

Under What Conditions Can People With Severe Dementia in Nursing Homes Benefit from a Multicomponent Psychosocial Intervention?

12-month Follow-up Results Following the MAKS-s Randomised Controlled Trial

Unter welchen Bedingungen können Menschen mit schwerer Demenz im Pflegeheim von einer psychosozialen Mehrkomponenten-Intervention profitieren?

12-Monats-Follow-up Ergebnisse im Anschluss an die randomisiert-kontrollierte MAKS-s Studie



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ABSTRACT

Background The majority of psychosocial interventions are considered effective in the treatment of dementia symptoms. However, there are hardly any evaluated concepts for people with severe dementia. An RCT study of patients with severe dementia in nursing homes during the Covid-19 pandemic found no effect of the newly developed multi-component intervention MAKS-s (motor, activities of daily living, cognitive, social version for persons with severe dementia) on patients' quality of life, behavioural and psychological symptoms.

Material and methods At the end of the controlled phase, 6 months after beginning of the study, the nursing staff of the control groups were also trained in MAKS-s. They were then free to decide whether and how often they wanted to use MAKS-s (open phase). By means of a written follow-up survey,

conducted with trained therapists, after another 6 months, predictors for positive effects of the intervention on people with severe dementia were to be identified. The survey also aimed to identify predictors of therapy fidelity. Data acquisition based on a self-developed questionnaire, assessing the therapists' subjective ratings of the three areas of structure, process and outcome quality of the MAKS-s intervention. Apart from descriptive evaluations, the predictors of benefit for people with severe dementia were analysed using a linear regression model and the predictors of therapy fidelity by using a binary logistic regression model.

Results The more pronounced the normative restrictions due to the Covid-19 pandemic were, the more frequently manual deviations were observed. Fewer deviations from the manual were significantly associated with positive effects on people with severe dementia.

Conclusion The results indicate the importance of therapy fidelity for the success of MAKS-s intervention. Therapy fidelity is decisive for the extent of the positive effects of MAKS-s, experienced by the therapists. Furthermore, the survey results show that activity-restricting pandemic policies in nursing homes negatively influenced the perceived effectiveness.

ZUSAMMENFASSUNG

Hintergrund Psychosoziale Interventionen gelten mehrheitlich als wirksame Mittel zur Behandlung von Demenzsymptomen. Allerdings gibt es kaum evaluierte Konzepte für Menschen mit schwerer Demenz. Für die neu entwickelte Mehrkomponenten-Intervention MAKS-s (Motorisch, Alltagspraktisch, Kognitiv, Sozial, Versions für Menschen mit schwerer Demenz) konnte in einer RCT-Studie in Pflegeheimen während der Covid-19 Pandemie keine, mit den verwendeten Verfahren objektivierbare Wirksamkeit auf die Lebensqualität oder psychische und Verhaltenssymptome nachgewiesen werden.

Material und Methoden Am Ende der kontrollierten Phase (6 Monate nach Studienbeginn) wurden auch die Pflege- und Betreuungskräfte der Kontrollgruppe in der Durchführung von MAKS-s geschult. Alle geschulten Therapeut*innen waren danach frei, zu entscheiden ob und in welcher Intensität sie MAKS-s anwenden wollten (offene Phase). Mit Hilfe einer schriftlichen Nachbefragung der Therapeut*innen nach weiteren 6 Monaten sollten Prädiktoren für positive Auswirkungen der Intervention auf Menschen mit schwerer Demenz identifiziert werden. Ebenso sollten Faktoren bestimmt werden, die die Manualtreue, d. h. die in der Schulung curricular vermittelte, standardisierte Vorgehensweise, vorhersagen können. Grundlage der Datenerhebung war ein selbst entwickelter Fragebogen, der die subjektive Einschätzung der MAKS-s Therapeut*innen zu den drei Bereichen Struktur-, Prozess- und Ergebnisqualität der MAKS-s Intervention erhob. Neben deskriptiven Auswertungen wurden die Prädiktoren der Ergebnisqualität mit Hilfe eines multiplen, linearen Regressionsmodells die der Prozessqualität mittels binär-logistischer Regression analysiert.

Ergebnisse 56 % der geschulten MAKS-s Therapeut*innen beantworteten den Fragebogen, 82 % davon wendeten die Intervention weiterhin an. Je ausgeprägter die normativen Einschränkungen durch die Covid-19 Pandemie waren, desto häufiger waren Manual-Abweichungen zu beobachten. Weniger Manual-Abweichungen wiederum standen in signifikantem Zusammenhang mit mehr von den Therapeut*innen wahrgenommenen positiven Auswirkungen der MAKS-s Intervention auf die Menschen mit schwerer Demenz.

Schlussfolgerung Die Ergebnisse zeigen, dass die „manualtreue“ Durchführung der psychosozialen MAKS-s Intervention maßgeblich ist, für das Ausmaß der von den Therapeut*innen erlebten positiven Wirkungen von MAKS-s. Außerdem belegen die Befragungsergebnisse, dass aktivitäts-einschränkende Pandemiemaßnahmen in Pflegeheimen die wahrgenommene Wirksamkeit negativ beeinflussten.

ABBREVIATIONS

PWSDs People with severe dementia

Background and research question

People with severe dementia in nursing homes

Dementia is a chronic progressive disease of the brain involving disturbances in many higher cortical functions (ICD-10). In Germany, the prevalence rate of dementia in the over-65 population is 8.5% [1]. In nursing homes, however, 68.6% of the residents suffer from dementia, and one third have severe dementia [2]. Severe dementia means that the cognitive impairments of these individuals have already progressed to such an extent that language is limited to a few words and even basic everyday activities can no longer be performed (independently). Often, these individuals are no longer able

to move or eat independently. In addition, altered behaviours, such as aberrant motor behaviour (e. g. nesting, unpacking and packing, wandering), aggression, or apathy can be observed in a large proportion of these individuals [3], thus posing great challenges to caregivers in everyday care.

Quality dimensions in healthcare

According to Donabedian [4, 5], three dimensions of quality in medical care can be distinguished: structural, process, and outcome quality. Structural quality includes material and personnel resources, organisational structures, and financial framework conditions. Process quality represents the execution of an intervention, while outcome quality describes the effect. In the case of a psychosocial intervention in nursing homes, structural quality includes the spatial conditions, the material equipment, and the qualifications of the staff. Process quality involves the proper implementation of the intervention (i. e. adherence to the time and con-

tent specifications). Outcome quality, or the quality of the results, is reflected in participants' satisfaction or gains in resources.

Psychosocial interventions for people with severe dementia

Psychosocial interventions include procedures that promote everyday practical, cognitive, social, or behavioural skills and thus enable those who are affected to live their lives as independently as possible [6]. A variety of psychosocial interventions are available for people with dementia. Reviews and meta-analyses have shown that the majority of these therapies have beneficial effects on cognition, daily living skills, or behavioural symptoms in people with dementia with different degrees of severity [7, 8]. For people with severe dementia (PWSDs), non-verbal treatments such as basal stimulation, aromatherapy, light therapy, or music therapy seem to be more suitable [9]. However, there are hardly any analyses on psychosocial interventions specifically for PWSDs. Thus far, the only meta-analysis that included mainly PWSDs showed an improvement in daily activities and a reduction in depressive symptoms in PWSDs through interventions such as music therapy, physical exercises, or massage [10]. Specially adapted to the needs and abilities of PWSDs, the multi-component MAKS-s (Motor, Everyday Practical, Cognitive, Social for people with severe dementia) intervention was developed. MAKS-s is executed in small groups of 3 to 6 people [11], and trained therapists carry out the four components in the order S-M-K-A during a one-hour intervention. In the randomised controlled trial conducted in German nursing homes during the COVID-19 pandemic, MAKS-s was examined in a standardised manner in nursing homes. The outcome measures quality of life and psychological and behavioural symptoms were assessed with observer rating scales by trained nursing staff who were not involved in the intervention. However, within the scope of the study, no significant effect on quality of life, behavioural symptoms, or daily living skills of the PWSDs could be determined in comparison with the control group [12].

Therapy fidelity

In the DeTaMAKS study, which investigated people with mild or moderate dementia in day care, the open study phase showed a lower effect size than was found during the controlled phase [13, 14]. The open study phase means that the intervention was no longer carried out under controlled conditions (all facilities were trained, the application of the intervention was optional). Other studies have also shown that the effectiveness of an intervention is substantially influenced by the "proper" implementation of the intervention [15]. Therapy fidelity (i. e. when an intervention is carried out in exact accordance with the manual) thus seems to have a significant influence on the effect of an intervention.

Research question

Since the MAKS-s intervention could not be shown to be effective in terms of quality of life and psychological and behavioural symptoms during the RCT phase, the question that arises is whether the lack of effectiveness might be related to a lack of therapy fidelity during the COVID-19 pandemic or whether other factors are responsible for the lack of effectiveness. Therefore, the present study was designed to investigate the following questions: 1) Did therapy

fidelity as a predictor influence the benefits (the social, everyday practical, and emotional gain) that people with severe dementia received?; 2) Which predictors influenced the process quality?

Methods

Design and sample

The MAKS-s baseline study [11, 12] was a two-arm, cluster-randomised, controlled intervention study with a waitlist control group design. The study was conducted in 26 nursing homes (13 intervention, 13 control groups) in different federal states of Germany. The intervention phase lasted 6 months (June to December 2020). The intervention was a psychosocial group intervention conducted three times a week for one hour by previously trained MAKS-s therapists. Each session consisted of four components: motor stimulation, ADL training, cognitive stimulation, and social functioning. The baseline study included 144 people with severe dementia. Severe dementia was defined as a Mini-Mental-State-Examination score < 10. The full description of the intervention and methods can be found in the internationally published and freely available study protocol [11]. After the end of the controlled phase, the nursing and care staff who were caring for the control groups were also trained to implement the MAKS-s intervention in accordance with the study protocol (waitlist control group design) so that all 26 nursing homes were able to implement MAKS-s afterwards. From this point—in the so-called open phase of the study—all participating nursing homes were able to decide independently whether and how often they wanted to carry out MAKS-s. In order to obtain additional information about the possible effects of MAKS-s, a questionnaire was sent to all trained MAKS-s therapists by post 6 months after the end of the RCT phase. The study coordinators in the nursing homes distributed the questionnaires to the trained MAKS-s therapists and collected them again. Four individuals were trained as MAKS-s therapists in each nursing home. These individuals belonged to one of the following professional groups: occupational staff, head of social care, nurse, or therapist.

Assessment

Unfortunately, validated instruments could not be used to assess the quality dimensions and the impact of the COVID-19 pandemic. At the time of the survey, there were no suitable and validated scales for assessing the stress caused by the COVID-19 pandemic. According to Donabedian, the quality criteria must always be individually adapted to the setting, and thus, there were no ready-made scales for the quality criteria either. The development of the questionnaire was concept-based. The 38 items captured the three quality dimensions of health care according to Donabedian [4, 5]: structural quality (3 items), process quality (2 items), and outcome quality (10 items). In addition, we assessed the impact of the COVID-19 pandemic (19 items) and the evaluation of the intervention (4 items). Each item was rated on a 5-point Likert scale (see the Additional Material for the questionnaire).

Structural quality was assessed with items such as "How do you rate your spatial and material conditions?" Process quality consisted of the two items "How often did the MAKS-s intervention take place per week?" and "Were you able to implement the interven-

tion in accordance with the instructions?” Process quality was dichotomously defined from these two items as therapy fidelity versus deviations from the manual. Therapy fidelity included therapists who delivered the MAKS-s intervention at least twice a week without changing the order or duration of the modules. Outcome quality was subdivided into two areas reflecting whether the outcome benefitted the PWSDs (5 items) or the therapists (5 items). According to Donabedian, outcome quality covers participants’ (i. e. therapists or patients’) satisfaction and gains. PWSDs’ satisfaction was surveyed in accordance with Clarke with the domains relevant to well-being, such as positive emotions, social participation, and social relationships [16]. An example satisfaction item is “PWSDs showed positive emotions.” Benefits for the therapists included items such as, “Since I have been doing the MAKS-s intervention, I am more satisfied with my job.” The effects of the COVID-19 pandemic were measured with items such as “Due to the pandemic, distance rules had to be followed during group sessions” or “Since the pandemic began, I have felt more psychologically stressed.” The intervention was evaluated with items such as “I will recommend MAKS-s to others.”

Statistical analyses

First, the approval rates for each item were determined and presented descriptively. The programme IBM SPSS version 28 was used for all statistical analyses.

- I. Principal component analysis to prepare the dataTo form summed values in an empirically supported way, the domains structural quality, benefits for the PWSDs, benefit for the therapists, influence of the COVID-19 pandemic, and evaluation of the intervention were first subjected to a principal component analysis (PCA) with an orthogonal rotation (VARIMAX) for each domain. The Kaiser-Meyer-Olkin criterion was applied to test the prerequisites for a PCA. Items that did not load clearly on a factor or had a factor loading <0.50 were removed. To determine the internal consistency of each domain, Cronbach’s alpha was then computed for each domain. At the item level, the discriminatory power and Cronbach’s alpha “if item deleted” were calculated for each item. Items with a discriminatory power <0.5 and items for which Cronbach’s alpha improved when it was deleted were removed from the scale.
- II. Linear regression analysis to determine the factors influencing outcome qualityTo determine the predictive power of the potential predictors evaluation of the intervention, benefits for the therapists, structural quality, normative constraints and psychosocial burdens from the COVID-19 pandemic, and process quality (therapy fidelity) on outcome quality (benefits for the PWSDs), a hierarchical linear regression model was calculated, and all variables were tested for multicollinearity ($r \geq 0.70$). In the first step, the two potential bias variables benefits for the therapists and evaluation of the intervention were included in the regression model. In the next step, the effects of the COVID-19 pandemic and structural quality were added, and in the last step, the therapy fidelity variable was inserted.
- III. Binary logistic regression to identify the factors that influence process quality

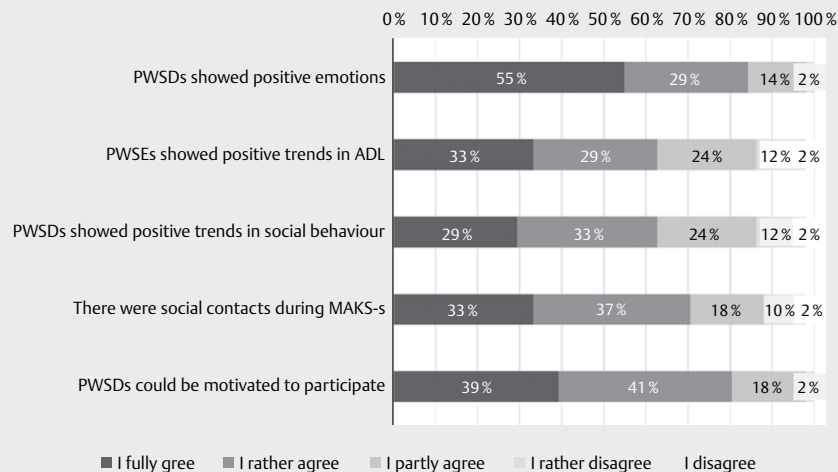
To identify the factors that could have a potential influence on process quality, group differences between therapy fidelity and deviations from the manual were first calculated for all potential predictors using a t-test for unconnected samples. The independent variables for which there were significant group differences ($p < 0.05$) with regard to process quality were tested for multicollinearity. If multicollinearity ($r \geq 0.70$) was identified between two variables, the variable with the lower correlation with the target variable was not included in the regression analysis.

The remaining variables were included as predictors in a binary logistic regression with process quality (therapy fidelity) as the dependent variable.

Results

Of the 26 nursing homes that originally participated in the study, 18 were willing to participate in the follow-up survey 12 months after the study began and 6 months after the open study phase began (t12). In 14 of these 18 nursing homes, the MAKS-s intervention was implemented in the open phase between t6 and t12. They were equally divided between the former intervention and control groups. Of the 104 trained MAKS-s therapists, 58 responded to the questionnaire, thus corresponding to a response rate of 56%. On average, 3 therapists from each nursing home responded ($M = 3.22$, $SD = 0.73$). With regard to the quality of outcomes (benefits for the PWSDs), there was an agreement rate (“fully agree”; “tend to agree”) of 71% across all 5 items. The item with the highest level of agreement (84%) was “The participating PWSD showed positive emotions during the MAKS-s intervention” (► Fig. 1).

- I. Principal component analyses: preparation of the dataThe principal component analyses (see the Additional Material) identified one factor each for the dimensions structural quality, benefits for the PWSDs, and evaluation of the intervention; all items had a loading of >0.7 and could thus be retained. The dimension benefits for the therapists also showed only one factor, but it had to be reduced by one item (“Since I have been carrying out the MAKS-s intervention, I feel more burdened”) due to a lack of loading. The scree plot for the principal component analysis on “effects of the COVID-19 pandemic”, which had a total of 19 items, revealed two different factors: “normative constraints due to COVID-19” (12 items) and “psychosocial effects of the COVID-19 pandemic” (7 items).With the exception of structural quality, the internal consistency of the individual scales was above 0.80, which can be considered high. The value of the structural quality was in the acceptable range with Cronbach’s alpha = 0.784. At the item level, discriminatory power >0.50 was achieved for all items with one exception: “The use of MAKS-s makes my workflow easier” (Cronbach’s alpha = 0.329). Therefore, this item was removed from the benefits for the therapists scale. In addition, one item had to be removed from the evaluation of the MAKS-s intervention scale, as it had both low discriminatory power and an unfavourable Cronbach’s alpha value “if item deleted”.After all the dimensions had been checked with PCAs, a sum value was formed for each dimension by adding up the respective item values. The structural quality dimension ranged from 0–12 points; the outcome quality dimension and



► **Fig. 1** Benefits for PWSDs participating in MAKS-s from the perspective of the MAKS-s therapists (n = 51).

► **Table 1** Mean comparisons of the implementation of the intervention with or without deviations from the manual.

| Variable | therapy fidelity | | deviations from the manual | | total | | p |
|--|------------------|--------|----------------------------|--------|-------|--------|-------------|
| | M | (SD) | M | (SD) | M | (SD) | |
| structural quality (range 0–12) <i>M (SD)</i> ; (n = 51) | 10,2 | (1,4) | 8,8 | (1,8) | 9,4 | (1,8) | ,004 |
| Benefit PWSDs (range 0–20), <i>M (SD)</i> ; (n = 51) | 16,9 | (3,3) | 13,5 | (4,0) | 15,0 | (4,0) | ,002 |
| Benefit therapist (range 0–12), <i>M (SD)</i> ; (n = 50) | 9,3 | (2,4) | 7,52 | (2,4) | 8,3 | (2,5) | ,013 |
| evaluation of the intervention (range 0–12), <i>M (SD)</i> ; (n = 48) | 11,1 | (1,2) | 9,6 | (2,6) | 10,27 | (2,2) | ,011 |
| Normative constraints due to COVID-19 (range 0–48), <i>M (SD)</i> ; (n = 42) | 17,9 | (10,7) | 29,8 | (11,0) | 25,3 | (12,2) | ,002 |
| Psychosocial effects of the COVID-19 pandemic (range 0–28), <i>M (SD)</i> ; (n = 55) | 11,2 | (5,9) | 13,9 | (6,3) | 15,2 | (7,0) | ,164 |

benefits for the PWSDs both ranged from 0–20 points; benefits for the therapists ranged from 0–12; evaluation of the intervention ranged from 0–12; psychosocial burdens from COVID-19 ranged from 0–28; and the normative constraints due to COVID-19 ranged from 0–48. Means and standard deviations for the total sample can be found in ► **Table 1**.

- II. Linear regression analysis: Factors influencing outcome quality
The regression analysis showed that therapy fidelity had a significant influence on the benefits (i.e. the social, everyday practical, and emotional gains) for the PWSDs (see ► **Table 2**). Of the potential bias variables that were added in the first step of the hierarchical regression, benefits for the therapist was a significant predictor ($\beta = 0.46$, $p < 0.001$). The two variables together explained 42.6% of the variance. The variables added in the next step were unable to bring about a significant change in the amount of explained variance. The therapy fidelity added in the last step showed a significant effect ($\beta = 0.45$, $p = 0.019$) and explained an additional 9.3% of the variance. The final model explained 59.5% of the variance and was statistically significant, $F(6,27) = 6.61$, $p < 0.001$ (► **Table 2**).

- III. binary-logistic regression: factors influencing process quality

The t-test showed significant differences in almost all dimensions between the therapy fidelity group and the group that deviated from the manual, in the sense that the therapy fidelity group

scored significantly better (► **Table 1**). The psychosocial impact of the pandemic was not significantly different and was therefore not included in the regression model. There was a high degree of multicollinearity ($r = 0.72$) between the variables benefits for the PWSDs and evaluation of MAKS-s, which is why the variable evaluation of MAKS-s was excluded from the regression. The binary logistic regression model was statistically significant, $\chi^2(4) = 34.25$, $p < 0.001$. It had a high variance resolution of Nagelkerke's $R^2 = .834$, meaning that the predictors we examined explained 83.4% of the variance in therapy fidelity (► **Table 3**). Significant predictors were normative constraints due to COVID-19 and benefits for the PWSDs. For each point increase in the normative constraints due to the COVID-19 scale, therapy fidelity (i.e. the likelihood that the MAKS-s intervention was delivered as specified) decreased by 42%. For each point increase in the benefits for the PWSDs scale, the likelihood that the intervention was delivered in accordance with the manual increased by a factor of four.

Discussion

The aim of the present study was to determine whether implementing the intervention in accordance with the manual had an influence on the fact that PWSDs could benefit from the psychosocial multi-component MAKS-s intervention in the open phase after the end of the RCT. In addition, the aim was to identify the predictors

► **Table 2** Hierarchical linear regression for the variables predicting the benefits for PWSDs; model: ENTER.

| | | B | SE(B) | β | p | ΔR² |
|---|---|----------|--------------|----------|----------|-----------------------|
| Step 1 | | | | | | .426, p < .001 |
| | Benefit therapist | 0,628 | 0,232 | 0,455 | .007 | |
| | Evaluation of the intervention | 0,322 | 0,242 | 0,223 | .099 | |
| Step 2 | | | | | | .076, p = .257 |
| | Benefit therapist | 0,444 | 0,259 | 0,322 | .038 | |
| | Evaluation of the intervention | 0,442 | 0,242 | 0,307 | .078 | |
| | Structural quality | -0,060 | 0,402 | -0,024 | .846 | |
| | Normative constraints due to COVID-19 | -0,038 | 0,063 | -0,096 | .570 | |
| Psychosocial effects of the COVID-19 pandemic | 0,259 | 0,121 | 0,366 | .064 | | |
| Step 3 | | | | | | .093, p = .019 |
| | Benefit therapist | 0,461 | 0,238 | 0,334 | .027 | |
| | Evaluation of the intervention | 0,306 | 0,228 | 0,213 | .176 | |
| | Structural quality | -0,407 | 0,394 | -0,164 | .286 | |
| | Normative constraints due to COVID-19 | 0,061 | 0,070 | 0,155 | .390 | |
| | Psychosocial effects of the COVID-19 pandemic | 0,105 | 0,127 | 0,149 | .479 | |
| Therapy fidelity | 3,831 | 1,528 | 0,447 | .019 | | |
| Total R ² | | | | | | .595 |

^a Therapy fidelity: 1 (yes); 0 (no).

► **Table 3** Binary logistic regression with therapy fidelity (process quality) as dependent variable (1 = therapy fidelity, 0 = deviations from the manual).

| | B | SE | Wald | p | Odds Ratio | 95 % CI for Odds Ratio | |
|---------------------------------------|----------|-----------|-------------|----------|-------------------|-------------------------------|--------------------|
| | | | | | | lower value | upper value |
| Structural quality | 0,72 | 0,75 | 0,91 | 0,341 | 2,04 | 0,47 | 8,91 |
| Benefit therapist | 0,23 | 0,42 | 0,30 | 0,585 | 1,26 | 0,55 | 2,90 |
| Benefit PWSDs | 1,14 | 0,64 | 5,36 | 0,021 | 4,42 | 1,26 | 15,71 |
| Normative constraints due to COVID-19 | -0,54 | 0,26 | 4,28 | 0,039 | 0,58 | 0,35 | 0,97 |

that influenced whether or not a nursing home had implemented the MAKs-s intervention in the open phase in accordance with the manual.

This current analyses provide additional results that complement the results of the RCT. The RCT did not find efficacy in terms of quality of life or psychological and behavioural symptoms. By contrast, the follow-up survey answered by the therapists 6 months after the end of the RCT showed positive effects of the intervention on the PWSDs' outcomes.

Outcome quality

During the open phase of the MAKs-s study, almost three quarters of the therapists observed positive effects of the MAKs-s intervention on the PWSDs. In particular, 84% of the interviewed therapists agreed that positive emotions emerged during the implementation of the MAKs-s intervention. The analysis showed that therapy fidelity (at least twice a week, all four modules in the given order, without time cuts) had a significant influence on whether PWSDs benefited from MAKs-s or not. This result is in line with findings from other studies, which also only achieved a positive effect when the intervention was carried out at the required intensity [17, 18]. During the randomised controlled phase of the MAKs-s trial, elements of the MAKs-s intervention might not have been delivered with therapy fidelity due to the restrictions from the COVID-19 pan-

dem. Unfortunately, therapy fidelity could not be adequately verified, also due to the restrictions from the pandemic (e.g. monitoring visits were not possible). Low therapy fidelity could therefore be one potential reason for why no significant effects on the quality of life and behavioural symptoms of the PWSDs were observed in A Kratzer et al. [19] during the controlled phase.

The fact that positive effects on PWSDs were observed during the intervention is in contrast with the observations of the nurses who did not perceive any positive changes during the controlled phase of the MAKs-s study [19]. How can these differences in the results be explained? The survey technique (observer rating scale) was the same in both cases. It is possible that the different observation times by different observers were responsible for the observed discrepancy. During the RCT phase, the primary nurses who were not involved in the MAKs-s intervention retrospectively assessed the PWSDs' daily behaviour across a period of several days. During the open phase, on the other hand, the MAKs-s therapists who carried out the intervention themselves reported their immediate perceptions during the intervention. Thus, the short-term effects of the intervention were assessed. These short-term and directly observable effects were predominantly assessed positively, which speaks for a positive effect of the MAKs-s intervention on the current well-being of the PWSDs. It seems that long-term changes in quality of life are no longer possible in PWSDs, evidence for which have also been found in other in-

ervention studies involving PWSs [10]. This tendency could also explain the lack of changes in longer-term quality of life during the RCT phase of the MAKS-s study.

Process quality

The second step was to examine which factors contributed to whether the intervention was carried out in accordance with the manual or whether substantial deviations from the manual occurred. The more positive the effects of the MAKS-s intervention that the therapists perceived in the PWSs, the greater the probability that the therapists had carried out the intervention in accordance with the manual. In addition, there was also a negative correlation between the degree of normative constraints from COVID-19 regulations and implementation in accordance with the manual. That is, the more regulations there were in a nursing home to observe hygiene measures and distance rules or to refrain from certain social activities, the greater the likelihood that the MAKS-s intervention was not carried out in accordance with the manual. This finding is consistent with a finding from the 2021 Nursing Report: Measures such as distance rules, contact restrictions, and bans on social group activities, which were intended to protect against COVID-19 infection, have conversely led to cuts in the health care of those in need of care [20].

In summary, it can be concluded that the normative constraints from COVID-19 significantly influenced the way in which the MAKS-s psychosocial intervention was implemented. These changes led to the fact that PWSs who were subject to very strict normative constraints were temporarily not allowed to participate in the intervention in some nursing homes and therefore could not benefit from the possible positive effects.

Strengths and limitations

The questions included on the assessment instrument were newly developed for the survey; the main reasons were to be able to react to the current situation (COVID-19 pandemic) with targeted questions and to keep participants' efforts in filling out the survey (number of questions) as low as possible. In order to at least meet the requirements of content validity, a concept-based approach that used Donabedian's dimensions of quality and Clarke's domains of well-being was used. In addition, all constructs were examined for internal consistency by computing a PCA so that the formation of sum values was empirically supported. Although all nursing homes and all trained therapists were invited to participate in the survey 12 months after the study began, the present study did not survey all potential participants. The response rate for the nursing homes was just under 70%. It can be assumed that selection factors, such as current staffing levels and personal attitudes towards the MAKS-s intervention, influenced participation. To reduce this bias, the evaluation of the MAKS-s intervention and benefits for the therapists were included as control variables in the first step of the hierarchical regression model. In general, all statements were subjective perceptions of individual groups of people (MAKS-s therapists) who made these statements retrospectively. In addition, the Hawthorne effect, recall, and social desirability biases, which are typical for a survey study, cannot be completely excluded. However, it can be assumed that a possible Hawthorne effect was reduced by controlling for the variables evaluation of the intervention and ben-

efits for the therapists. A possible recall bias can work in both positive and negative directions, which is why it can be assumed that any effects should have averaged out. In addition, the social desirability bias could have been minimised by the completely anonymous survey, although not completely.

The strength of the present study lies in the fact that the results reflect the reality of care after the "rigid" requirements of an RCT have ended.

CONCLUSIONS FOR PRACTICE

- Therapy fidelity seems to be a decisive factor in whether people with severe dementia benefit from the MAKS-s psychosocial intervention. Therefore, it is recommended that the MAKS-s manual be followed without shortcuts or changes.
- Future randomised controlled trials on the effects of psychosocial interventions should include therapy fidelity as a mediating variable.
- In order to examine the effect of a psychosocial intervention on PWSs, future studies should not look primarily for lasting effects but should rather focus on the short-term effects that can be directly observed. Contact restrictions, distance bans, and bans on certain social activities meant that the MAKS-s psychosocial group intervention often could not be carried out in accordance with manual. Since social contacts — especially for people with severe dementia — are a central element for establishing contact with the environment, socially restrictive measures reduce the potential benefits of a psychosocial intervention.

Compliance with ethical guidelines

All of the human studies described were conducted with the approval of the relevant ethics committee, in accordance with national law, and in accordance with the Declaration of Helsinki of 1975 (in its current, revised version) (Ref.295_19B). Informed consent was obtained from all individuals involved.

Contributor's Statement

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Conflict of Interest

None

Reference

- [1] Gesellschaft DA. Mittlere Prävalenzrate von Demenzerkrankungen nach Alter und Geschlecht im Jahr 2021. 2022;
- [2] Schäufele M et al. [Prevalence of dementia and medical care in German nursing homes: a nationally representative survey]. *Psychiatr Prax* 2013; 40: 200–206
- [3] Diehl K et al. The Psychopharmacological Treatment of People With Severe Dementia-Findings of a Cross-Sectional Study. *Dtsch Arztebl Int* 2022; 119: 664–665
- [4] Donabedian A. The quality of care. How can it be assessed? *JAMA* 1988; 260: 1743–1748
- [5] Donabedian A. Evaluating the quality of medical care. 1966.. *Milbank Q* 2005; 83: 691–729
- [6] Möller H-J, Laux G, Kapfhammer H-P. *Psychiatrie, Psychosomatik, Psychotherapie: Band 1: Allgemeine Psychiatrie Band 2: Spezielle Psychiatrie*. 2009 Springer-Verlag;
- [7] Olazarán J et al. Nonpharmacological therapies in Alzheimer's disease: a systematic review of efficacy. *Dement Geriatr Cogn Disord* 2010; 30: 161–178
- [8] Oyeboode JR, Parveen S. Psychosocial interventions for people with dementia: An overview and commentary on recent developments. *Dementia (London)* 2019; 18: 8–35
- [9] Bartholomeyczik S. Rahmenempfehlungen zum Umgang mit herausforderndem Verhalten bei Menschen mit Demenz in der stationären Altenhilfe. *Demenz* 2006
- [10] Na R et al. A Systematic Review and Meta-Analysis of Nonpharmacological Interventions for Moderate to Severe Dementia. *Psychiatry Investig* 2019; 16: 325–335
- [11] Diehl K, Kratzer A, Graessel E. The MAKS-s study: multicomponent non-pharmacological intervention for people with severe dementia in inpatient care - study protocol of a randomised controlled trial. *BMC Geriatr* 2020; 20: 405
- [12] Kratzer A et al. Non-pharmacological, psychosocial MAKS-s intervention for people with severe dementia in nursing homes: results of a cluster-randomised trial. *BMC Geriatr* 2022; 22: 1001
- [13] Gräßel E et al. Implementierung und Wirkung der multimodalen psychosozialen MAKS-Intervention in der Tagespflege bei Menschen mit kognitiven Beeinträchtigungen: Ergebnisse in der offenen Phase nach Beendigung des RCT. *Das Gesundheitswesen* 2022; 84: 1154–1157
- [14] Straubmeier M et al. Non-pharmacological treatment in people with cognitive impairment—results from the randomized controlled German Day Care Study. *Deutsches Ärzteblatt International* 2017; 114: 815–821
- [15] Park HG, Perumean-Chaney SE, Bartolucci AA. Exploring Factors Associated With Successful Nonpharmacological Interventions for People With Dementia. *Dement Neurocogn Disord* 2022; 21: 1–16
- [16] Clarke C et al. Measuring the well-being of people with dementia: a conceptual scoping review. *Health Qual Life Outcomes* 2020; 18: 249
- [17] Hoffmann K et al. Moderate-to-High Intensity Physical Exercise in Patients with Alzheimer's Disease: A Randomized Controlled Trial. *J Alzheimers Dis* 2016; 50: 443–453
- [18] Hill HC, Erickson A. Using implementation fidelity to aid in interpreting program impacts: A brief review. *Educational Researcher* 2019; 48: 590–598
- [19] Kratzer A et al. Non-pharmacological, psychosocial MAKS-s intervention for people with severe dementia in nursing homes: results of a cluster-randomised trial. *BMC Geriatrics*, in press
- [20] Räker M, Klauber J, Schwinger A. Pflegerische Versorgung in der ersten Welle der COVID-19-Pandemie, in *Pflege-Report 2021*. Springer; Berlin, Heidelberg: 2021: 33–58