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Personally tailored activities for improving psychosocial outcomes for people with dementia in long-term care (Review)

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[Intervention Review]

Personally tailored activities for improving psychosocial outcomes for people with dementia in long-term care

Ralph Möhler[1], Stella Calo[1], Anna Renom[2], Helena Renom[3], Gabriele Meyer[4]

[1]Institute for Health Services Research and Health Economics, Centre for Health and Society, Medical Faculty and University Hospital Düsseldorf, Heinrich-Heine-University, Düsseldorf, Germany. [2]Department of Geriatrics, Parc de Salut Mar, Barcelona, Spain. [3]Physical Medicine and Rehabilitation (MFRHB), Hospital de la Santa Creu i Sant Pau, Barcelona, Spain. [4]Institute of Health and Nursing Sciences, Medical Faculty, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

Contact: Ralph Möhler, ralph.moehler@uni-duesseldorf.de.

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ABSTRACT

Background

People with dementia who are being cared for in long-term care settings are often not engaged in meaningful activities. We wanted to know whether offering them activities which are tailored to their individual interests and preferences could improve their quality of life and reduce agitation. This review updates our earlier review published in 2018.

Objectives

· To assess the effects of personally tailored activities on psychosocial outcomes for people with dementia living in long-term care facilities.

· To describe the components of the interventions.

· To describe conditions which enhance the effectiveness of personally tailored activities in this setting.

Search methods

We searched the Cochrane Dementia and Cognitive Improvement Group's Specialized Register, on 15 June 2022. We also performed additional searches in MEDLINE, Embase, PsycINFO, CINAHL, Web of Science, ClinicalTrials.gov, and the World Health Organization (WHO) ICTRP, to ensure that the search for the review was as up-to-date and as comprehensive as possible.

Selection criteria

We included randomised controlled trials (RCTs) and controlled clinical trials offering personally tailored activities. All interventions included an assessment of the participants' present or past preferences for, or interest in, particular activities as a basis for an individual activity plan. Control groups received either usual care or an active control intervention.

Data collection and analysis

Two authors independently selected studies for inclusion, extracted data and assessed the risk of bias of included studies. Our primary efficacy outcomes were agitation and participant quality of life. Where possible, we pooled data across studies using a random effects model.

Main results

We identified three new studies, and therefore included 11 studies with 1071 participants in this review update. The mean age of participants was 78 to 88 years and most had moderate or severe dementia. Ten studies were RCTs (three studies randomised clusters to the study groups, six studies randomised individual participants, and one study randomised matched pairs of participants) and one study was a non-randomised clinical trial. Five studies included a control group receiving usual care, five studies an active control group (activities which were not personally tailored) and one study included both types of control group. The duration of follow-up ranged from 10 days to nine months.

In nine studies personally tailored activities were delivered directly to the participants. In one study nursing staff, and in another study family members, were trained to deliver the activities. The selection of activities was based on different theoretical models, but the activities delivered did not vary substantially.

We judged the risk of selection bias to be high in five studies, the risk of performance bias to be high in five studies and the risk of detection bias to be high in four studies.

We found low-certainty evidence that personally tailored activities may slightly reduce agitation (standardised mean difference −0.26, 95% CI −0.53 to 0.01; I^2 = 50%; 7 studies, 485 participants). We also found low-certainty evidence from one study that was not included in the meta-analysis, indicating that personally tailored activities may make little or no difference to general restlessness, aggression, uncooperative behaviour, very negative and negative verbal behaviour (180 participants). Two studies investigated quality of life by proxy-rating. We found low-certainty evidence that personally tailored activities may result in little to no difference in quality of life in comparison with usual care or an active control group (MD -0.83, 95% CI -3.97 to 2.30; I^2 = 51%; 2 studies, 177 participants). Self-rated quality of life was only available for a small number of participants from one study, and there was little or no difference between personally tailored activities and usual care on this outcome (MD 0.26, 95% CI −3.04 to 3.56; 42 participants; low-certainty evidence). Two studies assessed adverse effects, but no adverse effects were observed.

We are very uncertain about the effects of personally tailored activities on mood and positive affect. For negative affect we found moderate-certainty evidence that there is probably little to no effect of personally tailored activities compared to usual care or activities which are not personalised (standardised mean difference -0.02, 95% CI −0.19 to 0.14; 6 studies, 632 participants). We were not able to undertake meta-analyses for engagement and sleep-related outcomes, and we are very uncertain whether personally tailored activities have any effect on these outcomes.

Two studies that investigated the duration of the effects of personally tailored activities indicated that the intervention effects they found persisted only during the period of delivery of the activities.

Authors' conclusions

Offering personally tailored activities to people with dementia in long-term care may slightly reduce agitation. Personally tailored activities may result in little to no difference in quality of life rated by proxies, but we acknowledge concerns about the validity of proxy ratings of quality of life in severe dementia. Personally tailored activities probably have little or no effect on negative affect, and we are uncertain whether they have any effect on positive affect or mood. There was no evidence that interventions were more likely to be effective if based on one theoretical model rather than another. We included three new studies in this updated review, but two studies were pilot trials and included only a small number of participants. Certainty of evidence was predominately very low or low due to several methodological limitations of and inconsistencies between the included studies. Evidence is still limited, and we remain unable to describe optimal activity programmes. Further research should focus on methods for selecting appropriate and meaningful activities for people in different stages of dementia.

PLAIN LANGUAGE SUMMARY

Personally tailored activities for people with dementia in long-term care

What are the benefits of activities that are tailored to the interests and preferences of people with dementia living in care homes

What was studied in this review?

People with dementia living in nursing or residential homes often have too little to do. Activities which are available may not be meaningful to them. If a person with dementia has the chance to take part in activities which match his or her personal interests and preferences, this may lead to a better quality of life, may reduce behaviours sometimes described as agitation (such as restlessness or aggression), and may have other positive effects.

What did we want to find out?

We aimed to investigate the effects of offering people with dementia who were living in care homes activities tailored to their personal interests. This review updates our previous review from 2018.

What did we do?

We searched for trials that had offered an activity programme to people with dementia based on their individual interests (an intervention group) and had compared them with other participants who were not offered these activities (a control group).

We found 11 studies including 1071 people with dementia living in care homes. Ten of the studies were randomised controlled trials (RCTs), meaning that it was decided at random whether participants were in the intervention group or the control group. One study was not randomised, which puts it at higher risk of biased results. The people included in the studies had moderate or severe dementia, and almost all had some kind of agitation when the study started. The studies lasted from 10 days to nine months. In all the studies, the people in the intervention groups got an individual activity plan. Most of the activities took place in special sessions run by trained staff, but in two studies the nursing staff or family members were trained to provide the activities during the daily care routine (nursing staff) or during visits (family members). The activities actually offered in the different studies did not vary a lot, but the number of activity sessions per week and the duration of the sessions did vary.

In five studies, the control group got only the usual care delivered in care homes; in five studies, the control group got different activities that were not personally tailored; one study had both types of control group.

What did we find?

The quality of the trials and how well they were reported varied, and this affected our confidence in the results. Offering personally tailored activities to people with dementia living in care homes may slightly improve agitation. In two studies, staff members judged the quality of life of the people with dementia, but offering the activities may result in little to no difference in quality of life. Only two studies mentioned looking for harmful effects; none were reported.

Personally tailored activities may have little or no effect on the negative emotions expressed by the participants. We could not draw any conclusion about effects on the participants' positive emotions, mood, engagement (being involved in what is happening around them) or quality of sleep, because some of the studies did not use the most appropriate methods to carry out their investigations. None of the studies measured effects on the amount of medication participants were given, or effects on carers.

We concluded that offering activity sessions to people with moderate or severe dementia living in care homes may help to manage agitation.

What are the limitations of the evidence?

Our confidence in the results was limited because of the small number of studies and because the studies did not always use the most appropriate methods to carry out their investigations. For example, in some studies it was not clear if they assigned people randomly to the study groups.

How up to date is this evidence?

This review updates our previous review, and the evidence is current to 15 June 2022.

Summary of findings 1. Personally tailored activities compared to usual care or non-personalised activities for people with dementia

Personally tailored activities compared to usual care or non-personalised activities for people with dementia

Patient or population: people with dementia
Setting: long-term care facilities
Intervention: personally tailored activities
Comparison: usual care or non-personalised activities (active control)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with usual care or non-personalised activities	Risk with Personally tailored activities				
Agitation (assessed with different scales, higher scores indicate more agitation); follow-up: range 10 days to 9 months	-	SMD 0.26 SD lower (0.53 lower to 0.01 higher)	-	485 (7 RCTs)	⊕⊕⊖⊖ LOW[a,b]	
Quality of life (self-rating by the participants; assessed with Quality of Life in Alzheimer's Disease scale; range 15 to 60; higher scores indicate a higher quality of life); follow-up: 28 weeks	The mean quality of life score with usual care was 33.00.	The mean quality of life score in the intervention group was on average 0.26 higher (3.04 lower to 3.56 higher).	-	42 (1 RCT)	⊕⊕⊖⊖ LOW[c]	Mean difference adjusted for baseline/demographic characteristics; clinical relevance (by study authors): 3-point difference; only about one-third of the participants completed the self-assessment.
Quality of life (proxy-rating; assessed with Quality of Life in Alzheimer's Disease scale; range 15 to 60; higher scores indicate a higher quality of life); follow-up: 8 weeks and 28 weeks	The mean quality of life score (proxy-rated) was 30.5 with usual care and 36.5 with the active control group.	The mean quality of life score in the intervention group was on average 0.83 lower (3.97 lower to 2.30 higher)	-	177 (2 RCTs)	⊕⊕⊖⊖ LOW[d,e]	Proxy-rating, clinical relevance (as defined by the authors of one of the studies): 3-point difference.

Adverse events; follow-up: range 10 days to 4 weeks	Two studies assessed adverse effects, but no adverse effects were reported in either study.		-	188 (2 RCTs)	-
Positive affect (assessed with different scales, higher scores indicate a greater display of positive affect); follow-up: range 10 days to 9 months	-	SMD 0.88 SD higher (0.43 higher to 1.32 higher)	-	498 (6 RCTs)	⊕⊝⊝⊝ VERY LOW[a,b,f]
Negative affect (assessed with different scales, higher scores indicate a greater display of negative affect); follow-up: range 10 days to 9 months	-	SMD 0.02 SD lower (0.19 lower to 0.14 higher)	-	632 (6 RCTs)	⊕⊕⊕⊝ MODERATE[b]
Mood (assessed with different scales, lower scores indicate improved mood); follow-up: range 4 weeks to 9 months	-	SMD 0.03 SD lower (0.21 lower to 0.27 higher)	-	265 (4 RCTs)	⊕⊝⊝⊝ VERY LOW[b,g]

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
CI: confidence interval; RCT: randomised controlled trial; SMD: standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a] Downgraded one level for imprecision: wide confidence interval, crossing the borders of clinical relevance defined by the study authors in one direction.
[b] Downgraded one level for risk of bias: high risk of selection bias, performance bias and detection bias in one study.
[c] Downgraded two levels for imprecision: wide confidence interval, crossing the border of clinical relevance defined by the study authors in both directions.
[d] Downgraded one level for risk of bias: high risk of selection bias and detection bias in some studies.
[e] Downgraded one level for imprecision: wide confidence interval, crossing the border of small effects (SMD) in one direction.
[f] Downgraded one level for inconsistency: substantial heterogeneity.
[g] Downgraded two levels for imprecision: wide confidence interval, crossing the border of small effects (SMD) in both directions.

BACKGROUND

Description of the condition

Dementia is a syndrome of progressive cognitive and functional decline, threatening the affected person's capacities to perform activities and to communicate. Worldwide, there were approximately 57.4 million people with dementia in 2019 and the absolute number is expected to rise (GBD 2019 Dementia Forecasting Collaborators 2022). In long-term care facilities, the estimated prevalence of dementia ranges between 40% and 80% (Helvik 2015; Stewart 2014).

People with dementia often spend their time without being engaged in meaningful activities or being involved with other people (Adlbrecht 2022; Edvardsson 2014; Smith 2018). Although nursing homes regularly offer activities to the residents, these activities tend to be passive, e.g. watching television and listening to music, and are often not perceived as meaningful by people with dementia, or are addressed to residents with better cognitive and functional status (Buettner 2003; Edvardsson 2014; Kristensen 2020). Hence, a lower cognitive function in people with dementia is associated with fewer social interactions and less participation in activities (Dobbs 2005; Edvardsson 2014). To be engaged in meaningful activities provides a sense of connectedness to self, others, and the environment, and helps maintain autonomy and identity in persons with dementia (Han 2016; Phinney 2007). Conversely, understimulation might magnify challenging behaviour, e.g. apathy, boredom, depression, loneliness and agitation (Cohen-Mansfield 2011; Michelet 2022). People with dementia wish to be involved in activities which meet their interests and which are perceived as meaningful. To be engaged in activities perceived as meaningful is expected to increase peoples' quality of life (Cooney 2009; Edvardsson 2014; Murphy 2007; Phinney 2007; Vernooij-Dassen 2007).

There is no clear definition of meaningful activities or occupation and therefore meaningfulness is often very broadly defined (Strick 2021). Activities are perceived as meaningful if they have a value for people with dementia and if they are tailored to their individual interests and preferences (Kristensen 2020; Strick 2021). Therefore, we use the term personally tailored activities rather than meaningful activities in this review.

Offering personally tailored activities to people with dementia primarily aims to improve psychosocial outcomes, e.g. agitation or quality of life, rather than to increase cognitive function or to improve particular skills. Since a remarkable sense of self-identity can persist until late stages of dementia (Kristensen 2020; Mills 1997; Strick 2021), engagement in personally tailored activities could be beneficial for people in all stages of dementia.

Description of the intervention

Interventions offering personally tailored activities for people with dementia living in long-term care facilities are likely to be complex interventions, comprising different methods of selecting activities tailored to people's interests and preferences, different types of activities, and different modes of delivering the activities (Craig 2008). We focus on interventions aimed at improving psychosocial outcomes (e.g. agitation or quality of life in people with dementia) rather than on interventions exclusively aimed at improving particular skills (e.g. basic activities of daily living, or cognitive function).

All interventions have to include an assessment of interests or preferences of the participants. Interventions can be based on specific models or concepts, e.g. the principles of Montessori or the concept of person-centred care. The choice of activities offered should be based on the assessment of personal interests or preferences. Activities offered within the interventions include instrumental activities of daily living (e.g. housework, preparing a meal), arts and crafts (e.g. painting, singing), work-related tasks (e.g. gardening), and recreational activities (e.g. games). The interventions can be delivered in groups or individually; duration and frequency of the sessions can differ. Providers of the interventions we expected to find include different professionals or a multidisciplinary team.

How the intervention might work

Being involved in personally tailored activities may evoke positive emotions, like interest, and reduce agitation. Also, participating in such activities can increase feelings of engagement which can reduce feelings of boredom and loneliness, and increase quality of life (Kristensen 2020; Michelet 2022; Strick 2021). Other expected benefits cover the evocation of autobiographical events (Guétin 2009), the preservation of a person's identity, an increase in the person's occupation and possible maintenance of their relationships (Kristensen 2020). These positive effects may reduce the use of psychotropic medication in people with dementia and may also result in benefits for the caregiver (e.g. increased sense of competence, decreased burden of care).

Why it is important to do this review

There is an increasing need for effective non-pharmacological interventions to improve psychosocial outcomes in people with dementia in clinical practice. In several dementia guidelines, the use of non-pharmacological interventions is recommended as a primary approach for behavioural and psychological symptoms (e.g. Fazio 2018; NICE 2018). Interventions offering personally tailored activities could be a promising approach due to their potential effects on agitation, quality of life and the level of engagement of people with dementia. Several studies have evaluated complex interventions offering personally tailored activities to people with dementia in long-term care facilities. These interventions are complex in nature due to differences in underlying theoretical models, the components of the interventions, the types of activities offered, and the intensity and duration of delivery.

In order to assess the effects of complex interventions properly, a description of the interventions' components is required to ensure comparability and reduce heterogeneity (Guise 2017; Viswanathan 2017). Since the effectiveness of complex interventions is also influenced by implementation fidelity, this information should be incorporated too, e.g. adherence, exposure, quality of delivery, participants' responsiveness and adherence.

This review updates the original Cochrane Review published in 2018 (Möhler 2018).

OBJECTIVES

- To assess the effects of personally tailored activities on psychosocial outcomes for people with dementia living in long-term care facilities.
- To describe the components of the interventions.
- To describe conditions which enhance the effectiveness of personally tailored activities in this setting.

METHODS

Criteria for considering studies for this review

Types of studies

As planned in the published review protocol (Möhler 2012), we included individual or cluster-randomised controlled trials, controlled clinical trials and controlled before-after studies.

Types of participants

All people with dementia living in long-term care facilities, irrespective of the stage of dementia, were eligible.

Types of interventions

All the interventions aimed to improve psychosocial outcomes by offering personally tailored activities to people with dementia in long-term care. The aims of the interventions did not necessarily include the improvement of a particular skill. The interventions had to comprise two elements.

1. Assessment of the participants' present or former preferences for particular activities or interests. We accepted both unstructured assessments, e.g. asking for the interests of the person with dementia, or the use of validated tools, e.g. the self-identity questionnaire (Cohen-Mansfield 2010), or the NEO Five-Factor Inventory (NEO-FFI, Kolanowski 2005). This assessment had to be performed primarily with the person with dementia; however, relatives or health professionals could also be informants, e.g. in later stages of dementia.
2. An activity plan tailored to the individual participant's present or former preferences. We accepted activities of various kinds: instrumental activities of daily living (e.g. housework, preparing a meal); arts and crafts (e.g. painting, singing); work-related tasks (e.g. gardening); and recreational activities (e.g. games). The intervention could be delivered by different professionals, e.g. nurses, occupational therapists, social workers or psychologists. The intervention could be delivered either to a group or to individual participants.

We excluded interventions which offered (1) only one specific type of activity (e.g. music or reminiscence), (2) specific care approaches (e.g. person-centred care) which included the delivery of activities, (3) multi-component interventions comprising drug treatment and the delivery of activities, and (4) interventions exclusively aimed at improving cognitive function or other particular skills (e.g. communication, basic activities of daily living).

We compared personally tailored activities against other types of psychosocial interventions, placebo interventions (e.g. non-specific personal attention), usual or optimised usual care.

Types of outcome measures

Primary outcomes

- Agitation or challenging behaviour, assessed by e.g. the Cohen-Mansfield Agitation Inventory (CMAI).
- Quality of life, assessed by e.g. Dementia Care Mapping, EuroQol (EQ-5D).
- Adverse effects of the interventions employed (e.g. injuries).

Secondary outcomes

- Affect (i.e. expression of emotion), assessed by e.g. Observed Emotion Rating Scale.
- Mood, assessed by e.g. Dementia Mood Picture Test.
- Level of engagement, assessed by e.g. Observational Measurement of Engagement Assessment, Index of Social Engagement.
- Other dementia-related symptoms such as sleep disturbances, hallucinations or delusions, assessed by e.g. Neuropsychiatric Inventory (NPI).
- Use of psychotropic medication.
- Effect on the caregivers, e.g. caregivers' distress (assessed by e.g. Neuropsychiatric Inventory Caregiver Distress Scale (NPI-D)), sense of competence (assessed by e.g. Sense of Competence Questionnaire (SCQ)), quality of life, health status (assessed by e.g. General Health Questionnaire (GHQ-12)).
- Cost.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Dementia and Cognitive Improvement Group's Specialized Register on 15 June 2022 using the following search terms: personally tailored OR individualized OR individualised OR individual OR person-centred OR meaningful OR personhood OR involvement OR engagement OR engaging OR identity.

The Register is maintained by the Information Specialists of the Cochrane Dementia and Cognitive Improvement Group and contains studies in the areas of dementia prevention, dementia treatment and cognitive enhancement in healthy individuals. The studies are identified from:

1. monthly searches of a number of major healthcare databases: MEDLINE, Embase, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycINFO and LILACS (Latin American and Caribbean Health Science Information database);
2. monthly searches of a number of trial registers: ISRCTN; UMIN (Japan's Trial Register); the World Health Organization (WHO) portal (which covers ClinicalTrials.gov; ISRCTN; the Chinese Clinical Trials Register; the German Clinical Trials Register; the Iranian Registry of Clinical Trials; and the Netherlands National Trials Register, plus others);
3. quarterly search of the Cochrane Library's Central Register of Controlled Trials (CENTRAL);
4. six-monthly searches of grey literature source: Web of Science Conference Proceedings.

Details of the search strategies used for the retrieval of reports of trials from the healthcare databases, CENTRAL and conference

proceedings can be viewed in the 'Methods used in reviews' section within the editorial information about the Dementia and Cognitive Improvement Group.

We also performed additional searches in many of the sources listed above to ensure that the search for the review was as up to date and as comprehensive as possible. The search strategies we used can be seen in Appendix 1.

Searching other resources

We screened reference lists and citations of all potentially eligible publications for additional trials and for additional data (e.g. interventions development, process-related data).

Data collection and analysis

Selection of studies

Two reviewers (RM, AR in the original review; RM, SC for this update) independently assessed all titles and abstracts obtained from the search for inclusion according to the Criteria for considering studies for this review. We resolved disagreements by discussion or, if necessary, we referred to a third reviewer (GM).

Data extraction and management

Two reviewers (RM, AR in the original review; RM, SC for this update) independently extracted data from all included publications using a standardised form. We checked results for accuracy and, in case of disagreement, called in a third reviewer (GM) to reach consensus.

For each study we extracted the following data: study design, characteristics of participants, baseline data, length of follow-up, outcome measures, study results, and adverse effects. For each intervention we extracted the following information: method of assessing the individual preferences, types of activities offered, duration and frequency of the intervention's components, information of the implementation fidelity. Additionally, we collected information on the intervention's development (i.e. underlying theoretical considerations, components and delivery) and process-related data. For cluster-randomised trials, we also extracted estimates of the intracluster correlation coefficient (ICC) if possible. If necessary, we contacted study authors to obtain missing information.

Assessment of risk of bias in included studies

We followed the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We assessed risk of bias in each study for the following criteria: selection bias, performance bias, attrition bias, detection bias, and additional design-related criteria for cluster-randomised and non-randomised trials. Two authors (RM, AR in the original review, and RM, SC for this update) independently assessed methodological quality of studies in order to identify any potential sources of systematic bias. In case of unclear or missing information, we contacted the corresponding author of the trial. We assessed the quality of evidence using the criteria proposed by the GRADE working group (Guyatt 2011).

Measures of treatment effect

For agitation and affect (including mood) we used the standardised mean difference (SMD), which is the absolute mean difference divided by the standard deviation (SD), since the included studies used different rating scales (see also Unit of analysis issues). We used the postintervention means of each scale's total score or subscore (for affect).

For continuous data that were not included in a meta-analysis we calculated the mean difference (MD). If it was not feasible for us to calculate the MD, e.g. in case of substantial baseline imbalances, we presented the study results in narrative form, e.g. as mean values and standard deviation.

None of the trials included in this review reported dichotomous data of interest to this review.

Unit of analysis issues

For all studies, we investigated whether randomisation was performed on individual or group (cluster) level. For cluster-randomised trials, we extracted information about the ICC, if available. Only one of the included cluster-randomised trials reported the ICC, with values ranging from 0 to 0.3 (Wenborn 2013). We used the ICC values of the corresponding outcomes (0.19 for agitation and 0.09 for affect) from this study to incorporate the cluster effect in the studies without information on the ICC - Cohen-Mansfield 2007 and Cohen-Mansfield 2012 - by recalculating the effective sample size using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). The numbers of included study participants and clusters in all three studies are comparable.

For cross-over trials, we checked the risk of a carry-over effect. In the study by van der Ploeg 2013, we found no evidence for the occurrence of a carry-over effect; after the intervention sessions, the values of most outcomes returned to the level assessed before the activity sessions started. We used data from the complete study period for both conditions in our analysis since the authors did not report or offer results for the first period. We cannot be sure to have avoided a unit-of-analysis error; however, this bias is conservative, being expected to lead to an under-estimate of the intervention effect (Higgins 2017). The second included cross-over trial did not perform a washout period, and the authors mentioned that they observed a carry-over effect (Mbakile-Mahlanza 2020). Since the authors did not report or offer information about the first period, we did not include this study in the analyses.

One study included four study groups (three different intervention groups and one control group) (Kolanowski 2011). We excluded two intervention groups from the analysis since they did not meet our inclusion criteria (see Description of studies) and we included the two other groups in the analysis (one intervention and the control group).

Dealing with missing data

For all included studies, we extracted the numbers of participants lost to follow-up, with reasons (see Characteristics of included studies). In case of missing information we contacted the study authors and asked for additional information.

Assessment of heterogeneity

We examined studies for clinical diversity in terms of characteristics of the interventions, participants, and outcomes. We combined data in meta-analyses only if we considered the studies to be sufficiently clinically homogeneous. To test for statistical heterogeneity, we used the Chi^2 and I^2 statistics.

Assessment of reporting biases

In order to minimise the risk of publication bias we performed a comprehensive search, including multiple databases, snowballing techniques and searching trials registers to identify unpublished or ongoing trials. We did not investigate publication bias by means of a graphical funnel plot analysis since we included only a small number of studies. To detect cases of selective reporting in the included studies, we checked trial register information if available.

Data synthesis

We performed meta-analyses for agitation, quality of life, positive and negative affect and for mood. In all cases, we used a random-effects model as planned in the protocol since we found clinical diversity of the interventions and statistical heterogeneity (I^2 > 50%). One study reported different types of (positive and negative) affect (Van Haitsma 2015). To include this study in the meta-analysis, we combined the different outcomes for positive affect and for negative affect, calculating a combined score for each. To calculate the variance of the combined means, we assumed a positive correlation of 0.5 between the individual outcomes of each category. In the meta-analysis for mood, the assessment instrument used in one study differed in the direction of the scale (Kolanowski 2011). We recalculated the data of this study using the methods from the *Cochrane Handbook for Systematic Reviews of Interventions* (we multiplied the mean values by −1 as described in chapter 9.2.3.2) (Higgins 2017).

As in the first published version of this review, we did not perform meta-analyses for any other outcomes and present the results in a narrative form.

Subgroup analysis and investigation of heterogeneity

Depending on the availability of sufficient data, we conducted subgroup analyses for studies with and without an active control group. In order to include in meta-analyses one study which included both usual care and active control groups, we split the experimental intervention group using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Chapter 16.5.4) (Higgins 2017).

Sensitivity analysis

We performed a sensitivity analysis to explore the effects of including the study for which we calculated the combined outcome for positive and negative affect (see Data synthesis).

Summary of findings and assessment of the certainty of the evidence

We used the GRADE approach to assess the quality of evidence for the most important outcomes. We assessed the quality of the evidence by judging study limitations, consistency of effect, imprecision, indirectness, and publication bias (Guyatt 2011). To determine imprecision, we defined the borders for minimal important difference as defined by study authors; e.g. in case of quality of life (Wenborn 2013), and for the analyses using the SMDs, we used an effect size of 0.2, which is described as a small effect for SMD in the *Cochrane Handbook for Systematic Reviews of Interventions* (chapter 12.6.2) (Higgins 2017). We rated quality of evidence as high, moderate, low or very low (Guyatt 2011). We created a summary of findings table for the following outcomes: agitation, quality of life (self-rating and proxy-rating), adverse events, positive affect, negative affect, and mood.

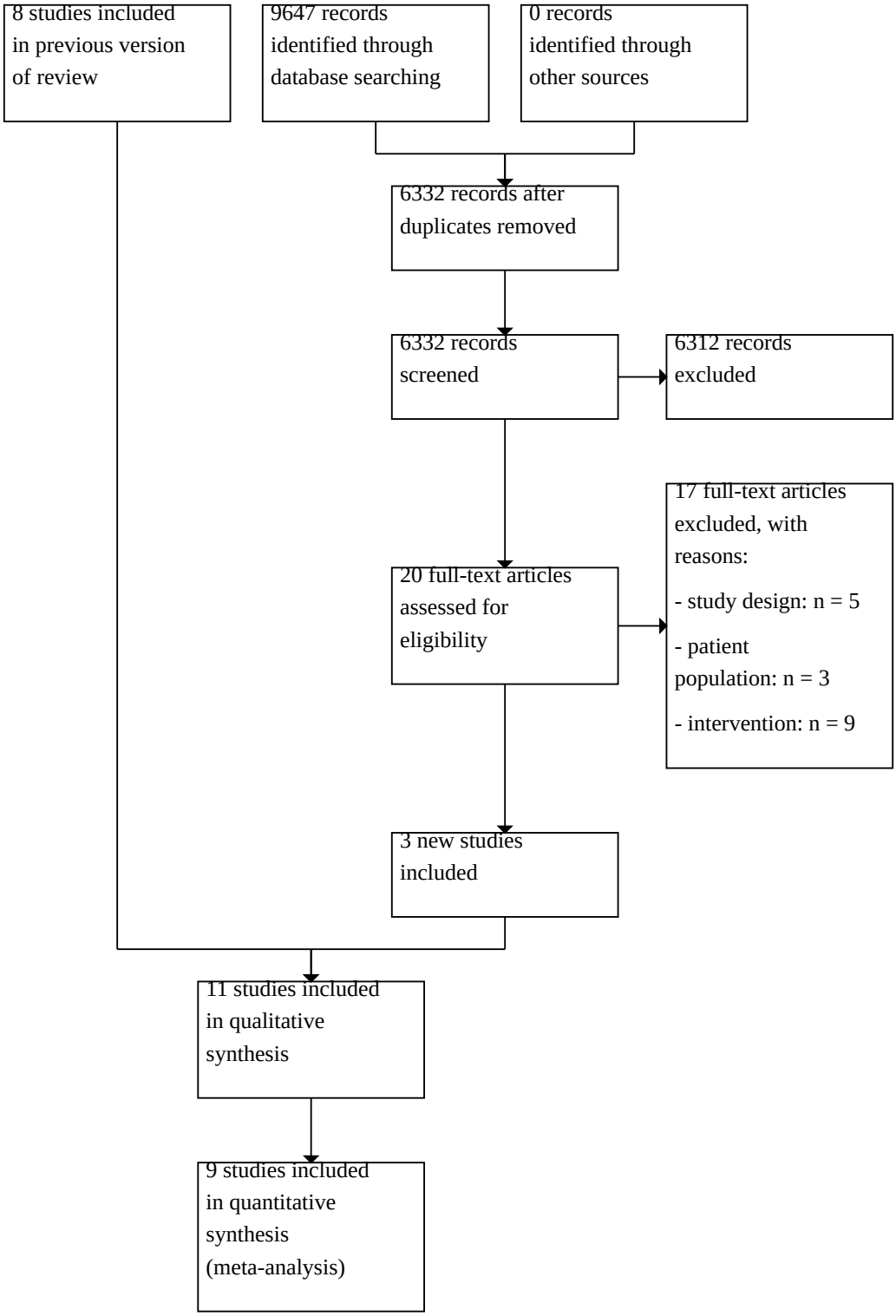
RESULTS

Description of studies

Results of the search

The search for this review update identified 6332 unique records (Figure 1). Two authors independently screened titles and abstracts against the inclusion criteria and excluded 6312 citations. We screened 20 publications in full text and included three new studies (Mbakile-Mahlanza 2020; Travers 2017; Yuen 2019).

Figure 1. Study flow diagram



In total, we included 11 studies in this review update (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; Richards 2005; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013; Yuen 2019).

Included studies

Ten of the included studies were randomised controlled trials (RCT) (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Mbakile-Mahlanza 2020; Richards 2005; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013; Yuen 2019), and one study was a non-randomised clinical trial (Orsulic-Jeras 2000). Most of the studies used a parallel group design and randomised clusters (the units of allocation were nursing homes or nursing home wards) to the study groups (Cohen-Mansfield 2007; Cohen-Mansfield 2012), individual participants (Kolanowski 2011; Richards 2005; Travers 2017; Van Haitsma 2015; Yuen 2019) or matched pairs of participants (Wenborn 2013). Two studies used a cross-over design and randomised clusters (Mbakile-Mahlanza 2020) and individual participants (van der Ploeg 2013) to the study groups. The duration of follow-up ranged from 10 days (Cohen-Mansfield 2007) to nine months (Orsulic-Jeras 2000).

Setting and Participants

Six studies were conducted in the USA (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015), three in Australia (Mbakile-Mahlanza 2020; Travers 2017; van der Ploeg 2013), one in the UK (Wenborn 2013), and one in Hong Kong (Yuen 2019). Most studies recruited the participants from nursing homes and one study recruited from a special care unit (Orsulic-Jeras 2000).

A total of 1339 participants were recruited, and 1071 participants completed the studies. The number of participants completing the studies ranged from 25 (Orsulic-Jeras 2000) to 180 (Van Haitsma 2015).

The mean age of participants ranged from 78 to 88 years; this information was not reported in one study (Mbakile-Mahlanza 2020). The majority of participants were female in most of the studies (63% to 92%), except in one study where the proportion of women was 48% (Richards 2005); no information was available in one study (Mbakile-Mahlanza 2020).

The studies assessed cognitive function at baseline with different instruments, but almost all of the participants in the included studies had severe dementia. Seven studies used the Mini-Mental State Examination (MMSE) (range 0 to 30, higher scores indicate more severe cognitive impairment). In most studies the mean MMSE scores were lower than 12 (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Orsulic-Jeras 2000; Richards 2005; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013). In one study the scores ranged from 12 to 15 (Kolanowski 2011), and in one study that used the standardised Mini-Mental State Examination (sMMSE) the mean scores were 19 (intervention group) and 16 (control group), respectively (Travers 2017). Mbakile-Mahlanza 2020 used the Clinical Dementia Rating Scale (range 6 to 30, higher scores indicate more severe cognitive impairment). The mean value in the group with the intervention period first was approximately 21.9, and the group who received the control period first had a mean score of 26.8. Yuen 2019 assessed cognition with the Global Deterioration Scale, and the participants were in stage 4 and 5 (intervention group 66%, control group 83%, moderate cognitive decline), and in stage 6 and 7 (intervention group 34%, control group 17%, severe cognitive decline).

In five studies, agitation or challenging behaviour at baseline was an inclusion criterion for participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Travers 2017; Yuen 2019); and in one study, physical agitation at baseline was an inclusion criterion (van der Ploeg 2013). In four studies without such an inclusion criterion, all participants showed some form of agitation or challenging behaviour (Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; Van Haitsma 2015; Wenborn 2013); one study provided no information about participants' agitation (Richards 2005) (see Characteristics of included studies).

Description of the interventions

Nine of the interventions offered personally tailored activities directly to the participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Yuen 2019). In the study by Mbakile-Mahlanza 2020, family members who regularly visit the people with dementia in the nursing home were trained to deliver the intervention. In the study by Wenborn 2013, members of the nursing staff were trained to deliver the personally tailored activities to the study participants.

In this section, we describe the included interventions using categories relevant for complex interventions (Hoffmann 2014; Möhler 2015).

Theoretical basis and components of the interventions

Choice of activities in the included studies was based on different theoretical models. The theoretical basis guided the selection of activities which could be offered to the participants, and the methods by which the interventions were individually tailored, i.e. how the activities were chosen for the individual participants. The interventions in Cohen-Mansfield 2007 and Cohen-Mansfield 2012 were based on the Treatment Routes for Exploring Agitation (TREA) framework. Kolanowski 2011 used the Need-Driven Dementia-Compromised Behavior (NDB) model and tested three different treatment conditions. Four studies used the principles of Montessori (Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; van der Ploeg 2013; Yuen 2019). In three studies, the interventions were not based on a specific theoretical framework; however, in all studies the choice of activities followed predefined principles.

The Treatment Routes for Exploring Agitation (TREA) framework

The TREA framework provides a systematic approach for individualising non-pharmacological interventions to unmet needs of people with dementia and agitation (Cohen-Mansfield 2000). The TREA framework assumes that different types of agitated behaviours have different aetiologies. To create an individual intervention, the aetiology of the agitated behaviour must be identified. Individual interventions have to be developed based on the remaining abilities of the individual, his/her deficits, e.g. in sensory perception, cognition, and mobility, and personal preferences, e.g. past work, hobbies, important relationships, and sense of identity. With the TREA framework, individual needs and preferences of people with dementia exhibiting agitated behaviours could be assessed by using information from formal or informal caregivers (e.g. nursing staff or family

members, respectively), or by observing the person's behaviour and environment. The TREA framework "can be viewed as a decision tree that guides caregivers through the necessary steps for exploring and identifying underlying unmet needs that contribute to agitated behaviours" (Cohen-Mansfield 2007).

The studies by Cohen-Mansfield 2007 and Cohen-Mansfield 2012 used the TREA decision tree protocol to identify all agitated behaviours exhibited by the individual participants and the possible reasons for these behaviours. For each participant, a 4-hour peak period of agitation was identified at baseline. The intervention was individualised and administered to each participant based on this peak period. Information on the needs and preferences of the participant was identified by providing his or her relatives with a questionnaire to complete, including items concerning the participant's medical history, self-identity, and social functioning. Based on this assessment, corresponding activities were offered (Cohen-Mansfield 2007; Cohen-Mansfield 2012).

Examples of activities offered were: individualised music, family videotapes and pictures, illustrated magazines and large print books, board games and puzzles, plush toys, sorting cards with pictures and words, stress balls, baby dolls, electronic massagers, pain treatment, outdoor trips to the garden of the nursing home, perfume, and Play-Doh (Cohen-Mansfield 2007; Cohen-Mansfield 2012).

Need-Driven Dementia-Compromised Behavior model

The NDB model defines behavioural symptoms as an indicator showing unmet needs of people with dementia (Algase 1996). Two aspects are described as potential reasons for behavioural symptoms: background risk factors (neuropathology, cognitive deficits, physical function, and premorbid personality); and proximal precipitating factors (qualities of the physical and social environment, and physiological and psychological need states) (Algase 1996). In this model, personally tailored activities can be seen as proximal factors that meet individual needs, since they aim to enrich the physical and social environment by matching the individual's background factors (Kolanowski 2005).

In the study by Kolanowski 2011, the activities offered based on the NDB model were individually tailored to the participants' cognitive and physical functional level and to their style of interest. Style of interest was defined by the participants' personality traits of extraversion (preferred amount of social stimulation) and openness (individual tolerance for the unfamiliar). Kolanowski 2011 assessed style of interest using form F from the Revised NEO Personality Inventory (NEO-PI-R, Costa 1992). For choosing the activities, both the participants' style of interest and the cognitive and physical functional levels were relevant. Kolanowski 2011 tested three treatment conditions based on this framework: (1) activities matched to the participants' (cognitive and physical) functional level, but opposite to their identified style of interest; (2) activities matched to the participants' style of interest, but not their functional level; (3) activities matched to both the participants' functional level and style of interest. Examples of activities offered were: games, puzzles, music (listening or making music), crafts (e.g. making a birdhouse), pet visits, sewing cards, cooking, painting (Kolanowski 2011). In this review, we considered only the activities matched both to the participants' functional level and style of interest to be personally tailored activities.

Principles of Montessori

The principles of Maria Montessori were originally developed to guide child education. This approach put emphasis on task breakdown, guided repetition, progression in difficulty from simple to complex, and the careful matching of demands to levels of competence. Meanwhile, the approach was adapted to be used with people with dementia. Activities offered to people with dementia "are designed to tap procedural memory which is better preserved than verbal memory while minimising language demands and providing external cues to compensate for cognitive deficits" (van der Ploeg 2013).

In the study by van der Ploeg 2013, a maximum of 10 activities were selected based on discussion with families about participants' former interests and hobbies. Mbakile-Mahlanza 2020 adapted the intervention and offered training for family caregivers regularly visiting the nursing home residents to select 10 activities based on the residents' former interests and current physical abilities and language skills. Orsulic-Jeras 2000 used the Myers Menorah Park/ Montessori Assessment System (MMP/MAS) to individualise the activities. MMP/MAS is a Montessori-based instrument and provides information on participants' areas of interest.

The intervention investigated by Yuen 2019 (DementiAbility Methods: The Montessori Way (DMMW)) aims to establish a meaningful engagement of people with dementia in individualised activities, roles, and routines in a prepared environment. The intervention comprise five steps.

1. Participants were invited via presenting the environment prepared for engagement in tailored activities.
2. Sequences of activities were demonstrated to facilitate participants to perform procedural movements and utilise activity materials.
3. Activities were tailored based on the participants' needs, interests, abilities, and skills.
4. The environment was prepared to be meaningful, purposeful, and home-like, and the materials used were familiar and pleasing to the participant.
5. The activities were performed and role-related tasks were accomplished with the participant and the next session was announced.

Examples of activities offered by Orsulic-Jeras 2000 were: individual Montessori activities (with materials usually taken from the everyday environment e.g. utensils, bowls, flowers, baskets); group Montessori-based activities (memory bingo); and a structured reading and discussion group. van der Ploeg 2013 offered activities like sorting cards or making puzzles from familiar photographs. Mbakile-Mahlanza 2020 and Yuen 2019 did not report examples of the activities offered.

Individualised social activity intervention

The intervention by Richards 2005 was based on a conceptual framework which postulated (based on the two-process model of sleep) that individualised activities can improve the homeostatic sleep drive and strengthen circadian processes; and that this may lead to improved nighttime sleep and decreased daytime sleep (Richards 2005).

The activities were preselected to match various interests as well as cognitive and functional abilities. About 100 different activities were identified by two therapeutic recreation specialists with more than 20 years of collective experience working with nursing home residents with dementia. A list was created comprising the following information for all activities: brief directions for use, which functional limitations preclude their use, and which previous interests of participants are associated with each activity. The activities were also grouped into activities which were appropriate for everyone, and those which were appropriate for participants with mild (MMSE > 15), moderate (MMSE 5 to 15), and severe (MMSE < 5) dementia. The activities offered were selected according to four characteristics of each participant: interests (work and leisure history), cognition and functional status (mobility, hearing, vision, fine motor skills), and napping patterns (time of unscheduled naps). This information was assessed by means of interviews with families, nursing staff, and participants, observation of participants' behaviour, chart review, and by using an Actigraph (for napping patterns).

Examples of the activities offered were: listening to music, petting a toy cat, tossing a ball, writing a letter, playing checkers, making a wreath, preparing and serving a snack (Richards 2005).

Occupational therapy programme

Wenborn 2013 offered an occupational therapy programme. The primary author, an occupational therapist with experience in working with older people with dementia, developed the intervention.

The intervention consisted of two components.

1. An assessment of the care home's physical environment, including recommendations on how it could be adapted and enhanced to enable the residents to engage in activities.
2. An education programme for nursing staff that aimed to enhance knowledge, attitudes and skills, based on the principles of experiential learning. The educational component comprised five two-hour education sessions covering these topics: identify the residents' interests and abilities; choose and offer activities; review and record the outcomes. The care home manager joined the last session to agree an activity action plan for continued implementation of the programme. To ensure the use of the skills and tools in clinical practice, work-based learning tasks with two residents were conducted between the educational sessions, and one-to-one coaching sessions with the primary investigator were held. The activities were personalised to each resident by the use of the Pool Activity Level Checklist (Wenborn 2008).

Individualised Positive Psychosocial Intervention

The study by Van Haitsma 2015 was based on two theoretical models: the Self-Determination Theory (Deci 2000); and Broaden-and-Build Theory (Fredrickson 2001). The Self-Determination Theory proposes that all people have innate needs for autonomy and competence, which must be fulfilled for psychological well-being; and the Broaden-and-Build Theory focusses on the critical role of positive emotions to improve the person's well-being. The study is described as being based on the work of Kolanowski 2011, but there were no details about how this study contributed to the design of the intervention or the study.

The Individualised Positive Psychosocial Intervention (IPPI) offered five basic types of activities reflective of the most common preferences.

- Physical exercises (e.g. outdoor walk, work with clay).
- Music (e.g. singing or listening to a favourite artist).
- Reminiscence (e.g. reviewing family photos, writing letters).
- Activities of daily living (e.g. manicures, preparing a snack).
- Sensory stimulation (e.g. hand massage with lotion, smelling fresh flowers).

From each group, two or more specific activity options were offered (a total of 30 activity options). The activities were selected by researchers and clinicians for each resident based on the Preferences for Everyday Living Inventory-Nursing Home (PELI-NH; Van Haitsma 2000). The information was taken directly from the participant or from a family member, activity therapist, or other direct care staff.

BE-ACTIV

The BE-ACTIV intervention was originally developed by Meeks 2008 to increase the engagement in activities of nursing home resident with depression. The intervention was based on the integrative behavioural model of depression in older adults. The aim of the intervention is to address reduced positive affect by systematically increasing positive events and activities (Meeks 2008). Travers 2017 adapted the intervention for people with mild to moderate dementia and depression, and to the local and cultural context of Australia.

A Mental Health Therapist offered weekly individual sessions for each participant to identify pleasant activities or events tailored to the participants' abilities and the nursing home environment, and to develop an individual activity plan that aimed to increase the frequency of those events. Furthermore, the events in the previous week were reviewed to identify barriers for being engaged in the planned pleasant events, solve problems and to revise the plan for the next week, if necessary. In addition, two 90-minutes sessions with information about depression and dementia in nursing home residents was offered to staff members and volunteers of the participating nursing homes. In each nursing home, one staff member was nominated to be actively involved as co-therapist during the intervention period. This staff member attended the therapist's sessions with the participants in the first, fourth and eighth week, and supported the engagement of the participant in the individually selected pleasant activity or event during the intervention period. If the participants agreed, the co-therapist also invited the participant's relatives to assist with the implementation of pleasant activities or events, for example with activities outside the nursing home.

The most often selected pleasant activities or events were: reading a book, newspaper or magazine; being pushed around the grounds in a wheelchair or scooter; sitting outside in the sun or fresh air; having a hand massage or manicure; and attending an event in the nursing home.

Feasibility/pilot test

Richards 2005 tested their intervention in a pilot study (Richards 2001). Kolanowski 2011 and Cohen-Mansfield 2012 used previous studies as a pilot-test for their interventions (Kolanowski 2005;

Cohen-Mansfield 2007). The intervention by Orsulic-Jeras 2000 was based on experiences from an earlier project. Mbakile-Mahlanza 2020 investigated an intervention that was already evaluated by van der Ploeg 2013Travers 2017 conducted a pilot study investigating an adapted version of an intervention that was already evaluated in a different population (people with depression, but no dementia; Meeks 2008). Prior to the Yuen 2019 study, the intervention had been implemented in practice projects in Hong Kong and some case series had been conducted in Canada, but no pilot study was conducted. The remaining four studies did not provide any information on a feasibility or pilot-test (Cohen-Mansfield 2007; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013).

Delivery of the intervention

In most studies, the interventions were delivered directly to the study participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Yuen 2019). In the study by Richards 2005, activities were delivered individually; however, when the same activity was selected for more than one participant at the same time, the activity was offered in groups of up to three participants. The intervention by Orsulic-Jeras 2000 comprised both individual and group activities (see above: 'Theoretical basis and components of the interventions – Principles of Montessori'). In the study by Wenborn 2013, members of the nursing staff were trained to select, plan and deliver the activities within daily care, and Mbakile-Mahlanza 2020 trained family members to offer the activities during their visits to the nursing home.

Although all studies based the selection of activities on an assessment of the participants' present or former preferences, no information was presented in any study about the number of participants who were able to express their individual interests or preferences. Also, no study reported information about the proportion of participants for whom preferences and interests were assessed through the primary caregiver or family members.

There were differences between studies in the number and frequency of sessions delivered, and in the length of the follow-up period. The frequency of delivering the activity sessions ranged from daily (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Richards 2005) to once per week (Travers 2017). Most studies included a short follow-up period, from 10 consecutive days (Cohen-Mansfield 2007) to up to three weeks (Van Haitsma 2015). Two studies had a longer follow-up period: eight weeks in Travers 2017 and nine months in Orsulic-Jeras 2000. A detailed overview of the delivery of the interventions is displayed in Table 1 (see also Characteristics of included studies).

Five studies used materials guiding the training and the implementation of the interventions (Kolanowski 2011; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013): Wenborn 2013 used written manuals or guidelines, and Kolanowski 2011 used a treatment fidelity plan. In the Travers 2017 study, the study coordinator additionally contacted the therapist once per week during the intervention period to improve the treatment fidelity and to address any difficulties that arose.

Information about the implementation process and the implementation fidelity was assessed in five studies (Cohen-Mansfield 2012; Kolanowski 2011; Travers 2017; Van Haitsma 2015; Wenborn 2013). Cohen-Mansfield 2012 used a questionnaire to assess information about the implementation process and barriers and facilitators. Kolanowski 2011 used a treatment fidelity plan to ensure the introduction of the intervention as planned. Also, the research assistants paid attention to potential confounding factors (e.g. pain, thirst, poor environmental conditions). Treatment fidelity was checked for 10% of the intervention sessions. Re-training took place if the intervention was not implemented according to the protocol. Only one deviation from the protocol occurred. Van Haitsma 2015 assessed implementation fidelity during randomly selected sessions. A member of the research team observed compliance with study procedures in both the intervention and active control group. Overall, adherence to protocol was 68%, with higher rates in the intervention group (73%) compared to the active control condition (60%). In the study by Wenborn 2013, the number of staff attending each session was recorded, and feedback regarding the work-based learning activities was collected from nursing staff and residents. A mean staff attendance of 73% was recorded for the education sessions (range 63 to 86) and a mean uptake of 81% for the individual coaching sessions (range 49 to 100). Reasons for non-attendance at the sessions included: being off duty (22%); annual leave (20%); on duty but not available (14%); sick leave (12%); study leave (11%); staff personal commitment (11%); and left the care home (9%). No information was collected on the amount of activities delivered to the residents by the nursing staff. Travers 2017 used qualitative interviews with nursing staff or volunteers (n = 14) to collect data about the target group's opinion regarding the feasibility of the intervention, implementation fidelity and the perceived impact on participants' mood or behaviour.

Characteristics of the control conditions

Six studies offered an active control condition (Kolanowski 2011; Mbakile-Mahlanza 2020; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Yuen 2019). The study by Kolanowski 2011 offered activities to the participants that were functionally challenging and opposed to the participant's style of interest (based on the NDM model). In the study by Mbakile-Mahlanza 2020, family members of the participants received an initial three-hour group session (30 minutes to complete the baseline questionnaires, 90 minutes of education about dementia, 60 minutes of discussion of the presented materials in small groups). Two active control sessions were conducted each week for two weeks. The family members were asked to read a newspaper with the resident to provide them with some structure. van der Ploeg 2013 used non-personalised one-to-one interactions aimed at engaging the participants in social interaction, e.g. general conversations or conversation based on newspaper stories and pictures. Van Haitsma 2015 offered standardised one-to-one social interaction activities (e.g. discussing a magazine). In the study by Travers 2017, a volunteer member of the nursing home staff engaged the participants in the control group in a walking and talking intervention for 30 minutes, based on the participants' walking ability and preferences (sitting and talking was also possible). The volunteers were to have used open-ended questions and stimuli from the environment to engage the resident in conversation. Yuen 2019 offered six sessions (45 minutes each) with structured social activities. Each session comprised an introduction, the implementation of preset activities (i.e. discussion on newspaper topics and pictures; table games), and a round-up.

In six studies, the control condition was usual care (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015; Wenborn 2013). Van Haitsma 2015 offered both an active control group and a usual care control group. In the study by Orsulic-Jeras 2000, the control group received the usual activities of the centre (individual, small-group, and large-group activities, including: bingo, storytelling, trivia, exercise, modified sporting activities, watching movies, discussion groups, musical programmes, sensory stimulation, and activities based on the participants' interests and hobbies; delivered by an activity therapist or nursing assistants). Cohen-Mansfield 2007 and Cohen-Mansfield 2012 offered a presentation to the nursing staff about the different forms of agitation, their aetiologies, and possible non-pharmacological intervention; but this was not counted as active control group. Three studies reported no further information about usual care (Richards 2005; Van Haitsma 2015; Wenborn 2013).

Outcomes and data collection methods

Primary outcomes

Agitation

Eight studies assessed agitation (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013; Yuen 2019).

Cohen-Mansfield 2007 and Cohen-Mansfield 2012 used the Agitation Behavior Mapping Instrument (ABMI; Cohen-Mansfield 1989a). ABMI is a 19-item instrument to rate agitation in nursing homes by direct observation (a higher score indicates more agitation).

Kolanowski 2011 and Orsulic-Jeras 2000 used the Cohen-Mansfield Agitation Inventory (CMAI; Cohen-Mansfield 1989b), and Yuen 2019 used the Chinese version (CMAI-C). The CMAI is a proxy-rating instrument used by nurses to assess agitation and comprises 29 agitated behaviours. Each behaviour is rated on a 7-point scale (1 = never to 7 = several times an hour). Higher scores indicate greater agitation.

Kolanowski 2011 also used the Passivity in Dementia Scale (PDS), a proxy-rating instrument with 53 items (range −16 to 40, a higher score indicates less passivity; Colling 2000).

van der Ploeg 2013 selected one specific behaviour for each participant based on the nurses' rating in a two-week period before baseline assessment by the CMAI. For each participant, the nurse directly observed whether this specific behaviour occurred within 30 minutes in one-minute intervals. The observation resulted in an individual behaviour score for each participant ranging from 0 to 30 points per session. The outcome score (mean and SD) was calculated using the observations from all sessions (n = 1.056 observations from all study participants). A higher score indicates a more frequent behaviour.

Van Haitsma 2015 assessed different categories of verbal and nonverbal behaviour by direct observation. Within a 10-minute "behaviour stream", the onset and cessation of specific behaviours were recorded. Verbal behaviour was categorised as very negative (swearing, screaming, mocking), negative (incoherent, repetitious statements, muttering), positive (coherent conversation, responding to questions), very positive (complimenting, joking) or no verbal behaviour. Nonverbal behaviour was categorised as: psychosocial task (manipulates or gestures towards an object, engages in conversation), restlessness (pacing, fidgeting, disrobing), null behaviour (stares with fixed gaze, eyes unfocused), eyes closed (sits or lies with eyes closed), aggression (hitting, kicking, pushing, scratching, spitting), uncooperative (pulling away, saying "no", turning head or body away), and positive touch (appropriate touching, hugging, kissing, hand holding). Higher scores indicated a higher frequency of the behaviour.

Wenborn 2013 used the Challenging Behaviour Scale (CBS; Moniz-Cook 2001) to assess the incidence, frequency and severity of challenging behaviour. The CBS is a 25-item proxy-rating instrument used by nurses (higher scores indicate more challenging behaviour).

Quality of life

Quality of life was assessed in two studies (Travers 2017; Wenborn 2013), and both studies used the Quality of Life in Alzheimer's Disease (QoL-AD) scale. The instrument comprises 15 items, each rated on a 4-point scale (1 (poor QoL) to 4 (excellent QoL), range 15 to 60, higher scores indicate a higher quality of life; Logsdon 1999).

Secondary outcomes

Affect

Cohen-Mansfield 2007 and Cohen-Mansfield 2012 used Lawton's Modified Behavior Stream (LMBS; Lawton 1996), covering the following modes of affect: pleasure, interest, anger, anxiety, and sadness. A higher score indicates greater display of the affect.

Four studies used the Philadelphia Geriatric Center Affect Rating Scale (ARS; Lawton 1996), covering the following modes of affect: pleasure, anger, anxiety, sadness, interest, and contentment (Kolanowski 2011; Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; van der Ploeg 2013). A higher score indicates greater display of the affect. In the study by Kolanowski 2011, anger and sadness were not used due to the inability to obtain adequate reliability for their measure. Two studies categorised results as positive or negative affect (Cohen-Mansfield 2012; van der Ploeg 2013); van der Ploeg 2013 used also the category 'neutral affect'. van der Ploeg 2013 calculated outcome scores (mean and SD) based on the observations from all sessions (n = 1.056 observations from all study participants).

Van Haitsma 2015 assessed the duration of different types of affect by direct observation within a 10-minute "behaviour stream". Positive affect included pleasure (smiling, laughing, singing, nodding) and alertness (eyes following object, intent fixation on object or person, visual scanning, eye contact maintained). Negative affect included sadness (crying, tears, moaning, sighing, mouth turned down at corners), anger (clenched teeth, grimace, pursed lips, eyes narrowed), and anxiety (furrowed brow, motoric restlessness, repeated or agitated motion, hand wringing, leg jiggling). A higher score indicates more frequent occurrence of the specific type of affect.

Wenborn 2013 assessed anxiety using the Rating Anxiety in Dementia scale (RAID; Shankar 1999), with scores of 11 or above indicating clinical anxiety.

Engagement

Three studies measured engagement. Kolanowski 2011 assessed time on task (minutes/seconds; range 0 to 20 minutes), and intensity of participation (ranging from 0 ("dozing") to 3 ("actively engaged"), based on Kovach 1998). Orsulic-Jeras 2000 used the Myers Research Institute Engagement Scale (MRI-ES; Judge 2000) (range 0 to 600, higher score indicates more engagement).

Mbakile-Mahlanza 2020 and van der Ploeg 2013 used the Menorah Park Engagement Scale (MPES) (range 0 to 30, higher values indicate more engagement) (Skrajner 2007). Both scales assessed four types of engagement: constructive engagement (e.g. actively handling objects or talking); passive engagement (e.g. watching or listening); self-engagement (e.g. fiddling with clothes); and non-engagement (e.g. a blank stare). van der Ploeg 2013 combined non- and self-engagement into the category 'negative engagement'; and calculated outcome scores (mean and SD) based on the observations from all sessions (n = 1.056 observations from all study participants).

Mood

For this outcome, we included studies that directly assessed mood and studies that assessed depression.

The study by Kolanowski 2011 assessed mood with the Dementia Mood Picture Test (range 0 to 12, higher score indicates more positive mood; Tappen 1995).

Three studies assessed depression. Orsulic-Jeras 2000 and Wenborn 2013 used the Cornell Scale for Depression (CSD; range 0 to 38; score ≥ 8 indicates depression; Alexopoulos 1988). Travers 2017 used the Geriatric Depression Scale, including 12 items about symptoms of depression suitable for older people with cognitive impairment (range from 0 to 12, a score ≥ 4 indicates probable depression).

Other outcomes (residents)

Richards 2005 assessed the daytime minutes slept, nighttime minutes to sleep onset, minutes slept, minutes awake, sleep efficiency, and the day/night sleep ratio using an Actigraph (motion-sensing device), as well as the costs of implementing the intervention.

Caregiver outcomes

Mbakile-Mahlanza 2020 assessed several caregiver outcomes: caregivers' quality of life (assessed by Carer-QoL, seven-item questionnaire); carer-resident's quality of relationship (instrument with a 5-point Likert scale and the Mutuality Scale of the Family Caregiving Inventory with 15 items); carer's mastery (assessed by the Pearlin Mastery Scale); and carer's mood (assessed by the Center for Epidemiological Studies Depression Scale (CES-D), a 20-item self-reported scale of depressive symptoms, including mood, self-esteem, energy, relationships, sleep and appetite).

Costs

Only one study assessed intervention cost, e.g. costs for staff training, delivery of activities and administration of the intervention (Richards 2005).

None of the included studies performed an economic evaluation.

Duration of the effects

Two studies aimed to assess the duration of the intervention effects. Kolanowski 2011 assessed the effect one week after the intervention period was completed, and van der Ploeg 2013 additionally assessed all outcomes after each session.

Excluded studies

We excluded studies because the intervention or the study design did not meet our inclusion criteria. See Characteristics of excluded studies for the reasons for exclusion of the studies screened in full text.

Risk of bias in included studies

For the original review we contacted corresponding authors of all studies and asked for additional information on methodological details that were not reported in the publications (we sent one reminder to all non-responding authors). Five authors responded to our request (A Kolanowski, J Cohen-Mansfield, S Orsulic-Jeras, E van der Ploeg, K Van Haitsma), and four authors offered additional information; one author did not, for personal reasons.

We also contacted corresponding authors of all newly included studies and for one study we also contacted the senior author (Mbakile-Mahlanza 2020). We sent one reminder to all authors. None of the contacted authors responded to our request.

The methodological quality of the included studies varied. We judged the risk of bias as unclear in at least two domains in all studies, and seven studies additionally had a high risk of bias in at least one domain (Cohen-Mansfield 2007; Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; Richards 2005; Travers 2017; van der Ploeg 2013; Van Haitsma 2015).

For further information see Characteristics of included studies, Figure 2, and Figure 3.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

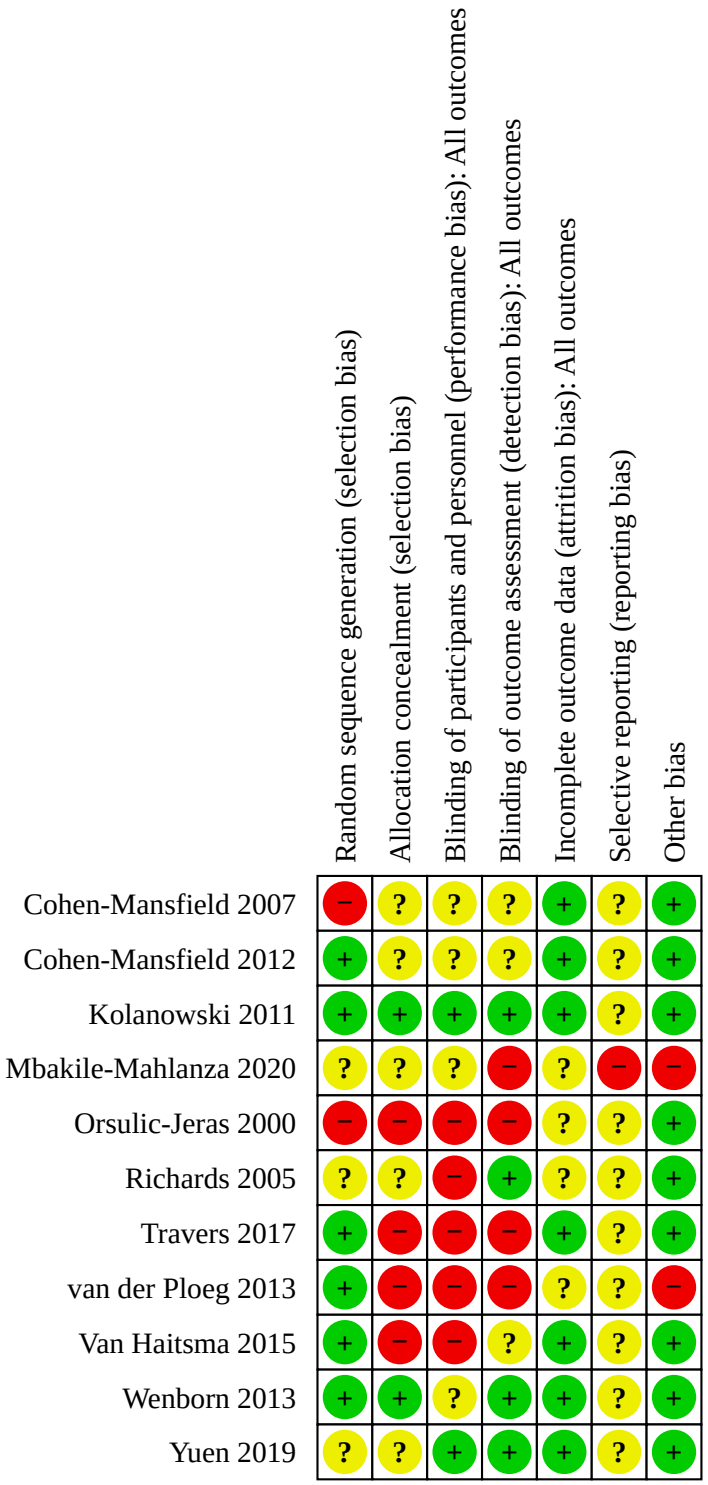
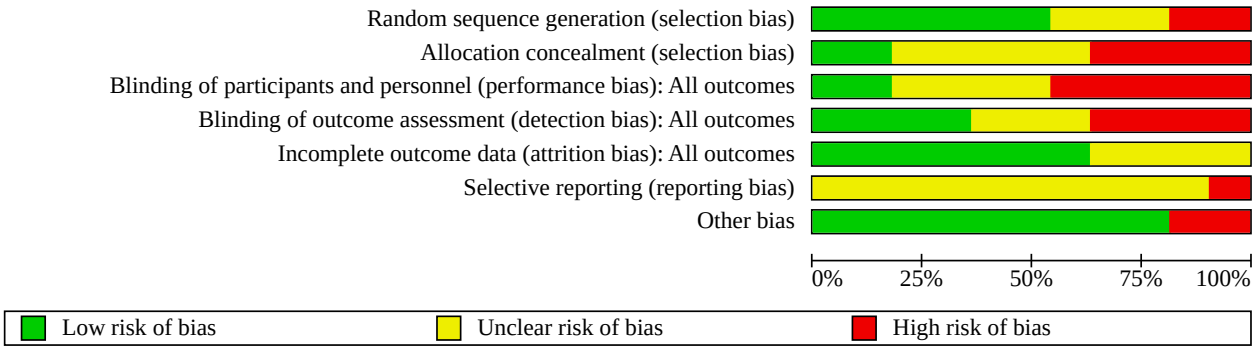


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

The randomisation sequence was adequately generated in six studies (Cohen-Mansfield 2012; Kolanowski 2011; Travers 2017; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013). Van Haitsma 2015 used a two-step randomisation procedure; in the first step the included nursing home units were allocated to deliver one of the two active treatments (intervention or active control); and in the second step, the eligible residents in each ward were allocated to the active treatment or usual care (eligible participants were identified before allocation). In the study by Mbakile-Mahlanza 2020, baseline imbalances in some criteria occurred, e.g. time the participants lived in the nursing home, dementia severity and physical agitation. These differences might be a result of the small sample size, but we have insufficient information to permit judgement of ‘low risk’ or ‘high risk'. Three studies did not report sufficient information about the method of sequence generation (Cohen-Mansfield 2007; Richards 2005; Yuen 2019). We considered risk of bias in this domain to be unclear for Richards 2005 and Yuen 2019. In the study by Cohen-Mansfield 2007 two clusters were not randomly assigned to the study groups, because the facility managers had a strong preference for the intervention group; we judged the risk of bias in this domain to be high.

Allocation to the study groups was adequately concealed in two studies (Kolanowski 2011; Wenborn 2013). Five studies reported insufficient information about allocation concealment (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Mbakile-Mahlanza 2020; Richards 2005; Yuen 2019) (risk of bias judged to be unclear); and in three studies allocation was not concealed (Travers 2017; van der Ploeg 2013; Van Haitsma 2015) (risk of bias judged to be high).

In the study by Orsulic-Jeras 2000 group allocation was not performed at random. Participants were allocated to the groups using matching based on the MMSE score, MMP/MAS and the reading subtest of the Wide Range Achievement Test (WRAT3). We considered this study to be at high risk of selection bias.

Blinding

In six studies, blinding of participants and personnel was not possible since the participants in the control group did not receive an intervention (usual care) (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015; Wenborn 2013). In three of these studies, clusters were allocated to the study groups, and we have insufficient information whether this might have led to a risk of bias (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Wenborn 2013). Three studies allocated individual participants to the study groups and personnel cared for participants in both the intervention and the control group (Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015). For these studies we judged risk of performance bias to be high. Of the five studies that offered an active control group, blinding of participants and personnel was adequate in two studies (Kolanowski 2011; Yuen 2019). Two studies reported insufficient information; one of these studies allocated clusters to the study groups, and we have insufficient information to permit judgement of 'low risk' or 'high risk' of bias (Mbakile-Mahlanza 2020). The other study allocated individual participants to the study groups and personnel cared for participants in both the intervention and the control groups. Although this study offered an active control group, personnel were aware of the study methods, and we judged risk of performance bias to be high (Travers 2017). In one study, personnel not blinded to group allocation delivered both the intervention and the active control activities; we judged the risk of performance bias to be high in this study (van der Ploeg 2013).

Outcome assessors were blinded to group allocation in three studies (Kolanowski 2011; Wenborn 2013; Yuen 2019). In Richards 2005, outcome assessors were not blinded to group allocation, but sleep-related outcomes were assessed by an objective measure (Actigraphy). We judged risk of detection bias to be low. In two studies, unblinded raters assessed study outcomes (Cohen-Mansfield 2007; Cohen-Mansfield 2012). For a subgroup of intervention participants, research assistants performed a blinded assessment based on videotaped activity sessions. There was high agreement between the blinded and unblinded ratings. In the study by Van Haitsma 2015, trained research assistants used a technical device to collect outcome data, but no information about blinding was reported. For these studies, we have insufficient information to permit judgement of ‘low risk’ or ‘high risk'. In four studies unblinded staff collected outcome data, and we judged risk of detection bias to be high (Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; Travers 2017; van der Ploeg 2013).

Incomplete outcome data

Attrition rates were low and reasons for attrition were documented in seven studies, so we judged the risk of attrition bias to be low (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Travers 2017; Van Haitsma 2015; Wenborn 2013; Yuen 2019).

The attrition rate in Richards 2005 was also low, but the study did not report any information about the group allocation of the participants lost to follow-up. Mbakile-Mahlanza 2020 reported an attrition rate of 20%, but did not report any information about the study period in which the participants were lost to follow-up (intervention or control condition first; cross-over trial), or the reasons for attrition. In the study by van der Ploeg 2013, the attrition rate was more than twice as high as anticipated (anticipated attrition rate 10%; actual attrition rate 23% (13/57)). In the study by Orsulic-Jeras 2000, only 25 of 44 participants completed the study, but the group allocation of the participants lost to follow-up was not reported. We considered the risk of attrition bias for these studies to be unclear, since there was no evidence that attrition was due to the intervention.

Selective reporting

Six studies were registered, two studies prospectively (Mbakile-Mahlanza 2020; Travers 2017), and a study protocol was available for the Mbakile-Mahlanza 2020 study. However, Mbakile-Mahlanza 2020 was planned as a cluster-randomised trial with a waiting-control group design, but conducted as a cross-over trial, and the primary endpoint defined in the study register was changed in the final publication. We judged risk of reporting bias to be high. Travers 2017 reported only the primary outcome defined in the study registry, and we judged risk of reporting bias to be unclear. The other studies were registered retrospectively (Cohen-Mansfield 2012; Kolanowski 2011; van der Ploeg 2013; Wenborn 2013), or not registered (Cohen-Mansfield 2007; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015; Yuen 2019), and we judged risk of reporting bias to be unclear.

Other potential sources of bias

We rated the two cross-over trials to be at high risk for other bias. Mbakile-Mahlanza 2020 did not include a wash-out period and a carry-over effects was observed. In van der Ploeg 2013 no paired data were available, only data from the entire study period.

Effects of interventions

See: **Summary of findings 1** Personally tailored activities compared to usual care or non-personalised activities for people with dementia

Primary outcomes

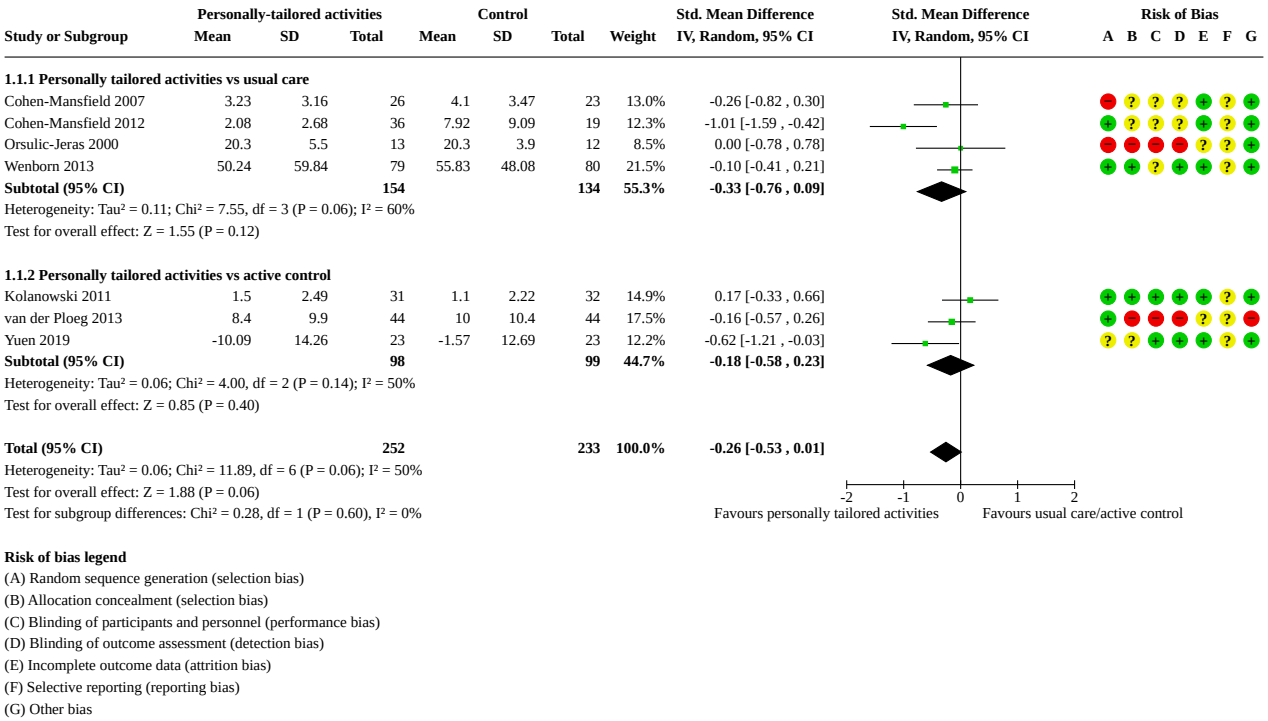
Agitation

We performed a meta-analysis for agitation, including seven studies (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000; van der Ploeg 2013; Wenborn 2013; Yuen 2019). One study was not included in the meta-analysis because the assessed types of behaviours were not comparable with the other studies (Van Haitsma 2015).

We used the SMD, calculated from mean values assessed during or directly after the intervention period or session. For two studies we recalculated the number of participants to incorporate the cluster effect, using an estimate of the ICC (Cohen-Mansfield 2007; Cohen-Mansfield 2012 – see Unit of analysis issues). We used a random-effects model since there was clinical diversity and evidence for moderate heterogeneity (I^2 = 50%). Higher scores indicate more severe agitation.

We found low-certainty evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly reduce agitation (SMD −0.26, 95% CI −0.53 to 0.01; I^2 = 50%; 7 studies, 485 participants; Analysis 1.1; Figure 4). We conducted a subgroup analysis comparing the four studies with a usual care control group and the three studies with an active control intervention. There was no statistically significant subgroup effect and no evidence that heterogeneity could be explained by the nature of the comparator intervention (test for subgroup differences P = 0.60, I^2 = 0%). We observed no other likely explanations for the heterogeneity based on other characteristics of the studies, e.g. population, intervention or outcome measures.

Figure 4. Forest plot (1.1 Agitation)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

In the study by Van Haitsma 2015, the outcomes of general restlessness, aggression, uncooperative behaviour, very negative and negative verbal behaviour seemed to best represent agitation. Higher scores indicate more severe agitation. We found low-certainty evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly improve general restlessness compared to usual care (MD −16.97, 95% CI −18.80 to −15.14; 137 participants; Analysis 1.2), but may make little or no difference in comparison with an active control group (MD 1.22, 95% CI −1.14 to 3.58; 87 participants; Analysis 1.2). Aggression and uncooperative behaviours were rarely observed in all groups; we found low-certainty evidence (downgraded for risk of bias and imprecision) that personally tailored activities may have little or no effect on aggression and uncooperative behaviours (aggression: personally tailored activities vs usual care MD 0.06, 95% CI 0.05 to 0.07; 137 participants; personally tailored activities vs active control MD −0.06, 95% CI −0.07 to −0.04; 87 participants; uncooperative behaviour: personally tailored activities vs usual care MD 0.01, 95% CI −0.00 to 0.02; 137 participants; personally tailored activities vs active control MD −0.13, 95% CI −0.15 to −0.12; 87 participants; Analysis 1.2). We also found low-certainty evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly increase very negative verbal behaviour in comparison with usual care (MD 7.75, 95% CI 5.51 to 9.99; 137 participants), but may reduce very negative verbal behaviour in comparison with an active control group (MD −29.33, 95% CI −32.22 to −26.44; 87 participants; Analysis 1.2). For negative verbal behaviours, we found low-certainty evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly increase negative verbal behaviour in comparison with usual care (MD 21.68, 95% CI 17.66 to 25.70; 137 participants; Analysis 1.2), and may make little or no difference to negative verbal behaviour in comparison with an active control group (MD 3.07, 95% CI −2.13 to 8.27; 87 participants; Analysis 1.2).

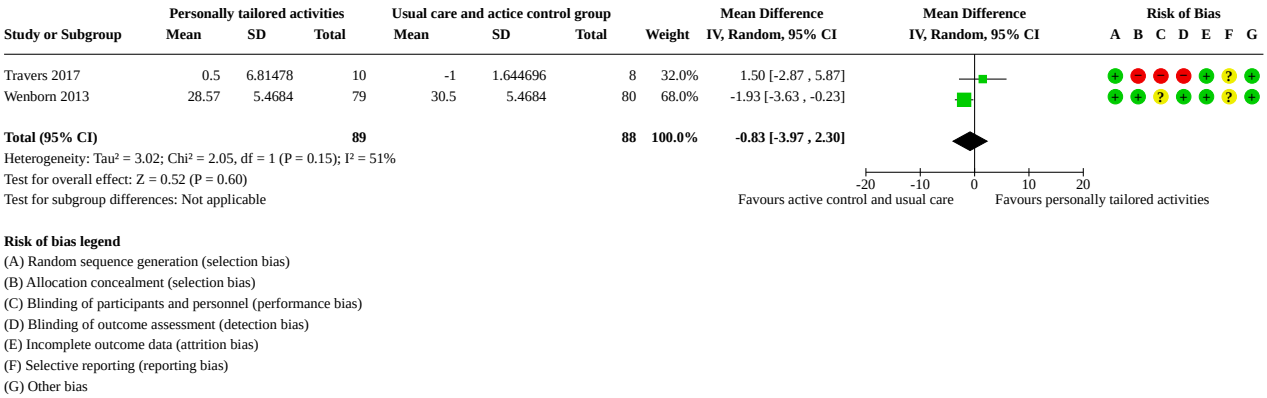
Quality of life

Two studies investigated the effects of personally tailored activities on quality of life using the same instrument, the QoL-AD (Nursing Home version) (Travers 2017; Wenborn 2013). In the study by Travers 2017 the trial co-ordinator assessed quality of life. In Wenborn 2013 study personnel assessed quality of life and a small group of participants, who were able to complete the assessment, rated their quality of life themselves (n = 42 out of n = 139). We used a minimum important difference of three points on the scale used, as defined by Wenborn 2013 (higher scores indicate better quality of life).

For self-rated quality of life, there was low-certainty evidence from one study (downgraded two levels for imprecision) indicating little or no difference between personally tailored activities and usual care (MD 0.26, 95% CI −3.04 to 3.56; 42 participants; Wenborn 2013).

For proxy-rated quality of life, we found low-certainty evidence (downgraded one level for risk of bias and imprecision) that personally tailored activities may result in little to no difference in quality of life in comparison with usual care or an active control group (MD -0.83, 95% CI -3.97 to 2.30; I^2 = 51%; 2 studies, 177 participants; Analysis 1.3; Figure 5). The moderate heterogeneity between the studies may be explained by some differences in the study populations and control groups. Travers 2017 included participants with mild to moderate dementia and depression and had an active control group, while Wenborn 2013 did not select participants with depression and the control group did not receive any intervention (usual care).

Figure 5. Forest plot (1.3 Quality of life - proxy-rate)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Adverse effects

Only two studies assessed adverse effects, and no adverse effects were observed in either study (Cohen-Mansfield 2012; Kolanowski 2011). No information about adverse effects was reported in the other studies.

Secondary outcomes

Affect

Only one of the newly included studies assessed affect (Mbakile-Mahlanza 2020), but the results of this cross-over trial were not included in the analysis since a carry-over effect occurred and no data of the first period of this trial were available.

We performed meta-analyses for positive and negative affect (including six studies in each analysis) and mood (including three studies). For positive affect, we used the results from four studies assessing pleasure (Cohen-Mansfield 2007; Cohen-Mansfield 2012; Kolanowski 2011; Orsulic-Jeras 2000), from one study assessing a combination of pleasure and contentment (van der Ploeg 2013), and for one study we calculated a combination of pleasure and alertness (Van Haitsma 2015; see Data synthesis).

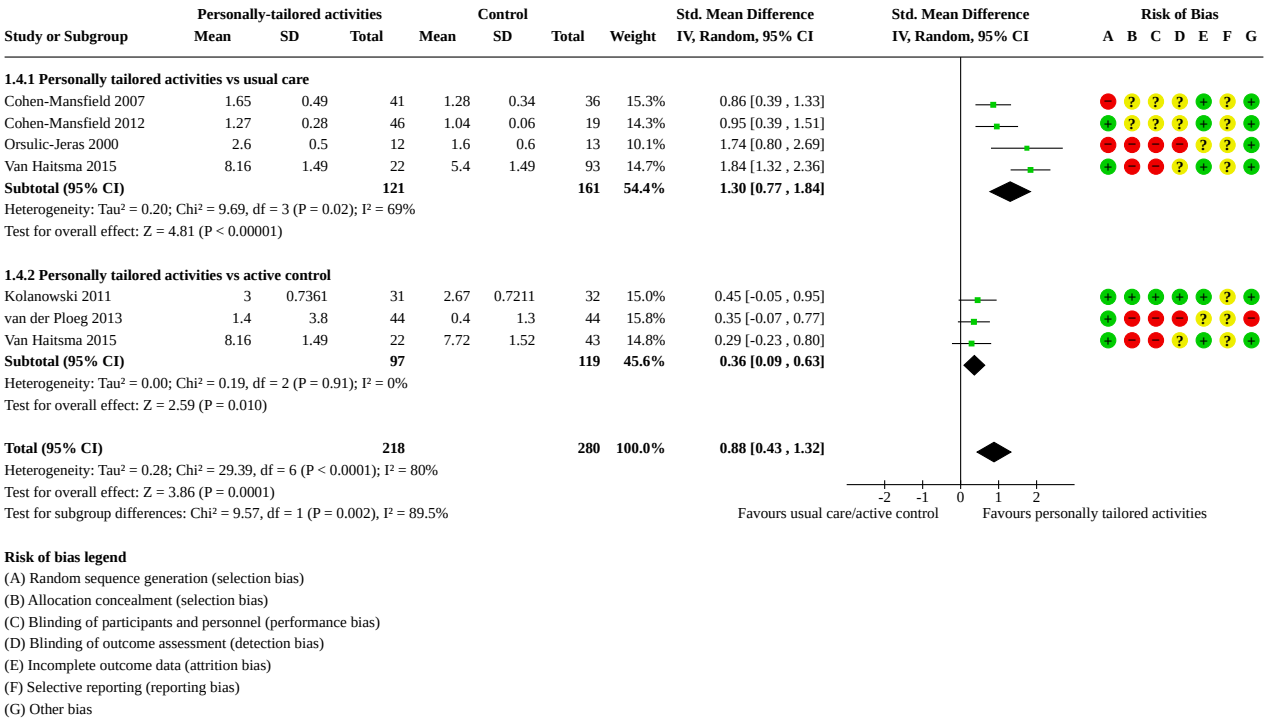
For negative affect, we used the following study data: negative affect calculated from anger, anxiety, and sadness (Cohen-Mansfield 2007; Cohen-Mansfield 2012), negative affect calculated from anger, sadness, and anxiety/fear (van der Ploeg 2013), anxiety or fear (Kolanowski 2011), and anxiety (Wenborn 2013). From Van Haitsma 2015, we calculated negative affect from sadness, anger, and anxiety (see Data synthesis).

For mood, we combined data on mood from one study (Kolanowski 2011), corrected for the differing direction of the scale (see Data synthesis); and data on depression from two studies (Orsulic-Jeras 2000; Wenborn 2013). We used the SMD, calculated from mean values assessed during or directly after the intervention period or session. For two studies, we recalculated the number of participants to incorporate the cluster effect, using an estimate of the ICC (Cohen-Mansfield 2007; Cohen-Mansfield 2012 – see Unit of analysis issues). We used a random-effects model since there was clinical diversity and substantial heterogeneity (I^2 = 84% for positive affect). Higher scores indicate more positive and negative affect, and better mood.

Positive affect

For positive affect, we found very low-certainty evidence (downgraded one level for risk of bias, inconsistency and imprecision) and we are uncertain whether personally tailored activities increase positive affect in comparison with active control groups or usual care (SMD 0.88, 95% CI 0.43 to 1.32; I^2 = 80%; 6 studies, 498 participants; Analysis 1.4; Figure 6). The evidence is also very uncertain about the effect of personally tailored activities on positive affect in comparison with active control groups (SMD 0.36, 95% CI 0.09 to 0.63; I^2 = 0%; 3 studies; 216 participants; Figure 6) or in comparison with usual care (SMD 1.30, 95% CI 0.77 to 1.84; I^2 = 69%; 4 studies; 282 participants; Figure 6; one study contributed to both subgroup analyses; test for subgroup differences P = 0.002; I^2 = 89.5%).

Figure 6. Forest plot (1.4 Positive affect)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

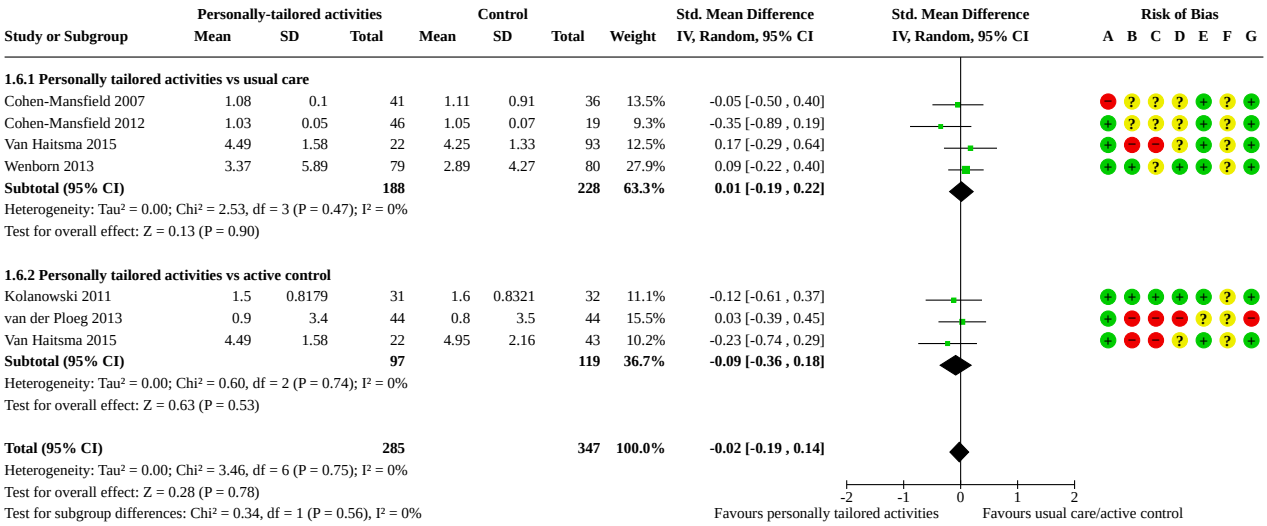
A sensitivity analysis excluding the study for which we derived a combined outcome measure showed an effect similar to the main analysis (SMD 0.76, 95% CI 0.38 to 1.13; I^2 = 58%; 5 studies; 318 participants; Analysis 1.5).

Negative affect

We found moderate-certainty evidence (downgraded one level for risk of bias) that personally tailored activities probably result in little to no difference in negative affect (SMD -0.02, 95% CI −0.19 to 0.14; I^2 = 0%; 6 studies; 632 participants; Analysis 1.6; Figure 7).

The subgroup analyses for the different types of control groups showed similar results (personally tailored activities vs usual care: SMD 0.01, 95% CI −0.19 to 0.22; I^2 = 0%; 4 studies; 416 participants; personally tailored activities vs active control group: SMD −0.09, 95% CI −0.36 to 0.18; I^2 = 0%; 3 studies; 216 participants; Figure 7). The sensitivity analysis excluding the study for which we calculated the combined outcome measure also showed similar results (SMD −0.03, 95% CI −0.22 to 0.16; I^2 = 0%; 5 studies; 452 participants; Analysis 1.7).

Figure 7. Forest plot (1.6 Negative affect)

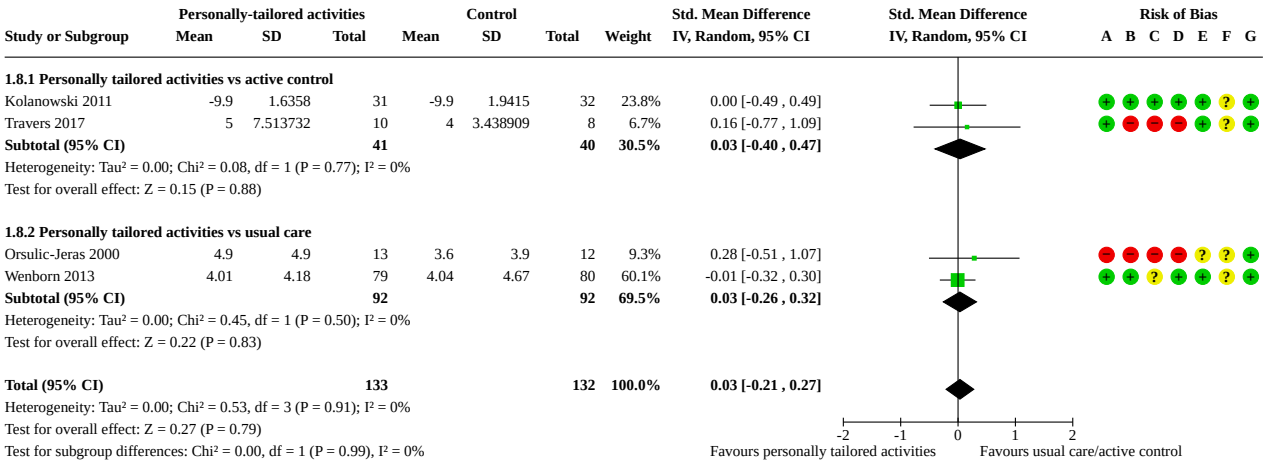


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Mood

We found very low-certainty evidence (downgraded one level for risk of bias and two levels for imprecision), and we are very uncertain whether personally tailored activities improve mood (SMD 0.03, 95% CI −0.21 to 0.27; I^2 = 0%; 4 studies; 265 participants; Analysis 1.8; Figure 8). The results of the subgroups comparing personally tailored activities with usual care and an active control group were comparable (Figure 8).

Figure 8. Forest plot (1.8 Mood)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

We performed a sensitivity analysis excluding the study that recruited people with dementia and depression, since the other included studies did not screen the participants for depression. The results were very similar in this sensitivity analysis (SMD 0.02, 95% CI −0.23 to 0.27; I^2 = 0%; 3 studies; 247 participants; Analysis 1.9).

Level of engagement

One of the newly included studies assessed engagement (Mbakile-Mahlanza 2020), but the results of this cross-over trial were not included in the analysis since a carry-over effect occurred and no data of the first period of this trial were available. Three studies were included in the analysis, but the studies assessed different types of engagement. The results were not pooled due to the diversity of the outcome measures. We calculated mean differences for the results of two studies (Kolanowski 2011; van der Ploeg 2013), but not for the study by Orsulic-Jeras 2000, due to pronounced baseline imbalances. Higher scores indicate more engagement. We judged engagement as an indirect (surrogate) outcome, because it is expected that the level of engagement in personally tailored activities might be associated with psychosocial outcomes, but the connection between the level of engagement and psychosocial outcomes is unclear.

Kolanowski 2011 assessed the intensity of participation. We found low-certainty evidence (downgraded one level each for indirectness and imprecision) that personally tailored activities may make little or no difference to the intensity of participation (MD 0.30, 95% CI 0.16 to 0.44; 63 participants; Analysis 1.10).

Two studies assessed constructive engagement: one study found an increase of constructive engagement in the intervention group in comparison with an active control group (MD 6.90, 95% CI 3.07 to 10.73; 88 participants; van der Ploeg 2013; Analysis 1.11); and Orsulic-Jeras 2000 found a decrease of constructive engagement in both groups (intervention group from 172 ± 171 at baseline to 96 ± 64 after six months; control group from 94 ± 79 at baseline to 49 ± 54 after six months; 25 participants). We found very low-certainty evidence (downgraded one level for risk of bias, indirectness and imprecision) and we are very uncertain whether personally tailored activities improve constructive engagement.

Two studies assessed passive engagement. van der Ploeg 2013 found a small reduction of passive engagement in comparison with an active control group (MD −1.60, 95% CI −4.99 to 1.79; 88 participants; Analysis 1.12) and Orsulic-Jeras 2000 found a decrease of passive engagement in the intervention group and nearly no change in the control group offering usual care (intervention group baseline 207 ± 132, after six months 91 ± 66; control group baseline 354 ± 158, after six months 345 ± 188; 25 participants). We found very low-certainty evidence (downgraded for risk of bias, indirectness and imprecision) and we are very uncertain about the effect of personally tailored activities on passive engagement.

For negative engagement, we found very low-certainty evidence (downgraded one level for risk of bias, indirectness and imprecision) from one study, and we are very uncertain whether personally tailored activities improve negative engagement in comparison with an active control group (MD −5.50, 95% CI −9.58 to −1.42; 88 participants; van der Ploeg 2013; Analysis 1.13).

Two studies investigated engagement after the sessions ended and all types of engagement returned to the baseline level (Kolanowski 2011; van der Ploeg 2013).

Sleep disturbances

For the sleep-related outcomes, we found very low-certainty evidence (downgraded one level for risk of bias, indirectness and imprecision) from one study (Richards 2005).

We are very uncertain whether personally tailored activities improve the amount of daytime sleep (minutes slept: MD −39.16, 95% CI −62.06 to −16.26; 139 participants; Analysis 1.14) or the amount of nighttime sleep (minutes slept: MD 28.81, 95% CI −22.65 to 80.27; 139 participants; Analysis 1.15); there were baseline imbalances between the study groups for nighttime sleep - minutes slept at baseline: intervention group 368.95 ± 158.13; control group 331.37 ± 135.20). We are also uncertain whether personally tailored activities improve the time awake during the night (no MD calculated due to pronounced baseline imbalances, minutes awake: intervention group baseline 266.19 ± 142.02, follow-up 252.14 ± 138.57; control group baseline 310.44 ± 129.63, follow-up 304.20 ± 151.31).

Psychotropic medication

No study offered information on the use of psychotropic medication.

Effects on caregivers

One of the newly included studies assessed caregiver outcomes (Mbakile-Mahlanza 2020), but the results of this cross-over trial were not included in the analysis since a carry-over effect occurred and no data of the first period of this trial were available.

Costs

Only the study by Richards 2005 assessed costs related to staff training, delivery of activities and administration of the intervention. Training costs comprised USD 1200 for teaching the project nursing assistants to conduct the intervention and training the registered nurses in the use of the outcome assessment. Costs for delivery of the activities were about USD 765 and included costs of commercial activities and perishable supplies. The mean cost per activity was estimated at USD 5. Administration costs were about USD 28 (one hour to complete the assessment).

Duration of the effects

Two studies investigated the duration of the intervention effect. In both studies, the values of most outcomes (agitation, positive and negative affect, engagement, and mood) returned to the baseline level. In the study by Kolanowski 2011, this was one week after the intervention period was completed, and in the study by van der Ploeg 2013, this was 30 minutes after the intervention sessions).

No information on the duration of intervention effects was available from the other studies.

Process evaluation

Five studies reported information about implementation fidelity and barriers or facilitators of the implementation process (Cohen-Mansfield 2012; Kolanowski 2011; Travers 2017; Van Haitsma 2015; Wenborn 2013).

Cohen-Mansfield 2012 reported that in about 20% of the sessions some participants did not take part in the activities offered, and 84% of the participants did not attend at least one of the sessions. The participants were unwilling or unresponsive (e.g. due to the severity of dementia) or unavailable (e.g. asleep or eating). The participants were more engaged in activities related to food/drink and one-to-one socialising activities and less engaged with puzzles, board games, art and craft activities (Cohen-Mansfield 2012). Kolanowski 2011 calculated the dose of the intervention received by the participants as the product of time on task and intensity of participation per day. The total dose of intervention per participant ranged widely, but the mean dose did not differ significantly between groups. In the study by Van Haitsma 2015, each participant received on average seven intervention sessions (range five to nine). Wenborn 2013 reported information on staff attendance at the training sessions: the participating nurses (n = 52) attended an average of 73% of the education sessions (range 63 to 86) and 81% of the individual coaching sessions (range 49 to 100). No information was reported regarding the amount of activities offered to the residents in the intervention group. In Travers 2017, all participants attended the activity sessions and most participants attended the walking and talking sessions (active control group). As planned, the therapist delivering the intervention had weekly meetings with the project coordinator and the co-therapists. The time required to plan the activities with the co-therapists was longer than expected at the beginning of the study (about 20 minutes instead of 10 minutes), but the time decreased during the study period as planning the activities became routine. Members of the nursing staff attended only a small number of the anticipated sessions in weeks one, four and eight (16.7% attendance rate). However, the feasibility of the intervention was judged to be good by most of the co-therapists and volunteers involved in the delivery of the activities, and they also described positive benefits for the participants based on their personal experience. Barriers to implementation were time restrictions, and some nurses judged the activities planning form to be too complex (Travers 2017).

DISCUSSION

Summary of main results

We included 11 studies in this review update, which evaluated interventions offering personally tailored activity for people with dementia living in long-term care. In most studies trained staff offered the activities directly to the people with dementia; in two studies nursing staff and family members, respectively, were trained to deliver the activities. The interventions varied in terms of the theoretical basis, the methods used to assess personal interests of the participants, the frequency and duration of the activity sessions and the length of follow-up; however, the activities delivered seem to be comparable across studies.

Although we included three new studies, our results were similar to those in the first version of this review. Offering personally tailored activities to people with dementia in long-term care may slightly reduce agitation. There was little information about the duration of effect, but data from two studies indicate that effects might only be detectable in the short or very short term, while the interventions are being delivered. In contrast to the first version of this review, the subgroups offering non-personalised activities and usual care showed similar negligible effects of personally tailored activities in this review update. One of the newly included studies, which contributed to this analysis, showed a positive effect of personally tailored activities in comparison with an active intervention. Our hypothesis that studies with a usual care control group may find larger intervention effects than studies using an active control group, i.e. non-personalised activities, was not supported in this analysis. We were unable to explain heterogeneity on the basis of the characteristics of the study populations or interventions.

Two studies investigated quality of life rated by proxy. Low-certainty evidence from a meta-analysis of these two studies indicated that personally tailored activities may make little to no difference to proxy-rated quality of life in comparison with usual care or an active control group. However, these two studies had important differences (e.g. participant characteristics, nature of comparator intervention), and there was statistical heterogeneity in the meta-analysis; the very small number of studies and the differences between them make this result difficult to interpret. For self-rated quality of life, low-certainty evidence indicated little to no difference between personally tailored activities and usual care, but data were only available for a small number of participants from one study. The instrument used to assess quality of life, the QoL-AD, covers a broad range of aspects, including physical and mental health, living situation, relationship with families and friends, and finances. Although personally tailored activities are expected to have positive effects on some of these aspects, e.g. mood or doing things that the person enjoys, the influence on other aspects seems to be limited, for example financial aspects and living situation. In addition, there is evidence that proxies rated quality of life lower that people with dementia themselves (Burks 2021). Therefore, the results for quality of life should be interpreted with caution.

Only two studies assessed adverse effects, but no adverse effects were observed in these studies.

Personally tailored activities may have little or no effect on negative affect. Due to the very low certainty of the evidence, we are uncertain whether personally tailored activities improve positive affect, mood, engagement or sleep-related outcomes. We found a relatively large effect size for positive affect, but in studies including an active control group there was only a small effect. Due to these differences and the very low-certainty evidence, we have very little confidence in this result. Only one study assessed intervention costs, and none of the studies performed an economic evaluation. Two studies investigated the duration of the intervention effects and in both studies effects were only observed during the time the activities were delivered; the majority of outcomes returned to the baseline level after the delivery of the activities ended.

We were not able to investigate conditions which enhance the effectiveness of personally tailored activities in long-term care, since no information about the context, such as environmental or staff-related information, was reported. There was no evidence that interventions were more likely to be effective if based on one theoretical model rather than another.

Overall completeness and applicability of evidence

Although all interventions based the selection of activities on the personal interests of the participants, little information was reported about the process of tailoring the activities. Almost all of the participants in the included studies had severe dementia, indicating a substantial decline of memory and severe limitations in activities of daily living. This might have had an influence on

the selection of suitable activities, and it seems probable that the activities were also tailored to the cognitive and physical abilities of the participants rather than to their interests only. Only one study described that the participants were more engaged in activities related to one-to-one socialising activities or interaction and less engaged with puzzles, board games, art and craft activities (Cohen-Mansfield 2012). All studies included in this review hypothesised that personally tailored activities are more likely to be meaningful than activities which are not personally tailored, but this aspect was not investigated in the studies. We have insufficient information to explore whether the selection of the activities had an impact on the effects of the interventions and whether the activities offered were judged as meaningful by the participants. The results of this review may not be applicable to residents of long-term care facilities whose dementia is less severe.

Another aspect that was not addressed in the included studies was the environment and context in which activities were offered. Two of the theoretical frameworks of the interventions comprise environmental aspects: the principles of Montessori (Mbakile-Mahlanza 2020; Orsulic-Jeras 2000; van der Ploeg 2013), and the occupational therapy intervention (Wenborn 2013); but no information about environmental aspects or how they were addressed during the delivery of the intervention was reported in the respective studies.

We included three new studies in this review update, but the number of studies contributing to the different outcomes of interest was still small (ranging from two to seven studies). Since almost all of the participants in the included studies had severe dementia, the results of this review may not be applicable to residents of long-term care facilities whose dementia is less severe. Only two studies investigated quality of life rated by proxy and one of these studies included people with dementia and depression, while the other study did not include an assessment of depressive symptoms. Also, the validity of proxy-rated quality of life in people with dementia is questioned (Burks 2021). We found clinical heterogeneity of the interventions (e.g. the different theoretical basis, duration and frequency of the activity sessions) and some methodological limitations of the included studies. Therefore, the results of this review must be interpreted with caution.

Quality of the evidence

As in the first version of this review, the certainty of evidence was predominately very low or low due to several methodological limitations of and inconsistencies between the included studies, and imprecision of the results. Two of the three newly included trials were pilot studies with a small number of participants, and the third study could not be included in the analysis since the required data were not available.

Seven out of the 11 included studies had a high risk of bias in at least one domain. Only two studies had a low risk of selection bias and four studies had a low risk of detection bias. We also found moderate to substantial heterogeneity in the meta-analyses on agitation and affect. For agitation, heterogeneity was reduced by excluding one study (Cohen-Mansfield 2012); however, we could not explain this heterogeneity from characteristics of this study. For positive affect we also could not identify the source of heterogeneity.

Generally, investigating the effects of personally tailored activities for people with dementia presents several methodological challenges. One challenge is the theoretical basis for preselecting the activities that could be offered to the participants and the process of choosing the activities for an individual person with dementia. Two models that were used as theoretical basis of the interventions, the Need-Driven Dementia-Compromised Behavior (NDB) model (Algase 1996) and Treatment Routes for Exploring Agitation (TREA) framework (Cohen-Mansfield 2000), assume that agitation is a symptom of unmet needs in people with dementia. Both models postulate that by targeting the identified unmet needs, the specific agitated behaviour could be modified. The principles of Montessori place emphasis on offering activities which best fit the level of competence of people with dementia. The principles focus on task breakdown, guided repetition and progression in difficulty from simple to complex (van der Ploeg 2013). The Individualized Positive Psychosocial Intervention, employed by Van Haitsma 2015, did not focus on specific needs of people with dementia but more general assumptions about a person's needs for autonomy and competence and the importance of positive emotions to improve a person's well-being. The pragmatic approach used by Travers 2017, which was not developed based on a specific theoretical model, also aimed to systematically increase positive events and activities to improve psychosocial outcomes of people with dementia. This study adapted an intervention developed for people with depression to people with dementia with depressive symptoms. Irrespective of the different theoretical models, the activities offered were very similar. Based on the results of this review, there is no evidence that interventions were more likely to be effective if based on one theoretical model rather than another.

The methods for assessing the participants' interests in order to tailor the activities also differed between studies. No information was available in any study about the number of participants who were able to express their individual interests or preferences. It might be challenging to assess the past or present interests in people with severe dementia. The assessment about interests can also be performed with family members and caregivers, but they might have differing perceptions about the interests and preferences of the participants, and whether activities are perceived as meaningful, than the people with dementia themselves. People with dementia judge activities as personally meaningful if the activities are connected with self (which represents the personal interests and the individual motivation to take part in a specific activity), with others, and with the environment (Han 2016). In addition, people also adapt their interests and preferences to changes of functional and cognitive abilities (Han 2016). Since the included studies did not investigate whether the relatives or primary caregivers were able to give valid information on the participants' interests and preferences, or whether the former interests and preferences changed over time or with progression of cognitive impairment, it remains unclear whether the activities offered were judged as meaningful by the study participants. The active control activities might also be seen as meaningful from the perspective of the study participants, especially the one-to-one interactions offered as active control in two studies (van der Ploeg 2013; Van Haitsma 2015), which are likely to meet the need for connectedness of people with dementia (Han 2016).

Another challenge is the characteristics of 'usual care'. There is evidence that people living in nursing homes have only few contacts with others, and that activities offered to them are often not perceived as meaningful (Edvardsson 2014; Harmer 2008; Hill 2010). The usual care offered to the control groups was not well described in several studies and the amount of activity available to the control group may have varied substantially between studies.

It was difficult to distinguish clearly between some of the outcomes addressed in this review, i.e. agitation, engagement and affect. Van Haitsma 2015 categorised several types of behaviour differently from other studies, e.g. "staring with a fixed gaze" was categorised as non-verbal behaviour in this study while a "blank stare" was categorised as engagement in the studies by Orsulic-Jeras 2000 and van der Ploeg 2013. We did not include all behaviours assessed by Van Haitsma 2015, but selected behaviours which were most comparable with the concept of agitation assessed in the other studies. The different instruments used to assess agitation or challenging behaviour also warrant consideration. One group of instruments rated the outcome based on direct observation of the participants and another group used proxy rating by the nursing staff. There is some evidence that proxy-rating instruments assessing quality of life are less valid than instruments based on direct observation, since there might be a stronger influence of personal factors of the proxy-raters, e.g. personal attitudes (Arons 2013; Gomez-Gallego 2015; Moyle 2012). For instruments assessing agitation or challenging behaviour, some studies found that the reliability of instruments was moderate to good (Cohen-Mansfield 2004; van der Linde 2014). In one study (van der Ploeg 2013), a single behaviour was investigated for each participant compared to the wide range of behaviours assessed by the rating scales used in other studies. Irrespective of these differences and uncertainties, the results of the different studies were homogenous, with the exception of one study (Cohen-Mansfield 2012). Therefore, pooling the results of the different instruments seemed to be feasible, with the caveats mentioned above.

Potential biases in the review process

We followed the method described in the review protocol (Möhler 2012). To reduce the risk of bias in the review process, we followed the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017; Higgins 2021). We conducted a comprehensive search in several sources (databases, trial registers), guided by the Cochrane Dementia and Cognitive Improvement Group's Information Specialist. We also performed backward and forward citation tracking for all included studies. However, due to the small number of studies, we were not able to investigate the risk for publication bias using formal statistical methods. Two reviewers independently conducted study selection, quality appraisal, and data extraction. We also contacted all study authors for missing information.

Agreements and disagreements with other studies or reviews

Two systematic reviews investigating the effects of activities offered to people with dementia in nursing homes have been published, but both reviews included a wide range of non-pharmacological interventions on psychosocial outcomes (Testad 2014; Travers 2016). Testad 2014 included, among others, interventions offering "pleasant activities with or without social interaction", but the inclusion criteria for both the interventions and the setting differed slightly from this review (e.g. cross-over trials were excluded and different types of long-term care settings were included). The review by Travers 2016 investigated, among others, the effects of individualised recreational activities. Both reviews described an improvement of agitation and, in contrast to our analysis, positive effects on pleasure and interest. However, due to the broader scope of both reviews, further studies were included that did not fit with our inclusion criteria. Testad 2014 did not perform meta-analyses and the narrative synthesis showed small intervention effects. Travers 2016 performed some meta-analyses including only two studies, and found no or small effects with wide CIs. Neither review rated the certainty of evidence using the GRADE approach (Guyatt 2011); and, therefore, no information about the certainty of the evidence was reported.

AUTHORS' CONCLUSIONS

Implications for practice

Offering personally tailored activities to people with dementia in long-term care may be considered as an intervention to reduce agitation, but the effect might be small and persist only as long as the activities are delivered. However, there is evidence that people with dementia living in nursing homes are often not engaged in activities and, from an ethical perspective, offering activities to people with dementia is necessary. Such activities should be selected based on the functional and cognitive abilities of nursing homes residents, but we can draw no conclusions from the existing body of trial evidence about other specific methods for selecting activities, the types of activity, or the duration and frequency of activities.

Implications for research

The results indicate that further studies should be conducted to explore the potential benefits of personally tailored activities for improving positive affect and reducing agitation in people with dementia living in long-term care facilities. But there is some evidence that the effects persists only as long as the activities are delivered.

The theoretical basis on which the activities are chosen seems less important, and the studies did not assess whether the participants judged the offered activities to be meaningful. The concept of 'meaningfulness' — how it could be assessed and how activities could be selected based on the results of such an assessment — needs to be investigated in more detail. Research on this topic seems to be feasible with people in earlier stages of dementia but more challenging in later stages of dementia. Assessing the interests and preferences of people with dementia and tailoring the activities to these interests, preferences and competencies (i.e. stage of dementia and the care dependency of the participants) also needs further investigation. In the context of active components, the effect of direct interaction alone (without offering specific activities) compared to direct interaction while offering specific (meaningful) activities has to be addressed. The role of direct interaction might also differ within the course of dementia, e.g. the activities might be more important in early stages of dementia. Another aspect to be explored is the role of the environment and the context in which activities are offered.

We included several pilot studies or studies with small sample sizes, but sufficiently powered trials are missing. Evaluation

studies should be planned that adhere to current methodological standards, especially using a randomised and concealed allocation to the study groups. Adequate blinding is also important, since psychosocial outcomes are generally subjective and often rated by proxies. Therefore, outcome assessment has to be blinded, for example by the use of external blinded research staff. Blinding of nursing staff and participants is possible if clusters are allocated to the study groups or, in case of individual randomisation, if an active control intervention is delivered by research staff without informing the nurses about the group allocation. Therefore, in future studies we recommend comparing personally tailored activities with an active control group, offering direct interaction with participants or activities suitable for people with dementia; or with two control groups — an active control group and a 'usual care' control group. Studies including three groups are time- and personnel-consuming; however, they can add valuable evidence to improve both research and clinical practice. Such studies should also include a process evaluation, which investigates implementation fidelity, barriers to and facilitators of the implementation, and contextual issues. Contextual issues include the willingness of people with dementia to be engaged in the activities, information about the meaningfulness of the activities offered, and details of the activities offered in the active control groups (Grant 2013; Moore 2015; Skivington 2021).

To ensure comprehensive reporting covering the complete research process (development, piloting and evaluation), the corresponding reporting statements should be used, e.g. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2) for complex interventions (Möhler 2015), the Template for Intervention Description and Replication (TiDieR) criteria for the description of the interventions (Hoffmann 2014), and CONSORT or the corresponding extension, e.g. for randomised pilot and feasibility trials (Eldridge 2016), or cluster-RCTs (Campbell 2012).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cohen-Mansfield 2007

Study characteristics	
Methods	**Study design:** cluster-randomised controlled trial (not registered) **Duration of follow-up:** 10 consecutive days **Study period:** not reported
Participants	**Country:** USA **Setting:** 12 clusters from 11 suburban nursing home facilities **Participants/clusters** • Inclusion criteria: all residents of the participating clusters with a diagnosis of dementia, who lived in the facility for more than 3 weeks and exhibited agitation several times per day • Exclusion criteria: residents with a diagnosis of bipolar disorder or schizophrenia and residents who manifested aggressive behaviours • Number of participants randomised: n = 230; intervention group n = 125, control group n = 105

Cohen-Mansfield 2007 *(Continued)*

- Number of participants lost to follow-up: intervention group n = 36 (2 bipolar, 10 deceased, 1 no dementia, 11 no agitation, 1 discharged, 1 administrator refused to allow participation, 3 illness, 2 comfort care, 5 logistic reasons), control group n = 27 (1 bipolar, 8 deceased, 9 no agitation, 3 discharged, 3 hospitalisation, 3 logistic reasons)
- Number of participants completing the study: n = 167; intervention group n = 89, control group n = 78

Baseline characteristics

- Age (mean ± SD), years: intervention group 88.0 ± 6.4, control group 85.0 ± 8.6
- Gender, female: intervention group 84%, control group 76%
- Cognitive status, MMSE (mean ± SD): intervention group 7.26 ± 6.0, control group 6.88 ± 6.5
- Care dependency, ADL performance (from MDS, 0 (independent) to 4 (total dependence)) (mean ± SD): intervention group 2.49 ± 1.01, control group 2.42 ± 1.03

Interventions	**Intervention:** activity programme based on the Treatment Routes for Exploring Agitation (TREA) framework **Control:** presentation for nursing staff describing the syndromes of agitation, their aetiologies, and possible non-pharmacologic interventions
Outcomes	**Primary**: agitation (ABMI) **Secondary**: affect (pleasure, interest, anger, anxiety, sadness)
Funding	National Institutes of Health; USA
Notes	Cluster effect was not incorporated in the analysis (risk unit-of-analysis error)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"To limit contamination of the interventions' effectiveness, buildings were assigned either control or intervention status (rather than having both within each building). We were unable at times to assign buildings randomly to either intervention or control groups because the administrators of two facilities insisted on making the decision as a condition of participation. Other facilities without such stipulations were randomly assigned to the treatment or control group while balancing the number of facilities in each group." No method of sequence generation was reported.
Allocation concealment (selection bias)	Unclear risk	No methods for allocation concealment was reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information about blinding of personnel and participants reported, but blinding seems not possible. The intervention was delivered at cluster level. We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Another measure of reliability examined the possible effect of the nonblindness of the observations. For this measure, 10 study participants were videotaped, and inter-rater reliability was obtained from a research assistant who was blinded both to the background characteristics of the observed residents and to the raters themselves. The average agreement between observed agitation recorded from videotape and direct observations of agitated behaviors was 95%".

Cohen-Mansfield 2007 *(Continued)*

		We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up: intervention group: "1 excluded due to illness during intervention", control group: "2 excluded due to hospitalisation after baseline assessment".
Selective reporting (reporting bias)	Unclear risk	Not registered, no study protocol available.
Other bias	Low risk	-

Cohen-Mansfield 2012

Study characteristics	
Methods	**Study design:** cluster-randomised controlled trial (NCT00820859, retrospectively registered) **Duration of follow-up:** 2 weeks **Study period:** June 2006 to December 2011
Participants	**Country:** USA **Setting:** 11 nursing homes in Rockville, Silver Spring, Takoma Park, Chevy Chase, and Gaithersburg, Maryland, USA. **Participants/clusters** • Inclusion criteria: all residents of the participating clusters with a diagnosis of dementia, at age ≥ 60 years, who lived in the facility for more than 3 weeks and exhibited agitation several times per day • Exclusion criteria: residents with a diagnosis of bipolar disorder or schizophrenia, an MMSE score ≥ 25, manifested aggressive behaviours, or took part in earlier studies testing a TREA intervention • Number of participants randomised: n = 231; intervention group n = 155, control group n = 76 • Number of participants lost to follow-up: 106; intervention group n = 66 (17 died, 6 bipolar disorder or schizophrenia diagnosis, 29 not agitated, 3 age < 60, 2 MMSE > 25, 6 discharged, 1 comfort care, 1 pending), control group n = 40 (6 died, 3 bipolar disorder, schizophrenia diagnosis, 25 not agitated, 3 age < 60 years, 2 participated in previous TREA study, 1 no diagnosis of dementia, 1 pending) • Number of participants completing the study: n = 125; intervention group n = 89, control group n = 36 **Baseline characteristics** • Age (mean ± SD) years: intervention group 85.9 ± 8.62, control group 85.3 ± 9.62 • Gender, female: intervention group 73%, control group 77.8% • Cognitive status, MMSE (mean ± SD): intervention group 7.62 ± 6.33, control group 9.38 ± 6.76 • Care dependency, ADL performance (from MDS, 0 (independent) to 4 (total dependence)) (mean ± SD): intervention group 2.72 ± 0.84, control group 2.75 ± 0.98
Interventions	**Intervention:** activity programme based on the Treatment Routes for Exploring Agitation (TREA) framework **Control:** presentation for nursing staff describing the syndromes of agitation, their aetiologies, and possible non-pharmacologic interventions
Outcomes	**Primary:** agitation (ABMI) **Secondary:** affect (pleasure, interest, anger, anxiety, sadness)

Cohen-Mansfield 2012 *(Continued)*

Funding	National Institutes of Health (grant 2 R01 AG010l72-10A2)
Notes	Cluster effect was not incorporated in the analysis (risk unit-of-analysis error)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization to intervention or placebo control protocols was performed using random numbers via a ratio of 1.5: 1, with the intent of having more intervention than control participants in order to investigate process issues."
Allocation concealment (selection bias)	Unclear risk	No methods for allocation concealment were reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"(...) once treatment started, research assistants were no longer blinded to group assignment." "Study participants were blinded as to their group assignment"; comment: since the control group did not receive an active control intervention, blinding of participants seems not possible. The intervention was delivered at cluster level. We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Research assistants could not be blinded once interventions began." "Another measure of reliability examined the possible effect of the nonblindness of the observations. For this measure, 25 study participants were videotaped, and interrater reliability was obtained from a research assistant blinded both to the background characteristics of the observed residents and to the original ratings. The ICC between videotaped and direct observation in the current study was 0.94 for verbal agitation, 0.93 for physical agitation, and 0.94 for total agitated behaviors." We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Residents not included after cluster randomisation: "Placebo (n = 36), bipolar disorder or schizophrenia diagnosis (n = 3), not agitated (n = 25), age < 60 years (n = 3), death(n = 2), participated in previous TREA study (n = 2), gave consent but could not be included before the data collection phase ended (n = 1). Intervention (n = 62), bipolar disorder or schizophrenia diagnosis (n = 6), not agitated (n = 29), age < 60 years (n = 3), MMSE > 25 (n = 2), no diagnosis of dementia (n = 1), death (n = 13), discharged (n = 6), life expectancy < 3 months (n = 1), gave consent but could not be included before the data collection phase ended (n = 1)" "Did not receive placebo as allocated (n = 4, lost to death), did not receive intervention as allocated (n = 4, lost to death)"
Selective reporting (reporting bias)	Unclear risk	Study was registered retrospectively, no study protocol available.
Other bias	Low risk	-

Kolanowski 2011

Study characteristics	
Methods	**Study design:** randomised controlled trial (NCT00388544, retrospectively registered) **Duration of follow-up:** 4 weeks (3-week interventions period + 1-week post-intervention period) **Study period:** August 2005 to November 2008
Participants	**Country:** USA **Setting:** 9 community-based nursing homes in Pennsylvania **Participants/clusters** • Inclusion criteria: diagnosis of dementia, a willing informant who knows the participant well and who can provide past personality and other data, a stable dose of any psychoactive drug from pre-baseline through final observation, and the presence of agitation or passivity • Exclusion criteria: residents with delirium or an unstable medical condition, Parkinson's disease, Huntington's disease, seizure disorder, stroke, alcoholism, drug abuse, head trauma with loss of consciousness, psychiatric illness preceding the onset of memory loss, severe vision or hearing impairment; received a new psychoactive medication in a 30-day period before baseline • Number of participants randomised and analysed: n = 128; intervention group 1 n = 32, intervention group 2 n = 33, intervention group 3 n = 31, control group n = 32 • Number of participants lost to follow-up: intervention group 1 n = 4 (2 died, 2 hospitalised), intervention, intervention group 2 n = 0, intervention group 3 n = 1 (withdrew), control group n = 1 (withdrew) **Baseline characteristics** • Age (mean ± SD) years: intervention group 1 85.3 ± 6.1, intervention group 2 87.2 ± 5.9, intervention group 3 86 ± 7.1, control group 85.9 ± 4.9 • Gender, female: intervention group 1 75%, intervention group 2 75.8%, intervention group 3 74.2%, control group 81.2% • Cognitive status, MMSE (mean ± SD): intervention group 1 15.1 ± 4.2, intervention group 2 15.8 ± 4.9, intervention group 3 12.7 ± 3.3, control group 13.2 ± 4.6 • Care dependency: not reported
Interventions	**Interventions:** activity programmes based on the Need-Driven Dementia-Compromised Behavior model • Intervention group A: activities matched to participants' cognitive and physical functional level and opposite to their identified style of interest • Intervention group B: activities matched to participants' style of interest and challenging for their functional level • Intervention group C: activities matched to both participants' functional level and style of interest **Control group:** activities opposite to participants' style of interest and challenging for their functional level
Outcomes	No primary outcome defined. • Agitation (CMAI, PDS), • Engagement, affect (ARS), • Mood (Dementia Mood Picture Test)
Funding	One author was supported by National Institutes of Health and another author received royalties from the NEO-PI-R and the NEOFFI and was supported in part by National Institutes of Health
Notes	

Kolanowski 2011 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The statistician determined participants' group assignment using a random number generator with random block sizes to ensure equal assignment across the four groups at the completion of the study and approximately equal assignments throughout the study to control for unknown temporal effects."
Allocation concealment (selection bias)	Low risk	"Group assignment was concealed until after all screening data were collected. The project director obtained the assignment from a secure central location after verifying that the participant qualified for the study."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Because all participants received some type of activity, it was possible to blind the interventionists, data collectors, video raters, nursing home staff, and participants."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Because all participants received some type of activity, it was possible to blind the interventionists, data collectors, video raters, nursing home staff, and participants."
Incomplete outcome data (attrition bias) All outcomes	Low risk	After randomisation, in both groups included in this review 1 participant was lost to follow-up but no participants were excluded from the analysis.
Selective reporting (reporting bias)	Unclear risk	Study was registered retrospectively, no study protocol available.
Other bias	Low risk	-

Mbakile-Mahlanza 2020

Study characteristics

Methods	**Study design:** cluster-randomised cross-over trial (ACTRN12611000998943) **Duration of follow-up:** 6 weeks **Study period:** not reported
Participants	**Country:** Australia **Setting:** 9 general and psychogeriatric nursing homes, state of Victoria **Participants/clusters** • Included criteria: residents: diagnosis of dementia or probable dementia, residency in the facility for ≥ 3 months; family carers: willing to visit at least twice a week, willing to follow study protocol, understand the contents of the Montessori training workshop and fill out questionnaires, willing to visit at least twice a week • Excluded criteria: residents with acute lifethreatening illness as reported by nursing staff • Number of participants randomised: n = 51; intervention first n = 25, intervention second n = 26 • Number of participants lost to follow-up: n = 11; intervention first n = 5, intervention second n = 6; reasons: 4 withdrew, 2 deceased, 5 never started, no information about the study period in which the participants were lost to follow-up

Mbakile-Mahlanza 2020 *(Continued)*

- Number of participants completing the study: n = 40; intervention first n = 20, intervention second n = 20 (no information about the number of clusters)

Baseline characteristics

- Age: no information reported
- Gender: no information reported
- Cognitive status (CDR, mean ± SD): group A (Montessori condition first) 21.9 ± 16.1, group B (control first) 26.8 ± 20.6
- Care dependency: not reported
- Agitation, (CMAI, mean ± SD): physical agitation group A (Montessori condition first) 4.9 ± 4.9, group B (control first) 7.5 ± 5.5; verbal agitation group A (Montessori condition first) 4.3 ± 4.6, group B (control first) 4.0 ± 5.0

Interventions	**Intervention:** Montessori-based activities **Control:** reading a newspaper
Outcomes	**Primary:** • Residents' affect (ARS) and engagement (Menorah Park Engagement Scale), • Quality of visits (overall satisfaction with each study visit on a 5-point Likert scale, truncated version of the Pearlin Mastery Scale) **Secondary:** • Carer-resident's quality of relationship (overall quality of their relationship with their relative on a 5-point Likert scale, Mutuality Scale of the Family Caregiving Inventory) • Carer's mastery (five items of the Pearlin Mastery Scale) • Carer's mood (Center for Epidemiological Studies Depression Scale) • Carer's quality of life (Carer-QoL)
Funding	Alzheimer's Australia as part of the National Quality Dementia Care Initiative (only reported in the study registration)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Participating nursing homes were randomized to either Montessori condition first (Group A) or control condition first (Group B) sequence, and the group allocation was randomly determined using Excel Random Number Generator." "At each nursing home, a staff member identified potential residents and sought agreement from the family member to be contacted by the research team. When verbal consent was given, a senior researcher contacted the family member to explain the study and answer queries. Those who expressed interest in the study were sent a Participant information and Consent Form package." "Out of the 16 nursing homes visited, a total of 9 facilities consented to participate in the study and a preselection screening was conducted to identify eligible participants." "Due to a small sample size, we were unable to adjust for the group imbalances".

Mbakile-Mahlanza 2020 *(Continued)*

		We found imbalances between groups for several criteria, e.g. time in the facility, dementia severity and physical agitation, but no information about the level of significance was provided. These differences might be based in the small sample size, and we have insufficient information to permit judgement of 'low risk' or 'high risk'.
Allocation concealment (selection bias)	Unclear risk	No information reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Participants and facility staff were blinded to the hypotheses of the study as well as the condition that the participants were in." "No blinding was applied to the researchers." The intervention was delivered on cluster level. We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Another limitation of this study was the absence of researcher blinding, which could potentially introduce bias into the study results during the scoring of resident observations. The nature of Montessori activities (with many materials and other prompts to elicit active participation) makes it virtually impossible to blind researchers to the type of condition that is being scored. Researchers were trained to record affect and engagement consistently across all sessions. Their inter-rater reliability was excellent." Outcomes were assessed by unblinded researchers.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Drop-out rate comparable between groups (approx. 20%), but no information about the period in which the participants were lost to follow-up and no reasons for drop-out were reported.
Selective reporting (reporting bias)	High risk	There are some important differences between the methods planned (described in the study register and study protocol) and the published study: • Design: "Wait list control group, incl. dementia education session to match for interaction with researchers during activities workshop. The control group will participate in the Montessori workshop asap after they completed all the measurements for the wait list period." (study register/protocol); cluster-randomised cross-over trial (main publication) • Primary outcome: quality of visits (study register/protocol); residents' affect and engagement, quality of visits (main publication)
Other bias	High risk	No wash-out period included. "We detected carryover effects of the experimental condition on several outcomes for the resident as well as on carers' mood."

Orsulic-Jeras 2000

Study characteristics	
Methods	**Study design:** controlled clinical trial (not registered) **Duration of follow-up:** 9 months **Study period:** not reported
Participants	**Country:** USA

Orsulic-Jeras 2000 *(Continued)*

	Setting: one dementia special care unit, Menorah Park Center for Senior Living (Orthodox Jewish facility with over 350 long-term care beds) **Participants** • No inclusion or exclusion criteria reported • Number of participants allocated and completing the study: n = 25; intervention group n = 13, control group n = 12 **Baseline characteristics** • Age (mean ± SD) years: 88 ± 6 • Gender, female: 92% • Cognitive status, MMSE (mean ± SD): 11 ± 6 • Care dependency: not reported
Interventions	**Intervention:** Montessori-based activities (group or individual activities) **Control:** usual care (regular activities)
Outcomes	No primary outcome defined. • Agitation (CMAI) • Depression (CSD) (9 months' follow-up) • Engagement (MRI-ES) • Affect (ARS) (6 months' follow-up)
Funding	Not mentioned
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Non-randomised trial; "Thirteen residents were assigned to the treatment condition and 12 to the control condition. Participants were matched across groups according to their scores on the MMSE, along with their performances on the Myers Menorah Park/Montessori Assessment System (MMP/MAS) and the reading subtest of the Wide Range Achievement Test (WRAT3)."
Allocation concealment (selection bias)	High risk	Not applicable (not an RCT)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Individual activity sessions "were run by either a trained volunteer, a research assistant, or the activities therapist on the unit." The two types of group activities were run "one day by a volunteer and one day by the activities therapist on the unit" and "led by either a trained volunteer or by the activities therapist on the unit" respectively. The participants in the control group received care and activities as usual and it seems not possible to blind personnel or participants. Since the same nurses cared for participants in both study groups there is a risk of contamination. We judged risk of performance bias to be high.
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Research staff interviewed nursing assistants on the special care unit at pretest and at final posttest for approximately 20 minutes for all measures".

Orsulic-Jeras 2000 *(Continued)*

		Outcome assessors were not blinded to group allocation and assessed subjective outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Forty-four residents from the dementia SCU were initially recruited. During the course of this 9-month study, 19 participants dropped out of the study, either because of death (n = 3), transfer to another unit within the facility (n = 12), or excessive absence (n = 4). Thus, 25 participants (23 women and 2 men) completed the study." No information about the group allocation for the participants lost to follow-up were reported.
Selective reporting (reporting bias)	Unclear risk	Not registered, no study protocol available.
Other bias	Low risk	-

Richards 2005

Study characteristics	
Methods	**Study design:** randomised controlled trial (not registered) **Duration of follow-up:** 21 consecutive days **Study period:** not reported
Participants	**Country:** USA **Setting:** one Department of Veterans Affairs nursing home and six for-profit community nursing homes, central southeastern United States. **Participants** • Inclusion criteria: age ≥ 55, baseline 85% sleep efficiency and at least 30 minutes of daytime sleep (Actigraph), living at the facility for at least 1 month, MMSE score ≤ 24 • Number of participants randomised: n = 147 (no information about number of participants per group) • Number of participants lost to follow-up: n = 8 (7 hospitalised, 1 moved) • Number of participants completing the study: n = 139; intervention group n = 71, control group n = 68 **Baseline characteristics** • Age (mean ± SD) years: 79 ± 8.4 • Gender, female: 48.2% • Cognitive status, MMSE (mean ± SD): 8.7 ± 7.1 • Care dependency: not reported
Interventions	**Intervention:** individualised activity-programme **Control:** usual care (including any scheduled activities that the nursing home provided).
Outcomes	No primary outcome defined. • 24-hour sleep/wake patterns (Actigraph) • costs (training, activities, administration)
Funding	Veterans Health Administration, National Institute of Nursing Research, National Institutes of Health/National Center for Research Resources to the General Clinical Research Center of the University of Arkansas for Medical Sciences; USA

Richards 2005 *(Continued)*

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Then participants were randomly assigned to one of two groups: ISAI or usual-care control". No further information reported.
Allocation concealment (selection bias)	Unclear risk	No information reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"The project nursing assistants implemented the ISAI and recorded the type, time, and duration of the activities. (...) As part of the ISAI, the project nursing assistants checked on the participants every hour, observed them for napping, wakened them if they were asleep, and provided ISAI. (...) Participants in this [control] group received usual care". Since the same nurses cared for participants in both study groups there is a risk of contamination. We judged risk of performance bias to be high.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The Actigraph (Ambulatory Monitoring, Ardsley, NY), a motion-sensing device that uses an algorithm to differentiate sleep from wake based on motor activity, measured sleep/wake pattern variables." No information about blinding reported, but the risk of bias was judged to be low since only objective outcomes were assessed via Actigraph.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Of the 147 remaining participants, seven were hospitalized, and one returned home." Comment: no information about the allocated groups of the participants lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Not registered, no study protocol available.
Other bias	Low risk	-

Travers 2017

Study characteristics

Methods	**Study design:** randomised controlled trial (ACTRN12613000296730) **Duration of follow-up:** 8 weeks **Study period:** not reported
Participants	**Country:** Australia **Setting:** four nursing homes, southern suburbs of Brisbane, Queensland, 48 to 126 beds. All catered for residents with high and low care needs and all were accredited with the National Accreditation Agency (Aged Care Standards and Accreditation Agency Ltd). The facilities were managed by religious (two), independent not-for-profit (one) and private (one) organisations and all facilities employed activities staff and provided a variety of organised activities for residents. **Participants**

Travers 2017 *(Continued)*

- Inclusion criteria: living in the nursing home for at least 3 months, being able to communicate in English, mild to moderate dementia (sMMSE score of 10 or higher), symptoms of depression (GDS-12R score of four or higher).
- Exclusion criteria: no diagnosis of dementia, participants receiving psychotherapy
- Number of participants randomised: n = 19; intervention group n = 10, control group n = 9
- Number of participants lost to follow-up: control group n = 1 (died)
- Number of participants completing the study: n = 18; intervention group n = 10, control group n = 8

Baseline characteristics

- Age (mean ± SD) years: intervention group 87.2 ± 7.7, control group 85.5 ± 10.9
- Gender, female: intervention group 80%, control group 100%
- Cognitive status, sMMSE (mean ± SD): intervention group 19 ± 3.87, control group 16.13 ± 3.7
- Care dependency: not reported
- Mobility status: intervention group: 10% independently ambulatory, 50% ambulatory with assistance, 40% non-ambulatory; control group 37.5% independently ambulatory, 50% ambulatory with assistance, 12.5% non-ambulatory

Interventions	**Intervention:** BE-ACTIV **Control:** walking and talking intervention
Outcomes	**Primary** (defined in the trial registration): • Depression (GDS-12R) • Quality of life (QoL-AD nursing home version) **Secondary:** agitation (CMAI - short form)
Funding	Funded by the JO & JR Wicking trust
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The Project Coordinator assigned participants a unique study identification number and randomly allocated them to either the BE-ACTIV or the Walking and Talking intervention using the SPSS randomization function."
Allocation concealment (selection bias)	High risk	"The Project Coordinator assigned participants a unique study identification number and randomly allocated them to either the BE-ACTIV or the Walking and Talking intervention using the SPSS randomization function." Not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"In the first instance, facility staff (activities staff in particular) and volunteers were invited to attend two 90-min depression training sessions that were conducted at the commencement of the study in each facility (...) An overview of the project including its rationale and methods was also provided." The therapist and the nursing staff was aware of the group allocation; no information about the blinding of the participants was reported. Since the same nurses cared for participants in both study groups there is a risk of contamination. We judged risk of performance bias to be high.

Travers 2017 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	High risk	"The measures of QOL (QOL-AD-NH), and depression (GDS-12R) were re-administered following completion of the interventions by the Project Coordinator only, who was not blinded regarding participant's group allocation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Ten participants were allocated to the BE-ACTIV intervention and nine to the Walking and Talking intervention. One resident who had been allocated to the Walking and Talking intervention, however, died prior to commencement of the intervention and his data were excluded from all analyses. All remaining participants completed the eight-week interventions."
Selective reporting (reporting bias)	Unclear risk	Only the primary outcomes defined in the trial register were reported.
Other bias	Low risk	-

van der Ploeg 2013

Study characteristics	
Methods	**Study design:** randomised cross-over trial (ACTRN12609000564257, retrospectively registered) **Duration of follow-up:** 4 weeks (2 weeks per condition, no washout period) **Study period:** July 2009 to September 2011
Participants	**Country:** Australia **Setting:** Nine residential facilities in metropolitan Melbourne, Australia **Participants** • Inclusion criteria: diagnosis of dementia, a physically agitated behaviour that occurred at least several times a day outside nursing interventions, confirmation by nurses, visiting physician, and/or psychiatrist that the behaviour was not due to untreated pain, physical illness, major depression, or psychosis, residence in a specialist dementia unit or psychogeriatric nursing home for at least 3 months • Exclusion criteria: psychotropic medications which were likely to be changed over the study period (medical and nursing staff were asked not to alter psychotropic medications during the study period if possible), an acutely life-threatening physical illness or a behaviour presenting a potential hazard to the researchers • Number of participants randomised: n = 57; Montessori first n = 21, Montessori second n = 36 • Number of participants lost to follow-up: Montessori first n = 6 (3 deceased, 3 refused intervention), Montessori second n = 7 (1 deceased, 1 refused intervention, 1 moved to other facility, 4 too busy to schedule sessions) • Number of participants completing the study: n = 44; Montessori first n = 15, Montessori second n = 29 **Baseline characteristics** • Age (mean ± SD) years: 78.1 ± 9.8 • Gender, female: 68.2% • Cognitive status, MMSE (mean ± SD): 6 ± 8 • Care dependency: not reported
Interventions	**Intervention:** personalised Montessori-based activities **Control:** non-personalised activities (active control)
Outcomes	**Primary:** one physically agitated behaviour specific for each participant (based on the CMAI)

van der Ploeg 2013 *(Continued)*

	Secondary • Affect (pleasure, contentment, interest, neutral affect, anger, sadness, anxiety/fear) (ARS) • Engagement (MPES)
Funding	Dementia Collaborative Research Centre (DCRC), Mason Foundation, National Health and Medical Research Council; Australia
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The primary investigator generated the random allocation sequence using Excel Random Number Generator."
Allocation concealment (selection bias)	High risk	Group allocation was not concealed (unpublished information from the study author).
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Participants and facility staff were blinded to the hypotheses of the study." "Treatment facilitators reported in supervision meetings that they were sometimes tempted to resort to the Montessori approach when the control activities failed to capture participants' interest." Staff delivering the intervention were not blinded to group allocation and delivered both the intervention and the active control activities (cross-over trial).
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Because of the nature of the activities, it was not possible to blind observers to the Montessori or the control conditions but they were trained to record behavior, affect, and engagement styles consistently across sessions and their inter-rater reliability was excellent." Outcome assessors were unblinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Allocated to Montessori intervention first lost to follow-up (n = 6): deceased (n = 3), refused intervention (n = 3); Allocated to Montessori intervention second lost to follow-up (n = 7): deceased (n = 1), refused intervention (n = 1), moved to other facility (n = 1), too busy to schedule sessions (n = 4)." Since the attrition rate was more than twice as high as planned, risk of bias was rated as unclear.
Selective reporting (reporting bias)	Unclear risk	Study was retrospectively registered, the study protocol was published after first participants were recruited.
Other bias	High risk	No paired data were available (risk of a unit-of-analysis bias) and we used the (unpaired) data of the complete study period.

Van Haitsma 2015

Study characteristics

Methods	**Study design:** randomised controlled trial (not registered) **Duration of follow-up:** 3 weeks

Van Haitsma 2015 *(Continued)*

	Study period: not reported
Participants	**Country:** USA **Setting:** eight units of a large nonprofit nursing home, Pennsylvania **Participants** • Inclusion criteria: all willing residents living in the nursing unit at baseline • Exclusion criteria: residents living in the nursing unit for less than 1 month, actively psychotic residents or residents receiving end-of-life care • Number of participants randomised: n = 195; intervention group n = 49, active control n = 49, usual care control n = 97 • Number of participants lost to follow-up: intervention group n = 5 (3 refused intervention, 1 died, 1 hospitalised), active control n = 6 (1 refused intervention, 5 hospitalised), usual care control n = 4 (2 refused intervention, 1 died, 1 hospitalised) • Number of participants completed the study: n = 180; intervention group n = 44, active control n = 43, usual care control n = 93 **Baseline characteristics** • Age (mean (range)) years: 88.7 (64 to 105); (mean ± SD) intervention group 87.66 ± 8.37, active control 88.71 ± 6.13, usual care control 89.21 ± 6.87 • Gender, female: 82.2% • Cognitive status, MMSE (mean ± SD): intervention group 7.4 ± 7.13, active control 10.35 ± 7.95, usual care control 9.02 ± 7.64 • Care dependency, MDS ADL (mean ± SD): intervention group 25.05 ± 12.52, active control 27.41 ± 10.49, usual care control 25.99 ± 11.18
Interventions	**Intervention:** Individualized Positive Psychosocial Intervention (IPPI) **Active control:** standardised 1-to-1 activities **Control:** usual care
Outcomes	No primary outcome defined. • Behaviour (verbal and nonverbal) • Affect (positive affect: pleasure, alertness; negative affect: sadness, anger, anxiety)
Funding	Alzheimer's Association Tacrine Fund (Pilot Research Grant TRG-95-006) and the Pennsylvania Department of Health (4100054858)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Drawing sealed ward-numbers (unpublished information).
Allocation concealment (selection bias)	High risk	No information reported, group allocation was not concealed (unpublished information from the study author).
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Having each unit provide only one of the two experimental conditions mitigated the possibility of cross-contamination because staff members were blinded to the condition of their unit."

Van Haitsma 2015 *(Continued)*

		On each unit, one group of residents received one type of activity programme (intervention or active control) and another group of participants received usual care; blinding of personnel refers only to the type of activity programme (intervention or active control). Since nursing staff was aware whether a participant received an activity programme or usual care there is a risk of contamination. We judged risk of performance bias to be high.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Before data collection began, RA training included studying the coding manual, observing senior researchers code resident behavior, discussing coding decisions, and practicing coding with a mentor. Within 2 months, all trainees showed adequate reliability (75% agreement or better) and could code interventions independently. Each week, the research team analysed reliability." Outcomes were assessed by trained research assistants using a technical device (event recorder). No information about blinding was reported. We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up: n = 15; intervention group: n = 5 (n = 3 refused, n = 1 died, n = 1 hospitalised), active control group: n = 6 (n = 1 refused, n = 0 died, n = 5 hospitalised), usual care group: n = 4 (n = 2 refused, n = 1 died, n = 1 hospitalised).
Selective reporting (reporting bias)	Unclear risk	Not registered, no study protocol available.
Other bias	Low risk	-

Wenborn 2013

Study characteristics	
Methods	**Study design:** cluster-randomised controlled trial (ISRCTN67952488, retrospectively registered) **Duration of follow-up:** 28 weeks (16 weeks delivery of the intervention, 12 weeks post-intervention follow-up) **Study period:** not reported
Participants	**Country**: UK **Setting:** care homes across London **Participants/clusters** • Inclusion criteria for clusters: sufficient staff available to attend the intervention programme (minimum of 3 per home), sufficient residents eligible for inclusion (double the number of staff designated to participate in the intervention) • Criteria for matching of clusters: provider (i.e. private company or statutory service or voluntary organisation), number of beds, registration category. For each participating organisation it was guaranteed to receive the intervention in at least 1 home • Inclusion criteria for residents: all residents ≥ 60 years, who had lived in the care home for at least 2 months and intending to stay, met the DSM-IV criteria for dementia (American Psychiatric Association 1994) and had a MMSE score less than 25 • Exclusion criteria: residents with other serious physical or mental health problems • Number of participants randomised: n = 210; intervention group n = 104 (8 clusters), control group n = 106 (8 clusters) • Number of participants lost to follow-up: intervention group n = 25 (17 died, 7 hospitalised, 1 moved), control group n = 26 (23 died, 1 hospitalised, 2 moved)

Wenborn 2013 *(Continued)*

- Number of participants completed the study: n = 159; intervention group n = 79, control group n = 80

Baseline characteristics

- Age (mean ± SD) years: intervention group 84.2 ± 7.6, control group 84.2 ± 7.6
- Gender, female: intervention group 63.5%, control group 70.8%
- Cognitive status, MMSE (mean ± SD): intervention group 5.8 ± 5.1, control group 5.5 ± 4.6
- Care dependency, CAPE-BRS (mean ± SD): intervention group 20.2 ± 4.3, control group 19.4 ± 4.6

Interventions	**Intervention**: staff training designed to enable care home staff to provide personalised activities **Control**: usual care
Outcomes	**Primary**: Quality of Life (QoL-AD, self- and caregiver-rating) **Secondary**: challenging behaviour (CBS), depression (CSD), anxiety (RAID), number and type of medication
Funding	North East London Mental Health NHS Trust – Occupational Therapy service; UK
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Care homes were recruited as matched pairs (matched according to provider: statutory, private or voluntary organisation and size). In each pair, 1 care home was allocated to the intervention group and the other to the control group using a computer random number generator (published and unpublished information).
Allocation concealment (selection bias)	Low risk	Allocation was performed by a remote randomisation service (unpublished information).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information reported. The nursing staff was trained to deliver the intervention; therefore blinding seems not possible, but the intervention was delivered at the cluster level. We have insufficient information to permit judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were assessed by the primary investigator "at baseline and by blinded assessors at follow-up." Baseline assessment was conducted before the clusters were randomised.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants lost to follow-up: n = 51; intervention group n = 25 (n = 17 died, n = 7 admitted to hospital, n = 1 moved), control group n = 26 (n = 23 died, n = 1 admitted to hospital, n = 2 moved).
Selective reporting (reporting bias)	Unclear risk	Study was retrospectively registered, no study protocol available.
Other bias	Low risk	-

Yuen 2019

Study characteristics	
Methods	**Study design:** randomised controlled trial (not registered) **Duration of follow-up:** 2 weeks **Study period:** not reported
Participants	**Country:** Hong Kong, New Territories West region **Setting:** one long-term care home **Participants** • Included criteria: diagnosis of dementia with moderate to severe cognitive decline (at least stage 4 on global deterioration scale (GDS)); expressing significant agitation (frequency score > 39 on the Chinese version of the Cohen-Mansfield agitation inventory (CMAI) for nursing home) • Excluded criteria: Indication of untreated pain, depression, and delirium; recent change in psychoactive medication; and medical emergency • Number of participants randomised: n=46 (intervention group: 23, control group: 23) **Baseline characteristics** • All participants completed the study • Age (mean ± SD) years: intervention group 86.17 ± 7.75, control group 86.74 ± 6.09 • Gender, female: intervention group 78%, control group 78% • Cognitive status (Global Deterioration Scale, stage, %): intervention group: stage 4-5 n = 14 (61%), stage 6-7 n = 9 (39%); control group: stage 4-5 n = 19 (83%), stage 6-7 n = 4 (17%) • Care dependency: not assessed
Interventions	**Intervention:** DementiAbility Methods: The Montessori Way **Control:** structured social activities
Outcomes	Agitation (CMAI, Chinese version)
Funding	No information reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"After screening, 46 demented residents with moderate to severe cognitive decline were randomly allocated into the DMMW intervention (DMMW; n = 23) group and the structured social activities (Structured social activities as control [SC]; n = 23) control group." Method of sequence generation not reported.
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The structure and format of the intervention and control groups were designed to parallel each other in terms of their duration (ie, 45 minutes per session) and frequency of sessions (ie, three times per week) and group size. The intervention group was administered by certified DMMW practitioner while the

Yuen 2019 *(Continued)*

		control group was administered by noncertified professional who had same years of allied health experience in dementia care." Participants of both study groups received any intervention and we judged risk of performance bias to be low.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The assessment on participants was conducted by trained raters, including personal care worker and nurse who were blind to group assignment of the participants."
Incomplete outcome data (attrition bias) All outcomes	Low risk	"There was full attendance and no attribution during the study period."
Selective reporting (reporting bias)	Unclear risk	Not registered, no study protocol available.
Other bias	Low risk	-

ABMI = Agitation Behavior Mapping Instrument; ADL = Activities of daily living; ARS = Philadelphia Geriatric Center Affect Rating Scale; CAPE-BRS = Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale; CBS = Challenging Behaviour Scale; CDR = Clinical Dementia Rating Scale; CMAI = Cohen-Mansfield Agitation Inventory; CSD = Cornell Scale for Depression; DMMW = DementiAbility Methods: The Montessori Way; DSM = Diagnostic and Statistical Manual of Mental Disorders; GDS-12R = Geriatric Depression Scale; MDS = Minimum Data Set; MMSE = mini mental state examination; MPES = Menorah Park Engagement Scale; MRI-ES = Myers Research Institute Engagement Scale; PDS = Passivity in Dementia Scale; QoL-AD = Quality of Life - Alzheimer's Disease; RAID = Rating Anxiety in Dementia scale; SD: standard deviation; sMMSE = standardized Mini-Mental State Examination score; TREA = Treatment Routes for Exploring Agitation

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
ACTRN12618001505291	Ineligible intervention
Beck 2002	Ineligible intervention
Chan 2021	Ineligible population
Chaudhry 2020	Ineligible study design
Cohen-Mansfield 2006	Ineligible setting (participants recruited from both long-term care facilities and day centres, no data on the different settings available)
Davison 2016	Ineligible intervention
Diehl 2020	Ineligible intervention
DiNapoli 2016	Ineligible setting (geriatric psychiatry)
Eloniemi-Sulkava 2019	Ineligible intervention
Farina 2006	Ineligible setting (day care centre)
Farina 2009	Ineligible setting (day care centre)
Gaspar 2020	Ineligible study design

Study	Reason for exclusion
Gerber 1991	Ineligible setting (psychiatric hospital)
Hong 2011	Ineligible intervention
Hopman-Rock 1999	Ineligible intervention
Hsu 2015	Ineligible intervention
Kolanowski 2005	Ineligible study design
Koskela 2017	Ineligible intervention
Kovach 2004	Ineligible intervention
Lin 2009	Ineligible intervention
Livingston 2019	Ineligible intervention
Luttenberger 2012	Ineligible intervention
Mansbach 2017	Ineligible intervention
Meeks 2008	Ineligible population
Morley 2014	Ineligible study design
Mowrey 2013	Ineligible study design
NCT04515875	Ineligible population
O'Sullivan 2021	Ineligible intervention
O'Sullivan 2022	Ineligible intervention
Patel 2016	Ineligible study design
Pieper 2016	Ineligible intervention
Politis 2004	Ineligible intervention
Rapp 2013	Ineligible intervention
Sackley 2009	Ineligible intervention
Sánchez 2016	Ineligible intervention
Schneider 2003	Ineligible study design
Smith 2019	Ineligible study design
Sung 2010	Ineligible intervention
Treusch 2015	Ineligible intervention
Vink 2014	Ineligible intervention

Study	Reason for exclusion
Wilkinson 2018	Ineligible intervention
Wilks 2019	Ineligible study design

DATA AND ANALYSES

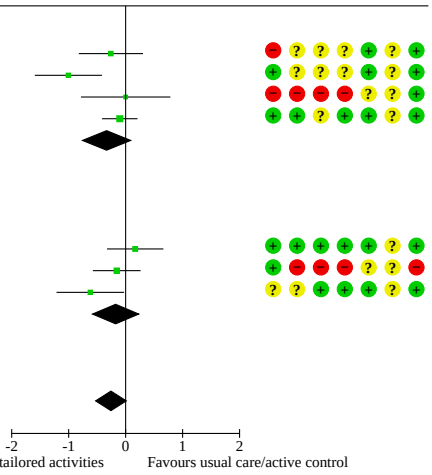
Comparison 1. Personally tailored activities vs usual care or active control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Agitation	7	485	Std. Mean Difference (IV, Random, 95% CI)	-0.26 [-0.53, 0.01]
1.1.1 Personally tailored activities vs usual care	4	288	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.76, 0.09]
1.1.2 Personally tailored activities vs active control	3	197	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.58, 0.23]
1.2 Behaviours (van Haitsma 2015)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2.1 General restlessness	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2.2 Aggression	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2.3 Uncooperative	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2.4 Very negative verbal	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2.5 Negative verbal	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.3 Quality of life (proxy-rated)	2	177	Mean Difference (IV, Random, 95% CI)	-0.83 [-3.97, 2.30]
1.4 Positive affect	6	498	Std. Mean Difference (IV, Random, 95% CI)	0.88 [0.43, 1.32]
1.4.1 Personally tailored activities vs usual care	4	282	Std. Mean Difference (IV, Random, 95% CI)	1.30 [0.77, 1.84]
1.4.2 Personally tailored activities vs active control	3	216	Std. Mean Difference (IV, Random, 95% CI)	0.36 [0.09, 0.63]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.5 Positive affect - sensitivity analysis excluding recalculated study results	5	318	Std. Mean Difference (IV, Random, 95% CI)	0.76 [0.38, 1.13]
1.6 Negative affect	6	632	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.19, 0.14]
1.6.1 Personally tailored activities vs usual care	4	416	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.19, 0.22]
1.6.2 Personally tailored activities vs active control	3	216	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.36, 0.18]
1.7 Negative affect - sensitivity analysis excluding recalculated study results	5	452	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.22, 0.16]
1.8 Mood	4	265	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.21, 0.27]
1.8.1 Personally tailored activities vs active control	2	81	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.40, 0.47]
1.8.2 Personally tailored activities vs usual care	2	184	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.26, 0.32]
1.9 Mood - sensitivity analysis excluding studies with people with depression	3	247	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.23, 0.27]
1.9.1 Personally tailored activities vs usual care	2	184	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.26, 0.32]
1.9.2 Personally tailored activities vs active control	1	63	Std. Mean Difference (IV, Random, 95% CI)	0.00 [-0.49, 0.49]
1.10 Intensity of participation	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.11 Constructive engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.12 Passive engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.13 Negative engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.14 Daytime minutes slept	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.15 Nighttime minutes slept	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 1: Agitation

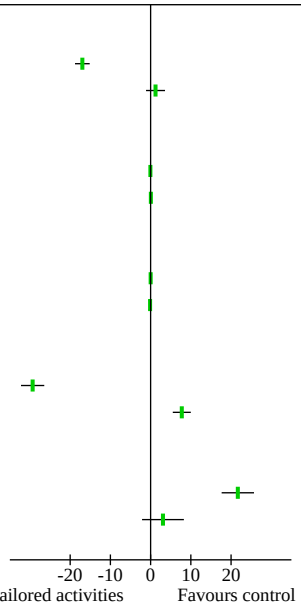
Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.1.1 Personally tailored activities vs usual care								
Cohen-Mansfield 2007	3.23	3.16	26	4.1	3.47	23	13.0%	-0.26 [-0.82 , 0.30]
Cohen-Mansfield 2012	2.08	2.68	36	7.92	9.09	19	12.3%	-1.01 [-1.59 , -0.42]
Orsulic-Jeras 2000	20.3	5.5	13	20.3	3.9	12	8.5%	0.00 [-0.78 , 0.78]
Wenborn 2013	50.24	59.84	79	55.83	48.08	80	21.5%	-0.10 [-0.41 , 0.21]
Subtotal (95% CI)			**154**			**134**	**55.3%**	**-0.33 [-0.76 , 0.09]**
Heterogeneity: Tau² = 0.11; Chi² = 7.55, df = 3 (P = 0.06); I² = 60%								
Test for overall effect: Z = 1.55 (P = 0.12)								
1.1.2 Personally tailored activities vs active control								
Kolanowski 2011	1.5	2.49	31	1.1	2.22	32	14.9%	0.17 [-0.33 , 0.66]
van der Ploeg 2013	8.4	9.9	44	10	10.4	44	17.5%	-0.16 [-0.57 , 0.26]
Yuen 2019	-10.09	14.26	23	-1.57	12.69	23	12.2%	-0.62 [-1.21 , -0.03]
Subtotal (95% CI)			**98**			**99**	**44.7%**	**-0.18 [-0.58 , 0.23]**
Heterogeneity: Tau² = 0.06; Chi² = 4.00, df = 2 (P = 0.14); I² = 50%								
Test for overall effect: Z = 0.85 (P = 0.40)								
Total (95% CI)			**252**			**233**	**100.0%**	**-0.26 [-0.53 , 0.01]**
Heterogeneity: Tau² = 0.06; Chi² = 11.89, df = 6 (P = 0.06); I² = 50%								
Test for overall effect: Z = 1.88 (P = 0.06)								
Test for subgroup differences: Chi² = 0.28, df = 1 (P = 0.60), I² = 0%								



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.2. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 2: Behaviours (van Haitsma 2015)

Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
1.2.1 General restlessness							
Van Haitsma 2015 (1)	6.5	5.66	44	23.47	3.6	93	-16.97 [-18.80 , -15.14]
Van Haitsma 2015 (2)	6.5	5.66	44	5.28	5.56	43	1.22 [-1.14 , 3.58]
1.2.2 Aggression							
Van Haitsma 2015 (2)	0.061	0.04	44	0.117	0.04	43	-0.06 [-0.07 , -0.04]
Van Haitsma 2015 (1)	0.061	0.04	44	0	0.02	93	0.06 [0.05 , 0.07]
1.2.3 Uncooperative							
Van Haitsma 2015 (1)	0.016	0.04	44	0.006	0.02	93	0.01 [-0.00 , 0.02]
Van Haitsma 2015 (2)	0.016	0.04	44	0.149	0.04	43	-0.13 [-0.15 , -0.12]
1.2.4 Very negative verbal							
Van Haitsma 2015 (2)	12.49	6.94	44	41.82	6.82	43	-29.33 [-32.22 , -26.44]
Van Haitsma 2015 (1)	12.49	6.94	44	4.74	4.42	93	7.75 [5.51 , 9.99]
1.2.5 Negative verbal							
Van Haitsma 2015 (1)	52.51	12.47	44	30.83	7.94	93	21.68 [17.66 , 25.70]
Van Haitsma 2015 (2)	52.51	12.47	44	49.44	12.26	43	3.07 [-2.13 , 8.27]

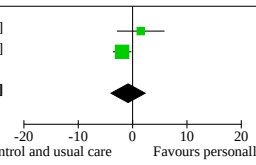


Footnotes
(1) Usual care control
(2) Active control

Analysis 1.3. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 3: Quality of life (proxy-rated)

Study or Subgroup	Personally tailored activities Mean	SD	Total	Usual care and actice control group Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Travers 2017	0.5	6.81478	10	-1	1.644696	8	32.0%	1.50 [-2.87 , 5.87]
Wenborn 2013	28.57	5.4684	79	30.5	5.4684	80	68.0%	-1.93 [-3.63 , -0.23]
Total (95% CI)			**89**			**88**	**100.0%**	**-0.83 [-3.97 , 2.30]**

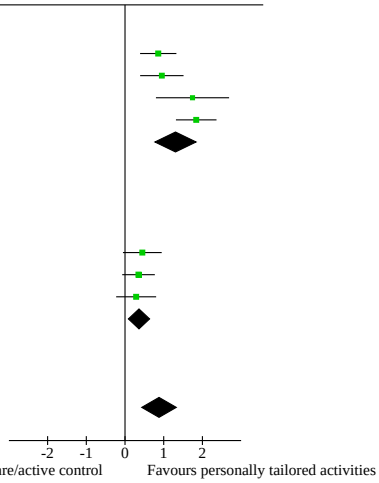
Heterogeneity: Tau² = 3.02; Chi² = 2.05, df = 1 (P = 0.15); I² = 51%
Test for overall effect: Z = 0.52 (P = 0.60)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

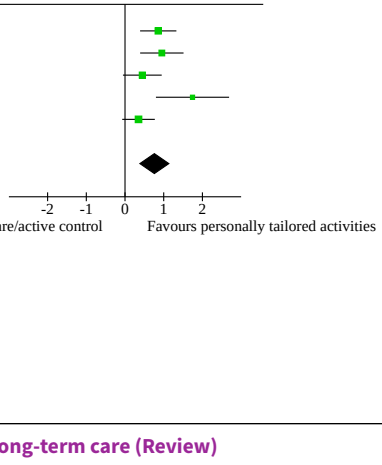
Analysis 1.4. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 4: Positive affect

Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.4.1 Personally tailored activities vs usual care								
Cohen-Mansfield 2007	1.65	0.49	41	1.28	0.34	36	15.3%	0.86 [0.39 , 1.33]
Cohen-Mansfield 2012	1.27	0.28	46	1.04	0.06	19	14.3%	0.95 [0.39 , 1.51]
Orsulic-Jeras 2000	2.6	0.5	12	1.6	0.6	13	10.1%	1.74 [0.80 , 2.69]
Van Haitsma 2015	8.16	1.49	22	5.4	1.49	93	14.7%	1.84 [1.32 , 2.36]
Subtotal (95% CI)			**121**			**161**	**54.4%**	**1.30 [0.77 , 1.84]**
Heterogeneity: Tau² = 0.20; Chi² = 9.69, df = 3 (P = 0.02); I² = 69%								
Test for overall effect: Z = 4.81 (P < 0.00001)								
1.4.2 Personally tailored activities vs active control								
Kolanowski 2011	3	0.7361	31	2.67	0.7211	32	15.0%	0.45 [-0.05 , 0.95]
van der Ploeg 2013	1.4	3.8	44	0.4	1.3	44	15.8%	0.35 [-0.07 , 0.77]
Van Haitsma 2015	8.16	1.49	22	7.72	1.52	43	14.8%	0.29 [-0.23 , 0.80]
Subtotal (95% CI)			**97**			**119**	**45.6%**	**0.36 [0.09 , 0.63]**
Heterogeneity: Tau² = 0.00; Chi² = 0.19, df = 2 (P = 0.91); I² = 0%								
Test for overall effect: Z = 2.59 (P = 0.010)								
Total (95% CI)			**218**			**280**	**100.0%**	**0.88 [0.43 , 1.32]**
Heterogeneity: Tau² = 0.28; Chi² = 29.39, df = 6 (P < 0.0001); I² = 80%								
Test for overall effect: Z = 3.86 (P = 0.0001)								
Test for subgroup differences: Chi² = 9.57, df = 1 (P = 0.002), I² = 89.5%								



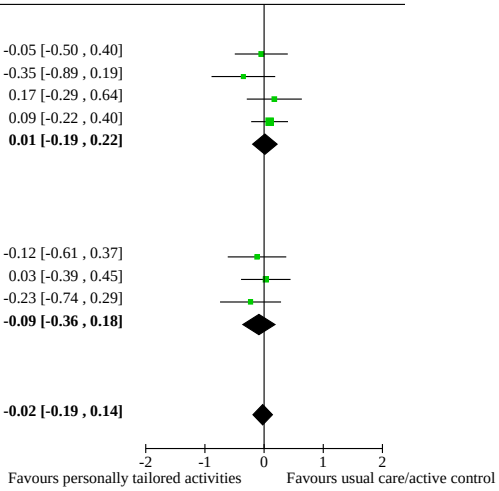
Analysis 1.5. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 5: Positive affect - sensitivity analysis excluding recalculated study results

Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Cohen-Mansfield 2007	1.65	0.49	41	1.28	0.34	36	22.9%	0.86 [0.39 , 1.33]
Cohen-Mansfield 2012	1.27	0.28	46	1.04	0.06	19	19.8%	0.95 [0.39 , 1.51]
Kolanowski 2011	3	0.7361	31	2.67	0.7211	32	21.8%	0.45 [-0.05 , 0.95]
Orsulic-Jeras 2000	2.6	0.5	12	1.6	0.6	13	10.9%	1.74 [0.80 , 2.69]
van der Ploeg 2013	1.4	3.8	44	0.4	1.3	44	24.6%	0.35 [-0.07 , 0.77]
Total (95% CI)			**174**			**144**	**100.0%**	**0.76 [0.38 , 1.13]**
Heterogeneity: Tau² = 0.10; Chi² = 9.53, df = 4 (P = 0.05); I² = 58%								
Test for overall effect: Z = 3.98 (P < 0.0001)								
Test for subgroup differences: Not applicable								



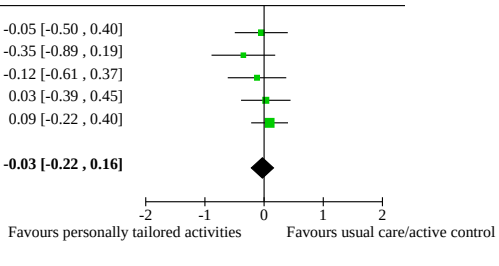
Analysis 1.6. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 6: Negative affect

Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.6.1 Personally tailored activities vs usual care								
Cohen-Mansfield 2007	1.08	0.1	41	1.11	0.91	36	13.5%	-0.05 [-0.50 , 0.40]
Cohen-Mansfield 2012	1.03	0.05	46	1.05	0.07	19	9.3%	-0.35 [-0.89 , 0.19]
Van Haitsma 2015	4.49	1.58	22	4.25	1.33	93	12.5%	0.17 [-0.29 , 0.64]
Wenborn 2013	3.37	5.89	79	2.89	4.27	80	27.9%	0.09 [-0.22 , 0.40]
Subtotal (95% CI)			**188**			**228**	**63.3%**	**0.01 [-0.19 , 0.22]**
Heterogeneity: Tau² = 0.00; Chi² = 2.53, df = 3 (P = 0.47); I² = 0%								
Test for overall effect: Z = 0.13 (P = 0.90)								
1.6.2 Personally tailored activities vs active control								
Kolanowski 2011	1.5	0.8179	31	1.6	0.8321	32	11.1%	-0.12 [-0.61 , 0.37]
van der Ploeg 2013	0.9	3.4	44	0.8	3.5	44	15.5%	0.03 [-0.39 , 0.45]
Van Haitsma 2015	4.49	1.58	22	4.95	2.16	43	10.2%	-0.23 [-0.74 , 0.29]
Subtotal (95% CI)			**97**			**119**	**36.7%**	**-0.09 [-0.36 , 0.18]**
Heterogeneity: Tau² = 0.00; Chi² = 0.60, df = 2 (P = 0.74); I² = 0%								
Test for overall effect: Z = 0.63 (P = 0.53)								
Total (95% CI)			**285**			**347**	**100.0%**	**-0.02 [-0.19 , 0.14]**
Heterogeneity: Tau² = 0.00; Chi² = 3.46, df = 6 (P = 0.75); I² = 0%								
Test for overall effect: Z = 0.28 (P = 0.78)								
Test for subgroup differences: Chi² = 0.34, df = 1 (P = 0.56), I² = 0%								



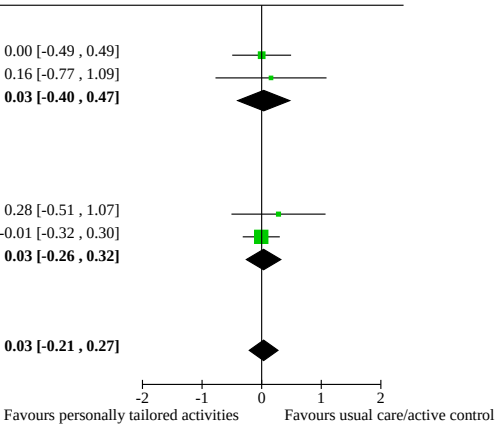
Analysis 1.7. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 7: Negative affect - sensitivity analysis excluding recalculated study results

Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Cohen-Mansfield 2007	1.08	0.1	41	1.11	0.91	36	17.4%	-0.05 [-0.50 , 0.40]
Cohen-Mansfield 2012	1.03	0.05	46	1.05	0.07	19	12.1%	-0.35 [-0.89 , 0.19]
Kolanowski 2011	1.5	0.8179	31	1.6	0.8321	32	14.3%	-0.12 [-0.61 , 0.37]
van der Ploeg 2013	0.9	3.4	44	0.8	3.5	44	20.0%	0.03 [-0.39 , 0.45]
Wenborn 2013	3.37	5.89	79	2.89	4.27	80	36.1%	0.09 [-0.22 , 0.40]
Total (95% CI)			**241**			**211**	**100.0%**	**-0.03 [-0.22 , 0.16]**
Heterogeneity: Tau² = 0.00; Chi² = 2.17, df = 4 (P = 0.70); I² = 0%								
Test for overall effect: Z = 0.30 (P = 0.77)								
Test for subgroup differences: Not applicable								

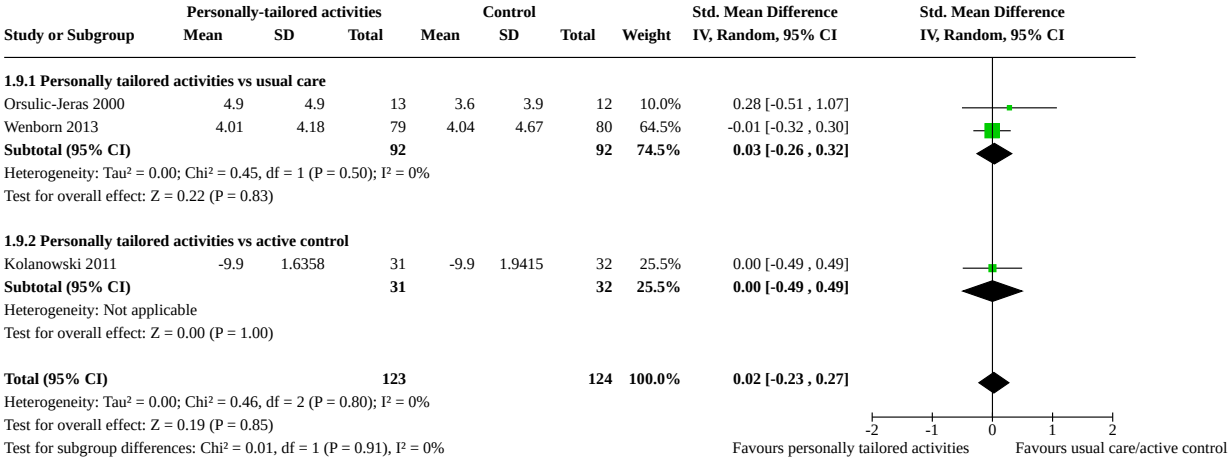


Analysis 1.8. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 8: Mood

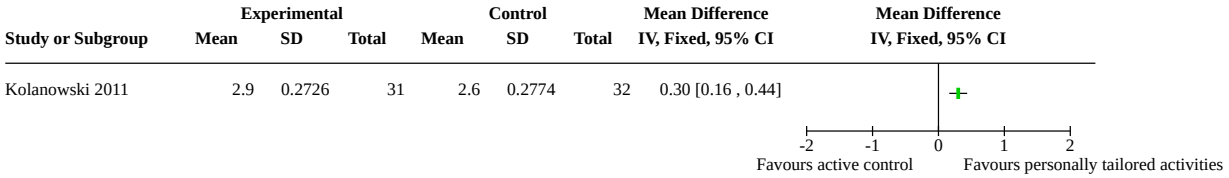
Study or Subgroup	Personally-tailored activities Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.8.1 Personally tailored activities vs active control								
Kolanowski 2011	-9.9	1.6358	31	-9.9	1.9415	32	23.8%	0.00 [-0.49 , 0.49]
Travers 2017	5	7.513732	10	4	3.438909	8	6.7%	0.16 [-0.77 , 1.09]
Subtotal (95% CI)			**41**			**40**	**30.5%**	**0.03 [-0.40 , 0.47]**
Heterogeneity: Tau² = 0.00; Chi² = 0.08, df = 1 (P = 0.77); I² = 0%								
Test for overall effect: Z = 0.15 (P = 0.88)								
1.8.2 Personally tailored activities vs usual care								
Orsulic-Jeras 2000	4.9	4.9	13	3.6	3.9	12	9.3%	0.28 [-0.51 , 1.07]
Wenborn 2013	4.01	4.18	79	4.04	4.67	80	60.1%	-0.01 [-0.32 , 0.30]
Subtotal (95% CI)			**92**			**92**	**69.5%**	**0.03 [-0.26 , 0.32]**
Heterogeneity: Tau² = 0.00; Chi² = 0.45, df = 1 (P = 0.50); I² = 0%								
Test for overall effect: Z = 0.22 (P = 0.83)								
Total (95% CI)			**133**			**132**	**100.0%**	**0.03 [-0.21 , 0.27]**
Heterogeneity: Tau² = 0.00; Chi² = 0.53, df = 3 (P = 0.91); I² = 0%								
Test for overall effect: Z = 0.27 (P = 0.79)								
Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.99), I² = 0%								



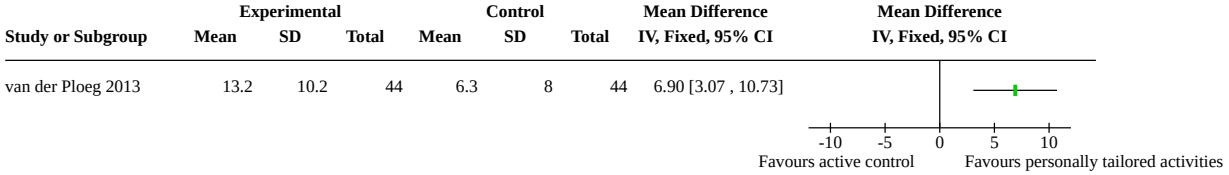
Analysis 1.9. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 9: Mood - sensitivity analysis excluding studies with people with depression



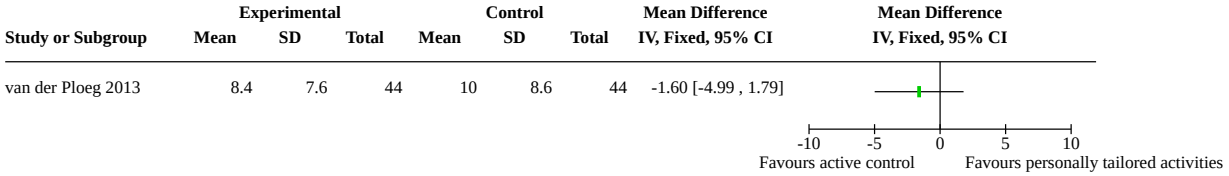
Analysis 1.10. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 10: Intensity of participation



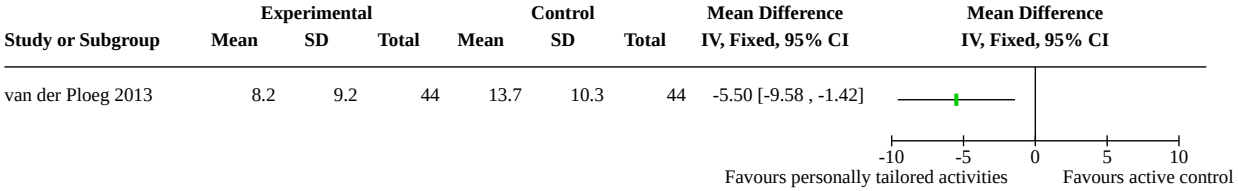
Analysis 1.11. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 11: Constructive engagement



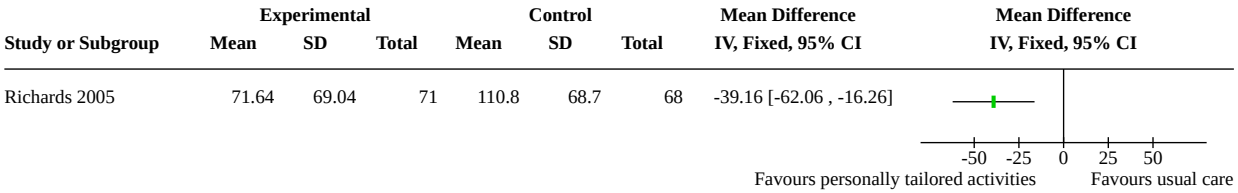
Analysis 1.12. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 12: Passive engagement



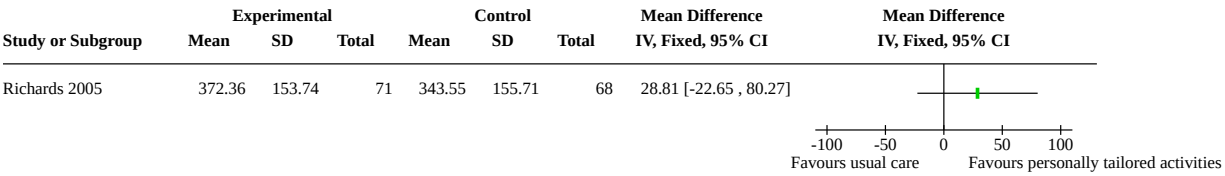
Analysis 1.13. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 13: Negative engagement



Analysis 1.14. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 14: Daytime minutes slept



Analysis 1.15. Comparison 1: Personally tailored activities vs usual care or active control, Outcome 15: Nighttime minutes slept



ADDITIONAL TABLES

Table 1. Delivery of the intervention

Reference	Delivered by	Frequency and duration of the sessions	Duration of follow-up
Cohen-Mansfield 2007	Research assistant (no further information reported)	Daily; up to 4 h per day (peak period of agitation)	10 consecutive days
Cohen-Mansfield 2012	Research assistant (no further information reported)	Daily; up to 4 h per day (peak period of agitation)	2 weeks
Kolanowski 2011	Research assistant (no further information reported)	5 days per week; up to 20 minutes twice per day (morning and afternoon)	4 weeks (3 weeks intervention period plus 1 week postintervention period)
Mbakile-Mahlanza 2020	Family members (trained by the senior researcher who had experiences with the Montessori approach, 3-hour group sessions in the nursing home, 30 min to assist the family members filling out the baseline questionnaire, one	2 sessions per week (30 min) in a quiet room with no distractions. Family members interacted with the residents while engaging with the activities.	2 weeks

Table 1. Delivery of the intervention *(Continued)*

	hour explaining the theoretical basis of Montessori activities in dementia, 90 min for selecting and practising possible activities in small groups)		
Orsulic-Jeras 2000	Trained volunteer, nursing assistant or activities therapist	At least twice a week; individual activities 10 to 30 min, group activities 25 to 45 min, QAR 30 min to 1 h	9 months
Richards 2005	Nursing assistant (no further information reported)	Daily; several sessions 15 to 30 min (max 1 to 2 h per day), between 9:00 a.m. and 5:00 p.m.	21 consecutive days
Travers 2017	Mental Health Therapist (qualified social worker experienced in working with older people with and without cognitive impairment), supported by nominated staff members (co-therapists)	One session per week (45 min/week)	8 weeks
van der Ploeg 2013	Activity facilitators (psychologists or higher-degree psychology students, received regular personal supervision throughout the study)	Twice a week; 30-min sessions (at times when participants' target behaviour was most frequent)	4 weeks (2 weeks per condition)
Van Haitsma 2015	Certified nursing assistants (no further information reported)	3 days per week; 10 min per session (not during mealtimes or shift change)	3 weeks
Wenborn 2013	Primary investigator (occupational therapist with extensive experience of working with older people with dementia)	Not reported; five 2-h educational sessions for nursing staff	28 weeks (16 weeks intervention period plus 12 weeks post-intervention period)
Yuen 2019	Certified DMMW practitioner (no further information provided)	3 sessions per week, 45 min.	2 weeks

DMMW = DementiAbility Methods: The Montessori Way; QAR = question asking reading group

APPENDICES

Appendix 1. Sources searched and search strategies

Source	Search strategy	Hits retrieved
1. CDCIG Register (https://crsweb.cochrane.org/login.html) [most recent search date: 15 June 2022]	#1 "personally tailored" OR individualized OR individualised OR individual OR person-centred OR meaningful OR personhood #2 involvement OR engagement OR engaging OR identity #3 #1 OR #2	May 2012: 149 April 2013: 0 March 2014: 6 January 2015: 1 January 2016: 2 October 2016: 2

(Continued)

		June 2017: 3 June 2020: 41 Oct 2021: 43 June 2022: 35
2. MEDLINE In-process and other non-indexed citations and MEDLINE 1946 to present (Ovid SP) [most recent search date: 15 June 2022]	1. exp Dementia/ 2. Delirium/ 3. Wernicke Encephalopathy/ 4. Delirium, Dementia, Amnestic, Cognitive Disorders/ 5. dement*.mp. 6. alzheimer*.mp. 7. (lewy* adj2 bod*).mp. 8. deliri*.mp. 9. (chronic adj2 cerebrovascular).mp. 10. ("organic brain disease" or "organic brain syndrome").mp. 11. ("normal pressure hydrocephalus" and "shunt*").mp. 12. "benign senescent forgetfulness".mp. 13. (cerebr* adj2 deteriorat*).mp. 14. (cerebral* adj2 insufficient*).mp. 15. (pick* adj2 disease).mp. 16. (creutzfeldt or jcd or cjd).mp. 17. huntington*.mp. 18. binswanger*.mp. 19. korsako*.mp. 20. or/1-19 21. activity.ti,ab. 22. activities.ti,ab. 23. psychosocial.ti,ab. 24. non-pharmacological.ti,ab. 25. individually-tailor*.ti,ab. 26. personally-tailor*.ti,ab. 27. (individual or individuals or individually-cent*).ti,ab. 28. meaning*.ti,ab. 29. involvement.ti,ab. 30. (engagement or engaging).ti,ab.	May 2012: 1656 April 2013: 205 March 2014: 177 January 2015: 182 January 2016: 185 October 2016: 367 June 2017: 358 June 2020: 913 Oct 2021: 643 June 2022: 590

(Continued)

	31. occupational*.ti,ab.	
	32. personhood.ti,ab.	
	33. person-centred.ti,ab.	
	34. identity.ti,ab.	
	35. or/21-34	
	36. 20 and 35	
	37. long-term care.ti,ab.	
	38. "care home*".ti,ab.	
	39. "residential care".ti,ab.	
	40. "nursing home*".ti,ab.	
	41. "residential facilit*".ti,ab.	
	42. Residential Facilities/	
	43. Nursing Homes/	
	44. "old people* home*".ti,ab.	
	45. or/37-44	
	46. 36 and 45	
3. Embase 1974 to present (Ovid SP) [most recent search date: 15 June 2022]	1. exp dementia/	May 2012:2400
	2. Lewy body/	April 2013: 382
	3. delirium/	March 2014: 452
	4. Wernicke encephalopathy/	January 2015: 492
	5. cognitive defect/	January 2016: 463
	6. dement*.mp.	October 2016: 777
	7. alzheimer*.mp.	June 2017: 691
	8. (lewy* adj2 bod*).mp.	June 2020: 1827
	9. deliri*.mp.	Oct 2021: 1116
	10. (chronic adj2 cerebrovascular).mp.	June 2022: 1026
	11. ("organic brain disease" or "organic brain syndrome").mp.	
	12. "supranuclear palsy".mp.	
	13. ("normal pressure hydrocephalus" and "shunt*").mp.	
	14. "benign senescent forgetfulness".mp.	
	15. (cerebr* adj2 deteriorat*).mp.	
	16. (cerebral* adj2 insufficient*).mp.	
	17. (pick* adj2 disease).mp.	
	18. (creutzfeldt or jcd or cjd).mp.	

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	19. huntington*.mp.	
	20. binswanger*.mp.	
	21. korsako*.mp.	
	22. CADASIL.mp.	
	23. or/1-22	
	24. activity.ti,ab.	
	25. activities.ti,ab.	
	26. psychosocial.ti,ab.	
	27. non-pharmacological.ti,ab.	
	28. individually-tailor*.ti,ab.	
	29. personally-tailor*.ti,ab.	
	30. (individual or individuals or individually-cent*).ti,ab.	
	31. meaning*.ti,ab.	
	32. involvement.ti,ab.	
	33. (engagement or engaging).ti,ab.	
	34. occupational*.ti,ab.	
	35. personhood.ti,ab.	
	36. person-centred.ti,ab.	
	37. identity.ti,ab.	
	38. or/24-37	
	39. 23 and 38	
	40. long-term care.ti,ab.	
	41. "care home*".ti,ab.	
	42. "residential care".ti,ab.	
	43. "nursing home*".ti,ab.	
	44. "residential facilit*".ti,ab.	
	45. residential home/	
	46. nursing home/	
	47. "old people* home*".ti,ab.	
	48. or/40-47	
	49. 39 and 48	
	50. 39 and 48	
4. PsycINFO	1. exp Dementia/	May 2012: 1633
	2. exp Delirium/	April 2012: 191

(Continued)

1806 to May present (Ovid SP); [most recent search date: 15 June 2022]	3. exp Huntingtons Disease/	March 2014: 202
	4. exp Kluver Bucy Syndrome/	January 2015: 207
	5. exp Wernickes Syndrome/	January 2016: 228
	6. exp Cognitive Impairment/	October 2016: 356
	7. dement*.mp.	June 2017: 268
	8. alzheimer*.mp.	June 2020: 610
	9. (lewy* adj2 bod*).mp.	Oct 2021: 387
	10. deliri*.mp.	June 2022: 316
	11. (chronic adj2 cerebrovascular).mp.	
	12. ("organic brain disease" or "organic brain syndrome").mp.	
	13. "supranuclear palsy".mp.	
	14. ("normal pressure hydrocephalus" and "shunt*").mp.	
	15. "benign senescent forgetfulness".mp.	
	16. (cerebr* adj2 deteriorat*).mp.	
	17. (cerebral* adj2 insufficient*).mp.	
	18. (pick* adj2 disease).mp.	
	19. (creutzfeldt or jcd or cjd).mp.	
	20. huntington*.mp.	
	21. binswanger*.mp.	
	22. korsako*.mp.	
	23. ("parkinson* disease dementia" or PDD or "parkinson* dementia").mp.	
	24. or/1-23	
	25. activity.ti,ab.	
	26. activities.ti,ab.	
	27. psychosocial.ti,ab.	
	28. non-pharmacological.ti,ab.	
	29. individually-tailor*.ti,ab.	
	30. personally-tailor*.ti,ab.	
	31. (individual or individuals or individually-cent*).ti,ab.	
	32. meaning*.ti,ab.	
	33. involvement.ti,ab.	
	34. (engagement or engaging).ti,ab.	
	35. occupational*.ti,ab.	
	36. personhood.ti,ab.	

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	37. person-centred.ti,ab. 38. identity.ti,ab. 39. or/25-38 40. 24 and 39 41. long-term care.ti,ab. 42. "care home*".ti,ab. 43. "residential care".ti,ab. 44. "nursing home*".ti,ab. 45. "residential facilit*".ti,ab. 46. exp Nursing Homes/ or exp Residential Care Institutions/ 47. "old people* home*".ti,ab. 48. institutionali?ed.ti,ab. 49. or/41-48 50. 40 and 49	
5. CINAHL (EBSCOhost) [most recent search date: 15 June 2022]	S60 S46 AND S59 S59 S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 S58 MH "Random Assignment" S57 MH "Single-Blind Studies" or MH "Double-Blind Studies" or MH "Triple-Blind Studies" S56 MH "Crossover Design" S55 MH "Factorial Design" S54 MH "Placebos" S53 MH "Clinical Trials" S52 TX "multi-centre study" OR "multi-center study" OR "multicentre study" OR "multicenter study" OR "multi-site study" S51 TX crossover OR "cross-over" S50 AB placebo* S49 TX random* S48 TX trial* S47 TX "latin square" S46 S19 and S34 and S45 S45 S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 S44 TX institutionalised OR institutionalized S43 TX institutional	May 2012: 2367 April 2013: 275 March 2014: 221 January 2015: 158 January 2016: 121 October 2016: 245 June 2017: 274 June 2020: 277 Oct 2021: 129 June 2022: 115

(Continued)

S42 TX "old people* home*"

S41 MH "Nursing Homes"

S40 MH "Residential Facilities"

S39 TX "residential facilit*"

S38 TX "nursing home*"

S37 TX "residential care"

S36 TX "care home*"

S35 TX "long-term care"

S34 S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33

S33 TX identity

S32 TX person-centred

S31 TX personhood

S30 TX occupational*

S29 TX engagement or engaging

S28 TX non-pharmacological

S27 TX psychosocial

S26 AB activities

S25 AB involvement

S24 AB meaningful

S23 AB individual OR individuals OR individually-cent*

S22 TX personally-tailor*

S21 TX individually-tailor*

S20 AB activity

S19 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18

S18 TX korsako*

S17 TX binswanger*

S16 TX huntington*

S15 TX creutzfeldt or jcd or cjd

S14 TX pick* N2 disease

S13 TX cerebral* N2 insufficient*

S12 TX cerebr* N2 deteriorat*

S11 TX "benign senescent forgetfulness"

S10 TX "normal pressure hydrocephalus" and "shunt*"

(Continued)

	S9 TX "organic brain disease" or "organic brain syndrome" S8 TX chronic N2 cerebrovascular S7 TX deliri* S6 TX lewy* N2 bod* S5 TX alzheimer* S4 TX dement* S3 MH "Wernicke's Encephalopathy" S2 (MH "Delirium") or (MH "Delirium, Dementia, Amnestic, Cognitive Disorders") S1 MH "Dementia+"	
6. Web of Science and conference proceedings: Clarivate [most recent search date: 15 June 2022]	TOPIC: (dementia OR alzheimer* OR lewy OR CJD OR JCD OR creutzfeldt OR binswanger OR korsako*) AND TOPIC: (activity OR activities OR psychosocial OR non-pharmacological OR "individually tailor*" OR "personally tailor*" OR individual OR meaningful* OR occupational OR personhood OR "person cent*" OR identity) AND TOPIC: ("long term care" OR "longterm care" OR "residential care" OR "nursing home*" OR "residential facilit*" OR "old people* home*" OR institutionalised OR institutionalized) AND TOPIC: (randomly OR randomised OR randomized OR "random allocat*" OR RCT OR CCT OR "double blind*" OR "single blind*" OR "double blind*" OR "single blind*" OR trial)	May 2012: 2153 April 2013: 311 March 2014: 104 January 2015: 216 January 2016: 391 October 2016: 773 June 2017: 766 June 2020: 420 Oct 2021: 254 June 2022: 170
7. LILACS (BIREME) [most recent search date: 15 June 2022]	dementia OR demencia OR demência OR alzheimer OR alzheimers OR alzheimer's [Words] and "personally tailored" OR "pessoalmente adaptado" OR "personal a medida" OR individual OR individualised OR individualized OR individualmente OR individualmente OR activity OR activites OR atividades OR "las actividades" OR occupational [Words]	May 2012: 313 April 2013: 21 March 2014: 0 January 2015: 3 January 2016: 52 October 2016: 52 June 2017: 67 June 2020: 201 Oct 2021: 67 June 2022: 46
8. CENTRAL (CRSO) [most recent search date: 15 June 2022]	#1 MeSH descriptor Dementia explode all trees #2 MeSH descriptor Delirium, this term only #3 MeSH descriptor Wernicke Encephalopathy, this term only	May 2012: 280 April 2013: 3 March 2014: 10 January 2015: 18

(Continued)

#4 MeSH descriptor Delirium, Dementia, Amnestic, Cognitive Disorders, this term only	January 2016: 13
#5 dement*	October 2016: 50
#6 alzheimer*	June 2017: 17
#7 "lewy* bod*"	June 2020: 210
#8 deliri*	Oct 2021: 46
#9 "chronic cerebrovascular"	June 2022: 68
#10 "organic brain disease" or "organic brain syndrome"	
#11 "normal pressure hydrocephalus" and "shunt*"	
#12 "benign senescent forgetfulness"	
#13 "cerebr* deteriorat*"	
#14 "cerebral* insufficient*"	
#15 "pick* disease"	
#16 creutzfeldt or jcd or cjd	
#17 huntington*	
#18 binswanger*	
#19 korsako*	
#20 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)	
#21 activity	
#22 activities	
#23 psychosocial	
#24 non-pharmacological	
#25 individually-tailor*	
#26 personally-tailor*	
#27 individual OR individuals OR individually-cent*	
#28 meaning*	
#29 involvement	
#30 engagement or engaging	
#31 occupational*	
#32 personhood	
#33 person-centred	
#34 identity	
#35 (#22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)	
#36 "long-term care" OT "longterm care" OR "long term care"	

(Continued)

	#37 "care home*" #38 "residential care" #39 "nursing home*" #40 "residential facilit*" #41 MeSH descriptor Residential Facilities explode all trees #42 MeSH descriptor Nursing Homes explode all trees #43 "old people* home*" #44 institutionalised OR institutionalized #45 (#36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44) #46 (#20 AND #35 AND #45)	
9. Clinicaltrials.gov (www.clinicaltrials.gov) [most recent search date: 15 June 2022]	(personally tailored OR individual OR person-centred OR meaningful OR personhood) | Interventional Studies | dementia OR VCI OR vascular dementia OR VaD OR vascular cognitive impairment OR cadasil OR multi-infarct OR binswanger | Senior	May 2012: 271 April 2013: 47 March 2014: 88 January 2015: 14 January 2016: 13 October 2016: 58 June 2017: 94 June 2020: 46 Oct 2021: 35 June 2022: 13
10. ICTRP Search Portal (apps.who.int/trialsearch) [most recent search date: 28 October 2021. Database not available 15 June 2022]	personally tailored OR individual OR person-centred OR meaningful OR personhood) | Interventional Studies | dementia OR VCI OR vascular dementia OR VaD OR vascular cognitive impairment OR cadasil OR multi-infarct OR binswanger	May 2012: 127 April 2013: 12 March 2014: 13 January 2015: 8 January 2016: 16 October 2016: 4 June 2017: 11 June 2020: unavailable Oct 2021: 3 June 2022: 0
TOTAL before de-duplication		May 2012: 11349 April 2012: 1455 March 2014: 1273 January 2015: 1296

(Continued)

	January 2016: 1435 October 2016: 2682 June 2017: 2549 June 2020: 4545 Oct 2021: 2723 June 2022: 2379
TOTAL after de-duplication and first assessment by CDCIG Information Specialists	May 2012: 532 April 2013: 50 March 2014: 52 January 2015: 54 January 2016: 61 October 2016: 105 June 2017: 180 June 2020: 2975 Oct 2021: 1767 June 2022: 1590

WHAT'S NEW

Date	Event	Description
13 March 2023	New search has been performed	This review has been extensively updated. New studies included. Conclusions changed. Additional author.
13 March 2023	New citation required and conclusions have changed	Three new studies were included in this review update. In total, there are 11 studies with 1071 participants. Following the *Cochrane Handbook,* adverse events are defined as a primary outcome in the review update, rather than secondary outcome as in the first version of this review.

HISTORY

Protocol first published: Issue 4, 2012
Review first published: Issue 2, 2018

CONTRIBUTIONS OF AUTHORS

RM and GM initially planned the study. RM, AR, HR and GM wrote the study protocol.

In the first version of this review (Möhler 2018), RM, AR and HR selected studies, conducted the critical appraisal and extracted data. RM, AR and GM interpreted the study data. RM contacted the study authors and wrote the drafts of the review. All authors contributed to all drafts of the review.

In this update, RM and SC selected studies, conducted the critical appraisal and extracted data. RM, SC, and GM interpreted the study data. RM contacted the study authors and wrote the drafts of the review. All authors contributed to all drafts of the review.

DECLARATIONS OF INTEREST

RM: none known.

SC: none known.

AR: none known.

HR: none known.

GM: none known.

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- No sources of support provided

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the protocol, adverse events were planned as secondary outcomes. Due to changes in the *Cochrane Handbook*, adverse events are a primary outcome in the review update.

INDEX TERMS

Medical Subject Headings (MeSH)

Affect; Anxiety; *Dementia [psychology]; *Long-Term Care; Quality of Life; Randomized Controlled Trials as Topic

MeSH check words

Aged; Aged, 80 and over; Humans