastly, none of the analyses of the mindfulness subscales *Describing*, *Acting with attention* and *Accepting without evaluation*, as well as cognitive performance, life satisfaction, and health-related quality of life indicated a significant effect of the intervention for the target group.

The high standardization (on-site courses by *one qualified* trainer; uniform video instructions in the app) of the intervention should be positively highlighted.

The results does not prove, but already indicate that the intervention improves the subjective well-being and mindfulness of the target group. Individual support could explain the higher effectiveness in the app group. The effectiveness of the intervention is consistent with results in other target groups. For example, Compen et al. (2020) also found that group-based and digital MBI are effective in reducing psychological stress compared to passive control groups (26).

The participant completion rate of over 70% can be seen as an indication of the high level of acceptance and feasibility of the intervention. A comparative study shows that in a mindfulness intervention the completion rate is higher for people with stress symptoms than for pain patients (27). Ernst et al. (2008) noticed that the study population of older people is more characterized by chronic complaints, which is how the authors explain the higher dropout rate in their study. In relation to the vulnerable target group at hand, the authors already consider a completion rate of 60% to be acceptable (5).

The “cushioning” effect on residents regarding a psychosocial outcome (here: subjective well-being) was also observed in preventive exercise interventions – here, although depressive symptoms were not reduced by the intervention, these remained constant for six months in comparison to a decline in the control group (28). However, in our RCT, the subjective well-being of the control group almost settled back to the original level at T2. This development could potentially be explained by a seasonal effect (winter). Long-term studies remain necessary.

The results of the as-treated analysis confirm one of the mindfulness principles of the necessity of regular practice to achieve desired outcomes (29). Parsons et al. (2017) reported in their meta-analysis small to moderate effects of exercise units in mindfulness interventions (30). Contrary, Keng et al. (2022) found no significant relationship between training duration and changes in the parameters examined (31). Overall, the dose-response relationship in meditation warrants further research.

A plausible explanation for the slightly better results of the app intervention regarding mindfulness (subscale *Observing*), in addition to the lower initial level (see differences from T0), could be the individual technical support available to these participants. A meta-analysis of digital-based mindfulness interventions showed, based on 97 included RCTs, that the stress-reducing effect was higher when the intervention was accompanied by specialist staff (32).

Limitations

The generalizability of the results to all residents is limited because most of the participants had care levels 2-3 (86.8%), whereas in Germany only 54% of those in need of care in inpatient facilities have these care levels (1). Most residents in Germany have higher care levels. It would be useful to develop an adapted intervention or alternative health promotion intervention for residents with care level 4 and 5. The sample size also limits generalizability. However, due to the nature of a pilot study, the analyses are exploratory in nature and must be interpreted accordingly.

The study was conducted in the context of the Covid-19 pandemic, which had a potential impact on the results. Political regulations, such as quarantine measures, were also present in the context of the study. For example, in one nursing facility (control group), a quarantine was prescribed immediately before T0, as in one of the on-site groups immediately after module 7, which meant that the last module could not be offered and the T1 survey was postponed. A systematic review shows that Covid-related visitor restrictions, in general, led to increased loneliness among residents (33).

It should be taken into account that the originally planned double-blinding (participants and interviewer) could not be implemented due to structural constraints. However, our alternative cluster-randomization enabled better feasibility: this also ensured that there was no mutual influence within an institution.

The randomization was largely successful, as shown by the differences from T0. However, for taking assumed differences into account, we used the reported change scores.

Limitations with regard to the data collection process apply because the surveys were provided in person, which could have led to socially desirable answers. This is, however, generally difficult to rule out in psychosocial studies (34). The additional use of objective measurements (e.g., for stress processing: salivary cortisol, etc.) could improve the reliability of the results in future studies.

Another limitation is that there can be daily fluctuations in the parameters collected (e.g., MMST) (35). It should also not be neglected that the request for a break during the survey was fulfilled (T0: n=3; T1: n=1). In such a case, the survey was continued on another day.

With respect to data preparation and statistical analysis, the single imputation method can be criticized (see, e.g. 36), among other things, because replacing missing values can reduce the actual variance of the data.

Another methodological limitation in this study concerns the multiple testing problem, we only corrected for post hoc testing. This was accepted, because the RCT is a pilot study (exploratory).

The results of the AT, unlike those of the ITT, cannot be interpreted as a cause-and-effect relationship because the allocation for the AT was not randomized. It can be assumed that confounders had an influence on the residents' participation intensity and effectiveness: For example, individuals with a low participation intensity showed a greater reduction in mental health (ΔT0-T2). It is possible that individuals practiced less because of this health development. It should also be taken into account that peers and companions (e.g., project employees, social service employees) could have influenced the motivation to participate in both directions.Further research with larger samples and a wider variety of participants is needed to improve the generalizability and robustness of the findings. In future research, it would be helpful to introduce a waiting control group and an active control group as comparison with another behavioral prevention intervention to see whether the results can be explained by the MII or mainly by, e.g., the increased personal attention.

Moreover, it can also be assumed that the structural conditions of the nursing homes have an influence on the intervention. Opportunities (e.g. technical support) and obstacles (e.g. missing group room) to the implementation of the intervention and the influence on effectiveness were discussed as part of the qualitative sub-study (14). In a further evaluation, those results of individual interviews should also be taken into account when constructing questionnaires.

Conclusion

Our RCT aimed to explore the feasibility and effectiveness of an eight-week mindfulness-informed mind-body intervention, which focuses on physical activity, strengthening of mental/cognitive resources, psychosocial health, and nutrition in residents of nursing homes. The results indicate, among others, that the intervention (on-site and app) is effective, e.g., by buffering against negative influences on subjective well-being, particularly when participation intensity was high. In addition, there was an increase regarding mindfulness (subscale *Observing*) in the app group immediately after the intervention. In addition to its effectiveness, there was also a high level of feasibility and acceptance (over 70% completion rate) among residents. Further evidence-based development and scientific evaluation of MBM interventions in the setting of nursing homes is recommended. Nevertheless, the present pilot study provides suitable initial indications for the positive health promoting effect of mind-body medicine interventions on residents in nursing homes and give a solid basis for a subsequent effectiveness study including sample size calculation.

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Fig. 1 Three survey timepoints (T0, T1, T2) of quantitative data collection

Fig. 2 Flow chart (participation rate per study group and survey time)

Fig. 3 Subjective well-being (WHO-5) at the three survey times per study group

Fig. 4 Subjective well-being (WHO-5) at the three survey times depending on participation intensity

Table 1: Sample description

Variable	Total n (%)	On-site n (%)	App n (%)	Control n (%)
Study participants	76 (100.0 %)	28 (36.8 %)	29 (38.2 %)	19 (25.0 %)
Gender				
female	57 (75.0 %)	18 (64.3 %)	24 (82.8 %)	15 (78.9 %)
male	19 (25.0 %)	10 (35.7 %)	5 (17.2 %)	4 (21.1 %)
Age				
70 to 79 years	12 (15.8 %)	5 (17.9 %)	2 (6.9 %)	5 (26.3 %)
80 to 89 years	40 (52.6 %)	14 (50.0 %)	17 (58.6 %)	9 (47.4 %)
90 to 99 years	23 (30.3 %)	8 (28.6 %)	10 (34.5 %)	5 (26.3 %)
Over 100 years	1 (1.3 %)	1 (3.6 %)	0 (0.0 %)	0 (0,0 %)
Care Level				
1	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
2	27 (35.5 %)	13 (46.4 %)	10 (34.5 %)	4 (21.1 %)
3	39 (51.3 %)	13 (46.4 %)	11 (37.9 %)	15 (78.9 %)
4	9 (11.84 %)	2 (7.1 %)	7 (24.1 %)	0 (0.0 %)
5	1 (1.3 %)	0 (0.0 %)	1 (3.4 %)	0 (0.0 %)
Marital status				
widowed	51 (67.1 %)	19 (67.9 %)	20 (69.0 %)	12 (63.2 %)
Married or registered civil partnership	10 (13.2 %)	4 (14.3 %)	3 (10.3 %)	3 (15.8 %)
Separated/divorced/ civil partnership annulled	6	1 (3.6 %)	3 (10.3 %)	2 (10.5 %)
single	9 (11.8 %)	4 (14.3 %)	3 (10.3 %)	2 (10.5 %)

APPENDIX 1: The eight-week health promotion course 'BERN - Healthy in Stress' is certified by the Central Prevention Testing Centre and has been awarded the 'German Standard Prevention' seal of approval. The course covers the four central 'lifestyle' pillars of stress-reducing **b**ehaviour, **e**xercise, **r**elaxation and mindful enjoyment and healthy eating (**n**utrition). These topics are covered in eight modules. The course has been adapted to the resources of residents in nursing homes as follows (modules and exercises):

Module 1: Stress and introduction to stress management

- Setting goals
- Source of strength
- New and good things

Module 2: Relaxation

- Diaphragmatic breathing
- Fist exercise
- Meditation - relaxation response
- Minis (mini-relaxations)
- Meditation in the daily routine

Module 3: Mindfulness and movement

- Body scan
- Yoga
- Qi Gong
- Walking meditation
- Prescription for movement
- STOP (Stop, Take a breath, Observe, Proceed)

Module 4: Nutrition

- Mindfulness exercise on drinking
- Mindfulness exercise on nutrition (raisins exercise)
- Guided imagination 'kitchen'

Module 5: Social network - joy, stress reduction and support from the environment

- Social atom - network of relationships
- 3 things (treasure chest)

Module 6: Language and expression

- Postcard
- Loving-Kindness Meditation

Module 7: Self-help and self-healing

- Meaning and purpose (self-help strategies)
- Humour

Module 8: Relapse Prevention

- Prescription - health care for self-prescription
- Conclusion

APPENDIX 2A

			Main Analysis (no participants were excluded)										Sensitivity Analysis (only participants with long-term sufficient cognitive performance were included)									
					T0			T1			T2					T0			T1			T2		
			Method	*p*	n	M	SD	n	M	SD	n	M	SD	Method	*p*	n	M	SD	n	M	SD	n	M	SD
Intention-to-Treat-analysis	**Primary Outcome**																							
	Subjective well-being (WHO-5)	On-site group	F	0,698	28	59,96	17,82	23	58,09	20,5	22	59,64	21,73	F	0,753	24	59	18,84	19	61,68	19,34	19	61,26	22,23
		App group		0,5	29	56,76	25,7	22	53,82	17,83	23	55,48	27,24		0,549	26	55,77	25,4	19	53,05	18,13	20	54	27,82
		Control group		0,052	19	60,21	18,35	15	46,67	25,24	15	61,6	24,51		0,052	19	60,21	18,35	15	46,67	25,24	15	61,6	24,51
	Sekundäre Outcomes																							
	Happiness (G-1/ESH)	On-site group	F	0,432	28	7,25	1,71	23	7,22	1,95	22	6,55	2,15	F	0,184	24	7,29	1,83	19	7,74	1,66	19	6,53	2,22
		App group		0,838	29	6,17	2,75	22	6,09	3,13	23	6,3	2,91		0,607	26	6,12	2,83	19	6,11	3,11	20	6,45	3,1
		Control group		0,674	19	5,84	2,36	14	5,71	2,27	15	6,47	2,48		0,674	19	5,84	2,36	14	5,71	2,27	15	6,47	2,48
	Life Satisfaction (L-1/ESH)	On-site group	F	0,432	28	8	2	23	7,52	2,13	22	7,41	2,13	F	0,932	24	7,75	2,03	19	7,84	1,98	19	7,37	2,24
		App group		0,623	28	8	2,18	22	7,59	3,13	23	7,61	2,17		0,767	25	8,04	2,11	19	7,47	3,32	20	7,6	2,23
		Control group		0,728	19	7,05	2,72	15	7,4	1,55	15	6,53	2,56		0,728	19	7,05	2,72	15	7,4	1,55	15	6,53	2,56
	Health-related Quality of Life (SF-12/first item)	On-site group	F	0,185	28	2,61	0,92	23	3	0,74	22	2,5	0,8	F	0,116	24	2,58	0,93	19	3	0,82	19	2,37	0,76
		App group		0,272	29	2,72	1,07	22	3	0,69	23	2,78	0,67		0,119	26	2,62	0,98	19	3	0,75	20	2,75	0,72
		Control group		0,968	19	2,42	0,84	15	2,6	0,63	15	2,53	0,83		0,968	19	2,42	0,84	15	2,6	0,63	15	2,53	0,83
	Mental Health (GDS-8 invers)	On-site group	F	0,627	28	6,36	1,64	23	6,48	1,83	21	5,9	2,28	F	0,786	24	6,38	1,69	19	6,68	1,57	19	6,05	2,3
		App group		0,599	29	6,1	2,19	19	6,58	2,01	23	6,48	2,29		0,491	26	6,04	2,22	17	6,41	2,06	20	6,3	2,41
		Control group		0,539	19	6,05	2,01	15	6,6	1,5	15	6,53	1,77		0,539	19	6,05	2,01	15	6,6	1,5	15	6,53	1,77
	Mindfulness - Overall score (KIMS D)	On-site group	F	0,916	28	3,84	0,37	22	3,83	0,37	22	3,78	0,42	A	0,833	24	3,91	0,35	19	3,88	0,35	19	3,83	0,43
		App group		0,316	29	3,55	0,54	22	3,7	0,33	22	3,71	0,35		0,014	26	3,58	0,52	19	3,75	0,32	19	3,79	0,29
		Control group		0,786	19	3,69	0,41	15	3,76	0,47	15	3,68	0,45		0,709	19	3,69	0,41	15	3,76	0,47	15	3,68	0,45
	Mindfulness - Observing (KIMS-D)	On-site group	F	0,835	28	4,02	0,47	22	4,04	0,42	22	3,95	0,51	F	0,824	24	4,04	0,47	19	4,02	0,4	19	3,95	0,52
		App group		0,09	29	3,47	0,95	22	3,83	0,52	23	3,73	0,64		0,109	26	3,52	0,95	19	3,87	0,55	20	3,79	0,63
		Control group		0,225	19	3,62	0,52	15	3,53	0,58	15	3,77	0,55		0,225	19	3,62	0,52	15	3,53	0,58	15	3,77	0,55
	Mindfulness - Describing (KIMS-D)	On-site group	A	0,601	28	3,91	0,74	22	3,87	0,75	22	3,76	0,86	F	0,57	24	4,05	0,67	19	3,97	0,65	19	3,86	0,85
		App group		0,988	29	3,51	0,91	22	3,57	0,7	23	3,65	0,6		0,895	26	3,5	0,88	19	3,65	0,71	20	3,71	0,61
		Control group		0,302	19	3,7	0,88	15	3,92	0,71	15	3,68	0,79		0,569	19	3,7	0,88	15	3,92	0,71	15	3,68	0,79
	Mindfulness - Acting with Attention (KIMS-D)	On-site group	F	0,599	28	3,5	0,71	22	3,55	0,9	22	3,48	0,91	F	0,724	24	3,57	0,72	19	3,65	0,86	19	3,54	0,93
		App group		0,142	29	3,13	1,08	22	3,29	0,85	23	3,28	0,75		0,274	26	3,21	1,1	19	3,33	0,89	20	3,33	0,79
		Control group		0,32	19	3,14	0,7	15	3,3	0,82	15	2,96	0,85		0,32	19	3,14	0,7	15	3,3	0,82	15	2,96	0,85
	Mindfulness - Accepting without Judgment (KIMS-D)	On-site group	F	0,44	28	3,75	0,82	22	3,67	0,91	22	3,75	0,74	F	0,689	24	3,8	0,87	19	3,75	0,94	19	3,79	0,78
		App group		0,837	29	3,96	0,81	22	3,88	0,75	22	3,89	0,82		0,717	26	3,96	0,81	19	3,95	0,78	19	4,02	0,81
		Control group		0,98	19	4,1	0,71	15	4,17	0,76	15	3,99	0,81		0,98	19	4,1	0,71	15	4,17	0,76	15	3,99	0,81
	Cognitive Performance (MMST)	On-site group	F	0,841	28	25,5	2,6	23	24,7	4,57	22	24,68	4,41	F	0,953	24	26,13	2,21	19	26	3,16	19	25,68	3,07
		App group		0,074	29	25,31	3,16	22	25,64	2,92	23	24,48	3,98		0,299	26	25,77	2,94	19	26,32	2,31	20	25,5	3,12
		Control group		0,29	19	26,16	2,67	15	26,73	2,58	15	27,2	2,31		0,29	19	26,16	2,67	15	26,73	2,58	15	27,2	2,31
As-Treated analysis	**Primary Outcome**																							
	Subjective well-being (WHO-5)	Control group	F	0,052	19	60,21	18,35	15	46,67	25,24	15	61,6	24,51	F	0,052	19	60,21	18,35	15	46,67	25,24	15	61,6	24,51
		Low participation intensity (0-6 modules completed)		0,264	23	53,61	20,6	11	45,09	15,19	13	44,62	23,99		0,887	19	51,05	21,57	7	47,43	13,55	10	43,2	26,18
		High participation intensity (7-8 modules completed)		0,488	34	61,53	22,71	34	59,53	19,14	32	62,75	23,07		0,505	31	61,16	22,25	31	59,61	19,5	29	62,48	23,28
	Sekundäre Outcomes																							
	Happiness (G-1/ESH)	Control group	F	0,674	19	5,84	2,36	14	5,71	2,27	15	6,47	2,48	F	0,674	19	5,84	2,36	14	5,71	2,27	15	6,47	2,47
		Low participation intensity		0,195	23	7	2,13	11	6,36	2,01	13	4,92	2,63		0,065	19	7	2,33	7	7,29	1,8	10	4,4	2,63
		High participation intensity		0,395	34	6,5	2,49	34	6,76	2,82	32	7,03	2,28		0,236	31	6,48	2,54	31	6,84	2,76	29	7,21	2,32
	Life Satisfaction (L-1/ESH)	Control group	F	0,728	19	7,05	2,72	15	7,4	1,55	15	6,53	2,56	F	0,728	19	7,05	2,72	15	7,4	1,55	15	6,53	2,56
		Low participation intensity		0,337	23	7,96	2,03	11	7,09	2,21	13	6,38	2,36		0,738	19	7,63	2,06	7	7,71	1,98	10	6	2,49
		High participation intensity		0,867	33	8,03	2,13	34	7,71	2,77	32	7,97	1,88		0,855	30	8,07	2,07	31	7,65	2,87	29	8	1,89
	Health-related Quality of Life (SF-12/first item)	Control group	F	0,968	19	2,42	0,84	15	2,6	0,63	15	2,53	0,83	F	0,968	19	2,42	0,84	15	2,6	0,63	15	2,53	0,83
		Low participation intensity		0,289	23	2,48	0,85	11	3	0,78	13	2,46	0,88		0,259	19	2,42	0,84	7	3	1	10	2,2	0,79
		High participation intensity		0,161	34	2,79	1,07	34	3	0,7	32	2,72	0,68		0,088	31	2,71	1,01	31	3	0,73	29	2,69	0,71
	Mental Health (GDS-8 invers)	Control group	F	0,539	19	6,05	2,01	15	6,6	1,5	15	6,53	1,77	F	0,539	19	6,05	2,01	15	6,6	1,5	15	6,53	1,77
		Low participation intensity		0,223	23	6,13	1,79	10	5,7	2,41	12	5	2,3		0,549	19	6,11	1,88	6	5,83	2,32	10	5,1	2,42
		High participation intensity		0,5	34	6,29	2,04	32	6,78	1,66	32	6,66	2,13		0,429	31	6,26	2,05	30	6,7	1,68	29	6,55	2,21
	Mindfulness - Overall score (KIMS D)	Control group	F	0,786	19	3,69	0,41	15	3,76	0,47	15	3,68	0,45	F	0,786	19	3,69	0,41	15	3,76	0,47	15	3,68	0,45
		Low participation intensity		0,924	23	3,81	0,43	10	3,84	0,42	13	3,83	0,35		0,962	19	3,89	0,43	7	3,99	0,37	10	3,93	0,31
		High participation intensity		0,724	34	3,62	0,51	34	3,74	0,33	31	3,71	0,4		0,541	31	3,64	0,49	31	3,78	0,32	28	3,76	0,37
	Mindfulness - Observing (KIMS-D)	Control group	F	0,225	19	3,62	0,52	15	3,53	0,58	15	3,77	0,55	F	0,225	19	3,62	0,52	15	3,53	0,58	15	3,77	0,55
		Low participation intensity		0,245	23	3,96	0,59	10	4,09	0,55	13	3,91	0,46		0,459	19	3,98	0,61	7	4,04	0,58	10	3,9	0,46
		High participation intensity		0,688	34	3,59	0,89	34	3,89	0,45	32	3,81	0,63		0,74	31	3,65	0,88	31	3,92	0,46	29	3,85	0,62
	Mindfulness - Describing (KIMS-D)	Control group	F	0,569	19	3,7	0,88	15	3,92	0,71	15	3,68	0,79	F	0,569	19	3,7	0,88	15	3,92	0,71	15	3,68	0,79
		Low participation intensity		0,412	23	3,65	0,84	10	3,94	0,9	13	3,8	0,86		0,26	19	3,78	0,84	7	4,23	0,63	10	4	0,81
		High participation intensity		0,524	34	3,74	0,87	34	3,66	0,68	32	3,67	0,69		0,771	31	3,75	0,83	31	3,72	0,68	29	3,71	0,7
	Mindfulness - Acting with Attention (KIMS-D)	Control group	F	0,32	19	3,14	0,7	15	3,3	0,82	15	2,96	0,85	F	0,32	19	3,14	0,7	15	3,3	0,82	15	2,96	0,85
		Low participation intensity		0,125	23	3,39	0,78	10	3,23	0,98	13	3,46	0,87		0,147	19	3,46	0,82	7	3,38	0,99	10	3,57	0,9
		High participation intensity		0,266	34	3,25	1,02	34	3,47	0,85	32	3,34	0,82		0,424	31	3,33	1,02	31	3,52	0,86	29	3,39	0,85
	Mindfulness - Accepting without Judgment (KIMS-D)	Control group	F	0,98	19	4,1	0,71	15	4,17	0,76	15	3,99	0,81	F	0,98	19	4,1	0,71	15	4,17	0,76	15	3,99	0,81
		Low participation intensity		0,717	23	4,02	0,79	10	3,77	0,91	13	3,97	0,5		0,887	19	4,15	0,8	7	4,03	0,95	10	4,12	0,43
		High participation intensity		0,805	34	3,74	0,83	34	3,78	0,82	31	3,75	0,87		0,627	31	3,72	0,83	31	3,81	0,85	28	3,83	0,88
	Cognitive Performance (MMST)	Control group	F	0,29	19	26,16	2,67	15	26,73	2,58	15	27,2	2,31	F	0,29	19	26,16	2,67	15	26,73	2,58	15	27,2	2,31
		Low participation intensity		0,973	23	25,17	2,89	11	23,45	5,32	13	24,46	4,94		0,887	19	25,89	2,6	7	26,29	2,43	10	26,3	2,31
		High participation intensity		0,068	34	25,56	2,9	34	25,71	3,13	32	24,63	3,87		0,231	31	25,97	2,64	31	26,13	2,84	29	25,34	3,28

Legend
A=one-way repeated measures ANOVA (normal distribution und variance homogeneity)
F=Friedman test (no normal distribution)
n=Number of Cases
M=Mean
SD=Standard Deviation

APPENDIX 2B

			Intention-to-Treat-analysis							As-Treated analysis						
				Post-hoc Tests			Effect sizes: Hedges´ correction				Post-hoc Tests			Effect sizes: Hedges´ correction		
			p	T0 vs. T1	T0 vs. T2	T1 vs. T2	T0 vs. T1	T0 vs. T2	T1 vs. T2	*p*	T0 vs. T1	T0 vs. T2	T1 vs. T2	T0 vs. T1	T0 vs. T2	T1 vs. T2
Main Analysis (no participants were excluded)	Subjective well-being (WHO-5)	Control group	0,052	0,03	0,705	0,073	0,82	0,155	-0,598	0,052	0,03	0,705	0,073	0,82	0,155	-0,598
Sensitivity Analysis (only participants with long-term sufficient cognitive performance were included)	Subjective well-being (WHO-5)	Control group	0,052	0,03	0,705	0,073	0,82	0,155	-0,598	0,052	0,03	0,705	0,073	0,82	0,155	-0,598
	Mindfulness - Overall score (KIMS-D)	App group	0,014	0,045	0,072	1	-0,572	-0,496	0,035							

APPENDIX 3A

Main Analysis (no participants were excluded)

		Total					Intention-to-Treat-analysis: On-Site group			App group			Control Group			As-Treated-analysis		Control Group			Low participation intensity			High participation intensity		
		n	M	SD	Method	*p*	n	M	SD	n	M	SD	n	M	SD	Met	*p*	n	M	SD	n	M	SD	n	M	SD
Primary Outcome																										
Subjective well-being (WHO-5)	T1T0	60	-7,25	18,8	A	0,112	23	-3,96	18,8	22	-4,73	17,4	15	-16	19,1	A	0,036	15	-16	19,1	11	-11,6	19,4	34	-2	17,1
	T2T0	60	-2,68	18,7	K	0,98	22	-1,05	19,8	23	-4,26	19,4	15	-2,67	17,2	A	0,203	15	-2,67	17,2	13	-10,5	27,9	32	0,5	14
Sekundäre Outcomes																										
Happiness (G-1/ ESH)	T1T0	59	-0,1	2,55	K	0,843	23	0,13	1,94	22	-0,05	2,55	14	-0,57	3,44	K	0,437	14	-0,57	3,44	11	-0,64	1,96	34	0,26	2,3
	T2T0	60	-0,05	2,77	K	0,607	22	-0,45	2,09	23	0,26	3,63	15	0,07	2,15	K	0,067	15	0,07	2,15	13	-1,77	3,14	32	0,59	2,65
Life Satisfaction (L-1/ESH)	T1T0	59	-0,22	2,45	A	0,471	23	-0,61	2,15	21	-0,24	2,47	15	0,4	2,87	A	0,36	15	0,4	2,87	11	-1	2,57	33	-0,24	2,19
	T2T0	59	-0,34	2,23	A	0,98	22	-0,41	1,89	22	-0,27	2,66	15	-0,33	2,13	A	0,177	15	-0,33	2,13	13	-1,31	2,36	31	0,06	2,16
Health-related Quality of Life (SF-12/first item)	T1T0	60	0,25	1,02	K	0,678	23	0,3	1,11	22	0,27	1,16	15	0,13	0,64	K	0,454	15	0,13	0,64	11	0,55	1,29	34	0,21	1,07
	T2T0	60	-0,05	0,91	K	0,895	22	-0,09	0,97	23	0	0,95	15	-0,07	0,8	K	0,898	15	-0,07	0,8	13	0,08	0,76	32	-0,09	1,03
Mental Health (GDS-8 invers)	T1T0	57	0,28	1,44	K	0,662	23	0,09	1,62	19	0,32	1,2	15	0,53	1,46	K	0,52	15	0,53	1,46	10	-0,3	1,83	32	0,34	1,29
	T2T0	59	0,1	1,8	K	0,392	21	-0,38	1,86	23	0,35	1,97	15	0,4	1,35	K	0,027	15	0,4	1,35	12	-1,08	1,98	32	0,41	1,78
Mindfulness - Overall score (KIMS-D)	T1T0	59	0,09	0,41	A	0,064	22	-0,01	0,28	22	0,25	0,5	15	0	0,38	K	0,843	15	0	0,38	10	0,12	0,38	34	0,13	0,43
	T2T0	59	0,05	0,41	A	0,078	22	-0,03	0,34	22	0,21	0,51	15	-0,06	0,28	K	0,531	15	-0,06	0,28	13	0,04	0,29	31	0,11	0,5
Mindfulness - Observing (KIMS-D)	T1T0	59	0,2	0,64	W	0,014	22	0,05	0,54	22	0,53	0,74	15	-0,06	0,41	A	0,19	15	-0,06	0,41	10	0,26	0,67	34	0,3	0,7
	T2T0	60	0,12	0,61	K	0,186	22	-0,09	0,46	23	0,3	0,7	15	0,13	0,61	K	0,731	15	0,13	0,61	13	-0,07	0,65	32	0,18	0,6
Mindfulness - Describing (KIMS-D)	T1T0	59	-0	0,7	W	0,832	22	-0,06	0,44	22	0,02	0,92	15	0,05	0,7	A	0,567	15	0,05	0,7	10	0,18	0,62	34	-0,08	0,74
	T2T0	60	-0,06	0,75	A	0,51	22	-0,1	0,59	23	0,08	0,95	15	-0,2	0,61	A	0,637	15	-0,2	0,61	13	0,07	0,69	32	-0,04	0,84
Mindfulness - Acting with Attention (KIMS-D)	T1T0	59	0,16	0,78	W	0,785	22	0,09	0,58	22	0,26	0,98	15	0,1	0,73	A	0,774	15	0,1	0,73	10	0,03	0,55	34	0,22	0,86
	T2T0	60	0,06	0,85	A	0,4	22	0,11	0,95	23	0,17	0,87	15	-0,2	0,65	A	0,394	15	-0,2	0,65	13	0,21	0,81	32	0,11	0,95
Mindfulness - Accepting without Judgment (KIMS-D)	T1T0	59	0	0,78	A	0,731	22	-0,08	0,53	22	0,1	0,94	15	-0,02	0,86	K	0,926	15	-0,02	0,86	10	-0,09	0,64	34	0,04	0,8
	T2T0	59	0,02	0,75	A	0,721	22	0,06	0,57	22	0,08	0,99	15	-0,11	0,6	A	0,724	15	-0,11	0,6	13	0,07	0,65	31	0,07	0,87
Cognitive Performance (MMST)	T1T0	60	-0,05	2,87	A	0,323	23	-0,74	3,21	22	0,23	2,58	15	0,6	2,69	A	0,142	15	0,6	2,69	11	-1,55	3,53	34	0,15	2,63
	T2T0	60	-0,57	2,94	K	0,066	22	-1,14	3,24	23	-1	3,05	15	0,93	1,71	K	0,067	15	0,93	1,71	13	-1,62	3,8	32	-0,84	2,82

Sensitivity Analysis (only participants with long-term sufficient cognitive performance were included)

		Total					Intention-to-Treat-analysis: On-Site group			App group			Control Group			As-Treated-analysis		Control Group			Low participation intensity			High participation intensity		
		n	M	SD	Method	*p*	n	M	SD	n	M	SD	n	M	SD	Method	p-Wert	n	M	SD	n	M	SD	n	M	SD
Primary Outcome																										
Subjective well-being (WHO-5)	T1T0	53	-5,96	18,3	A	0,028	19	0,42	16,9	19	-4,42	16,6	15	-16	19,1	A	0,038	15	-16	19,1	7	-4	18,5	31	-1,55	16,6
	T2T0	54	-1,89	18,8	K	0,751	19	1,89	18,5	20	-4,9	20,6	15	-2,67	17,2	A	0,482	15	-2,67	17,2	10	-7,8	30,1	29	0,55	14,6
Sekundäre Outcomes																										
Happiness (G-1/ ESH)	T1T0	52	0,1	2,57	K	0,474	19	0,63	1,61	19	0,05	2,63	14	-0,57	3,44	K	0,637	14	-0,57	3,44	7	0,29	1,5	31	0,35	2,32
	T2T0	54	0,04	2,83	K	0,429	19	-0,47	2,09	20	0,5	3,79	15	0,07	2,15	K	0,03	15	0,07	2,15	10	-2,2	3,29	29	0,79	2,65
Life Satisfaction (L-1/ESH)	T1T0	52	-0,02	2,28	K	0,979	19	0	1,56	18	-0,39	2,43	15	0,4	2,87	K	0,784	15	0,4	2,87	7	0,43	1,27	30	-0,33	2,14
	T2T0	53	-0,28	2,25	A	0,985	19	-0,21	1,96	19	-0,32	2,69	15	-0,33	2,13	A	0,312	15	-0,33	2,13	10	-1,2	2,7	28	0,07	2,12
Health-related Quality of Life (SF-12/first item)	T1T0	53	0,3	0,99	K	0,485	19	0,32	1,16	19	0,42	1,07	15	0,13	0,64	K	0,316	15	0,13	0,64	7	0,71	1,5	31	0,29	1,01
	T2T0	54	-0,06	0,88	K	0,554	19	-0,21	0,98	20	0,1	0,85	15	-0,07	0,8	K	0,843	15	-0,07	0,8	10	-0,1	0,74	29	-0,03	0,98
Mental Health (GDS-8 invers)	T1T0	51	0,37	1,3	K	0,786	19	0,26	1,24	17	0,35	1,27	15	0,53	1,46	K	0,789	15	0,53	1,46	6	0	0,63	30	0,37	1,33
	T2T0	54	0,13	1,75	K	0,707	19	-0,21	1,87	20	0,25	1,92	15	0,4	1,35	K	0,121	15	0,4	1,35	10	-0,9	2,13	29	0,34	1,72
Mindfulness - Overall score (KIMS-D)	T1T0	53	0,09	0,41	A	0,034	19	-0,02	0,28	19	0,29	0,48	15	0	0,38	K	0,803	15	0	0,38	7	0,12	0,44	31	0,13	0,42
	T2T0	53	0,06	0,42	A	0,03	19	-0,05	0,36	19	0,26	0,5	15	-0,06	0,28	K	0,383	15	-0,06	0,28	10	0,02	0,32	28	0,13	0,5
Mindfulness - Observing (KIMS-D)	T1T0	53	0,17	0,64	W	0,019	19	-0,01	0,56	19	0,52	0,73	15	-0,06	0,41	A	0,258	15	-0,06	0,41	7	0,18	0,79	31	0,27	0,68
	T2T0	54	0,1	0,63	K	0,193	19	-0,14	0,45	20	0,3	0,73	15	0,13	0,61	K	0,674	15	0,13	0,61	10	-0,14	0,7	29	0,17	0,61
Mindfulness - Describing (KIMS-D)	T1T0	53	0,02	0,69	W	0,595	19	-0,09	0,42	19	0,11	0,88	15	0,05	0,7	A	0,706	15	0,05	0,7	7	0,2	0,68	31	-0,04	0,7
	T2T0	54	-0,04	0,75	A	0,369	19	-0,12	0,62	20	0,14	0,93	15	-0,2	0,61	A	0,602	15	-0,2	0,61	10	0,1	0,77	29	-0,01	0,82
Mindfulness - Acting with Attention (KIMS-D)	T1T0	53	0,15	0,8	W	0,933	19	0,12	0,6	19	0,21	1,03	15	0,1	0,73	A	0,933	15	0,1	0,73	7	0,1	0,6	31	0,18	0,89
	T2T0	54	0,03	0,88	A	0,495	19	0,11	1,02	20	0,13	0,89	15	-0,2	0,65	A	0,445	15	-0,2	0,65	10	0,23	0,92	29	0,08	0,97
Mindfulness - Accepting without Judgment (KIMS-D)	T1T0	53	0,04	0,78	A	0,56	19	-0,07	0,48	19	0,19	0,95	15	-0,02	0,86	K	0,962	15	-0,02	0,86	7	-0,04	0,57	31	0,09	0,8
	T2T0	53	0,07	0,72	A	0,386	19	0,05	0,57	19	0,23	0,92	15	-0,11	0,6	K	0,599	15	-0,11	0,6	10	0,05	0,68	28	0,17	0,8
Cognitive Performance (MMST)	T1T0	53	0,19	2,68	A	0,683	19	-0,21	2,74	19	0,26	2,7	15	0,6	2,69	A	0,641	15	0,6	2,69	7	-0,57	2,76	31	0,16	2,71
	T2T0	54	-0,24	2,67	K	0,138	19	-0,79	2,7	20	-0,6	3,05	15	0,93	1,71	K	0,132	15	0,93	1,71	10	-1,1	3,14	29	-0,55	2,78

Legend

A= ANOVA (normal distribution and variance homogeneity)
W=Welch-ANOVA (normal distribution and no variance homogeneity)
K=Kruskal-Wallis-Test (no normal distribution)
n= Numer of Cases
M=Mean
SD=Standard Deviation

APPENDIX 3B

			Intention-to-Treat							As-Treated-Analyse								
					Pos-hoc-Tests			Effect sizes: Hedges´ correction					Pos-hoc-Tests			Effect sizes: Hedges´ correction		
			p	Method	On-site vs. App	On-site vs. Control	App vs. Control	On-site vs. App	On-site vs. Control	App vs. Control	*p*	Method	control group vs low participation intensity	control group vs high participation intensity	low vs high participation intensity	control group vs low participation intensity	control group vs high participation intensity	low vs high participation intensity
Main Analysis (no participants were excluded)	Subjective well-being (WHO-5)	T1T0	0,112	T	0,989	0,127	0,168	0,042	0,623	0,611	0,036	T	0,808	0,039	0,285	-0,225	-0,778	-0,532
	Mental Health (GDS-8 invers)	T2T0									0,027	D	0,027	0,957	0,01	-0,869	0,004	0,799
	Mindfulness - Observing (KIMS-D)	T1T0	0,014	G	0,052	0,758	0,011	-0,717	0,221	0,911								
Sensitivity Analysis (only participants with long-term sufficient cognitive performance were included)	Subjective well-being (WHO-5)	T1T0	0,028	T	0,67	0,023	0,142	0,283	0,898	0,638	0,038	T	0,301	0,03	0,94	-0,611	-0,817	-0,142
	Happiness (G-1/ESH)	T2T0									0,03	D	0,075	0,438	0,008	0,825	-0,286	-1,039
	Mindfulness - Overall score (KIMS-D)	T1T0	0,034	T	0,044	0,98	0,095	-0,774	-0,077	0,636								
		T2T0	0,03	T	0,055	0,995	0,061	-0,69	0,038	0,748								
	Mindfulness - Observing (KIMS-D)	T1T0	0,019	G	0,022	0,964	0,018	-0,796	0,103	0,928								

Legend
D=Dunn-Bonferroni-Test
G=Games-Howell Test