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[Intervention Review]

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

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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. Offering them activities which are tailored to their individual interests and preferences might improve their quality of life and reduce challenging behaviour.

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 ALOIS, the Cochrane Dementia and Cognitive Improvement Group's Specialized Register, on 16 June 2017 using the terms: personally tailored OR individualized OR individualised OR individual OR person-centred OR meaningful OR personhood OR involvement OR engagement OR engaging OR identity. We also performed additional searches in MEDLINE (Ovid SP), Embase (Ovid SP), PsycINFO (Ovid SP), CINAHL (EBSCOhost), Web of Science (ISI 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 and controlled clinical trials offering personally tailored activities. All interventions included an assessment of the participants' present or past preferences for, or interests in, particular activities as a basis for an individual activity plan. Control groups received either usual care or an active control intervention.

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Data collection and analysis

Two authors independently checked the articles for inclusion, extracted data and assessed the methodological quality of included studies. For all studies, we assessed the risk of selection bias, performance bias, attrition bias and detection bias. In case of missing information, we contacted the study authors.

Main results

We included eight studies with 957 participants. The mean age of participants in the studies ranged from 78 to 88 years and in seven studies the mean MMSE score was 12 or lower. Seven studies were randomised controlled trials (three individually randomised, parallel group studies, one individually randomised cross-over study and three cluster-randomised trials) and one study was a non-randomised clinical trial. Five studies included a control group receiving usual care, two studies an active control intervention (activities which were not personally tailored) and one study included both an active control and usual care. Personally tailored activities were mainly delivered directly to the participants; in one study the nursing staff were trained to deliver the activities. The selection of activities was based on different theoretical models but the activities did not vary substantially.

We found low-quality evidence indicating that personally tailored activities may slightly improve challenging behaviour (standardised mean difference (SMD) −0.21, 95% confidence interval (CI) −0.49 to 0.08; I^2 = 50%; 6 studies; 439 participants). We also found low-quality 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). There was very little evidence related to our other primary outcome of quality of life, which was assessed in only one study. From this study, we found that quality of life rated by proxies was slightly worse in the group receiving personally tailored activities (moderate-quality evidence, mean difference (MD) −1.93, 95% CI −3.63 to −0.23; 139 participants). Self-rated quality of life was only available for a small number of participants, and there was little or no difference between personally tailored activities and usual care on this outcome (low-quality evidence, MD 0.26, 95% CI −3.04 to 3.56; 42 participants). We found low-quality evidence that personally tailored activities may make little or no difference to negative affect (SMD −0.02, 95% CI −0.19 to 0.14; I^2 = 0%; 6 studies; 589 participants). We found very low quality evidence and are therefore very uncertain whether personally tailored activities have any effect on positive affect (SMD 0.88, 95% CI 0.43 to 1.32; I^2 = 80%; 6 studies; 498 participants); or mood (SMD −0.02, 95% CI −0.27 to 0.23; I^2 = 0%; 3 studies; 247 participants). We were not able to undertake a meta-analysis for engagement and the sleep-related outcomes. We found very low quality evidence and are therefore very uncertain whether personally tailored activities improve engagement or sleep-related outcomes (176 and 139 participants, respectively). Two studies that investigated the duration of the effects of personally tailored activities indicated that the intervention effects persisted only during the delivery of the activities. Two studies reported information about adverse effects and no adverse effects were observed.

Authors' conclusions

Offering personally tailored activities to people with dementia in long-term care may slightly improve challenging behaviour. Evidence from one study suggested that it was probably associated with a slight reduction in the quality of life rated by proxies, but may have little or no effect on self-rated quality of life. We acknowledge concerns about the validity of proxy ratings of quality of life in severe dementia. Personally tailored activities may have little or no effect on negative affect and we are uncertain whether they improve positive affect or mood. There was no evidence that interventions were more likely to be effective if based on one specific theoretical model rather than another. Our findings leave us unable to make recommendations about specific activities or the frequency and duration of delivery. 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

Background

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 challenging behaviour such as restlessness or aggression, and may have other positive effects.

Purpose of this review

We wanted to investigate the effects of offering people with dementia who were living in care homes activities tailored to their personal interests.

Studies included in the review

In June 2017 we searched for trials that had offered some participants an activity programme based on their individual interests (an intervention group) and had compared them with other participants who were not offered these activities (a control group).

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We found eight studies including 957 people with dementia living in care homes. Seven 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 number of participants included in the studies ranged from 25 to 180. They all had moderate or severe dementia and almost all had some kind of challenging behaviour 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 one study, the nursing staff were trained to provide the activities during the daily care routine. 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 three studies, the control group got different activities that were not personally tailored; one study had both types of control group.

The quality of the trials and how well they were reported varied, and this affected our confidence in the results.

Key findings

Offering personally tailored activities to people with dementia living in care homes may slightly improve challenging behaviour when compared with usual care, although we did not find evidence that it was any better than offering activities which were not personally tailored. In one study, staff members reported that people in the group receiving personally tailored activities had a slightly worse quality of life than the control group. Personally tailored activities may have little or no effect on the negative emotions expressed by the participants. Because the quality of some of the evidence was very low, we could not draw any conclusions about effects on the participants' positive emotions, mood, engagement (being involved in what is happening around them) or quality of sleep. Only two studies mentioned looking for harmful effects; none were reported. None of the studies measured effects on the amount of medication participants were given, or effects on carers.

Conclusions

We concluded that offering activity sessions to people with moderate or severe dementia living in care homes may help to manage challenging behaviour. However, we did not find any evidence to support the idea that activities were more effective if they were tailored to people's individual interests. More research of better quality is needed before we can be certain about the effects of personally tailored activities.

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Summary of findings for the main comparison. Personally tailored activities compared to usual care or unspecific activities for people with dementia

Personally tailored activities compared to usual care or unspecific activities for people with dementia

Patient or population: people with dementia
Setting: Long-term care facilities
Intervention: Personally tailored activities
Comparison: usual care or unspecific activities

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with usual care or unspecific activities	Risk with Personally tailored activities				
Quality of life (self-rating by the participants; assessed with Quality of Life in Alzheimer's Disease scale; higher scores indicate a higher quality of life); follow-up: 28 weeks	The mean quality of life was 33.00 (6.20)	MD 0.26 higher (3.04 lower to 3.56 higher)	-	42 (1 RCT)	⊕⊕⊖⊖ LOW [1]	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; higher scores indicate a higher quality of life); follow-up: 28 weeks	The mean quality of life was 31.35 (4.68)	MD 1.93 lower (3.63 lower to 0.23 lower)	-	139 (1 RCT)	⊕⊕⊕⊖ MODERATE [2]	Proxy-rating, mean difference adjusted for baseline/demographic characteristics; clinical relevance (by study authors): 3 point difference.
Challenging behaviour (assessed with different scales, higher scores indicate more challenging behaviour; follow-up: range 10 days to 9 months	-	SMD 0.21 SD lower (0.49 lower to 0.08 higher)	-	439 (6 RCTs)	⊕⊕⊖⊖ LOW [3 4]	

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Adverse events; follow up: range 10 days to 4 weeks	Only 2 studies assessed adverse effects, but in both studies no adverse effects were reported.		-	(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)	-	455 (6 RCTs)	⊕⊝⊝⊝ VERY LOW [3 4 5]
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)	-	589 (6 RCTs)	⊕⊕⊝⊝ LOW [3 4]
Mood (assessed with different scales, lower scores indicate improved mood); follow-up: range 4 weeks to 9 months	-	SMD 0.02 SD lower (0.27 lower to 0.23 higher)	-	247 (3 RCTs)	⊕⊝⊝⊝ VERY LOW [3 6]

*__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; **RR:** Risk ratio; **OR:** Odds ratio;

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

[1] Downgraded 2 levels due to imprecision (wide confidence interval, crossing the borders of clinical relevance defined by the study authors in both directions)
[2] Downgraded 1 level due to imprecision (wide confidence interval, crossing the border of clinical relevance defined by the study authors in 1 direction)
[3] Downgraded one level due to study limitations: high risk of bias due to lack of adequate randomisation and allocation concealment, blinding of outcome assessors and recruitment bias in some included studies
[4] Downgraded one level due to imprecision (wide confidence interval, crossing the border of small effects (SMD) in one direction)
[5] Downgraded one level due to inconsistency: substantial heterogeneity
[6] Downgraded two levels due to imprecision (wide confidence interval, crossing the border of small effects (SMD) in both directions)

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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. Approximately six million people in Europe are affected by dementia and the absolute number is expected to rise (Prince 2013; Wittchen 2011). In long-term care facilities, the estimated prevalence of dementia ranges between 40% and 80% (Bernstein 2007; Nygaard 2003).

People with dementia living in long-term care facilities often spend their time not engaged in meaningful activities or uninvolved with other people (Cohen-Mansfield 2009a; Edvardsson 2014; Hill 2010; Kolanowski 2006). However, people with dementia wish to be involved in activities which meet their interests and are perceived as meaningful (Murphy 2007; Phinney 2007; Vernooij-Dassen 2007).

To be engaged in activities experienced as meaningful might increase quality of life in residents with dementia (Cooney 2009; Edvardsson 2014; Murphy 2007; Zimmerman 2005). However, activities offered in nursing homes tend to be passive, e.g. watching television and listening to music, and are often not perceived as meaningful by people with dementia (Harmer 2008), or are addressed to residents with better cognitive and functional status (Buettner 2003; Edvardsson 2014). Hence, a lower cognitive function in people with dementia is associated with fewer social interactions and less participation in activities (Chen 2000; Dobbs 2005; Edvardsson 2014). Understimulation might magnify challenging behaviour, e.g. apathy, boredom, depression, loneliness and agitation (Cohen-Mansfield 1992; Cohen-Mansfield 2011; Cohen-Mansfield 2012c). To be meaningful for a specific person with dementia, activities have to be individualised based on the person's interests, since the judgment of whether an activity is meaningful differs both between different people with dementia and between people with dementia and nurses (Harmer 2008).

Offering personally tailored activities to people with dementia primarily aims to improve psychosocial outcomes, e.g. challenging behaviour 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 (Cohen-Mansfield 2006; Hubbard 2002; Mills 1997), the 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 types of activities and different ways of delivering the intervention (Craig 2008). We focus on interventions aimed at improving psychosocial outcomes (e.g. challenging behaviours 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 challenging behaviour (Cohen-Mansfield 2007; Cohen-Mansfield 2009b; Harmer 2008; Phinney 2007). Also, participating in such activities can increase feelings of engagement which can reduce feelings of boredom and loneliness (Cohen-Mansfield 2009a), and increase quality of life (Hoe 2009; Murphy 2007; Zimmerman 2005). Further expected benefits cover the evocation of autobiographical events (Guétin 2009), the preservation of a person's identity, and increasing their occupation and maintaining their relationships (Harmer 2008). 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 of effective non-pharmacological interventions to improve psychosocial outcomes in people with dementia in clinical practice (Ballard 2013; O'Neil 2011). In several dementia guidelines, the use of non-pharmacological interventions is recommended as a primary approach for behavioural and psychological symptoms (BPSD) (Azermai 2012; Ngo 2015; Vasse 2012). Interventions offering personally tailored activities could be a promising approach due to their potential effects on challenging behaviours, quality of life and the level of engagement of people with dementia. Several studies evaluated complex interventions offering personally tailored activities to people with dementia in long-term care facilities (Cohen-Mansfield 2007; Kolanowski 2011). These interventions are of complex nature due to different underlying theoretical models, the composition of components, the types of activities offered, and intensity and duration of delivery.

To assess the effects of complex interventions, a description of the interventions' components is required to ensure comparability and reduce heterogeneity (Shepperd 2009). Since the effectiveness of complex interventions is also influenced by implementation fidelity, this information should be incorporated, e.g. adherence, exposure, quality of delivery, participants' responsiveness and adherence (Shepperd 2009).

Currently, no systematic review is available describing the characteristics of these interventions and summarising their effects on people with dementia. We intended this review to expand the knowledge on non-pharmacological treatments aiming to improve psychosocial outcomes and quality of life of people with dementia living in long-term care facilities. We also hoped the results would be helpful for decision making about the implementation of evaluated programmes offering personally tailored activities as well as for the development of new interventions.

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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

In this review, we included individual or cluster-randomised controlled trials, controlled clinical trials and controlled before-after studies.

Types of participants

People with dementia living in long-term care facilities, irrespective of the stage of dementia.

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-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).

Comparison: other types of psychosocial interventions, placebo interventions (e.g. non-specific personal attention), usual or optimised usual care.

Types of outcome measures

Primary outcomes

- 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).

Secondary outcomes

- Affect (i.e. expression of emotion), assessed by e.g. Observed Emotion Rating Scale.
- Level of engagement, assessed by e.g. Observational Measurement of Engagement Assessment, Index of Social Engagement.
- Mood, assessed by e.g. Dementia Mood Picture Test.
- 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)).
- Adverse effects of the interventions employed (e.g. injuries).
- Cost.

Search methods for identification of studies

Electronic searches

We searched ALOIS (www.medicine.ox.ac.uk/alois) — the Cochrane Dementia and Cognitive Improvement Group's Specialized Register — on 16 June 2017. The search terms used were: personally tailored OR individualized OR individualised OR individual OR person-centred OR meaningful OR personhood OR involvement OR engagement OR engaging OR identity.

ALOIS 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, PsycINFO and LILACS;
2. monthly searches of a number of trial registers: ISRCTN; UMIN (Japan's Trial Register); the 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: ISI 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

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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) independently assessed all titles and abstracts obtained from the search for inclusion according to the inclusion criteria. We resolved disagreements by discussion or, if necessary, we referred to a third reviewer (GM).

Data extraction and management

Two reviewers (RM, AR) extracted data independently 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 intra-cluster correlation coefficient (ICCC) 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 2011). 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) 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 challenging behaviour 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 post-intervention 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 individuals or groups (clusters) were randomised.

For cluster-randomised trials, we extracted information about the intracluster correlation coefficient (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 challenging behaviour 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 2012a — by re-calculating the effective sample size using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The number 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. There was no evidence for the occurrence of a carry-over effect in the one included cross-over study (van der Ploeg 2013); after the intervention sessions the values of most outcomes returned to the level assessed before the activities were offered. We used data from the complete study period for both conditions in our analysis since no results for the first period were available. We cannot be sure to have avoided a unit-of-analysis bias; however, this bias is conservative, being expected to lead to an under-estimate of the intervention effect (Higgins 2011).

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 only two groups (one intervention and the control group) in the analysis.

Dealing with missing data

For all included studies, numbers of participants lost to follow-up, with reasons, were extracted and presented in Characteristics of included studies. Where information was missing, the study authors were contacted 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

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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 challenging behaviour, for positive and negative affect and for mood. In all cases, we used a random-effects model as planned in the protocol due to the clinical diversity of the interventions or statistical heterogeneity (I^2 > 50%). In one study, different types of (positive and negative) affect were reported (Van Haitsma 2015). To include this study in the meta-analysis, we combined the corresponding outcomes for positive and negative affect by calculating a combined score. 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 scales used in two studies differed in the direction of the scale (Orsulic-Jeras 2000; Wenborn 2013). We re-calculated 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 2011).

We did not perform meta-analysis for any other outcomes and present the results in a narrative form.

Subgroup analysis and investigation of heterogeneity

We conducted the pre-planned subgroup analyses for studies with and without an active control group. Since we included one study in both subgroup analyses (this study — Van Haitsma 2015 — compared the intervention group with both an active and a usual care control), we split the intervention group using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Chapter 16.5.4) (Higgins 2011). Where applicable, we also explored possible causes of heterogeneity by conducting pre-planned analyses excluding studies with non-overlapping confidence intervals (CI).

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

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 2011). We rated quality of evidence as high, moderate, low or very low (Guyatt 2011). We created 'Summary of findings for the main comparison' for the outcomes 'challenging behaviour', 'positive affect' and 'negative affect' with GRADEpro GDT.

RESULTS

Description of studies

Results of the search

The search retrieved a total of 19,357 citations (Figure 1). The Information Specialists of the Cochrane Dementia and Cognitive Improvement Group carried out an initial assessment; then two authors independently screened titles and abstracts of 919 records for potential eligibility. Thirty-three publications were screened in full text and eight studies met all inclusion criteria (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013).

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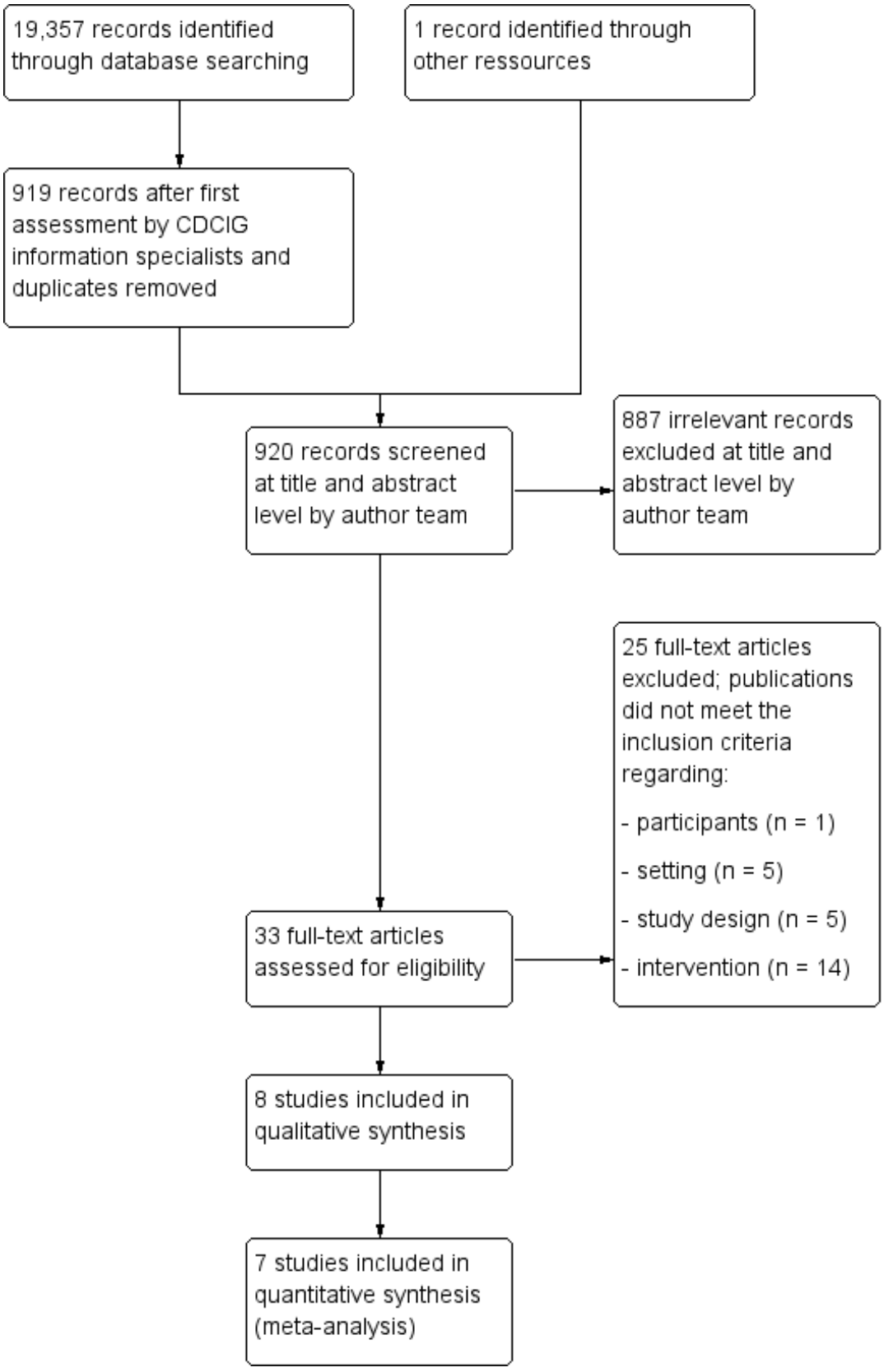
Figure 1. Study flow diagram.



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Included studies

Seven included studies were randomised controlled trials (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Richards 2005; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013); and one study was a non-randomised clinical trial (Orsulic-Jeras 2000). Three of the RCTs used cluster-randomisation (the units of allocation were nursing homes or nursing home wards) (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Wenborn 2013); three allocated individual participants (Kolanowski 2011; Richards 2005; Van Haitsma 2015); and one used a cross-over design (van der Ploeg 2013). In the study by Wenborn 2013, matched pairs were randomised.

Setting and Participants

Six studies were conducted in the USA (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015); one in Australia (van der Ploeg 2013); and one in the UK (Wenborn 2013). Six studies recruited participants from several nursing homes (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Richards 2005; van der Ploeg 2013; Wenborn 2013), the number of facilities ranging from 4 to 16. Two studies recruited participants from one facility; one study included participants from one large non-profit nursing home (Van Haitsma 2015); and one study recruited people with dementia from a special care unit (Orsulic-Jeras 2000).

A total of 1080 participants were recruited and 957 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. In six studies most participants were female (63% to 92%); in one study the proportion of women was 48% (Richards 2005). In seven studies the mean MMSE score was lower than 12 (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Orsulic-Jeras 2000; Richards 2005; van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013); and in one study the score ranged from 12 to 15 (Kolanowski 2011).

In three studies, challenging behaviour at baseline was an inclusion criterion for participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011); and in one study, physical agitation at baseline was an inclusion criterion (van der Ploeg 2013). In three studies without these inclusion criteria, all participants showed some form of challenging behaviour or agitation (Orsulic-Jeras 2000; Van Haitsma 2015; Wenborn 2013). One study offered no information on challenging behaviour (Richards 2005) (see Characteristics of included studies).

Description of the interventions

In seven of the interventions, personally tailored activities were offered directly to the participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; van der Ploeg 2013). In one study, members of the nursing staff were trained to deliver the personally tailored activities to the study participants (Wenborn 2013).

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 2012a 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. The principles of Montessori were used in two studies (Orsulic-Jeras 2000; van der Ploeg 2013). The interventions by Richards 2005 and Wenborn 2013 were not based on a specific theoretical framework; however, in both studies the choice of activities followed predefined principles.

The Treatment Routes for Exploring Agitation (TREA) framework

The TREA framework provides a systematic approach for individualizing 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).

In the studies by Cohen-Mansfield 2007 and Cohen-Mansfield 2012a, the TREA decision tree protocol was used 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 2012a).

Examples of activities offered are: 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 2012a).

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Need-Driven Dementia-Compromised Behavior (NDB) 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 at enriching the physical and social environment by matching the individual's background factors (Kolanowski 2005).

In the studies 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 by the use of the 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 level was 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 are: 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 developed to guide child education. They put emphasis on task breakdown, guided repetition, progression in difficulty from simple to complex, and the careful matching of demands to levels of competence. These principles were 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 2010).

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. 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.

Examples of activities offered by Orsulic-Jeras 2000 are: 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.

Individualized social activity intervention (ISAI)

The intervention by Richards 2005 was based on a conceptual framework which postulates (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 intervention was developed by the primary author, an occupational therapist with experience in working with older people with dementia.

The intervention consists 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 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 used. The activities were personalised to each resident by the use of the Pool Activity Level Checklist (Wenborn 2008).

Individualized 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

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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 it is not described how this study contributed to the design of the intervention or the study.

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

- Physical exercises (outdoor walk, work with clay).
- Music (singing or listening to a favourite artist).
- Reminiscence (reviewing family photos, writing letters).
- Activities of daily living (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.

Feasibility/pilot test

Richards 2005 tested their intervention in a pilot study (Richards 2001); the studies by Kolanowski 2011 and Cohen-Mansfield 2012a used previous studies as a pilot-test for their interventions (Kolanowski 2005; Cohen-Mansfield 2007); and the intervention by Orsulic-Jeras 2000 was based on experiences from an earlier project.

No information on a feasibility or pilot-test was provided by Cohen-Mansfield 2007, van der Ploeg 2013, Van Haitsma 2015, and Wenborn 2013.

Delivery of the intervention

In most studies, the interventions were delivered directly to the study participants (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; van der Ploeg 2013; Van Haitsma 2015). 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.

In all studies, trained staff delivered the interventions. Training was guided by written manuals or guidelines in three studies (van der Ploeg 2013; Van Haitsma 2015; Wenborn 2013); and a treatment fidelity plan in one study (Kolanowski 2011). The number and frequency of sessions delivered as well as the follow-up period differed between studies. An overview is displayed in Table 1 (see also Characteristics of included studies).

Table 1 –Delivery of the intervention

Reference	Delivered by	Frequency and duration of the sessions	Duration of follow-up
Cohen-Mansfield 2007	Research assistant	Daily; up to 4 h per day (peak period of agitation)	10 consecutive days
Cohen-Mansfield 2012a	Research assistant	Daily; up to 4 h per day (peak period of agitation)	10 consecutive days
Kolanowski 2011	Research assistant	5 days per week; up to 20 minutes twice per day (morning and afternoon)	4 weeks (3-week interventions period + 1-week post-intervention period)
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	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
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)

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Van Haitsma 2015	Certified nursing assistants	3 days per week; 10 min per session (not during mealtimes or shift change)	3 weeks
Wenborn 2013	Primary investigator	Not reported; five 2 h educational sessions for nursing staff	28 weeks (16 weeks' intervention period + 12 weeks' post intervention period)

Despite all studies basing the selection of the 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.

The degree of delivery of the interventions was assessed in three studies (Kolanowski 2011; Van Haitsma 2015; Wenborn 2013); and Cohen-Mansfield 2012a assessed barriers to the intervention's implementation (Cohen-Mansfield 2012b).

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 on the amount of activities delivered to the residents by the nursing staff was collected.

In the study by Cohen-Mansfield 2012a, in approximately 22% of the sessions some participants were unwilling to participate in the activities offered, and 84% of the participants were unwilling to participate in at least one of the sessions (Cohen-Mansfield 2012b).

Characteristics of the control conditions

An active control condition was used in three studies. Kolanowski 2011 offered a control group with activities that were functionally challenging and opposed to the participant's style of interest (based on the NDM model). 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 six studies, the control condition was usual care. (The study by Van Haitsma 2015 offered both an active control group and a control group with usual care). The nursing staff in the centres allocated to the control condition in Cohen-Mansfield 2007 and Cohen-Mansfield 2012a received a presentation on the different forms of agitation, their aetiologies and possible non-pharmacological interventions. 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, activities based on the participants' interests and hobbies, delivered by an activities therapist or nursing assistants). The participants in the control groups in the studies by Richards 2005, Van Haitsma 2015 and Wenborn 2013 received usual care of the nursing home, but no information on the type and amount of activities offered was published.

Outcomes and data collection methods

Challenging behaviour

In the studies by Cohen-Mansfield 2007 and Cohen-Mansfield 2012a, challenging behaviour was assessed with 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) to assess challenging behaviour. The CMAI is a proxy-rating instrument used by nurses to assess agitation and comprises four subscales (physically non-aggressive behaviours, physically aggressive behaviours, verbally non-aggressive behaviours, and verbally aggressive behaviours; range 0 to 29; a higher score indicates 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, it was rated by direct observation whether this specific behaviour occurred within 30 minutes in 1-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

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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 toward 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 only one study — Wenborn 2013 — by the use of the Quality of Life in Alzheimer’s Disease (QOL-AD) scale (self- and caregiver-rating) (Logsdon 1999). Higher scores indicate a higher quality of life.

Affect

Cohen-Mansfield 2007 and Cohen-Mansfield 2012a 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.

Kolanowski 2011, Orsulic-Jeras 2000 and van der Ploeg 2013 used the Philadelphia Geriatric Center Affect Rating Scale (ARS, Lawton 1996), covering the following modes of affect: pleasure, anger, anxiety, sadness, interest, and contentment. 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. In two studies, results were categorised as positive or negative affect (Cohen-Mansfield 2012a; 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) and negative affect included sadness (crying, tears, moan, sigh, 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 by the use of 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 scores indicates more engagement); and van der Ploeg 2013 used the Menorah Park Engagement Scale (MPES) (range 0 to 30, higher values indicates 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

Kolanowski 2011 assessed mood by use of the Dementia Mood Picture Test (range 0 to 12, higher score indicates more positive mood; Tappen 1995). Orsulic-Jeras 2000 and Wenborn 2013 assessed depression by the use of the Cornell Scale for Depression (CSD, Alexopoulos 1988). A score of 8 or above indicates depression.

Other outcomes

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.

Duration of the effects

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

Excluded studies

Studies were excluded 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

We contacted authors of all studies and asked for additional information on methodological details which 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.

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The methodological quality of the included studies varied. We judged two studies to have no domains in which the risk of bias was high (Kolanowski 2011; Wenborn 2013). We judged all the other studies to be at high risk of bias in at least one domain (see Characteristics of included studies; Figure 2; Figure 3 and Appendix 2; Appendix 3; Appendix 4).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

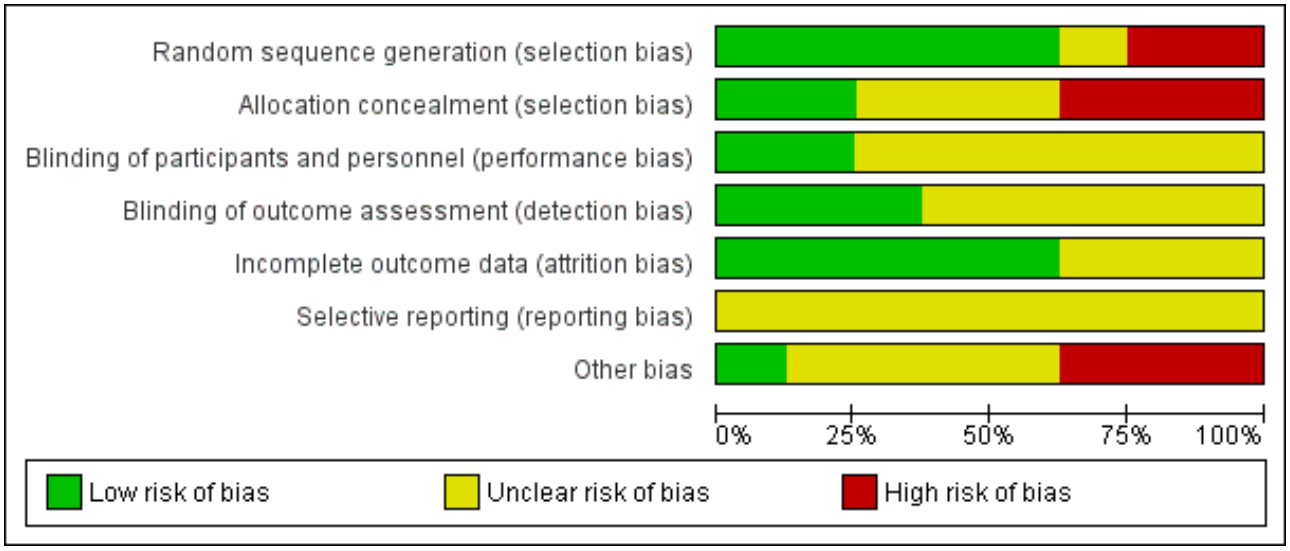

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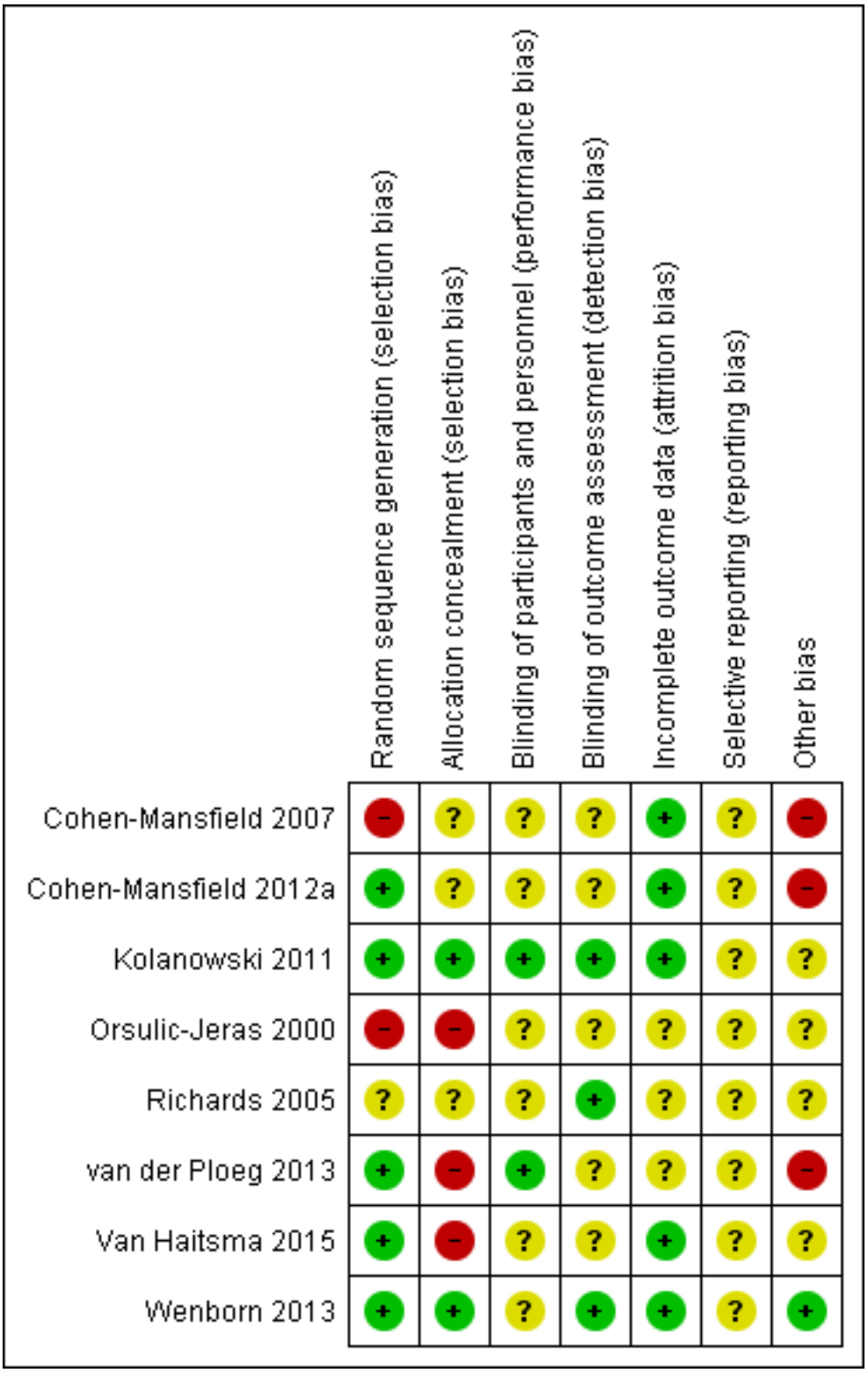
Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

The randomisation sequence was adequately generated in five studies (Cohen-Mansfield 2012a; Kolanowski 2011; 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

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treatment or usual care (eligible participants were identified before allocation).

No information on the method of sequence generation was available in two studies (Cohen-Mansfield 2007; Richards 2005). We considered the risk of bias in this domain to be unclear for Richards 2005. In the study by Cohen-Mansfield 2007 two clusters were not assigned randomly due to preferences of the facility managers so we judged the risk of bias in this domain to be high.

Group allocation was adequately concealed in two studies (Kolanowski 2011; Wenborn 2013). In three studies no information on the allocation concealment was available (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Richards 2005) (risk of bias judged to be unclear); and in two studies allocation was not concealed (van der Ploeg 2013; Van Haitsma 2015) (risk of bias judged to be high). In two cluster-randomised studies, the participants were identified after the allocation of clusters (Cohen-Mansfield 2007; Cohen-Mansfield 2012a).

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, Myers Menorah Park/ Montessori Assessment System (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

Blinding of participants and personnel was adequate in two studies (Kolanowski 2011; van der Ploeg 2013); both studies offered a form of active treatment to all participants. In six studies, blinding of participants and personnel was not possible (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015; Wenborn 2013). We considered it to be unclear whether this introduced a bias.

Outcome assessors were blinded to group allocation in three studies (Kolanowski 2011; Richards 2005; Wenborn 2013). In five studies blinding of outcome assessors was not possible, because data were collected by proxies, such as unblinded nursing staff. Two studies attempted to assess the impact of the lack of blinding on the study results. Ten and 25 intervention sessions were videotaped and the outcomes were assessed by a blinded rater (Cohen-Mansfield 2007; Cohen-Mansfield 2012a). There was a high agreement between the blinded and unblinded rater. Generally, we considered it to be unclear whether the lack of blinding led to a bias.

Incomplete outcome data

In six studies attrition rates were low and reasons for attrition were documented (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Kolanowski 2011; Richards 2005; Van Haitsma 2015; Wenborn 2013). 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 the reasons for attrition were available and there was no evidence that attrition was due to the intervention.

Selective reporting

Four studies were registered, but all retrospectively (Cohen-Mansfield 2012a; Kolanowski 2011; van der Ploeg 2013; Wenborn 2013); and a protocol was published for one study (van der Ploeg 2013). The primary outcome was defined in four studies (Cohen-Mansfield 2007, Cohen-Mansfield 2012a, van der Ploeg 2013; Wenborn 2013). Based on this information, results for all outcomes were reported as planned. We considered the risk of selective reporting bias in all studies to be unclear due to the retrospective or absent registration.

Other potential sources of bias

We considered there to be a high risk of bias in three studies (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; van der Ploeg 2013). There was a high risk of unit-of-analysis bias in Cohen-Mansfield 2007 and Cohen-Mansfield 2012a, since neither study considered the cluster effect in their analyses. The study by van der Ploeg 2013 was at high risk of a unit-of-analysis bias since no paired data were available.

We considered the risk of other bias to be unclear in four studies since they did not define a primary outcome and did not include an adequate adjustment for multiple testing (Kolanowski 2011; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015).

Effects of interventions

See: **Summary of findings for the main comparison** Personally tailored activities compared to usual care or unspecific activities for people with dementia

Primary outcomes

Challenging behaviour

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

We used the standardised mean difference (SMD), calculated from mean values assessed during or directly after the intervention period or session. For two studies, the number of participants was re-calculated to incorporate the cluster effect, using an estimate of the intra-cluster correlation coefficient (Cohen-Mansfield 2007; Cohen-Mansfield 2012a – 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 challenging behaviour.

For challenging behaviour, we found low-quality evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly reduce challenging behaviour (SMD −0.21, 95% CI −0.49 to 0.08; I^2 = 50%; random-effects model; 6 studies; 439 participants; Analysis 1.1; Figure 4). Compared with studies only including a usual care control group, personally tailored activities may slightly reduce challenging behaviour (SMD −0.33, 95% CI −0.76 to 0.09; 288 participants; I^2 = 60%; random-effects model; 4 studies; 288 participants; Figure 4), but personally tailored activities may have little or no effect on challenging behaviour compared with studies including active control groups

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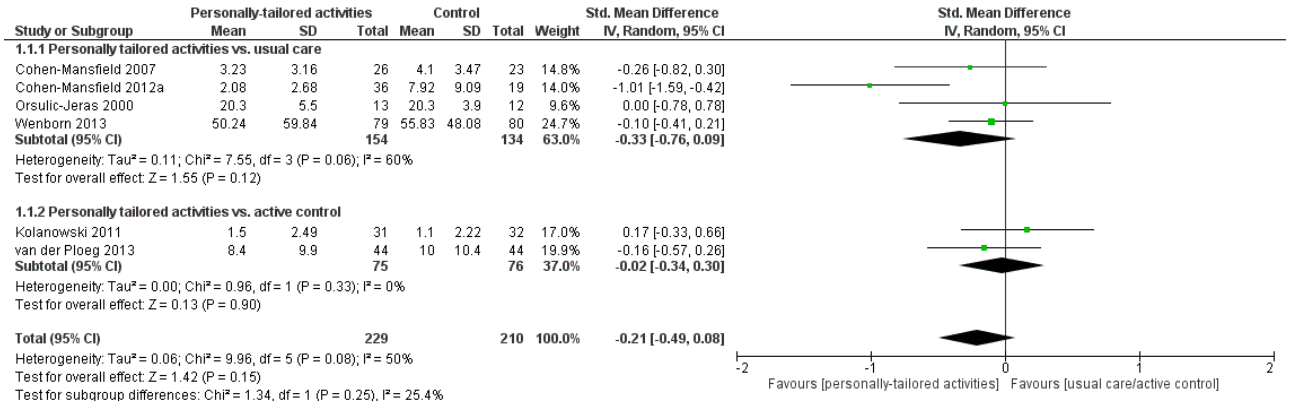
(SMD −0.02, 95% CI −0.34 to 0.30; I^2 = 0%; random-effects model; 2 studies; 151 participants; Figure 4). However; there is no statistically significant difference between the results of the usual care active control subgroups (test for subgroup differences P = 0.25, I^2 = 25.4%). To further explore the potential reasons for heterogeneity, an analysis was performed excluding one study (Cohen-Mansfield 2012a), which appeared to be an outlier. After excluding this study, the I^2 was reduced to 0% and the effect size was reduced to little or no effect (low-quality evidence, SMD −0.08, 95% CI −0.28 to 0.12; 5 studies; 384 participants; Analysis 1.2). We could not explain the heterogeneity based on the characteristics of this study, e.g. population, intervention or outcome measures.

Figure 4. Forest plot of comparison: 1 Challenging behaviour, outcome: 1.1 Personally tailored activities vs. usual care or active control.



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 challenging behaviour. Higher scores indicate a higher frequency of the behaviour. We found low-quality 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) but may make little or no difference compared to the active control group (MD 1.22, 95% CI −1.14 to 3.58; 87 participants). Aggression and uncooperative behaviours were rarely observed in all groups; we found low-quality 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). We also found low-quality evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly increase very negative verbal behaviour compared to usual care (MD 7.75, 95% CI 5.51 to 9.99; 137 participants) but may reduce very negative verbal behaviour compared to the active control group (MD −29.33, 95% CI −32.22 to −26.44; 87 participants). For negative verbal behaviours, we found low-quality evidence (downgraded for risk of bias and imprecision) that personally tailored activities may slightly increase negative verbal behaviour compared to usual care (MD 21.68, 95% CI 17.66 to 25.70; 137 participants) and may make little or no difference to negative verbal behaviour compared to the active control group (MD 3.07, 95% CI −2.13 to 8.27; 87 participants).

Quality of life

Only one study investigated the effects of personally tailored activities on quality of life (Wenborn 2013). Quality of life was assessed by the study personnel (proxy-rating) and by a small group of participants who were able to complete the assessment (self-rating, n = 42 out of n = 139). Clinical relevance was defined by the study authors as three points on the scale used (higher scores indicates better quality of life). For proxy-rated quality of life, there was moderate-quality evidence (downgraded one level for imprecision) that personally tailored activities were associated with a slight reduction in quality of life compared to usual care (MD −1.93, 95% CI −3.63 to −0.23; adjusting for baseline and demographic characteristics; 139 participants). For self-rated quality of life, there was low-quality evidence (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; adjusting for baseline and demographic characteristics; 42 participants).

Secondary outcomes

Affect

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 2012a; 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 2012a), negative affect calculated from anger, sadness, and anxiety/fear (van der Ploeg 2013), anxiety or fear (Kolanowski 2011), and anxiety (Wenborn 2013). From Van

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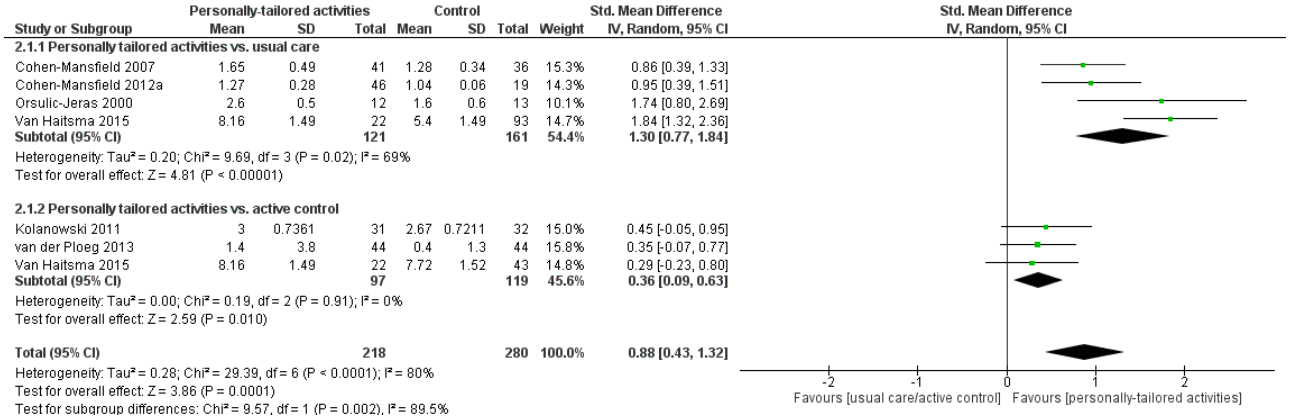
Haitsma 2015, we calculated negative affect from sadness, anger, and anxiety (see Data synthesis).

For mood we combined data on mood from one study (Kolanowski 2011, data were 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 standardised mean difference (SMD), calculated from mean values assessed during or directly after the intervention period or session. For two studies, the number of participants was re-calculated to incorporate the cluster effect, using an estimate of the intra-cluster correlation coefficient (Cohen-Mansfield 2007; Cohen-Mansfield 2012a – 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 quality evidence (downgraded for risk of bias, inconsistency and imprecision) and we are therefore very uncertain whether personally tailored activities improve positive affect (SMD 0.88, 95% CI 0.43 to 1.32; I^2 = 80%; 6 studies; 498 participants; Analysis 2.1; Figure 5). We are also uncertain whether personally tailored activities improve positive affect compared to studies with active control groups (SMD 0.36, 95% CI 0.09 to 0.63; I^2 = 0%; 3 studies; 216 participants; Figure 5) or compared to studies with usual care control groups (SMD 1.30, 95% CI 0.77 to 1.84; I^2 = 69%; 4 studies; 282 participants; Figure 5) (one study contributed to both subgroup analyses). A sensitivity analysis excluding the study for which we calculated the combined effect 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 2.2).

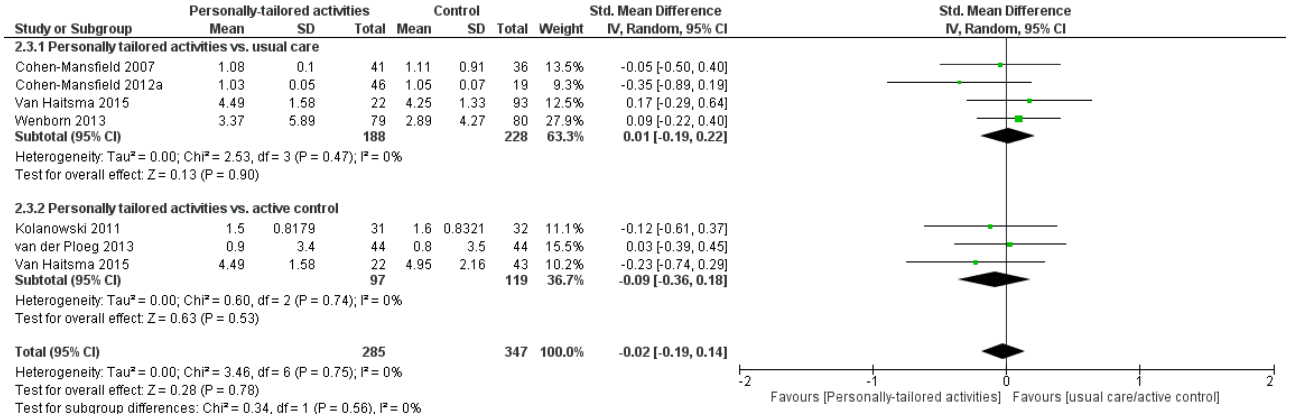
Figure 5. Forest plot of comparison: 2 Affect, outcome: 2.1 Positive affect.



Negative affect

We found low-quality evidence (downgraded for risk of bias and imprecision) that personally tailored activities may make little or no difference to negative affect (SMD 0.01, 95% CI −0.15 to 0.18; I^2 = 0%; 6 studies; 589 participants; Analysis 2.3; Figure 6). 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; Analysis 2.3; Figure 6). The sensitivity analysis excluding the study for which we calculated the combined effect also showed similar results (SMD −0.03, 95% CI −0.22 to 0.16; I^2 = 0%; 5 studies; 452 participants; Analysis 2.4).

Figure 6. Forest plot of comparison: 2 Affect, outcome: 2.3 Negative affect.



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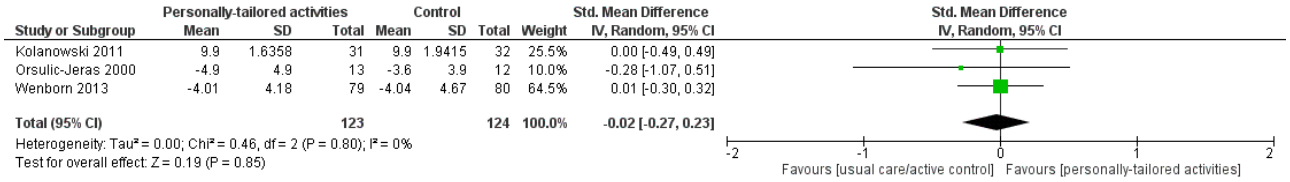
Mood

We found very low quality evidence (downgraded one level for risk of bias and two levels for imprecision) and we are therefore very uncertain whether personally tailored activities improve mood (SMD −0.02, 95% CI −0.27 to 0.23; I^2 = 0%; 3 studies; 247 participants; Analysis 2.5; Figure 7).

Figure 7. Forest plot of comparison: 2 Affect, outcome: 2.5 Mood.



Level of engagement

Three studies reported results on participants' engagement but 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.

Kolanowski 2011 assessed the intensity of participation. We found low-quality evidence (downgraded 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).

For constructive engagement we found very low quality evidence (downgraded for risk of bias, indirectness and imprecision) and we are therefore very uncertain whether personally tailored activities improve constructive engagement (personally tailored activities vs. active control: MD 6.90, 95% CI 3.07 to 10.73; 88 participants; van der Ploeg 2013). In the study by Orsulic-Jeras 2000, constructive engagement decreased 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).

For passive engagement, we found very low quality evidence (downgraded for risk of bias, indirectness and imprecision) and we are therefore very uncertain whether personally tailored activities improve passive engagement (personally tailored activities vs. active control: MD −1.60, 95% CI −4.99 to 1.79; 88 participants; van der Ploeg 2013). In the study by Orsulic-Jeras 2000 passive engagement decreased in the intervention group and was nearly unchanged in the control group (intervention group baseline 207 ± 132, after six months 91 ± 66; control group baseline 354 ± 158, after six months 345 ± 188; 25 participants).

For negative engagement, we found very low quality evidence (downgraded for risk of bias, indirectness and imprecision) from one study and we are therefore very uncertain whether personally tailored activities improve negative engagement (MD personally tailored activities vs. active control −5.50, 95% CI −9.58 to −1.42; 88 participants) (van der Ploeg 2013).

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 quality evidence (downgraded for risk of bias, indirectness and imprecision) from one study (Richards 2005). We are therefore 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) or the amount of nighttime sleep (MD 28.81, 95% CI −22.65 to 80.27; 139 participants; there were baseline differences between the groups — 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).

Duration of the effects

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

No information on the duration of the effects were available from the other studies (Cohen-Mansfield 2007; Cohen-Mansfield 2012a; Orsulic-Jeras 2000; Richards 2005; Van Haitsma 2015; Wenborn 2013).

Psychotropic medication

No study offered information on the use of psychotropic medication.

Effects on caregivers

No study offered information on the effects of the interventions on caregivers.

Adverse effects

Only two studies reported any information on adverse effects. No adverse effects were observed in either study (Cohen-Mansfield 2012a; Kolanowski 2011).

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

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project nursing assistants to conduct the ISAI 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).

Process evaluation

Four studies offered information about the implementation process or barriers to the implementation of the intervention (Cohen-Mansfield 2012a; Kolanowski 2011; Van Haitsma 2015; Wenborn 2013).

Three studies offered information on the dose of the intervention received by the participants. Kolanowski 2011 calculated the dose received 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. 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 the study by Van Haitsma 2015, each participant received on average seven intervention sessions (range 5 to 9).

In the study by Cohen-Mansfield 2012a several barriers to implementation were identified. Participants were partly unwilling, unresponsive (e.g. due to the severity of dementia) or unavailable (e.g. asleep or eating) and did not participate in the offered activities. The participants were more engaged in activities related to food/drink and one-to-one socializing activities and less engaged with puzzles, board games, art and craft activities (Cohen-Mansfield 2012b).

DISCUSSION

Summary of main results

We included eight studies evaluating interventions offering personally tailored activity for people with dementia living in long-term care facilities. The activities were offered directly to the people with dementia in seven studies and in one study the nursing staff were trained to deliver the activities. The interventions varied in terms of the theoretical basis, the way that personal interests of the participants were assessed, the frequency and duration of the activity sessions and the length of follow-up; however, the activities themselves were comparable across studies.

Offering personally tailored activities to people with dementia in long-term care may slightly improve challenging behaviour. In subgroup analyses, this effect was present when personally tailored activities were compared with usual care, but not when they were compared with an active control intervention. We also found that offering personally tailored activities probably slightly reduced proxy-rated quality of life, but quality of life was only investigated in one study and the validity of proxy-rating (in this case, by study personnel) of quality of life in severe dementia has been questioned. Personally tailored activities may also have little or no effect on negative affect and, due to the very low quality 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 quality of evidence we have very little confidence in this result. Adverse events related to personally tailored activities were assessed in only two studies and neither reported any adverse events. In summary, our results suggests that offering structured activities to people with dementia might have positive effects on some psychosocial outcomes, particularly challenging behaviour, when compared to usual care, but we found no evidence of additional effects of tailoring the activities to the person's preferences or interests.

Two studies investigated the duration of the intervention effects and in both studies the majority of the outcomes returned to the baseline level after the delivery of the activities ended (in one study 30 minutes after the activities were offered and in one study one week after the intervention period ended) (Kolanowski 2011; van der Ploeg 2013). In these studies, the positive effects of the activities offered persisted only during the time the activities were delivered. However, such results were not available for six studies and therefore it is not possible to draw clear conclusions.

Overall completeness and applicability of evidence

The number of studies contributing to the different outcomes of interest in this review was small. We included from three to six studies in the meta-analyses. Only one study investigated quality of life. Due to the clinical heterogeneity of the interventions (e.g. the different theoretical basis, duration and frequency of the activity sessions) and the methodological limitations of the included studies, the results of this review must be interpreted with caution. Additional high-quality studies are needed.

Almost all of the participants in the included studies had severe dementia. The results may not be applicable to residents of long-term care facilities whose dementia is less severe.

Quality of the evidence

We evaluated the quality of evidence following the GRADE approach (Guyatt 2011). We judged the quality of evidence to be very low to moderate due to several methodological limitations in the studies, inconsistency between studies and imprecision of the results. The risk of bias varied in the included studies. Allocation concealment was adequate in only two out of seven randomised trials and one study was not randomised. The outcome assessors were blinded to group allocation in only three studies.

We also found moderate to substantial heterogeneity in the meta-analyses on challenging behaviour and affect. For challenging behaviour, this heterogeneity was reduced by excluding one study (Cohen-Mansfield 2012a); however, we could not explain this heterogeneity from characteristics of this study. For positive affect we 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. The theoretical basis for selecting the activities differed between the studies. Two models, the Need-Driven Dementia-Compromised Behavior (NDB) model (Algase 1996) and Treatment Routes for Exploring Agitation (TREA) framework (Cohen-Mansfield

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2000), assume that challenging behaviour is a symptom of unmet needs in people with dementia. Both models postulate that by targeting the identified unmet needs the specific challenging behaviour could be modified. The principles of Montessori lay 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 2010). 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. 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. In all studies data were collected directly from the participant, their relatives or the primary caregiver. No information was available in any study about the number of participants who were able to express their individual interests or preferences. The majority of participants had severe dementia (MMSE lower than 12), indicating a substantial risk of memory and ability loss. There is evidence that both family members and caregivers might have differing perceptions about the meaningfulness of activities compared to 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). 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 the progression of the 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). 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.

Care dependency and cognitive impairment are also expected to have a restricting influence on the selection of activities, e.g. sports or crafts might be difficult to offer in a nursing home and reading a book or a newspaper might be difficult due to poor sight. One study reported challenges in implementing several activities due to unwillingness or unresponsiveness of participants with severe cognitive impairment. Simple activities, e.g. one-to-one socialising activities, were implemented more easily than more complex activities, e.g. puzzles, board games or craft activities (Cohen-Mansfield 2012b).

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. challenging behaviour, 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 challenging behaviour assessed in the other studies. The different instruments used to assess 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 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), one 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 quite similar, with the exception of one study (Cohen-Mansfield 2012a). Therefore, pooling the results of the different instruments seemed to be feasible, with the caveats mentioned above.

Potential biases in the review process

We have made efforts in the review process to reduce the risk of bias. Publication bias is unlikely to have affected the results because we conducted an intensive literature search, covering database search (including electronic databases and trial registers, guided by the CDCIG) as well as snowballing techniques 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 for people with dementia in nursing homes have been published in recent years. Both reviews used a broader approach investigating 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

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2016 investigated, among others, the effects of individualised recreational activities. There was large agreement regarding the main results between this review and the reviews by Testad 2014 and Travers 2016, but in this review several studies were excluded based on the more specific inclusion and exclusion criteria.

Both reviews described positive effects on pleasure and interest and, in contrast to our analysis, an improvement of agitation. However, Testad 2014 performed no meta-analysis 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 quality 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 for challenging behaviour. Offering any activities to people with dementia seems to be necessary from an ethical perspective. However, we can present no recommendations on the method for selecting activities, the types of activity, or the duration and frequency of activities based on the results of this review.

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 challenging behaviour in people with dementia living in long-term care facilities.

The development and evaluation of programmes offering personally tailored activities should adhere to the methodological recommendations for complex interventions (Craig 2008). When developing new interventions, more emphasis should be laid on potentially active components of such interventions. The theoretical basis on which the activities are chosen seems less important and it was not assessed whether the participants judged the offered activities as 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. Because of these challenges, comprehensive feasibility and pilot studies should be performed prior to evaluation studies (Craig 2008).

Evaluation studies should be planned adhering to current methodological standards, e.g. a randomised and concealed allocation; adequate blinding (at least the participants (this is possible if an active control group is offered) and outcome assessors); recruitment of sufficiently large study samples; and adequate statistical methods, e.g. randomised clusters rather than individuals (Higgins 2011). In future studies we recommend comparing a personally tailored group 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. Furthermore, a process evaluation should be an integral part of the evaluation study, assessing the degree of the intervention's implementation, information about the need to tailor the intervention to a specific study context (e.g. study centres) and barriers to, and facilitators of, the intervention's implementation (Grant 2013; Moore 2015).

To ensure comprehensive reporting covering the complete research process (development, piloting and evaluation), the corresponding reporting statements should be used, e.g. CReDECI 2 for complex interventions (Möhler 2015), the 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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Wittchen HU, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jönsson B, et al. The size and burden of mental disorders and other disorders of the brain in Europe 2010. *European Neuropsychopharmacology* 2011;**21**(9):655-79.

Zimmerman 2005

Zimmerman S, Sloane PD, Williams CS, Reed PS, Preisser JS, Eckert JK, et al. Dementia care and quality of life in assisted living and nursing homes. *Gerontologist* 2005;**1**(Suppl 1):133-46.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Cohen-Mansfield 2007

Methods	Cluster-randomised controlled trial Duration of follow-up: 10 consecutive days
Participants	Country: USA Participants were recruited from 12 clusters in 11 suburban nursing home facilities (6 clusters per group) 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 completing the study: n = 167 (intervention group n = 89, control group n = 78) 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 Minimum Data Set (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)

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Cohen-Mansfield 2007 *(Continued)*

	Secondary: affect (pleasure, interest, anger, anxiety, sadness) (LMBS)
Funding	National Institutes of Health; USA
Notes	

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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"...nonblindness of the observations". No further information reported.
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	No trial registration and no study protocol is available.
Other bias	High risk	Cluster effect was not incorporated in the analysis (unit-of-analysis bias).

Cohen-Mansfield 2012a

Methods	Cluster-randomised controlled trial; registration number: NCT00820859 Duration of follow-up: 10 consecutive days Conducted between June 2006 and December 2011
Participants	Country: USA Participants were recruited from 11 nursing homes (n = 6 intervention group, n = 5 control group), in Rockville, Silver Spring, Takoma Park, Chevy Chase, and Gaithersburg, Maryland, USA. 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

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Cohen-Mansfield 2012a *(Continued)*

	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 completing the study: n = 125 (intervention group n = 89, control group n = 36) 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 Minimum Data Set (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) (LMBS)
Funding	National Institutes of Health; USA
Notes	

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	"The research assistants who gathered initial baseline data were blind to the group allocation of residents; of course, 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Research assistants could not be blinded once interventions began."
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)"

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Cohen-Mansfield 2012a *(Continued)*

		"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	All outcomes reported, but the study was registered retrospectively and no study protocol is available.
Other bias	High risk	Cluster effect was not incorporated in the analysis (unit-of-analysis bias).

Kolanowski 2011

Methods	Randomised controlled trial; registration number: NCT00388544 Duration of follow-up: 4 weeks (3-week interventions period + 1-week post-intervention period) Conducted between August 2005 and November 2008
Participants	Country: USA Participants were recruited from 9 community-based nursing homes in Pennsylvania. 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 completing the study: n = 128 (intervention group 1 n = 32, intervention group 2 n = 33, intervention group 3 n = 31, control group n = 32) 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	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	Agitation (CMAI, PDS), engagement, affect (ARS), mood (Dementia Mood Picture Test)
Funding	1 author was supported by National Institutes of Health and 1 author received royalties from the NEO-PI-R and the NEOFFI and was supported in part by National Institutes of Health; USA

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Kolanowski 2011 *(Continued)*

Notes	

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	All outcomes reported, but the study was registered retrospectively and no study protocol is available.
Other bias	Unclear risk	No primary outcome defined (multiple testing).

Orsulic-Jeras 2000

Methods	Non-randomised trial Duration of follow-up: 9 months
Participants	Country: USA Participants were recruited from 1 dementia special care unit of the Menorah Park Center for Senior Living, an Orthodox Jewish facility with over 350 long-term care beds. No inclusion or exclusion criteria reported Number of participants completing the study: n = 25 (intervention group n = 13, control group n = 12). 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)

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Orsulic-Jeras 2000 *(Continued)*

	Control: usual care (regular activities)
Outcomes	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	Unclear risk	Individual activity sessions "were run by either a trained volunteer, a research assistant, or the activities therapist on the unit." The 2 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. Comment: the control group received no additional activities and so it seems not possible to blind the personnel or the participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Research staff interviewed nursing assistants on the special care unit at pretest and at final posttest for approximately 20 minutes for all measures"; comment: nursing assistants were not blinded to group allocation.
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	No trial registration and no study protocol is available.
Other bias	Unclear risk	No primary outcome defined (multiple testing).

Richards 2005

Methods	Randomised controlled trial Duration of follow-up: 21 consecutive days
Participants	Country: USA

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Richards 2005 *(Continued)*

	Participants were recruited from 1 Department of Veterans Affairs nursing home and 6 for-profit community nursing homes in the central southeastern United States. 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 completing the study: n = 139 (intervention group n = 71, control group n = 68) 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	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
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	Unclear risk	No blinded to group allocation. "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".
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." Comment: no information about blinding reported, but the risk of bias was judged as low since only objective outcome 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	No trial registration and no study protocol is available.

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Richards 2005 *(Continued)*

Other bias	Unclear risk	No primary outcome defined (multiple testing).

van der Ploeg 2013

Methods	Crossover trial, registration number: ACTRN12609000564257 Duration of follow-up: 4 weeks (2 weeks per condition, no washout period) Conducted between July 2009 and September 2011
Participants	Country: Australia Participants were recruited from 9 residential facilities in metropolitan Melbourne, Australia. 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 completing the study: n = 44 (group 1 (intervention first) n = 15, group 2 (control first) n = 29) 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: unspecific activities (active control)
Outcomes	Primary: 1 physically agitated behaviour specific for each participant (based on the CMAI) 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).

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van der Ploeg 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Participants and facility staff were blinded to the hypotheses of the study."
Blinding of outcome assessment (detection bias) All outcomes	Unclear 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."
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	All outcomes reported, but the study was registered retrospectively and 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

Methods	Randomised controlled trial Duration of follow-up: 3 weeks
Participants	Country: USA Participants were recruited from 8 units of a large nonprofit nursing home in Pennsylvania. 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 completed the study: n = 180 (intervention group n = 44, AC n = 43, control group n = 93) Age (mean (range)) years: 88.7 (64 to 105); (mean ± SD) intervention group 87.66 ± 8.37, AC 88.71 ± 6.13, control group 89.21 ± 6.87 Gender, female: 82.2% Cognitive status, MMSE (mean ± SD): intervention group 7.4 ± 7.13, AC 10.35 ± 7.95, control group 9.02 ± 7.64 Care dependency, MDS ADL (mean ± SD): intervention group 25.05 ± 12.52, AC 27.41 ± 10.49, control group 25.99 ± 11.18
Interventions	Intervention: Individualized Positive Psychosocial Intervention (IPPI) Active control: standardised 1-to-1 activities Control: usual care

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Van Haitsma 2015 *(Continued)*

Outcomes	Behaviour (verbal and nonverbal), affect (positive affect: pleasure, alertness; negative affect: sadness, anger, anxiety)
Funding	Alzheimer's Association Tacrine Fund and the Pennsylvania Department of Health
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	Unclear 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." Comment: on each unit, 1 group of residents received 1 type of activity programme (intervention or active control) and another group of participants received usual care. Nursing staff was aware whether a participant received an activity programme or usual care; therefore blinding of personnel refers only to the type of activity programme (intervention or active control).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information reported; however, outcomes were assessed before, during and after the intervention session and therefore a blinding of the group allocation (activities vs. usual care) seems not possible.
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	No trial registration and no study protocol is available.
Other bias	Unclear risk	No primary outcome defined (multiple testing).

Wenborn 2013

Methods	Cluster-randomised controlled trial, registration number: ISRCTN67952488 Duration of follow-up: total of 28 weeks (16 weeks delivery of the intervention, 12 weeks' post-intervention follow-up)
Participants	Country: UK (London) Number of participants completed the study: n = 159 (intervention group n = 79, control group n = 80) Number of clusters: 16 nursing homes (8 clusters per group) 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%

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Wenborn 2013 *(Continued)*

	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 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 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) Inclusion criteria: 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 (Folstein 1975) less than 25 Exclusion criteria: residents with other serious physical or mental health problems
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 interventions 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.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were assessed by the [primary investigator (before randomisation)] "at baseline and by blinded assessors at follow-up."
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	All outcomes reported, but the study was registered retrospectively and no study protocol is available.

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Wenborn 2013 *(Continued)*

Other bias	Low risk

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

Study	Reason for exclusion
Beck 2002	Intervention (no personally tailored activities)
Cohen-Mansfield 2006	Setting (participants recruited from both long-term care facilities and day centres, no data on the different settings available)
DiNapoli 2016	Setting (geriatric psychiatry)
Farina 2006	Setting (day care centre)
Farina 2009	Setting (day care centre)
Gerber 1991	Setting (psychiatric hospital)
Hong 2011	Intervention (multisensory stimulation)
Hopman-Rock 1999	Intervention (no personally tailored activities)
Hsu 2015	Intervention (no personally tailored activities)
Kolanowski 2005	Design (no randomised controlled trial)
Kovach 2004	Intervention (re-organisation of activities)
Lin 2009	Intervention (acupressure and activities)
Luttenberger 2012	Intervention (no personally tailored activities)
Mansbach 2017	Intervention (no personally tailored activities)
Meeks 2015	Population (not people with dementia)
Morley 2014	Design (editorial)
Mowrey 2013	Design (no control group, retrospective study)
Patel 2016	Design (no control group)
Pieper 2016	Intervention (no personally tailored activities)
Politis 2004	Intervention (activity-based cognitive stimulation)
Rapp 2013	Intervention (non-pharmacological and pharmacological components)
Sackley 2009	Intervention (no personally tailored activities)
Schneider 2003	Design (no control group)

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Study	Reason for exclusion
Sung 2010	Intervention (only listening to music as an activity)
Sánchez 2016	Intervention (no personally tailored activities)
Treusch 2015	Intervention (no personally tailored activities)
Vink 2014	Intervention (no personally tailored activities)
Wilks 2017	Design (no control group)

DATA AND ANALYSES

Comparison 1. Challenging behaviour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Personally tailored activities vs. usual care or active control	6	439	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.49, 0.08]
1.1 Personally tailored activities vs. usual care	4	288	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.76, 0.09]
1.2 Personally tailored activities vs. active control	2	151	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.34, 0.30]
2 Investigating heterogeneity	5	384	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.28, 0.12]
3 Behaviours van Haitsma 2015	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 General restlessness	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Aggression	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Uncooperative	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.4 Very negative verbal	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.5 Negative verbal	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

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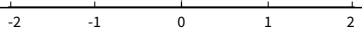
Analysis 1.1. Comparison 1 Challenging behaviour, Outcome 1 Personally tailored activities vs. usual care or active control.

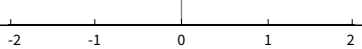
Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
1.1.1 Personally tailored activities vs. usual care							
Cohen-Mansfield 2007	26	3.2 (3.2)	23	4.1 (3.5)		14.77%	-0.26[-0.82,0.3]
Cohen-Mansfield 2012a	36	2.1 (2.7)	19	7.9 (9.1)		14.02%	-1.01[-1.59,-0.42]
Orsulic-Jeras 2000	13	20.3 (5.5)	12	20.3 (3.9)		9.57%	0[-0.78,0.78]
Wenborn 2013	79	50.2 (59.8)	80	55.8 (48.1)		24.69%	-0.1[-0.41,0.21]
Subtotal ***	**154**		**134**			**63.05%**	**-0.33[-0.76,0.09]**
Heterogeneity: Tau²=0.11; Chi²=7.55, df=3(P=0.06); I²=60.28%							
Test for overall effect: Z=1.55(P=0.12)							
1.1.2 Personally tailored activities vs. active control							
Kolanowski 2011	31	1.5 (2.5)	32	1.1 (2.2)		17.02%	0.17[-0.33,0.66]
van der Ploeg 2013	44	8.4 (9.9)	44	10 (10.4)		19.93%	-0.16[-0.57,0.26]
Subtotal ***	**75**		**76**			**36.95%**	**-0.02[-0.34,0.3]**
Heterogeneity: Tau²=0; Chi²=0.96, df=1(P=0.33); I²=0%							
Test for overall effect: Z=0.13(P=0.9)							
Total ***	**229**		**210**			**100%**	**-0.21[-0.49,0.08]**
Heterogeneity: Tau²=0.06; Chi²=9.96, df=5(P=0.08); I²=49.81%							
Test for overall effect: Z=1.42(P=0.15)							
Test for subgroup differences: Chi²=1.34, df=1 (P=0.25), I²=25.35%							



Favours [personally-tailored activities] Favours [usual care/active control]

Analysis 1.2. Comparison 1 Challenging behaviour, Outcome 2 Investigating heterogeneity.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Cohen-Mansfield 2007	26	3.2 (3.2)	23	4.1 (3.5)		12.64%	-0.26[-0.82,0.3]
Kolanowski 2011	31	1.5 (2.5)	32	1.1 (2.2)		16.4%	0.17[-0.33,0.66]
Orsulic-Jeras 2000	13	20.3 (5.5)	12	20.3 (3.9)		6.52%	0[-0.78,0.78]
van der Ploeg 2013	44	8.4 (9.9)	44	10 (10.4)		22.93%	-0.16[-0.57,0.26]
Wenborn 2013	79	50.2 (59.8)	80	55.8 (48.1)		41.5%	-0.1[-0.41,0.21]
Total ***	**193**		**191**			**100%**	**-0.08[-0.28,0.12]**
Heterogeneity: Tau²=0; Chi²=1.53, df=4(P=0.82); I²=0%							
Test for overall effect: Z=0.82(P=0.41)							



Favours [personally-tailored activities] Favours [usual care/active control]

Analysis 1.3. Comparison 1 Challenging behaviour, Outcome 3 Behaviours van Haitsma 2015.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.3.1 General restlessness						

Favours [personally-tailored activities] Favours [control]

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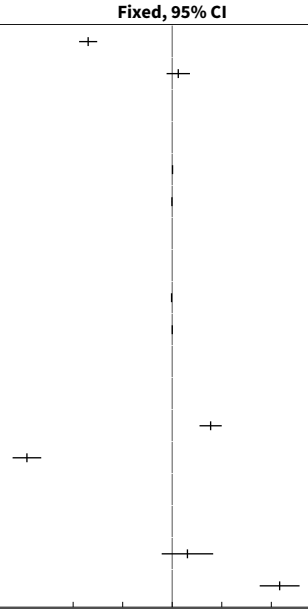
Study or subgroup	Personally-tailored activities		Control		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Van Haitsma 2015	44	6.5 (5.7)	93	23.5 (3.6)		-16.97[-18.8,-15.14]
Van Haitsma 2015	44	6.5 (5.7)	43	5.3 (5.6)		1.22[-1.14,3.58]
1.3.2 Aggression						
Van Haitsma 2015	44	0.1 (0)	93	0 (0)		0.06[0.05,0.07]
Van Haitsma 2015	44	0.1 (0)	43	0.1 (0)		-0.06[-0.07,-0.04]
1.3.3 Uncooperative						
Van Haitsma 2015	44	0 (0)	43	0.1 (0)		-0.13[-0.15,-0.12]
Van Haitsma 2015	44	0 (0)	93	0 (0)		0.01[-0,0.02]
1.3.4 Very negative verbal						
Van Haitsma 2015	44	12.5 (6.9)	93	4.7 (4.4)		7.75[5.51,9.99]
Van Haitsma 2015	44	12.5 (6.9)	43	41.8 (6.8)		-29.33[-32.22,-26.44]
1.3.5 Negative verbal						
Van Haitsma 2015	44	52.5 (12.5)	43	49.4 (12.3)		3.07[-2.13,8.27]
Van Haitsma 2015	44	52.5 (12.5)	93	30.8 (7.9)		21.68[17.66,25.7]



Comparison 2. Affect

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Positive affect	6	498	Std. Mean Difference (IV, Random, 95% CI)	0.88 [0.43, 1.32]
1.1 Personally tailored activities vs. usual care	4	282	Std. Mean Difference (IV, Random, 95% CI)	1.30 [0.77, 1.84]
1.2 Personally tailored activities vs. active control	3	216	Std. Mean Difference (IV, Random, 95% CI)	0.36 [0.09, 0.63]
2 Positive affect-excluding recalculated study results	5	318	Std. Mean Difference (IV, Random, 95% CI)	0.76 [0.38, 1.13]
3 Negative affect	6	632	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.19, 0.14]
3.1 Personally tailored activities vs. usual care	4	416	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.19, 0.22]
3.2 Personally tailored activities vs. active control	3	216	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.36, 0.18]
4 Negative affect-excluding recalculated study results	5	452	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.22, 0.16]
5 Mood	3	247	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.27, 0.23]

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Analysis 2.1. Comparison 2 Affect, Outcome 1 Positive affect.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
2.1.1 Personally tailored activities vs. usual care							
Cohen-Mansfield 2007	41	1.7 (0.5)	36	1.3 (0.3)		15.32%	0.86[0.39,1.33]
Cohen-Mansfield 2012a	46	1.3 (0.3)	19	1 (0.1)		14.28%	0.95[0.39,1.51]
Orsulic-Jeras 2000	12	2.6 (0.5)	13	1.6 (0.6)		10.09%	1.74[0.8,2.69]
Van Haitsma 2015	22	8.2 (1.5)	93	5.4 (1.5)		14.7%	1.84[1.32,2.36]
Subtotal ***	**121**		**161**			**54.4%**	**1.3[0.77,1.84]**
Heterogeneity: Tau^2=0.2; Chi^2=9.69, df=3(P=0.02); I^2=69.04%							
Test for overall effect: Z=4.81(P<0.0001)							
2.1.2 Personally tailored activities vs. active control							
Kolanowski 2011	31	3 (0.7)	32	2.7 (0.7)		14.97%	0.45[-0.05,0.95]
van der Ploeg 2013	44	1.4 (3.8)	44	0.4 (1.3)		15.84%	0.35[-0.07,0.77]
Van Haitsma 2015	22	8.2 (1.5)	43	7.7 (1.5)		14.79%	0.29[-0.23,0.8]
Subtotal ***	**97**		**119**			**45.6%**	**0.36[0.09,0.63]**
Heterogeneity: Tau^2=0; Chi^2=0.19, df=2(P=0.91); I^2=0%							
Test for overall effect: Z=2.59(P=0.01)							
Total ***	**218**		**280**			**100%**	**0.88[0.43,1.32]**
Heterogeneity: Tau^2=0.28; Chi^2=29.39, df=6(P<0.0001); I^2=79.59%							
Test for overall effect: Z=3.86(P=0)							
Test for subgroup differences: Chi^2=9.57, df=1 (P=0), I^2=89.55%							

Favours [usual care/active control] Favours [personally-tailored activities]

Analysis 2.2. Comparison 2 Affect, Outcome 2 Positive affect-excluding recalculated study results.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Cohen-Mansfield 2007	41	1.7 (0.5)	36	1.3 (0.3)		22.89%	0.86[0.39,1.33]
Cohen-Mansfield 2012a	46	1.3 (0.3)	19	1 (0.1)		19.83%	0.95[0.39,1.51]
Kolanowski 2011	31	3 (0.7)	32	2.7 (0.7)		21.8%	0.45[-0.05,0.95]
Orsulic-Jeras 2000	12	2.6 (0.5)	13	1.6 (0.6)		10.88%	1.74[0.8,2.69]
van der Ploeg 2013	44	1.4 (3.8)	44	0.4 (1.3)		24.6%	0.35[-0.07,0.77]
Total ***	**174**		**144**			**100%**	**0.76[0.38,1.13]**
Heterogeneity: Tau^2=0.1; Chi^2=9.53, df=4(P=0.05); I^2=58.03%							
Test for overall effect: Z=3.98(P<0.0001)							

Favours [usual care/active control] Favours [personally-tailored activities]

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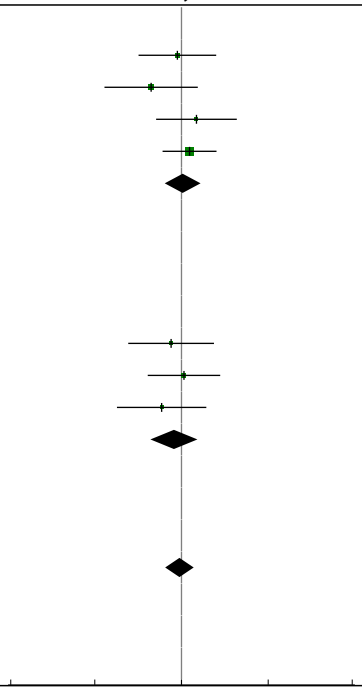
Analysis 2.3. Comparison 2 Affect, Outcome 3 Negative affect.

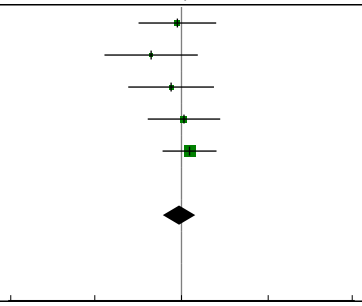
Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
2.3.1 Personally tailored activities vs. usual care							
Cohen-Mansfield 2007	41	1.1 (0.1)	36	1.1 (0.9)		13.49%	-0.05[-0.5,0.4]
Cohen-Mansfield 2012a	46	1 (0.1)	19	1.1 (0.1)		9.34%	-0.35[-0.89,0.19]
Van Haitsma 2015	22	4.5 (1.6)	93	4.3 (1.3)		12.49%	0.17[-0.29,0.64]
Wenborn 2013	79	3.4 (5.9)	80	2.9 (4.3)		27.95%	0.09[-0.22,0.4]
Subtotal ***	**188**		**228**			**63.27%**	**0.01[-0.19,0.22]**
Heterogeneity: Tau²=0; Chi²=2.53, df=3(P=0.47); I²=0%							
Test for overall effect: Z=0.13(P=0.9)							
2.3.2 Personally tailored activities vs. active control							
Kolanowski 2011	31	1.5 (0.8)	32	1.6 (0.8)		11.06%	-0.12[-0.61,0.37]
van der Ploeg 2013	44	0.9 (3.4)	44	0.8 (3.5)		15.48%	0.03[-0.39,0.45]
Van Haitsma 2015	22	4.5 (1.6)	43	5 (2.2)		10.18%	-0.23[-0.74,0.29]
Subtotal ***	**97**		**119**			**36.73%**	**-0.09[-0.36,0.18]**
Heterogeneity: Tau²=0; Chi²=0.6, df=2(P=0.74); I²=0%							
Test for overall effect: Z=0.63(P=0.53)							
Total ***	**285**		**347**			**100%**	**-0.02[-0.19,0.14]**
Heterogeneity: Tau²=0; 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%							



Favours [Personally-tailored activities] Favours [usual care/active control]

Analysis 2.4. Comparison 2 Affect, Outcome 4 Negative affect-excluding recalculated study results.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Cohen-Mansfield 2007	41	1.1 (0.1)	36	1.1 (0.9)		17.45%	-0.05[-0.5,0.4]
Cohen-Mansfield 2012a	46	1 (0.1)	19	1.1 (0.1)		12.08%	-0.35[-0.89,0.19]
Kolanowski 2011	31	1.5 (0.8)	32	1.6 (0.8)		14.31%	-0.12[-0.61,0.37]
van der Ploeg 2013	44	0.9 (3.4)	44	0.8 (3.5)		20.03%	0.03[-0.39,0.45]
Wenborn 2013	79	3.4 (5.9)	80	2.9 (4.3)		36.14%	0.09[-0.22,0.4]
Total ***	**241**		**211**			**100%**	**-0.03[-0.22,0.16]**
Heterogeneity: Tau²=0; Chi²=2.17, df=4(P=0.7); I²=0%							
Test for overall effect: Z=0.3(P=0.77)							



Favours [personally-tailored activities] Favours [usual care/active control]

Analysis 2.5. Comparison 2 Affect, Outcome 5 Mood.

Study or subgroup	Personally-tailored activities N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Kolanowski 2011	31	9.9 (1.6)	32	9.9 (1.9)		25.54%	0[-0.49,0.49]

Favours [usual care/active control] Favours [personally-tailored activities]

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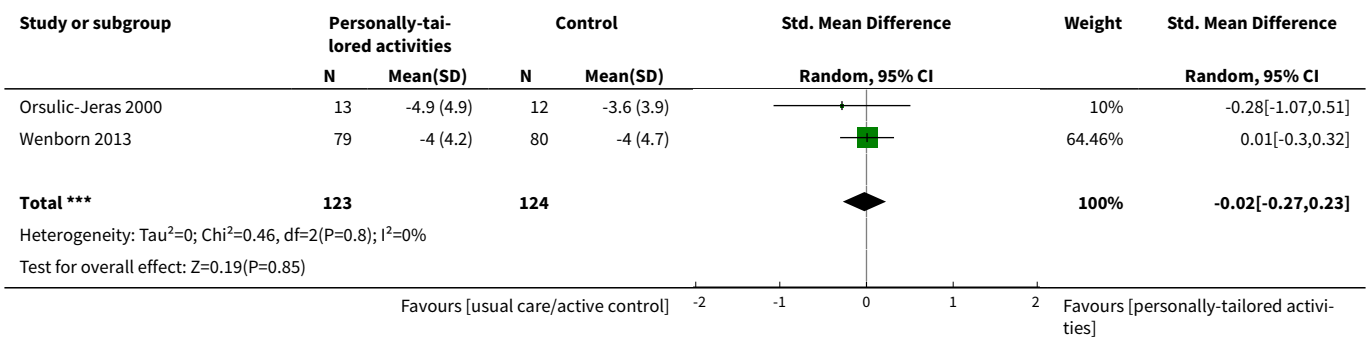
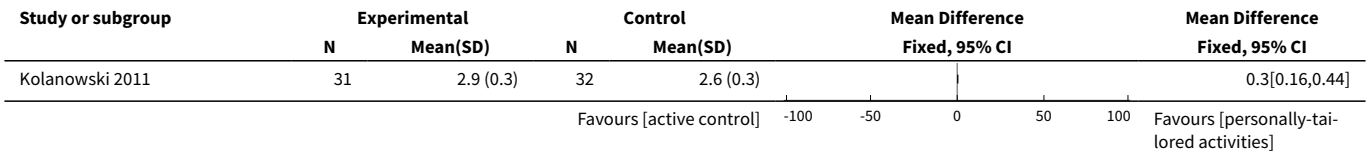


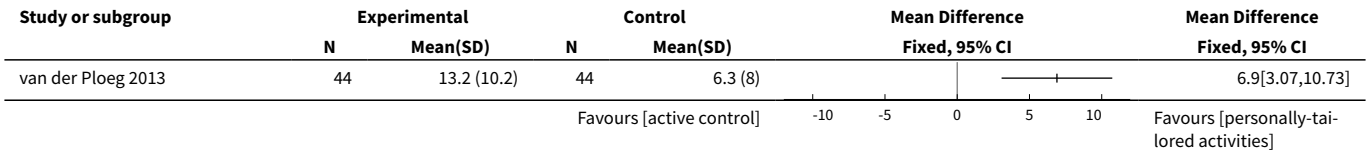
Comparison 3. Engagement

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intensity of participation	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Constructive engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3 Passive engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4 Negative engagement	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

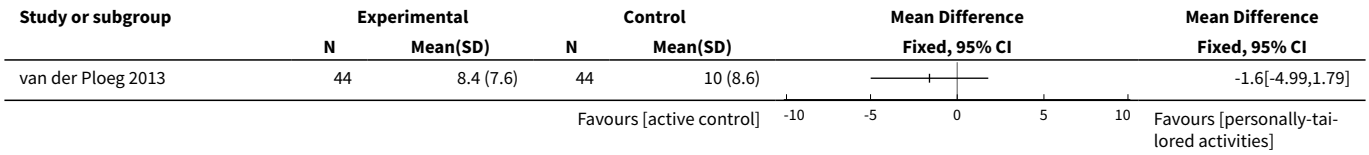
Analysis 3.1. Comparison 3 Engagement, Outcome 1 Intensity of participation.



Analysis 3.2. Comparison 3 Engagement, Outcome 2 Constructive engagement.



Analysis 3.3. Comparison 3 Engagement, Outcome 3 Passive engagement.



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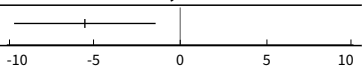
Analysis 3.4. Comparison 3 Engagement, Outcome 4 Negative engagement.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
van der Ploeg 2013	44	8.2 (9.2)	44	13.7 (10.3)		-5.5[-9.58,-1.42]



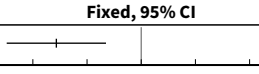
Favours [personally-tailored activities] Favours [active control]

Comparison 4. Sleep-related outcomes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Daytime minutes slept	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Nighttime minutes slept	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 4.1. Comparison 4 Sleep-related outcomes, Outcome 1 Daytime minutes slept.

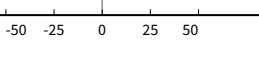
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
Richards 2005	71	71.6 (69)	68	110.8 (68.7)		-39.16[-62.06,-16.26]



Favours [personally-tailored activities] Favours [usual care]

Analysis 4.2. Comparison 4 Sleep-related outcomes, Outcome 2 Nighttime minutes slept.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
Richards 2005	71	372.4 (153.7)	68	343.6 (155.7)		28.81[-22.65,80.27]



Favours [usual care] Favours [personally-tailored activities]

APPENDICES

Appendix 1. Searches May 2012, April 2013, March 2014, January 2015, January 2016, July 2017

Source	Search strategy	Hits retrieved
1. ALOIS (www.medicine.ox.ac.uk/alois) [most recent search date: 16 June 2017]	#1 "personally tailored" OR individualized OR individualised OR individual OR person-centred OR meaningful OR personhood #2 involvement OR engagement OR engaging OR identity	May 2012: 149 April 2013: 0 March 2014: 6

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(Continued)

	#3 #1 OR #2	January 2015: 1 January 2016: 2 October 2016: 2 June 2017: 3
2. MEDLINE In-process and other non-indexed citations and MEDLINE 1946 to present (Ovid SP) [most recent search date: 16 June 2017]	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.	May 2012: 1656 April 2013: 205 March 2014: 177 January 2015: 182 January 2016: 185 October 2016: 367 June 2017: 358

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(Continued)

	30. (engagement or engaging).ti,ab.	
	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 2011 December 29 (Ovid SP); then 1974 to 2013 week 12; then 1974 to 2014 week 11; then 1974 to 2016 October 14 [most recent search date: 16 June 2017]	1. exp dementia/	May 2012:2400 April 2013: 382 March 2014: 452 January 2015: 492 January 2016: 463 October 2016: 777 June 2017: 691
	2. Lewy body/	
	3. delirium/	
	4. Wernicke encephalopathy/	
	5. cognitive defect/	
	6. dement*.mp.	
	7. alzheimer*.mp.	
	8. (lewy* adj2 bod*).mp.	
	9. deliri*.mp.	
	10. (chronic adj2 cerebrovascular).mp.	
	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.	

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(Continued)

17. (pick* adj2 disease).mp.
18. (creutzfeldt or jcd or cjd).mp.
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

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4. PsycINFO 1806 to May week 1 2012 (Ovid SP); then March week 4 2013 (Ovid SP); then 1806 to March week 1 (Ovid SP); then 1806 to October week 2 (Ovid SP) [most recent search date: 16 June 2017]	1. exp Dementia/ 2. exp Delirium/ 3. exp Huntingtons Disease/ 4. exp Kluver Bucy Syndrome/ 5. exp Wernickes Syndrome/ 6. exp Cognitive Impairment/ 7. dement*.mp. 8. alzheimer*.mp. 9. (lewy* adj2 bod*).mp. 10. deliri*.mp. 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.	May 2012: 1633 April 2012: 191 March 2014: 202 January 2015: 207 January 2016: 228 October 2016: 356 June 2017: 268

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(Continued)

	34. (engagement or engaging).ti,ab. 35. occupational*.ti,ab. 36. personhood.ti,ab. 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: 16 June 2017]	S1 (MH "Dementia+") S2 (MH "Delirium") or (MH "Delirium, Dementia, Amnestic, Cognitive Disorders") S3 (MH "Wernicke's Encephalopathy") S4 TX dement* S5 TX alzheimer* S6 TX lewy* N2 bod* S7 TX deliri* S8 TX chronic N2 cerebrovascular S9 TX "organic brain disease" or "organic brain syndrome" S10 TX "normal pressure hydrocephalus" and "shunt*" S11 TX "benign senescent forgetfulness" S12 TX cerebr* N2 deteriorat* S13 TX cerebral* N2 insufficient* S14 TX pick* N2 disease S15 TX creutzfeldt or jcd or cjd	May 2012: 2367 April 2013: 275 March 2014: 221 January 2015: 158 January 2016: 121 October 2016: 245 June 2017: 274

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(Continued)

	S16 TX huntington*	
	S17 TX binswanger*	
	S18 TX korsako*	
	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	
	S20 AB activity	
	S21 AB activities	
	S22 TX psychosocial	
	S23 TX non-pharmacological	
	S24 TX individually-tailor*	
	S25 TX personally-tailor*	
	S26 AB individual OR individuals OR individually-cent*	
	S27 AB meaningful	
	S28 AB involvement	
	S29 TX engagement or engaging	
	S30 TX occupational*	
	S31 TX personhood	
	S32 TX person-centred	
	S33 TX identity	
	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	
	S35 TX "long-term care"	
	S36 TX "care home*"	
	S37 TX "residential care"	
	S38 TX "nursing home*"	
	S39 TX "residential facilit*"	
	S40 (MH "Residential Facilities")	
	S41 (MH "Nursing Homes")	
	S42 TX "old people* home*"	
	S43 TX institutional	
	S44 TX institutionalised OR institutionalized	
	S45 S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44	
	S46 S19 and S34 and S45	
6. Web of Science and conference proceedings	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	May 2012: 2153 April 2013: 311

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[most recent search date: 16 June 2017]	individual OR meaningful* OR occupaional 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) Timespan=All Years. Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH. Lemmatization=On	March 2014: 104 January 2015: 216 January 2016: 391 October 2016: 773 June 2017: 766
7. LILACS (BIREME) [most recent search date: 16 June 2017]	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: 0 January 2016: 3 October 2016: 52 June 2017: 67
8. CENTRAL (in The Cochrane Library) (Issue 4 2012 and Issue 2 2013) [most recent search date: 16 June 2017]	#1 MeSH descriptor Dementia explode all trees #2 MeSH descriptor Delirium, this term only #3 MeSH descriptor Wernicke Encephalopathy, this term only #4 MeSH descriptor Delirium, Dementia, Amnestic, Cognitive Disorders, this term only #5 dement* #6 alzheimer* #7 "lewy* bod*" #8 deliri* #9 "chronic cerebrovascular" #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*	May 2012: 280 April 2013: 3 March 2014: 10 January 2015: 18 January 2016: 13 October 2016: 50 June 2017: 17

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#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"

#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: 16 June 2017]	(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

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		October 2016: 58 June 2017: 94
10. ICTRP Search Portal (apps.who.int/trialsearch) [includes: Australian New Zealand Clinical Trials Registry; ClinicalTrilas.gov; ISRCTN; Chinese Clinical Trial Registry; Clinical Trials Registry – India; Clinical Research Information Service – Republic of Korea; German Clinical Trials Register; Iranian Registry of Clinical Trials; Japan Primary Registries Network; Pan African Clinical Trial Registry; Sri Lanka Clinical Trials Registry; The Netherlands National Trial Register] [most recent search date: 16 June 2017]	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
TOTAL before de-duplication		May 2012: 11349 April 2012: 1455 March 2014: 1273 January 2015: 1296 January 2016: 1435 October 2016: 2682 June 2017: 2549
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

Appendix 2. Appendix 2 - Complete results of the risk of bias assessment (parallel group RCTs – individually and cluster randomised)

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Item	Cohen-Mansfield 2007	Cohen-Mansfield 2012a	Kolanowski 2011	Richards 2005	Van Haitsma 2015	Wenborn 2013
Allocation sequence adequately generated	No	Yes	Yes	Unclear	Yes*	Yes*
Allocation adequately concealed	Unclear	Unclear	Yes	Unclear	No*	Yes*
Participants identified before randomisation	Unclear	Unclear	Yes	Yes	Yes	Yes
If no: no evidence for biased selection of participants	-	-	-	-	-	-
Inclusion/exclusion criteria for participants clearly defined	Yes	Yes	Yes	Yes	Yes	Yes
Inclusion/exclusion criteria for clusters clearly defined	No	No	n. a.	n. a.	n. a.	Yes*
Adequate sample size calculation	No	Unclear	Yes	Yes	No	Yes
Absence of relevant differences between groups after randomisation	Yes	Yes	Unclear	Unclear	Yes	Yes
Loss to follow-up less 5% of participants	Yes	Yes	Yes	No	No	No
Were incomplete data adequately explained	Yes	Yes	Yes	Yes	Yes	Yes
All groups treated equally, except of intervention or control	Yes	Yes	Yes	Yes	Yes	Yes
Primary outcome clearly stated?	Yes	Yes	No	No	No	Yes*
Participants blinded to group allocation	Unclear	Yes	Yes	Unclear	Yes*	Unclear
Personnel blinded to group allocation	No	No	Yes	Unclear	No	Yes
Outcome assessors blinded to group allocation	No	No	Yes	No	No	Yes
Data collection started immediately after randomisation	Unclear	Unclear	Yes*	Unclear	Varied*	Unclear
Intention to treat analysis	Unclear	Yes	Yes	Yes	Yes*	Yes
Complete reporting of outcome (as scheduled)	Yes	Yes	Yes	Yes	Yes	Yes
Methods of analysis adequate for cluster-randomised trials	No	No	n. a.	n. a.	n. a.	Yes
Conflicts of interest mentioned	No	Yes	Yes	Yes	No	Yes

* Items marked with an asterisk have been answered by the study authors after personal request

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Appendix 3. Appendix 3 - Complete results of the risk of bias assessment (cross-over RCTs)

Item	van der Ploeg 2013
Cross-over design appropriate	Yes
Absence of bias from a carry-over effect	Yes
Allocation sequence adequately generated	Yes
Allocation adequately concealed	No*
Order of treatments randomised?	Yes
Participants identified before randomisation	Yes
If no: no evidence for biased selection of participants	-
Inclusion/exclusion criteria for participants clearly defined	Yes
Adequate sample size calculation	Yes
Absence of relevant differences between groups after randomisation	Unclear
Loss to follow-up less 5% of participants	No
Were incomplete data adequately explained	Yes
Primary outcome clearly stated?	Yes
Participants blinded to group allocation	Yes
Personnel blinded to group allocation	No
Outcome assessors blinded to group allocation	No
Data collection started immediately after randomisation	Unclear
Intention to treat analysis	Yes*
Complete reporting of outcome (as scheduled)	Yes
Conflicts of interest mentioned	Yes
* Items marked with an asterisk have been answered by the study authors after personal request	

Appendix 4. Appendix 4 - Complete results of the risk of bias assessment (non-randomised trials)

Item	Orsulic-Jeras 2000
Inclusion/exclusion criteria for participants clearly defined	No*

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(Continued)

Reporting of all relevant characteristics of the participants	Yes
Absence of relevant differences between groups after randomisation	Yes*
Adequate sample size calculation	No*
Loss to follow-up less 5% of participants	No
Were incomplete data adequately explained	Yes
All groups treated equally, except of intervention or control	Yes
Primary outcome clearly stated?	No
Participants blinded to group allocation	No
Personnel blinded to group allocation	No
Outcome assessors blinded to group allocation	No
Intention to treat analysis	Yes*
Complete reporting of outcome (as scheduled)	Yes
Conflicts of interest mentioned	No
* Items marked with an asterisk have been answered by the study authors after personal request	

CONTRIBUTIONS OF AUTHORS

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

DECLARATIONS OF INTEREST

None known.

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INDEX TERMS

Medical Subject Headings (MeSH)

*Affect; *Long-Term Care; Dementia [*psychology]; Non-Randomized Controlled Trials as Topic; Psychomotor Agitation [*therapy]; Quality of Life [*psychology]; Randomized Controlled Trials as Topic; Social Participation [psychology]

MeSH check words

Aged; Aged, 80 and over; Humans

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