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Functional analysis-based interventions for challenging behaviour in dementia (Review)

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[Intervention Review]

Functional analysis-based interventions for challenging behaviour in dementia

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ABSTRACT

Background

Functional analysis (FA) for the management of challenging behaviour is a promising behavioural intervention that involves exploring the meaning or purpose of an individual's behaviour. It extends the 'ABC' approach of behavioural analysis, to overcome the restriction of having to derive a single explanatory hypothesis for the person's behaviour. It is seen as a first line alternative to traditional pharmacological management for agitation and aggression. FA typically requires the therapist to develop and evaluate hypotheses-driven strategies that aid family and staff caregivers to reduce or resolve a person's distress and its associated behavioural manifestations.

Objectives

To assess the effects of functional analysis-based interventions for people with dementia (and their caregivers) living in their own home or in other settings.

Search methods

We searched ALOIS: the Cochrane Dementia and Cognitive Improvement Group's Specialized Register on 3 March 2011 using the terms: FA, behaviour (intervention, management, modification), BPSD, psychosocial and Dementia.

Selection criteria

Randomised controlled trials (RCTs) with reported behavioural outcomes that could be associated with functional analysis for the management of challenging behaviour in dementia.

Data collection and analysis

Four reviewers selected trials for inclusion. Two reviewers worked independently to extract data and assess trial quality, including bias. Meta-analyses for reported incidence, frequency, severity of care recipient challenging behaviour and mood (primary outcomes) and caregiver reaction, burden and mood were performed. Details of adverse effects were noted.

Main results

Eighteen trials are included in the review. The majority were in family care settings. For fourteen studies, FA was just one aspect of a broad multi-component programme of care. Assessing the effect of FA was compromised by ill-defined protocols for the duration of component parts of these programmes (i.e. frequency of the intervention or actual time spent). Therefore, establishing the real effect of the FA component was not possible.

Overall, positive effects were noted at post-intervention for the frequency of reported challenging behaviour (but not for incidence or severity) and for caregiver reaction (but not burden or depression). These effects were not seen at follow-up.

Authors' conclusions

The delivery of FA has been incorporated within wide ranging multi-component programmes and study designs have varied according to setting - i.e. family care, care homes and hospital, with surprisingly few studies located in care homes. Our findings suggest potential beneficial effects of multi-component interventions, which utilise FA. Whilst functional analysis for challenging behaviour in dementia care shows promise, it is too early to draw conclusions about its efficacy.

PLAIN LANGUAGE SUMMARY

Inconclusive, but promising evidence for the efficacy of functional analysis interventions for challenging behaviour in dementia

The management of challenging behaviour, such as aggression and agitation in dementia has been dominated by drug therapies such as the antipsychotics, despite their modest efficacy, side effects and potential detriment to quality of life. Functional analysis (FA) is a behavioural intervention that is described by international guidelines as the first line alternative to drug therapy for challenging behaviour. FA typically requires the therapist to develop an understanding of the function or meaning behind the person's distressed behaviour. It uses this understanding to develop individually tailored strategies aimed at both the person with dementia and the caregivers, to relieve the distress caused by the behaviour. FA can be applied in home settings where the family or informal caregiver is offered support from a therapist, or in care homes, hospitals or assisted living settings, where training in FA and specialist support to deliver interventions is provided for staff.

In this review we analysed the effectiveness of functional analysis-based interventions for challenging behaviour in dementia. We found eighteen randomised controlled trials suitable for analysis in all four types of care settings. The majority were in family care settings and there were surprisingly few care home based studies. Most evaluated broad programmes of care, where FA was just one component of a wide range of other interventions. This made it hard to determine the real effect of FA for the management of challenging behaviour in dementia.

However, positive results were noted in the frequency of the person's reported problem behaviours and the caregiver's reaction to them. No significant effects were found for incidence or severity of mood and other problem behaviours. Similarly, no significant effects were found for caregiver mood or burden.

Whilst it is too early to reach a firm conclusion on the evidence for FA in the management of challenging behaviour in dementia, we note emerging beneficial effects on challenging behaviour where multi-component psychosocial interventions have used FA as part of the programme of care.

BACKGROUND

Challenging behaviours or 'behaviours that challenge us' (NICE 2006), sometimes also referred to as 'behavioural and psychological symptoms of dementia (BPSD) or neuropsychiatric symptoms' (Finkel 1997), involve disturbances in people's mood, behaviours, thoughts and perceptions. They include 'symptoms' such as delusions, hallucination anxiety, depression, apathy, agitation, aggression, wandering and disinhibition (Ballard 2001) or behaviours such as confusion, calling out, repetitive questioning, toileting difficulties, misidentifications and sexual challenge (Stokes 2000). These behaviours are described as 'challenging' because they are perceived to be 'unreasonable' and challenge the norms and rules of the contexts within which they occur. Bird 2008 propose that challenging behaviour in dementia is a manifestation of distress or suffering in the person, or distress in the caregiver. According to this definition, challenging behaviour can be seen as an active attempt by the person to meet or express a physiological or psychological need (Stokes 2000). Interventions for challenging behaviour can include those that address a family or staff caregivers' ability to cope, or their efficacy in the management of challenging behaviours.

Until recently, pharmacological regimens were used to treat these problematic behaviours, but increasing concerns over their modest efficacy, significant side effects and potential detrimental impact on quality of life (Ballard 2005) have resulted in calls for non-pharmacological approaches as the first-line interventions (Howard 2001; NICE 2006). 'Time for Action' (Banerjee 2009) supports the position that pharmaceuticals have limited positive effects and they can cause significant harm to people with dementia. It is suggested that out of the 180,000 people being treated with anti-psychotic medication each year in the UK, only 20% will derive some benefit (Banerjee 2009). As was seen in the USA following implementation of the 1987 Omnibus Budget Reconciliation Act, a 30% reduction in the use of some types of drugs, such as antipsychotics, can be achieved through legislation (Lantz 1996). In the UK, enhanced non-pharmacological interventions that impact on the practices of prescribing doctors can also lead to reductions in the use of drugs (Fossey 2006). Despite this, psycho-geriatricians appear to prefer pharmacological treatment (Greve 2005) and their use of drugs for managing challenging behaviour in dementia may actually be on the increase (Dempsey 2005). If professionals are required to reduce their reliance on medication, they will need to be confident in the use of non-pharmacological alternatives.

A promising non-pharmacological treatment has its roots in behaviour therapy, sometimes referred to as 'behavioural intervention' (Spira 2006), 'behaviour management' (DoH 2001; Livingston 2005) or 'behaviour modification'. Behavioural intervention programmes are usually based on either a behavioural analysis, or the updated approach to behavioural analysis, which is termed functional analysis (Stokes 2000). These are now collectively described as behavioural or functional analysis (NICE 2006) and can include interventions where staff and family caregivers meet the person's need (Cohen-Mansfield 2000) by deriving an understanding of the purpose or meaning of the individual's behaviour (Moniz-Cook 2001). In this review we refer to this non-pharmacological approach for challenging behaviour in dementia as functional analysis-based intervention, since, when compared with traditional behavioural analysis, this reflects a wider and conceptually stronger description of the range of such interventions.

Functional analysis-based interventions arise out of behavioural analysis, or what is also known as the 'ABC' approach. The method requires clear specification of a problem behaviour ('B') that is understood in terms of the observed influence of events preceding it (antecedents 'A'), and the events consequent ('C') upon it (Stokes 2000). Traditional 'ABC' behavioural interventions imply that behaviour is always observable and linear in nature. However, this is not necessarily true for the development and maintenance of challenging behaviour in dementia. For example, staff anxiety may be a consequence ('C') of a challenging behaviour ('B) but staff behaviour (including anxiety) can also simultaneously act as an antecedent ('A'); see Moniz-Cook 2000. This non-linear relationship between antecedents, behaviour and consequences (ABCs) is also seen in a case study where a man's (unobservable) superstitious belief ('A') precipitated aggression ('B'), which led to the use of an antipsychotic ('C'), which in turn reduced his efficacy ('A'), requiring increased staff supervision ('A') and further exacerbated aggression ('B'); see Moniz-Cook 2001. Furthermore, a given behaviour may have different functions for different individuals, or more than one function for a particular individual and it may originate for one reason and be maintained by another; or originate for more than one reason among different people (Moniz-Cook 2003). Thus, although the principles are straightforward, in practice the relationship between features is often complex. In order to clarify such relationships, therapists therefore undertake a functional analysis of the behaviour.

Functional analysis-based intervention builds on the empirical rigour of behaviour analysis, but is not restricted to the immediate 'observable' antecedents and/or consequences of behaviour (Moniz-Cook 2001; Stokes 2000). It extends analysis and associated management to an understanding or a formulation (James 1999; James 2011) of the meaning or purpose of the behaviour (i.e. the function served by the behaviour). It can thus overcome the impractical search for a single explanatory hypothesis for a given behaviour that is intrinsic to the 'ABC' approach (Jones 1992; Owens 1992). For example, when examining the wider context of the challenging behaviour, one might determine that the problems may reflect coping strategies on the part of the person with dementia. Thus, aggression (which in its own right is poorly defined, see Stokes 2000) may represent a means of communicating loneliness or anxiety or avoiding shame, or a response to discomfort, pain or fear.

Functional analysis-based interventions aim to develop hypothesis-driven strategies to help caregivers reduce and potentially resolve a person's distress and the associated behavioural manifestation of this, in three main ways.

(1) Identifying the antecedents ('A's), consequences ('C's) or maintaining factors of challenging behaviours, and then intervening at the appropriate point in the sequence.

(2) Identifying the function of the behaviour for the individual, based on knowledge of factors such as pre-morbid history and an understanding of the 'unmet need' that is being communicated by the distressed person. Based on the functional analysis and a formulation of the behaviour in its broader context, hypothesis-driven interventions are derived.

(3) Training and supporting family and staff caregivers to apply, monitor and provide information that allows the therapist to evaluate these individually tailored hypothesis-driven interventions.

OBJECTIVES

To evaluate the effectiveness and impact of functional analysis-based intervention in the management and resolution of 'behaviours that challenge' family and staff caregivers.

Since challenging behaviour in dementia may be influenced by factors, such as training of the caregiver and the interaction between the person and the caregiver, the impact (and if possible sustainability) of interventions on the person's behaviour and mood as well as on the caregiver's experience, is considered.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) which included functional analysis-based intervention for dementia compared with control conditions of 'care as usual', or other types of intervention, were eligible if they had: adequate information or that which was obtained from the authors; data on the reported occurrence (incidence or frequency) of challenging behaviour, using a validated assessment measure, and were published in English as a journal article or with relevant information translated to English for evaluation by reviewers. Interrupted time series trials were excluded.

Types of participants

People with dementia, irrespective of its cause or diagnostic subtype, with reported BPSD or 'behaviours that challenge', receiving support or treatment from mental health workers, care staff or family or other informal caregivers, were included. Participants could be living at home alone or with a carer, or in care homes or cared for in psycho-geriatric hospital wards, special care units, or other dementia facilities.

Types of interventions

Formulation-led individualised interventions targeting reduction in the person's distress and/or resolution of the caregivers' management difficulties, by identifying the underlying 'unmet need' (Cohen-Mansfield 2000) or 'cause' (Bird 2008) or the 'antecedents' and 'consequences' of the person's distressed behaviour (i.e. ABCs). Studies where the intervention fulfilled this criterion were identified from the published report, or written confirmation from the report's senior author.

FA intervention also needed to include all of the following criteria:
(a) the intervention involved an initial elucidation by a trained professional therapist of an unmet need(s) or cause(s) of behaviour;
(b) an individually tailored package of care was designed on the basis of this elucidation; and
(c) the intervention was applied by a family or staff caregiver in collaboration with (or supervised by) a professional therapist.

Interventions that were limited to just one antecedent of behaviour, such as those occurring which targeted specific episodes of care, such as bathing or specific times (e.g. Sloane 2004, aggression occurring during showering or bathing) were excluded, since these protocols were weighted towards using episode-specific strategies, rather than individualised solutions based on the function or meaning of the person's particular behaviour.

Studies could compare the intervention to 'care as usual' that is normally provided in the study setting, including medication for behavioural problems and referral to psychiatric or community mental health services. Concurrent interventions, such as medication use (e.g. for pain relief), psychotropic drug withdrawal programmes, aromatherapy, bright-light, other psychosocial interventions or admission to another setting to reduce challenging behaviour, were recorded.

Where more than one control condition existed (e.g. studies which compared alternative treatments), FA was evaluated against the 'usual care' condition. Where studies used more than two intervention conditions the most salient treatment that aligned to FA criteria was used. For example, Chenoweth 2009 used three conditions (Person Centred Care - PCC, Dementia Care Mapping - DCM and Usual Care) and we analysed data from the DCM condition against Usual Care, since DCM used individualised care plans based on an elucidation of the person's needs, history and preferences. Teri 2000 used four conditions, three pharmacological (trazodone, haloperidol and placebo control) and one FA (Behaviour Management Techniques - BMT). We analysed data from BMT and the placebo drug condition.

No restrictions were placed on the duration or number of treatment sessions, although these were noted in order to make comparisons between studies.

Types of outcome measures

Primary outcome

Changes in the reported incidence, frequency and severity of the range of challenging behaviours (e.g. verbal and physical aggression, restlessness) and mood (depression), using informant reports (caregiver ratings) on standardised measures, e.g. NPI, BEHAVE-D, CMAI, RAGE, RMBPC, CBS, CDDS (Cornell Depression in Dementia Scale). Some commonly used measures such as the Neuro-Psychiatric Inventory (NPI) provide behaviour and mood ratings for incidence, frequency and severity (mild, moderate or marked), whilst others such as the Revised Memory and Behaviour Problem Checklist (RMBPC) provide these for incidence and frequency only. Both tools provide ratings for the impact of challenging behaviours on the caregiver in terms of distress (NPI) or 'bother' (RMBPC). Although caregiver perception may influence their reports of challenging behaviour, for the purpose of this review the severity rating is seen as distinct from ratings of impact (i.e. distress, bother, coping or perceived management difficulty) on the caregiver.

Secondary outcomes

Changes in caregiver (i.e. family or care staff) self-report of reaction to challenging behaviours, using ratings on standardised measures e.g. NPI, RMBPC and PC. Irrespective of how this was defined by authors, for the purposes of this review this outcome included ratings of caregiver distress, upset, 'bother', coping

and perceived management difficulty associated with a given challenging behaviour. Other measures of family or staff carer well-being (mood, morale, efficacy and burden) were also considered.

Short-term (up to one month) and long-term (one month to two years) outcomes were considered. Rates of attrition and reasons for this were noted.

See Table 1 for a Description of the Primary and Secondary outcome measures used by the Included Studies.

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 3 March 2011. The search terms used were: functional analysis, behaviour (intervention, management, modification), BPSD, psychosocial and Dementia.

ALOIS is maintained by the Trials Search Co-ordinator 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 searches of *The Cochrane Library*'s Central Register of Controlled Trials (CENTRAL);
4. six-monthly searches of a number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses.

To view a list of all sources searched for ALOIS see About ALOIS on the ALOIS web site.

Details of the search strategies used for the retrieval of reports of trials from the healthcare databases, CENTRAL and conference proceedings can be viewed in the 'methods used in reviews' section within the editorial information about the Dementia and Cognitive Improvement Group.

Additional searches were performed in many of the sources listed above to cover the timeframe from the last searches performed for ALOIS to ensure that the search for the review was as up-to-date and as comprehensive as possible. The search strategies used can be seen in Appendix 1.

Searches carried out in the previous version(s) of the review can be viewed in Appendix 2 and Appendix 3.

The latest search (March 2011) retrieved a total of 712 results. After a first-assess and a de-duplication of these results the authors were left with 165 references to further assess.

Selection of studies

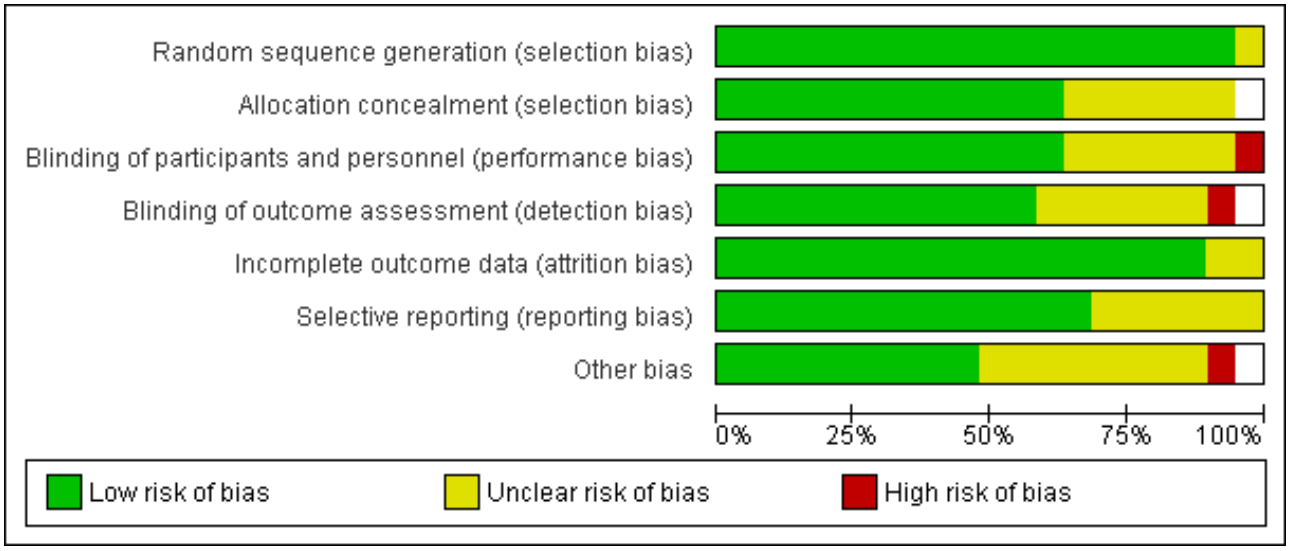
Reviewers worked in two independent pairs (IJ and EM-C; and MdV and FV) to assess publications for eligibility. First, the title was reviewed then the abstracts were examined, and finally for studies that remained, hard copies of the full texts were obtained. The reviewer pairs then considered relevant trials including additional information accessed from study authors. A standard form documenting the inclusion and exclusion criteria was used for each study by all four reviewers. The reviewers' selections of trials were compared and a list of studies to be included was reached by consensus across all four reviewers.

Data collection and analysis

Quality assessment

Two reviewers (EM-C and KRS) assessed the methodological quality of each study using the Cochrane risk of bias tool and the guidance provided in the Cochrane Handbook (Higgins 2009), to identify potential sources of systematic bias. Criteria for appraisal of internal validity of studies covered bias in selection, performance, detection, attrition, reporting and any other bias identified, which were categorised into low, moderate or high risk of bias. Reviewer consensus was used to complete risk of bias summaries (Figure 1). Studies were also assessed for clinical quality and sustainability (Table 2).

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Data extraction

Data were extracted from each published report or from author information, using a standard form.

For each trial, data for primary outcomes of behaviour (i.e. incidence, frequency, severity) and mood (patient depression) were extracted first, followed by the secondary outcome of caregiver reaction. Finally, we extracted data of other secondary outcomes for caregiver mood and burden. Details on intervals from post-intervention to post-test were not always clear from the text. Where clarification from authors was not available, this was assumed as the first data collection period from baseline.

Since the primary aim of this review was to examine the behavioural outcomes of FA, where these were absent and other (secondary) outcomes were reported, studies were excluded from the review (see for example Robinson 1994). Some rating scales, such as the RMPBC provided data for both primary and secondary outcomes, e.g. reported frequency of care recipient behaviour and caregiver reaction. Identical outcome measures, where these existed across the 18 studies, were used in the pooled analysis. The exception was where a particular assessment was specifically noted in text as the primary outcome measure. The RMPBC was used to assess either incidence or frequency or both domains of patient behaviour in nine out of 14 potential studies. For caregiver reaction eight studies used the RMBPC to measure caregiver 'bother' associated with care recipient challenging behaviours. The CMAI was used to assess patient behaviour in two of the three care home studies. The NPI was used as to measure the severity of patient behaviour or caregiver reaction (distress) in just three of the 18 studies (See Table 1 for an overview of measures where data were used for analysis).

The summary statistics obtained for each trial and each outcome for continuous data were the mean change from baseline, the standard error of the mean change, and the number of patients for each treatment group at each assessment. The baseline assessment was defined as the latest available assessment prior to randomisation, but no longer than two months prior to randomisation.

For each outcome measure, to allow an intention-to-treat analysis, the data were sought irrespective of compliance, whether or not the patient was subsequently deemed ineligible or otherwise excluded from treatment or follow-up. If intention-to-treat data were not available in the publication, 'on-treatment' data were sought (i.e. the data of those who completed the trial). For crossover trials, only data from the first treatment phase after randomisation were extracted because of the likelihood of carryover effects.

Data on adverse effects and drop-outs were also noted.

Data analysis

Summary statistics (N, mean and standard deviation) were required for each rating scale at all assessment points, for both treatment groups in each trial for change from baseline. For continuous data (or ordinal data approximating a normal distribution), the mean change from baseline, the standard deviation, and the number of patients for each treatment group at all assessments were analysed.

The meta-analysis required the combination of data from trials that used or did not use the same rating scale or test to assess an outcome. The measure of the treatment difference for any outcome was the weighted mean difference when the pooled trials used the same scale, and the standardised mean difference (the absolute mean difference divided by the standard deviation) when they used different scales.

We have presented overall estimates of the treatment difference from both fixed-effect and random-effects models and performed a test for heterogeneity using a standard Chi-squared statistic and an I^2 statistic. If there was a significant heterogeneity a random-effects model was preferred. In using a fixed-effect model, the true effect of intervention is assumed to be identical across studies (e.g. 'a fixed value'). This is assuming no statistical heterogeneity between studies. In the random-effects model, the estimated effects are not identical across trials with more weight awarded to smaller studies. If both random-effects and fixed-effect models give the

same results this indicates that no important heterogeneity was found across studies.

Sensitivity analyses were also undertaken to assess the robustness of the results of fixed-effect versus random-effects models via excluding studies. If the treatment effects in the sensitivity analysis were of similar magnitude to the main analysis, a definite conclusion about the treatment effectiveness could be stated; otherwise no firm conclusion could be made on the effectiveness of the treatment.

The following comparisons were undertaken:

Primary outcomes

1) Incidence (presence) of a challenging behaviour: comparing intervention versus usual care in family care settings only, at post-intervention and six month follow-up. Pooled data from four trials using the Revised Memory Behaviour Problem Checklist (RMBPC) were included in the meta-analysis.

2) Frequency of behaviour: comparing intervention versus usual care in 14 studies and three settings (i.e. family, residential and assisted living care). Frequency data at post-intervention, six and 12 month follow-up assessments were analysed. Of the 10 family care studies included, pooled data from eight of these using the RMBPC (or its precursor Memory Behaviour Checklist – MBCL) contributed to the meta-analysis and for care home studies data from the Cohen Mansfield Agitation Inventory – CMAI were used. In order to examine whether studies with a strong focus on FA interventions were effective, frequency data at post-intervention for two family care studies were pooled for analysis.

3) Severity of behaviour: comparing intervention versus usual care in four care settings (family, residential, assisted and hospital care) at post-intervention only.

The meta-analysis included only five out of the 18 studies, of which two used the Neuropsychiatric Inventory (NPI). In order to examine whether studies with a strong focus on FA interventions were effective, severity data at post-intervention for two 'institutional' (care home and hospital) studies were pooled for analysis.

4) Patient depression: comparing intervention versus usual care in three settings (family care, residential care and assisted living) at post-intervention only. Of the four studies included in the meta-analysis, two studies used the Depression sub scale of the RMBPC, one study used the Cornell Depression in Dementia Scale – CDDS and one study used the Automatic Geriatric Examination for Computer Assisted Taxonomy – AGECAT.

Secondary outcomes

1) Caregiver reaction in two settings (family care and assisted living care) at post-intervention and six months follow-up. The meta-analysis comprised 10 family care studies and one in an assisted living setting. Of these, nine studies used the RMBPC scale (or its precursor MBCL).

2) Caregiver depression for family care setting only at post-intervention and six months follow-up. The meta-analysis comprised four family care studies, of which three used the Centre for Epidemiological Studies depression scale (CES-D) and one used the Hospital and Anxiety depression scale (HADs).

3) Caregiver burden for family setting only at post-intervention and six months follow-up. The meta-analysis included six family care studies, of which four used the Zarit Burden Interview (ZBI) and two used the Scale for Caregiver Burden (SCB). In order to examine whether studies with a strong focus on FA interventions were effective, caregiver burden at post-intervention for two family care studies were pooled for analysis.

Sustainability of interventions was examined using follow-up data where these existed. The most commonly occurring follow-up time-points were 6 and 12 months, so data from these studies were analysed.

The reviewers discussed and reached consensus on the interpretation of the statistical analysis, seeking specialist statistical advice from CDCIG as required. The review was then drafted and circulated for comment to peer reviewers and commentators with knowledge in the area, leading to production of the final version for submission to CDCIG.

RESULTS

Description of studies

A total of 3335 references were identified by the Cochrane Dementia and Cognitive Improvement group, of which 262 abstracts were reviewed. From these abstracts, 144 papers were retrieved in full text, of which 19 were selected for inclusion into the review; one paper (Weiner 2002) reports follow-up data of an included study (Teri 2000), therefore, the total number of studies included in the review is 18.

See: Characteristics of included studies and Characteristics of excluded studies.

Four studies (Mador 2004; Moniz-Cook 2008a; Teri 2000; Zarit 1987) had all data required documented in the published paper. Additional data or information were provided by authors for nine studies(Chenoweth 2009; Farran 2004; Fossey 2006; Gitlin 2003; Gitlin 2010; Losada-Baltar 2004; Teri 2003; Teri 2005a; Teri 2005b) . For two studies (Burgio 2003; Gonyea 2006) additional data were unavailable and for a further three studies the authors did not respond to requests for additional information (Gormley 2001; Huang 2003; Proctor 1999).

Included studies

See: Characteristics of included studies and Table 2.

Eighteen RCTs, with a baseline total of 2558 care recipients were included in the review. All but one study from Taiwan were carried out in Europe (England and Spain), America and Australia. The majority, 13 studies with a total of 1713 care recipients, were carried out in family care settings (Burgio 2003; Farran 2004; Gitlin 2003; Gitlin 2010; Gonyea 2006; Gormley 2001; Huang 2003; Losada-Baltar 2004; Moniz-Cook 2008a; Teri 2000; Teri 2003; Teri 2005a; Zarit 1987). Only three studies with a total of 743 residents were located in care homes (Chenoweth 2009; Fossey 2006; Proctor 1999). Two further studies were found, one in an assisted living setting (Teri 2005b) and the other in a hospital setting (Mador 2004), with 31 and 71 participants, respectively. Data from the latter two were pooled with that of care homes since delivery of the intervention involved staff (rather than family) caregivers.

Characteristics of the interventions

Interventions in the majority of studies were multi-component programmes, where FA was just one part of the intervention. Fourteen interventions focused on enhancing knowledge and skills in family and staff caregivers through training support and supervision. Four trials (one residential, one hospital and two family care) utilised interventions which appeared to focus mostly on FA and are described as Behaviour Management. The time devoted to FA interventions in these trials were determined to some extent by the setting (see Table 2). For example, the hospital intervention had daily treatment for just nine days whilst the care home study lasted six months with weekly visits from a specialist therapist. One family care study consisted of just four sessions delivered over eight weeks (Gormley 2001).

Across the 18 trials included in the review there was considerable diversity on a number of parameters. Firstly, concepts underlying the development of the intervention were varied and included, for example, knowledge and/or training approaches, the stress-coping model, the Progressively Lowered Stress Threshold model and Problem-Solving approaches. Secondly, the time spent in delivering the intervention varied in length from nine days to 18 months. Similarly, variation in the degree of contact (i.e. intensity or 'dosage' of therapist contact) was wide ranging and in turn influenced pre-post test intervals. Reviewers measured this as minimal (1-2 sessions), moderate (3-5 sessions), medium (6-10 sessions) and high or intensive (>10 sessions). Thirdly, follow-up data varied from no follow-up/data unavailable/data not suitable for analysis (9 studies) to 24 month follow-up (Zarit 1987). Table 2 provides an overview of the interventions examined.

Excluded studies

One hundred and twenty-five studies from a total of 144 were excluded (see Characteristics of included studies and Characteristics of excluded studies).

FA was observed in a number of studies, which were not included in the review due to the following reasons:

a) Not an RCT: Four studies (Ballard 2009; Bird 2007; Cohen-Mansfield 2007; Davison 2007).

b) Case series: Five studies (Baker 2006; Buchanan 2002;Heard 1999; Moniz-Cook 2001; Moniz-Cook 2003).

c) RCT but focused on one episode of care such as bathing: Two studies (Hoeffer 2006; Sloane 2004).

d) No extractable data for primary outcome: Three studies (Hinchliffe 1995; Robinson 1994; Visser 2008). Reasons for exclusion: Dichotomous data for the primary outcome (Hinchliffe 1995); only secondary caregiver outcomes reported (Robinson 1994); only sub-scale scores reported for the primary outcome; author unable to provide total scores (Visser 2008).

Interventions for challenging behaviour that targeted specific behaviours, such as wandering (see for example Mayer 1991) were excluded as FA is based on the observation that a given function or 'unmet need' can manifest itself in a variety of differing behavioural repertoires. Seven trials of psychosocial interventions were excluded since descriptions of FA, according to our criteria, were absent from the text (Belle 2006;Burns 2003; Callahan 2006; Deudon 2009; Kovach 2006; Opie 2002; Tibaldi 2004). Other reasons for exclusion of studies were: review papers, no pre–post data available (e.g. Hoehn-Anderson 1992), pharmacological studies, other psychosocial therapies (e.g. reminiscence therapy, cognitive stimulation therapy, caregiver counselling, activity programmes, occupational therapy, emotion-orientated care) and other types of non-pharmacological therapies (e.g. bright light therapy, snoezelen, multisensory stimulation).

Risk of bias in included studies

Quality and risk of bias in included studies

See: Risk of bias summary (Figure 1) and Characteristics of included studies .

Overall the quality of combined studies included in this review was judged as low to moderate since it was compromised in a number of ways. First, there was bias towards publishing results using test instruments, or parts of instruments that demonstrated significant post-test gains (see Table 1), requiring additional information from authors (see Description of studies). This may explain why some researchers used two or more similar instruments to measure the same or a similar outcome (such as caregiver reaction) and were, thus, able to report significant effects on some but not all of these equivalent measures. Fifty-three different assessment tools were used to measure outcomes across the 18 studies (see Table 3: Overview of outcome measures). Of these, 35 were relevant to our stated outcomes (see Table 3) but in order to avoid aggregating data for wide-ranging clinical outcomes, only 15 instruments (see Table 1) were pooled for meta-analyses. Secondly, despite our precautions in extracting data from identical measures, data from outcomes for the same domain (such as care recipient behaviour) were pooled for similar but not identical instruments. Thirdly, publication bias, where studies reporting significant results are more likely to be published, may have led to the difficulty we encountered in extracting definitive information on the extent or 'dosage' of FA elements of an intervention to determine the cause of the improvement. Authors did not record the time devoted to component parts of multi-component interventions and although outcomes on behaviour and mood were taken for care recipients, not all studies had a primary aim of reducing challenging behaviour (for example, see Farran 2004 where the primary aim was to reduce emotional distress in caregivers). Fourthly, variation in concepts underlying the development of the intervention, which were not always indicated, may have resulted in reporting bias on primary and secondary outcomes. Finally, sample sizes varied across the studies. At baseline, three trials (Huang 2003; Losada-Baltar 2004; Teri 2005b) had < 50 participants; four trials had < 100 participants (Gonyea 2006; Gormley 2001; Mador 2004; Teri 2005a). Seven trials had between 100-200 hundred participants at baseline (Burgio 2003; Gitlin 2003; Moniz-Cook 2008a; Teri 2000; Teri 2003; Proctor 1999; Zarit 1987). The remaining four trials had > 200 participants at baseline (Chenoweth 2009; Farran 2004; Fossey 2006; Gitlin 2010).

This variation became important when four studies of FA-focused interventions were analysed since it was not possible to determine whether lack of positive effects were due to insufficient intervention 'dosage' (see Table 2 for example Gormley 2001) or reduced power, or both.

Selection bias was judged as low risk for randomisation, although in six studies the procedure used was not stated and some studies did

not report detail for concealment. Bias in performance was judged as low risk but this is often hard to evaluate in non-pharmacological studies, since staff can have different expectations of treatment groups and control conditions varied. Six of the included studies had an attention control condition where minimal support, advice, education or placebo drug was provided. Eleven trials reported a 'usual care' condition and one used a wait list control. The content of 'usual care' was unclear. Blinding of care-recipients and caregivers was seldom reported so it was not possible to judge whether patients in some studies were aware that they might be receiving preferential support. Authors reported the methods used to achieve and maintain blinding of interventionists and some reported where blinding had failed. Blinding of outcome assessors was not always clear and one study reported that the interventionists had a dual function as outcome assessors. Most reports outlined protocols and procedures for treatment fidelity and adherence (see Table 2) but this did not mean that variation across therapists did not occur in all studies. Only one study was judged as high risk as the authors documented 'poor adherence' to the protocol. Attrition reporting was achieved in the majority of trials, although reasons for dropout were often unclear, often described as 'lost to follow-up' or 'missed'. One study reported withdrawal due to adverse effects in a pharmacological comparison treatment condition.

Effects of interventions

All comparisons for analyses compared functional analysis based intervention with control group (usual care). See Data and analyses.

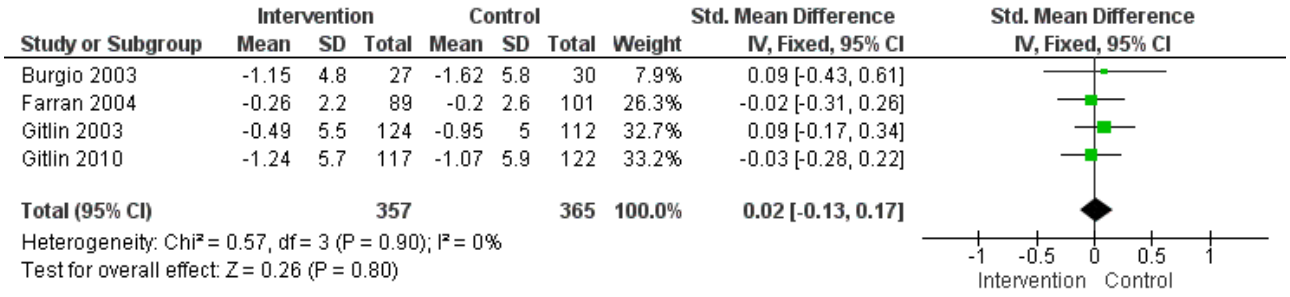
Primary outcomes

The primary outcomes were measurement of the reported incidence, frequency and severity of problematic behaviours. Patient depression was also included in this category.

Effects on behaviour

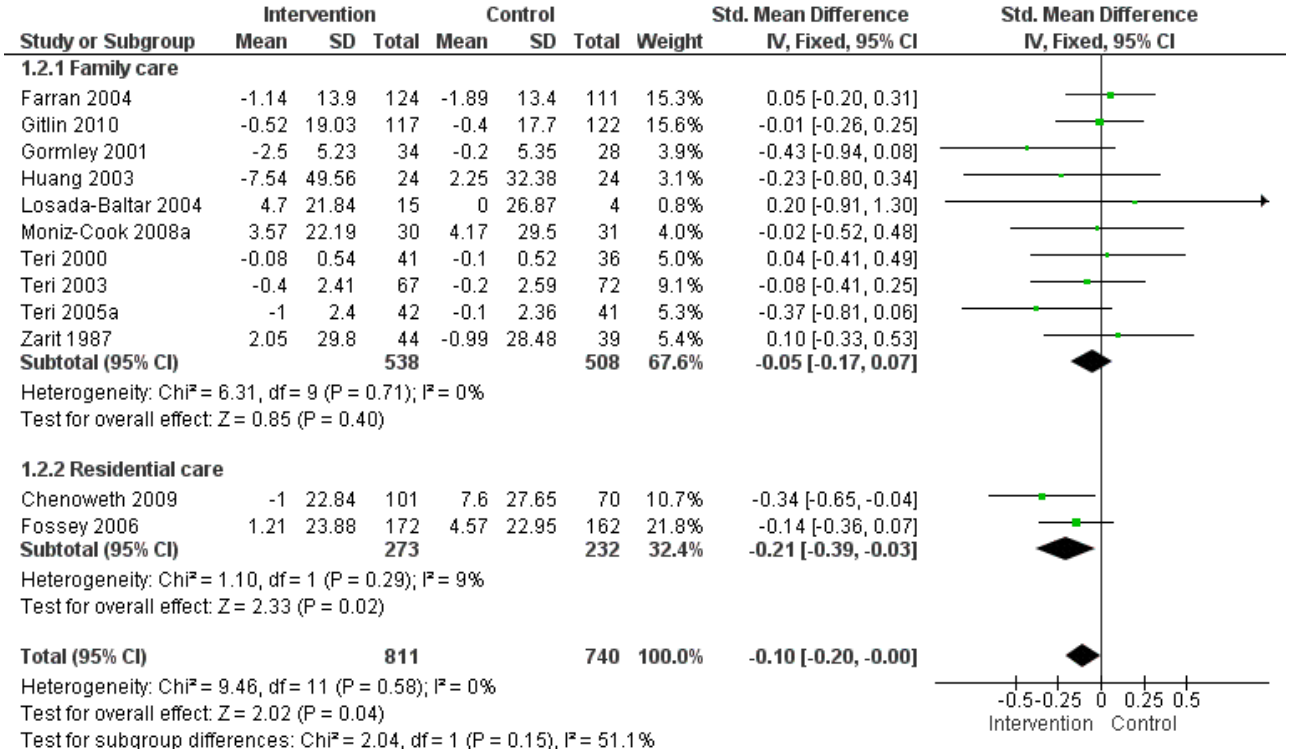
There were no significant reductions in the incidence of challenging behaviours as reported by four family care studies at post-intervention (SMD 0.02, 95% CI -0.13 to 0.17, P = 0.80, N = 722; Figure 2). Post-test intervals ranged from three months to six months. At six months follow-up, no significant effect was seen for two studies (Farran 2004; Gitlin 2010) (SMD 0.08, 95%CI -0.11 to 0.27, P = 0.41, N = 436).

Figure 2. Forest plot of comparison: 1 Functional analysis versus usual care - primary outcomes at post-intervention, outcome: 1.1 Incidence of problem behaviours - family care only. [Instruments used: RMPBC]



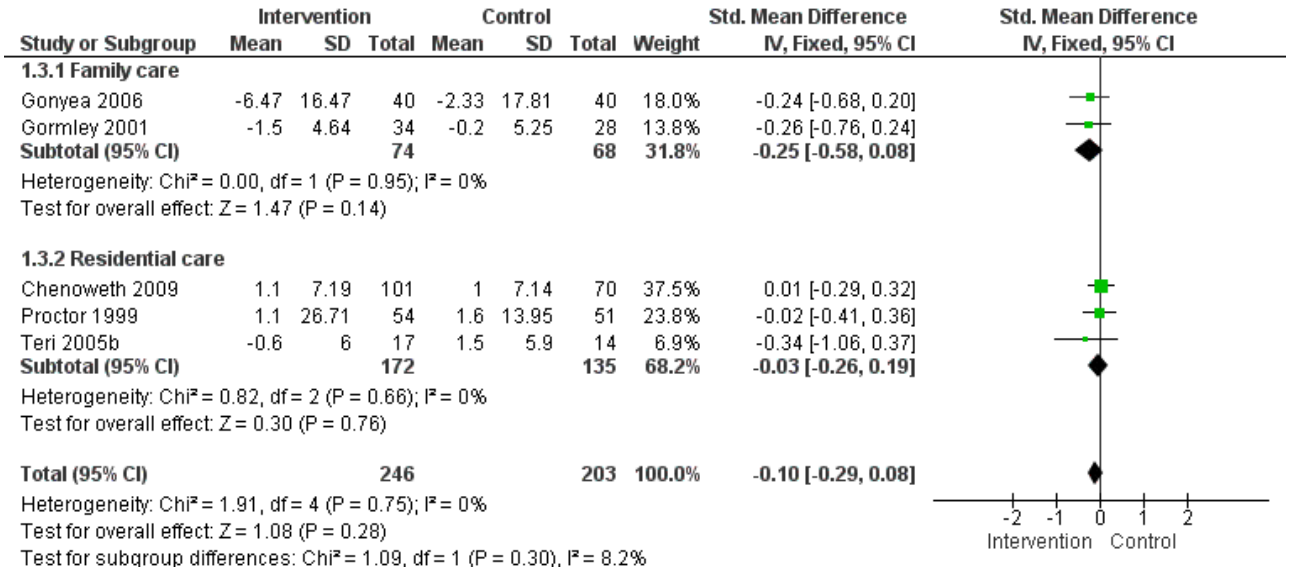
There was a significant reduction in the frequency of challenging behaviours at post-intervention for 10 family care studies (N = 1046), two residential studies (N = 505) and one assisted living study (N = 31), (SMD -0.12, 95% CI -0.22 to -0.02, P = 0.02, N = 1582). Sensitivity analysis due to moderate heterogeneity (I^2 = 37%), resulted in removal of the assisted living study (Teri 2005b) and no heterogeneity (I^2 = 0%) (SMD -0.10, 95% CI -0.20 to -0.00, P = 0.04, N = 1551), see Figure 3. Post-test intervals ranged from 3 weeks to 12 months. At six months follow-up, there was no effect in four family care studies (Farran 2004; Gitlin 2010; Teri 2003; Teri 2005a) (SMD 0.00, 95% CI -0.16 to 0.16, P = 0.99, N = 627). Similarly, no effect was found at 12 months for three family care studies (Farran 2004; Moniz-Cook 2008a; Teri 2000) (SMD 0.02, 95% CI -0.22 to 0.27, P = 0.86, N = 266).

Figure 3. Forest plot of comparison: 1 Functional analysis versus usual care - primary outcomes at post-intervention, outcome: 1.2 Frequency of problem behaviours. [Instruments used: PC, RAGE, RMBPC, CMAI and MBCL]



Although the results of the meta-analysis for severity of challenging behaviour were in a direction that favoured the intervention, no significant effect at post-intervention was found Figure 4. The analysis included two family care studies, two residential care studies, one assisted living study and one hospital care study, respectively (SMD 0.02, 95% CI -0.15 to 0.20, P = 0.79, N = 520). Given high heterogeneity (I^2 = 68%), sensitivity analysis resulted in the removal of the hospital study (Mador 2004, N = 71) and 0% heterogeneity (SMD -0.10, 95% CI -0.29 to 0.08, P = 0.28, N = 449). No follow-up data were available for analysis.

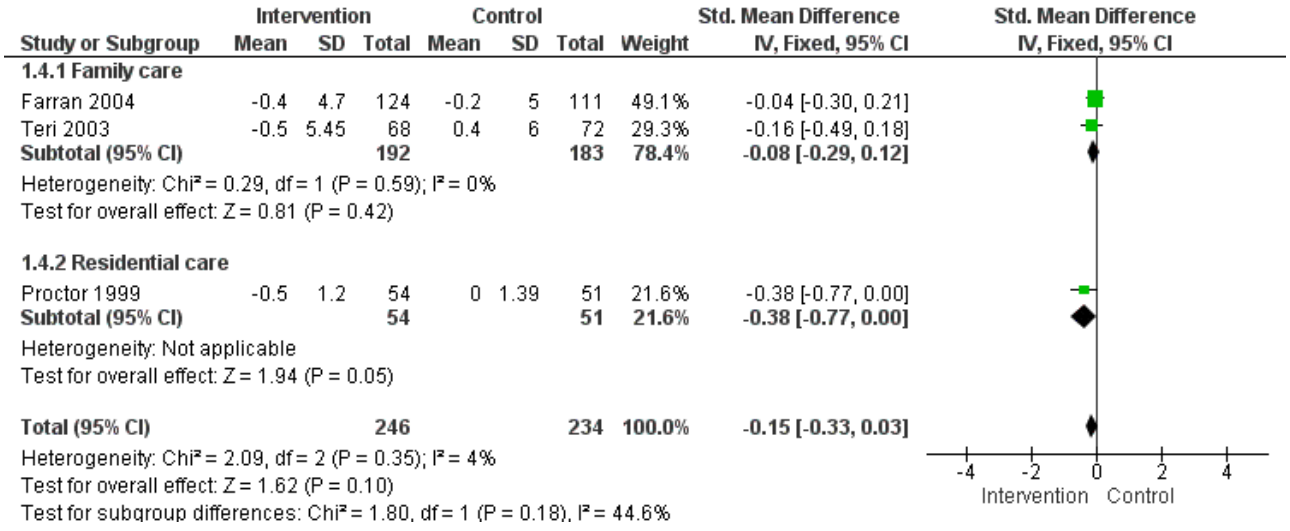
Figure 4. Forest plot of comparison: 1 Functional analysis versus usual care - primary outcomes at post-intervention, outcome: 1.3 Severity of problem behaviours. [Instruments used: PAS, NPI, Behave-AD and Crichton Royal Behavioural Scale].



Effects on patient depression

A significant positive effect was found at post-intervention on patient depression for four studies. This effect was dominated by the assisted living study for which a moderate heterogeneity occurred: I^2 = 44%, (SMD -0.19, 95% CI -0.36 to -0.01, P = 0.04). Removal of the assisted living study (Teri 2005b) from the analysis resulted in a reduction of the heterogeneity to 4%. There was no significant effect for the remaining studies - two family care studies and one care home study (SMD -0.15, 95%CI -0.33 to 0.03, P = 0.10, N = 480: Figure 5).

Figure 5. Forest plot of comparison: 1 Functional analysis versus usual care - primary outcomes at post-intervention, outcome: 1.4 Patient depression. [Instruments used: RMPBC Depression sub scale, AGECAT and CDDS]



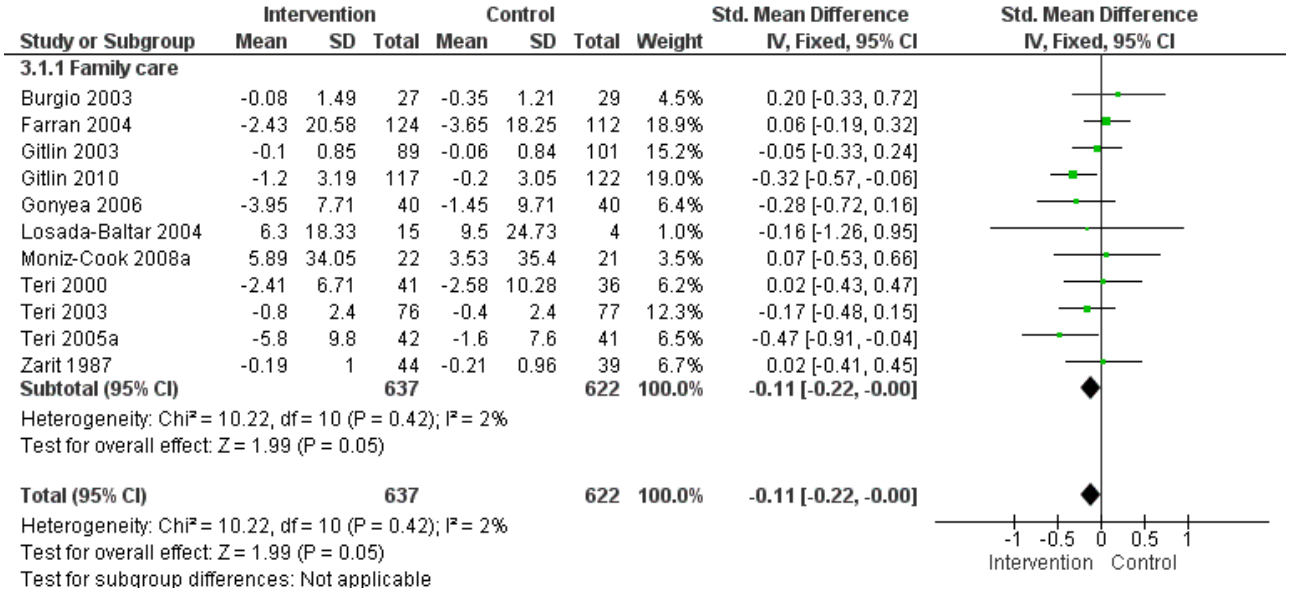
Secondary outcomes

Self reported changes in staff or family carer management, such as reaction and burden, were included in the analysis. Data from measures of caregiver mood were also analysed. Data for aggregation of staff caregiver experience were not available.

Effects on caregiver reaction and burden

A significant positive effect on caregiver reaction to challenging behaviour for 10 family care studies and one assisted living study at post-intervention was found (SMD -0.13, 95% CI -0.24 to -0.02, P = 0.02, N = 1284). Sensitivity analysis due to mild heterogeneity (21%), suggested removal of the assisted living study (Teri 2005b), which reduced the heterogeneity to 2% (SMD -0.11, 95% CI -0.22 to -0.00, P = 0.05, N = 1259: Figure 6). Post–test intervals ranged from two to six months. At six months follow-up, four family care studies (Farran 2004; Gitlin 2010; Teri 2003; Teri 2005a) had available data, and analysis of the effect of the intervention was not maintained (SMD -0.11, 95% CI -0.27 to 0.04, P = 0.15, N = 653). Although the results for caregiver burden were in a direction that favoured the intervention, no significant reductions were found at post-intervention for six studies (Gitlin 2010; Gonyea 2006; Gormley 2001; Teri 2000; Teri 2005a; Zarit 1987) (SMD -0.13, 95% CI -0.29 to 0.03, P = 0.10, N = 624 or at six months follow-up for two studies (Gitlin 2010; Teri 2005a) (SMD -0.14, 95% CI -0.38 to 0.09, P = 0.23, N = 286).

Figure 6. Forest plot of comparison: 3 Functional analysis versus usual care - secondary outcomes at post-intervention, outcome: 3.1 Caregiver reaction. [Instruments used: PC, RMBPC -reaction, NPI -distress and ABID -reaction].



Effects on caregiver depression

Although the results were in a direction that favoured the intervention, no significant reduction of caregiver depression was found at post-intervention for five family care studies (Burgio 2003; Farran 2004; Losada-Baltar 2004; Moniz-Cook 2008a; Teri 2005a) (SMD -0.12, 95% CI -0.30 to 0.06, P = 0.21, N = 473). Post-test intervals ranged from two to six months. At six months follow-up no significant effect was seen for two studies (Farran 2004; Teri 2005a) (MD -0.93, 95% CI -2.56 to 0.70, P = 0.26, N = 290).

Behaviour management trials: effects on behaviour and caregiver burden

Three separate analyses were conducted for four trials (Gormley 2001; Mador 2004; Proctor 1999; Teri 2000) where behaviour management appeared to be the primary focus of the intervention (see Data and analyses).

Firstly, we analysed the primary outcome 'frequency of challenging behaviours' where two trials (Gormley 2001; Teri 2000) had data that could be pooled at post-test, but no significant effect was found (SMD -0.17, 95% CI -0.50 to 0.17, P = 0.33, N = 139) and moderate heterogeneity (I^2 = 46%) was noted. Secondly, we examined the severity of challenging behaviours at post-test where data from two trials of hospital care and a care home setting were available (Mador 2004; Proctor 1999). A significant effect was found (SMD 0.33, 95% CI 0.02 to 0.63, P = 0.03, N = 176), but this was not in the direction of the intervention, and a high heterogeneity was noted (I^2 = 88%). Thirdly, we examined caregiver burden at post-test for two family care studies (Gormley 2001; Teri 2000). As was the case for the previous meta-analysis using six studies on this variable, the findings were in a direction that favoured the intervention, but no significant effect was found (SMD -0.13, 95% CI -0.46 to 0.21, P = 0.45, N = 139).

DISCUSSION

The aim of this review was to evaluate the evidence for the efficacy of functional analysis-based interventions for challenging behaviour in dementia. Eighteen trials, where functional analysis was usually referred to as 'behaviour management', were included in the review. The majority, 13 studies, were in family care settings. Surprisingly, there were only three care home studies and a further two smaller studies in an assisted living and a hospital setting, respectively. For 14 studies, FA was just one aspect of a broad multi-component programme of care; thus, only four focused on FA as the main intervention, two in family settings, one in a care home and one in hospital. Data for all studies incorporating FA showed beneficial effects on both the reported frequency of challenging behaviours (Figure 3) and caregiver reaction to these (Figure 6) at post-intervention. No significant effects were found at any follow-up periods. Analyses using four studies where behaviour management appeared to be the main focus of the intervention did not show significant effects in favour of FA (see Data and analyses) although as we outline later, reasons for this are likely to be associated with the quality of the studies that we were able to include in the meta-analysis.

The strength of the conclusions that can be drawn from these results at this stage is limited by a number of important caveats.

First, as noted by other reviews of BPSD (Black 2004) and family caregiver support (Parker 2008), FA interventions tended to be conceived within a range of theoretical models. These in turn influenced the time and number of sessions devoted to treatment, the overall duration of the intervention, the way it was delivered and the instruments used to measure outcomes. The caregiver stress-coping model was used in the earliest study (Zarit 1987) and remained the commonest approach in subsequent family care studies, although other constructs such as the progressively lowered stress threshold - PSLT approach (for example Huang 2003) were also described. Most family caregiver studies used

what appear to be experienced professionals or highly educated therapists, such as those with Masters level qualifications, to deliver the intervention, although the level of training and experience was not always clear. This hampered the conclusions that can be made about critical process variables, such as therapeutic qualities that may have influenced the reported outcomes. This is a well documented difficulty of studies of this type (see for example Bourgeois 1996 for a review). Insufficient 'dosage' in behaviour management interventions (for example Gormley 2001), or detail of FA within multi-component interventions, limit our conclusions on the effects of FA as an intervention in its own right.

Few RCTs in care home settings were located. The absence of studies arising from the USA, where psychosocial intervention in long term care has a worthy history, was surprising. This may have been a consequence of our definition of functional analysis (and associated criteria for trial selection), which arose from the growing knowledge base over the past decade (see Bird 2008; Cohen-Mansfield 2007; James 2011; Stokes 2000) . We were over-inclusive in our perusal of studies that offered any aspect of behaviour management and then scrutinized the reasons for excluding studies. These were associated with both methodology as well the underlying theory and the focus of the intervention, which varied across studies. For example, a key family care study was excluded, since our inclusion criterion of utilising behavioural outcomes was not met (Burns 2003). This might have been because the intervention was conceived to address caregiver distress about the care recipient's behaviour, rather than to reduce distress and associated challenging behaviours in the care recipient *per se*. The study described an educational intervention of behaviour management compared with behaviour management alone and demonstrated that the combined condition had better outcomes on some caregiver variables. In contrast, a landmark care home intervention (Cohen-Mansfield 2007) was conceived to address 'unmet need' in distressed residents, with appropriate measurement of behavioural outcome, but had to be excluded because the researchers were unable to achieve full randomisation.

It was hard to establish the underlying conceptual basis for two of the included care home studies (Chenoweth 2009; Fossey 2006), which contributed to the positive findings of a reduction in the frequency of challenging behaviour. Person-Centred Care and Dementia Care Mapping originate from theories of person-centred care in dementia (Kitwood 1997) and were underlying constructs used to develop these respective interventions (Chenoweth 2009; Fossey 2006). The latter (Chenoweth 2009) also drew heavily on the theory of behaviour as a function of 'unmet need' (Cohen-Mansfield 2007), a notion that is also understood within functional-analysis models of behaviour (Bird 2008; James 2011; Moniz-Cook 2001; Stokes 2000 and). Similarly, one of the earliest studies of behaviour management in care homes (Proctor 1999) appeared to incorporate aspects of person-centred care. The intervention involved staff training about therapeutic activities and goal planning based on the resident's strengths and abilities; the text documented a case example where social interaction was identified as an unmet need and non-contingent social contact combined with offering toileting care resolved the resident's repeated requests for the toilet. Notably, the researchers found that their 'behaviour management' intervention improved depression but not challenging behaviours in care recipients. Future analyses of more studies (particularly in care home settings) that have conceptually defined components of interventions – for example, those that address aggression and agitation as well as those that address depression - will provide better evidence for functional analysis in the management of both behavioural as well as mood problems in care recipients.

Secondly, across the studies reviewed, primary and secondary outcomes were often not clearly defined or matched to the main focus of the intervention and there was conceptual confusion on the choice of instruments selected to measure particular outcomes. For example, the RMBPC 'caregiver reaction' domain was described by study authors in a variety of ways as a measure of appraisal, bother, upset, subjective burden and reaction. In some studies more than one assessment was used to measure a given outcome, such as patient behaviour or mood. When conducting meta-analyses we decided to use measures that were identical where possible but there were 20 instruments of potential relevance that were not used in analyses, many of which were associated with caregiver experience. Our analysis of data of six studies found no positive effects of FA on family caregiver burden. This is consistent with other reviews suggesting this construct may be a good outcome predictor for interventions addressing caregiver support but not for multi-component interventions that include behaviour management (Parker 2008). The construct of family caregiver burden may in itself be outdated as some reviewers have noted that it is poorly defined and insensitive to change (see Parker 2008) whilst others suggest that a refined and more clinically relevant conceptualisation is required (Black 2004). This review adds weight to the recommendations of similar reviews (Black 2004; Parker 2008), which have highlighted inconsistencies of instruments to evaluate outcome and inadequacy of these in the measurement of constructs within the intervention, suggesting that these are priorities for future research. Thus, we conclude that the literature on FA in dementia care, unlike other areas, such as pharmacological studies or cognitive stimulation therapy, is underdeveloped, since the knowledge base has only relatively recently emerged in terms of both concepts (Bird 2008; James 2011; Stokes 2000) and associated measurement (Moniz-Cook 2008b).

Thirdly, the development of FA interventions was often determined by setting, i.e. family care, assisted living, care home and hospital. This dissimilarity of setting is important as an explanation of the heterogeneity noted in the assisted living and hospital-based trials. In these studies, clinical heterogeneity such as the characteristics of people, the treatments offered and the outcomes measured (which rendered pooling of data in meta-analysis as inappropriate) may all have been due to the context within which the intervention was delivered. For example, in the short nine day hospital-based intervention of Mador 2004, 48% of the patients had delirium, which in a relatively small study of just 71 participants compromises the conclusions that could be reached about reported findings. Also, hospital admission criteria appeared to have influenced the findings through the route of floor effects, since the authors indicate that patients in the study were possibly not agitated enough at baseline to show significant improvement.
A further difficulty in comparing FA as an intervention across care settings relates to caregiver factors since not only do professional and family carers experience strain or challenges in different ways to each other, but overall the experience of challenging behaviour is thought to be reflective of caregiver appraisal and the interpersonal context, i.e. 'in the eye of the beholder' (Bird 2008).

Another limitation was that comparison conditions differed. Some studies used an active treatment 'attention control'

condition, which may have masked the comparative effects of the intervention. Details of what the usual care condition might involve were often absent and became important in interpretation of the meta-analysis of the four studies where behaviour management was the main focus of the intervention. For example, in the behaviour management study of Teri 2000, data from a drug placebo condition was used for comparison. In the hospital study (Mador 2004) it was not clear whether 'usual' pharmacological treatment, 'usual' nursing care or the experimental 'enhanced care intervention' influenced the reported outcome of the study. Other aspects of quality might also have contributed to the results of the four focused behaviour management studies (for example, allocation and performance bias in Gormley 2001). Our review concurs with others suggesting that the literature on behaviour management as an effective intervention is emerging but requires well designed and conducted RCTs (Livingston 2005). Studies should also address the need for adequate sample sizes, well defined interventions and control groups and adequate follow-up periods (Parker 2008).

Finally, despite suggestions that psychosocial interventions may have a suppressant effect on challenging behaviours, which becomes evident over a long period in the trajectory of dementia care (Moniz-Cook 2008b), judgment of the sustainability of FA remains in the balance. Conclusions are hampered by the variation in the length of interventions and the variation in time intervals to post- and follow-up measurements.

Despite the limitations noted above, a promising finding of this review is that where FA is a component of the intervention, positive post-intervention effects can be seen on the frequency of challenging behaviours in both family care and care home settings and on caregiver reaction. Studies that give due attention to the methodological constraints we document, including using standard primary and secondary outcomes (Moniz-Cook 2008b), that are matched to the main focus of the intervention could in the future clarify the true effectiveness of functional analysis as an intervention for challenging behaviour in dementia care. Implementation studies of successful randomised controlled trials will need to address the translational potential of the evidence for FA given the noted expertise and qualities of trainers or therapists who deliver interventions in research studies.

Adverse effects for haloperidol were reported in a dropout analysis carried out by the authors of the four arm agitation trial of Teri 2000, but our meta-analysis did not include data from this condition. There were no indications from the outcome measures of the eighteen studies included in the current analysis of any harm or distress to participants with dementia.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence of functional analysis-based interventions in the management and resolution of challenging behaviour in dementia is promising but it is too early to draw robust conclusions about its efficacy.

The evidence base for the effectiveness of functional analysis-based interventions continues to rest on randomised controlled trials that incorporate multiple components, leaving the dosage and intensity of functional analysis within the intervention variable and unclear. It is too early to provide indication of the true effectiveness of functional analysis-based intervention in comparison to other psychosocial interventions for the management and resolution of challenging behaviour in dementia. However, as a component part of psychosocial intervention programmes, including those that focus on training and supporting caregivers, it remains a promising intervention. The finding that positive effects were seen post-intervention on not only frequency of challenging behaviour but also caregiver reaction to it has clinical relevance, as this is an important predictor of nursing home placement (de Vugt 2005). Other reviewers have also noted that behaviour management can have lasting effects for both care recipients (Livingston 2005) and family caregivers (Selwood 2007).

Implications for research

There is a clear need for more RCTs of functional analysis-based interventions in family care and care homes settings. We suggest that the current knowledge base that we have outlined in this review, including the development for manuals of FA for behaviours that challenge (James 2011) has potential for developing interventions that are conceptually and theoretically sound. RCTs of functional analysis will require clear treatment protocols that separate caregiver training and support from care plan delivery to the patient, with research designs to measure the relative effects of these on behaviour outcomes. Studies need to also pay attention to clear definitions of: control groups; standardised instruments (see Moniz-Cook 2008b) to measure outcomes on patient behaviour as well as caregiver experience, and time intervals to post-intervention and follow-up. To assist synthesis of future meta-analysis in this area, we suggest that there is now scope for RCTs to develop mature methodologies that attend to the common sources of bias that have compromised the quality of studies that have evaluated FA to date.

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CHARACTERISTICS OF STUDIES

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

Burgio 2003

Methods	Random assignment to intervention or control condition. The intervention was delivered through a group workshop followed by 16 in-home treatment sessions over 12 months. The paper reports only 6 months follow-up.
Participants	70 white and 48 African American primary caregivers (PCG) of individuals with dementia. Care recipients (CR) were required to score < 24 on MMSE, exhibit one limitation in ADLs or IADLs and display 3 problem behaviours as identified by the PCG. CR mean MMSE score was 14.53 for white participants and 10.98 for African American participants, with a mean age of 78.83.
Interventions	Caregiver Skill Training Intervention based on a manual Minimal Support Condition (control) Primary aim of intervention: CR problem behaviour, CG appraisal, social support, activity, well-being (e.g. depression & anxiety) and desire to institutionalise CR. (See Table 2)
Outcomes	Revised Memory and Behaviour Problem Checklist (RMBPC) RMBPC Appraisal Leisure Time Satisfaction Measure The Center for Epidemiologic studies-Depression Scale (CES-D) State-Trait Personality Inventory Desire to Institutionalise (see Table 3)
Notes	Country of origin: America

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Blinding of participants and personnel (performance bias) All outcomes	Low risk	

Burgio 2003 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	High risk	'Staff were not blinded to group assignment; however. intervention and assessment were never conducted by same individual'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Chenoweth 2009

Methods	Cluster randomised controlled trial. Study duration 8 months.
Participants	289 residents from 15 residential homes, of similar management structure, standards and size. Residents had to show need-driven behaviours, which made it difficult for staff to provide them with quality care. Residents mean age was 85 years.
Interventions	Caregiver training and support intervention in either: Person Centered Care (PCC) or Dementia Care Mapping (DCM) Control (Usual Care) Primary aim of the intervention: To decrease need driven dementia compromised behaviours, improve resident quality of life and reduce the use of psychotropic drugs, restraints, rates of accidents and injuries. (See Table 2)
Outcomes	Cohen Mansfield Agitation Inventory (CMAI) Neuropsychiatric Inventory (NPI) Quality of life in late stage dementia (QUALID) Quality interactions schedule (QUIS) (See Table 3)
Notes	Country of origin: Sydney, Australia For the purpose of this review the DCM condition was compared with usual care. Interventionist visited sites for 6 hours per day over 2 days.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomised at site level, using an SAS system'.
Allocation concealment (selection bias)	Low risk	Allocation performed by study statistician unaware of sites' identities, using a balanced incomplete-block design, remaining sites used a complete block design.

Chenoweth 2009 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Used a protocol and manual. There is no report of checking treatment fidelity or adherence to the manual. Membership to the intervention or control group was masked to outcome assessors; however, it is not reported if participants and other staff members were blind to allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Research assistants were trained in measurement and remained masked to group intervention by means of a signed agreement with staff and managers not to mention the intervention information'
Incomplete outcome data (attrition bias) All outcomes	Low risk	26 died and 4 transferred after randomisation. A further 21 died and 2 transferred after the intervention.
Selective reporting (reporting bias)	Low risk	Only reported total NPI score, not sub scale scores for frequency and severity.
Other bias	Unclear risk	Not other sources of bias identified.

Farran 2004

Methods	Randomised clinical trial. Study duration 18 months.
Participants	295 care recipients (CR) with Alzheimer's disease (AD) or other dementia syndrome, with MMSE < 24, and their family caregiver (CG), who provided a minimum of 6 months care, with four hours direct contact per day. CR mean MMSE score was 12.6, CR mean age was not reported. CGs had a mean age of 64.4, 225 were female and 70 male.
Interventions	Caregiver skill (CSB) Intervention Information and Support Orientated Group Intervention (ISO) (Comparison Condition) Primary aim of intervention: Reducing emotional distress in CG & improving CG management of behaviour problems. (See Table 2)
Outcomes	The Center for Epidemiologic studies-Depression Scale (CES-D) for CG Behaviour Management Skill Revised (BMS-R) The Revised Memory and Problem Behaviour Checklist (RMPBC) Time to Institutionalisation (see Table 3)
Notes	Country of Origin: Chicago, USA 12 weekly sessions, 5 group sessions, 7 individualised telephone contact sessions, 2 group booster sessions (6 and 12 months after enrolment) and as needed telephone contact during 12 month period.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Participants were randomly assigned to treatment condition'

Farran 2004 *(Continued)*

Allocation concealment (selection bias)	Low risk	Statistician generated randomised sequence of binary codes (1 or 2) for each block of 10 to 20 participants. Sequence position determined by an alphabetically ordered list of participant names within each block. Coin toss to determine group 1 or 2 as intervention or control.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participant assignment list and identification number exclusive to project director. Trained interviewers blind to assignment. Treatment protocol for intervention. To assure fidelity, each staff member received 40 hours training and followed a detailed manual of prescribed material for each session. Supervised implementation, corrective feedback and group sessions taped and reviewed. Intervention staff remained blind to baseline and follow-up assessment data.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessments conducted over the telephone. Assessment of key outcomes by reviewers blind to treatment condition.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition reported (23 participants terminated early, reasons included: transportation/schedule difficulties (30%), health status (22%), nursing home placement or death (13%) and other reasons/not interested (26%)).
Selective reporting (reporting bias)	Low risk	Only coefficients reported, however, full data set supplied by author.
Other bias	Low risk	No crossover or carryover effects reported.

Fossey 2006

Methods	Cluster randomised controlled trial with blinded assessment of outcome. Study duration: 12 months.
Participants	346 residents from 12 residential homes. The mean age of residents was 82 years. The majority of residents had a clinical dementia rating of severe.
Interventions	Training and Support Intervention for nursing home staff. Control (treatment as usual) Primary aim of intervention: To reduce the proportion of residents with dementia who are prescribe neuroleptics. CG training in behavioural management techniques and person centred care, positive care planning, awareness of environmental design, ABC models, development of individualised interventions, active listening and communication and reminiscence techniques. (See Table 2)
Outcomes	Cohen Mansfield Agitation Inventory (CMAI) Daily drug dosage of residents (See Table 3)
Notes	Country of origin: London, Newcastle and Oxford, UK. The intervention was delivered over two days a week for 10 months by a psychologist, occupational therapist or nurse.
Risk of bias	

Fossey 2006 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomly assigned'
Allocation concealment (selection bias)	Low risk	'Statistician randomly assigned homes to intervention or control, stratified by region and baseline neuroleptic use. Allocations were computer generated using stratified block randomisation (fixed block size of two) with strata version 8'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Statistician blinded to identification of homes. Follow-up assessments completed by blinded research assistants. Intervention described as 'the package', however, it is not reported whether there was a manual or assessments of adherence.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Follow-up assessments completed by a research assistant who was not employed during the intervention period. However, the paper reports that 'because the package was designed to influence the whole care approach of staff, it is likely that the research assistant would have been able to detect which homes had received the intervention'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All reported, some reasons reported as unknown (105 participants died, 4 moved home, 14 unknown reason).
Selective reporting (reporting bias)	Low risk	All data reported.
Other bias	Low risk	No other risks identified.

Gitlin 2003

Methods	Randomised controlled trial. Study duration: 12 months.
Participants	The participants were 255 persons with Alzheimer's disease or related disorder and their family caregiver, of which 190 were available at follow-up. CR were to have a MMSE of < 24. Care recipients had a mean age of 80.85, with an average MMSE score of 12.05. CGs had to be at least 21 years of age, providing care for 4 hours per day for 6 months. CGs were predominantly African American with a mean age of 60.45.
Interventions	Home Environmental Skill-Building program (ESP) for family CG Control (usual care) Primary aim of intervention: CG well-being (e.g. Mastery, skill enhancement), Burden & Distress & CR functioning (behaviour & ADL/IADL) delivered by interventionists who received 25 hours of training (See Table 2)
Outcomes	Revised Memory and Behaviour Problem Checklist (RMBPC) Caregiver Burden (RMBPC) Caregiving Mastery Index Task Management Strategy Index

Gitlin 2003 *(Continued)*

	(See Table 3)
Notes	Country of origin: Philadelphia, USA 5 in home contacts, one telephone contact, Active treatment phase for the first 6 months, maintenance phase for the subsequent 6 months which consisted of 1 home contact and 3 brief telephone sessions. 12 month follow-up data are reported in Gitlin 2005 but data reported for CR behaviour for the primary outcome measure not equivalent to the data reported in Gitlin 2003.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias) All outcomes	Low risk	
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Low risk	

Gitlin 2010

Methods	Randomised trial with comparison group. Study duration: 6 months.
Participants	272 caregivers (CG) and people with dementia (CR) with a mean age: 82.1 years, of which 220 were available at follow-up. CR MMSE score of < 24. Caregivers had to be at least 21 years of age, English speaking and planning to live in the area for 6 months, not actively seeking a nursing home placement, managing problem behaviours and reporting upset.
Interventions	Caregiver skills training in managing problem behaviours - the Advanced Caregiver Training (ACT) No treatment control group Primary aim of intervention: CG confidence in managing problem behaviours and associated upset. CG, well-being (e.g. skill enhancement, management skills, communication, perceived change and perceived benefits), burden and mood. (See Table 2)
Outcomes	Incidence and frequency of problem behaviours, measured by: Agitated Behaviours in Dementia Scale -16 items, Revised Memory and Behaviour Problem Checklist (RMBPC) - 3 items, and other behaviours - families could specify other behaviours which were not listed. Caregiver upset was measured by averaging caregiver responses over all occurring behaviours, with higher scores indicating greater upset. Caregiver depression measured by CES-D Caregiver burden measured by Zarit Burden Interview (ZBI)

Gitlin 2010 *(Continued)*

	Caregiver change (managing care challenges, affect and somatic) - Perceived Change Index (PCI) Task Managment Strategy Index Communication Index Perceived Benefits (See Table 3)
Notes	Country of origin: Philadelphia, USA Occupational therapists and nurse delivered intervention.16 week active phase of 9 occupational therapy sessions and two nursing sessions (one home, one telephone) and a maintenance phase (16-24 weeks) of three brief OT telephone contacts to reinforce strategy use. Help caregivers identify antecedents and consequences or potential modifiable triggers of the target problem behaviour.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Two group randomised trial.
Allocation concealment (selection bias)	Low risk	Stratified according to relationship (spouse vs non spouse) and randomised within each of two strata using permuted blocks. Study statistician developed a blocking number which was unknown to others. Randomisation lists and two sets of randomisation forms were prepared using opaque envelopes. The Project director randomised each participant within 48 hours of baseline interview. Project director performed randomisation.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	10 licensed OTs and 1 nurse had 35 hours training. Treatment fidelity monitored and maintained through twice monthly meetings involving case presentations. Audiotaped 10% of home sessions for review and feedback. Documentation of contacts was kept in order to review delivery adherence. Interviewers were masked to treatment assignment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers masked to participants assignment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete outcome data addressed but specific reasons for dropout not noted, only reported as % lost to follow-up or missed.
Selective reporting (reporting bias)	Low risk	All data reported.
Other bias	Low risk	None reported or determined.

Gonyea 2006

Methods	Randomised controlled trial. Study duration: 6 weeks.
Participants	80 caregivers (CG) with a mean age of 64.4 years, providing a weekly minimum of 4 hours care to 80 care recipients (CR) with a confirmed diagnosis of Alzheimer's disease (mean age: 77) in the mild to moder-

Gonyea 2006 *(Continued)*

	ate severity range, with at least one neuropsychiatric symptom. Caregivers were mostly spouses, female and Caucasian.
Interventions	Caregiver group based training intervention (Project CARE) Psychoeducational control group using similar structure to the intervention group. Primary aim: CG distress associated with CR behaviour, CG burden and CR behaviour problems. (See Table 2)
Outcomes	Neuropsychiatric inventory (NPI) - Severity & Distress Zarit Burden Interview (ZBI) (See Table 3)
Notes	Country of origin: Boston, USA. Caregiver based multi-component behavioural group intervention, delivered over 5-weekly 90 minute sessions with 15 minutes individual time. The intervention was delivered in a group format (5 -10 members). The intervention was based on the principles of behaviour therapy and activation and designed to teach behavioural techniques for managing care recipients neuropsychiatric symptoms in the home environment. Caregivers were taught ABC behavioural analysis. The control group had a similar structure to the intervention, but consisted of only general information on aging and Alzheimer's disease, home safety, support and techniques for improved communication. The total study duration was 6 weeks.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'We then assigned participants by block randomisation'
Allocation concealment (selection bias)	Low risk	'We assigned participants by block randomisation to one of the two conditions'. Unclear as to who performed the randomisation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Therapists had 16-20 hours training in intervention protocols. To monitor treatment fidelity, PI consulted with therapists on a regular basis to review group sessions and assess group progress. Not all caregivers adhered to the intervention (did not submit homework).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Reported in the discussion 'It was also not possible to blind all interviewers to the caregivers treatment condition at the post-intervention assessment'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Specific reasons for withdrawal not reported; however, the number withdrawn is recorded. (11 caregivers did not complete)
Selective reporting (reporting bias)	Unclear risk	NPI frequency not reported, only severity.
Other bias	Unclear risk	Generalisabilty to the general population difficult due to low numbers of ethnically and racially diverse individuals.

Gormley 2001

Methods	Randomised controlled trial. Study duration 10 weeks.
Participants	62 care recipients (CR) with a diagnosis of dementia and their co-resident carer. Care recipients with dementia were required to be rated by their carer as mildly aggressive. Care recipient mean age was 75.95 years, with an average MMSE score of 13.3. Caregivers (CG) mean age was 68.45 and were predominantly female.
Interventions	Caregiver Behaviour Management Training Programme Control group Primary aim of intervention: CR behaviour & severity and CG burden. (See Table 2)
Outcomes	Rating Scale for Aggressive Behaviour in the Elderly (RAGE) Behavioural Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD) Zarit Burden Interview (ZBI) (See Table 3)
Notes	Country of origin: Kent, UK. 4 sessions over 8 weeks, providing education, ABC analysis and behavioural interventions.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomly allocated patients and their carers to intervention or control group'
Allocation concealment (selection bias)	Low risk	Randomisation was concealed from the second author.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The paper does not report the use of a manual or checking adherence to the manual. The intervention and control were conducted by the first author, only the second author was blinded to allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Second author blind to treatment allocation conducted assessments.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All reasons and number of withdrawals noted. Three patients dropped out of the trial shortly after their initial assessment: two were admitted to hospital and the third was admitted to residential care.
Selective reporting (reporting bias)	Low risk	All results reported.
Other bias	Unclear risk	Author conducted the intervention.

Huang 2003

Methods	Randomised controlled trial, Pilot study. Study duration: 12 weeks.
Participants	48 patients with dementia and their family caregiver (CG). Care recipients (CR) had to be aged 65 or over and score 50 or above on the CMAI. CRs were predominantly female with a mean age of 75.8 years. Twenty had a CDR rating of mild, 17 moderate, 10 severe and 1 very severe, with an average MMSE score of 13.1. CGs were predominantly female, with a mean age of 55.6.
Interventions	A home-based Caregiver Training Programme Control (written materials only) Primary aim of intervention: To improve CG self efficacy and decrease CR problem behaviours. (See Table 2)
Outcomes	Chinese version of Cohen Mansfield Agitation Inventory (CMAI) (CR Frequency of problem behaviours & CG Self efficacy).
Notes	Country of origin: Northern Taiwan. 2 week in home training programme, plus telephone consultations every two weeks.The control group received educational materials and social telephone follow-ups every two weeks. At the third week and third month assessments were conducted.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Randomly assigned to intervention or control group'
Allocation concealment (selection bias)	Unclear risk	Randomised by patient registration number, odd registration numbers to intervention, even to control. The paper does not report who performed randomisation,
Blinding of participants and personnel (performance bias) All outcomes	Low risk	'Although caregivers knew they were in a study, they did not know whether they were in the experimental or control group'. A manual was developed by the research team as a guide for the training program.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Investigator ran the intervention, unclear as to level of blinding and who conducted assessments.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition reported (11 participants were lost to follow-up because either the caregiver was unwilling to continue, the patient was hospitalised or the address was changed).
Selective reporting (reporting bias)	Low risk	All results reported.
Other bias	Unclear risk	None determined.

Losada-Baltar 2004

Methods	Randomised trial with 2 treatment and 1 control arm (for the purpose of this review the PSP condition was compared with the control condition). Study duration: 5 months.
Participants	31 family caregivers (CG) of a relative with dementia. CG had a mean age of 61.1 years and were predominantly female. Care recipients (CR) had a mean age of 80.4.
Interventions	Caregiver Cognitive Behavioural Intervention (PCC) Caregiver Problem-Solving Skills Training Intervention (PSP) Control group For the purpose of this review PSP was compared to the Control group. Primary aim of intervention: Modifying CR behavioural problems, CG stress associated with problem behaviours, CG depression and CG dysfunctional thoughts. (See Table 2)
Outcomes	Memory and Behaviour Check List (MBCL) - Frequency & Reaction Perception of Social Support (PSQ) Caregiver depression measured by CES-D Perceived Stress Scale (PSS) CG dysfunctional thoughts on care (CPD) (See Table 3)
Notes	Country of origin: Madrid, Spain. The paper is reported in Spanish. Our translation of this study led us to believe it was suitable for inclusion in the review as causes of behaviour were identified and hypothesis and strategies formed to alleviate the targeted behaviour. The intervention was delivered by two psychologists in one 2-hour session a week for 8 weeks, totalling 16 hours. A post-intervention assessment was taken after the 8 weeks, and 3 months following the end of the intervention. The total study duration was 5 months.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomly assigned'
Allocation concealment (selection bias)	Unclear risk	Unsure who performed the randomisation procedure and how it was conducted.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	'Interventionists carried out assessments, however, were unaware of membership at the time'. Due to difficulty translating the paper we were unable to establish whether the intervention has a manual or whether adherence checks were executed to ensure full delivery of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unable to determine due to difficulty translating the paper
Incomplete outcome data (attrition bias)	Low risk	Data reported.

Losada-Baltar 2004 *(Continued)*

All outcomes

Selective reporting (reporting bias)	Unclear risk	No risks identified, however, due to difficulty in translation of the paper, we have graded this as unclear.
Other bias	Low risk	None idenitified.

Mador 2004

Methods	Randomised trial - Behaviour Advisory Service compared with Usual Care. Study duration: 9 days.
Participants	71 patients with dementia and behavioural disturbance judged to be problematic with a mean age: 82.5.
Interventions	Staff Training Hospital Behaviour Advisory Service Usual Care Primary aim of intervention: Modify level of patient agitation over time, appropriateness of psychotropics, length of stay, discharge destination, falls, restraint use and CG satisfaction with care provided. (See Table 2)
Outcomes	Pittsburgh Agitation Scale (PAS) Medication Appropriateness Index (MAI) Discharge destination Falls Restraint use CG satisfaction with care Length of stay (See Table 3)
Notes	Country or origin: South Australia Patients assessed within 24 hours of randomisation. Nurse formulated management plan with respect to non-pharmacological strategies to help manage patients problematic behaviours, discussed the plan with ward nursing staff and provided ongoing support and education for nursing staff.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Pragmatic randomised controlled trial. 'Patients were randomised' (not by ward or hospital only by patient).
Allocation concealment (selection bias)	Low risk	Randomisation by hospital pharmacy department using sequential sealed opaque envelopes by external person using stratified blocks. Computer generated random numbers, allocation via external person.
Blinding of participants and personnel (performance bias)	Unclear risk	It is not reported if a manual was used or whether checks were completed to ensure accurate delivery of the intervention. The level of blinding of participants and personnel is not reported. Adherence was not formally measured 'it

Mador 2004 *(Continued)*

All outcomes		is possible that, although the EPN was offering advice and providing frequent follow-up visits to reinforce their suggestions, the ward nursing staff were not carrying out the strategies suggested'.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unsure as to the level of blinding of the EPN. Ward nurses conducted assessments unsure as to level of blinding. 'Treatment and control patients were both nursed on the same wards so it is possible that nursing staff may have picked up on useful strategies and applied them to the control group'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All reported (4 died, 67 discharged).
Selective reporting (reporting bias)	Unclear risk	Only follow-up data for the PAS is reported (in the abstract).
Other bias	Unclear risk	No other potential sources of bias identified.

Moniz-Cook 2008a

Methods	Randomised controlled trial. Study duration:18 months
Participants	113 care recipients (CR) and their family caregiver (CG). CR had a mean age of 77.2 years; CG had a mean age of 63.2 years and were predominantly female.
Interventions	Community Mental Health Nurses Training Intervention (CMHN) Control (usual practice) Primay aim of intervention: Training CMHNs in systematic psychosocial interventions (PSI) to help family caregivers manage behavioural changes in their relative with dementia. (See Table 2)
Outcomes	The General Health Questionnaire (GHQ) The adapted-Gilleard Problem Checklist (PC) The Hospital Anxiety and Depression Scale (HADS) The Global Deterioration Scale (GDS) (See Table 3)
Notes	Country of origin: Hull, UK. 4 consecutive weekly in home visits following which CMHN exercised clinical judgment about future contact and attended in service clinical supervision with a Clinical Psychologist (Esme Moniz-Cook) and senior nurse for the duration of the 18 month study, 2 hours, once a week for the first 6 months and once a fortnight for the following 6 months. Individual sessions were held once a month for the final 5 months.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Dyads (i.e. CR and CG) were randomly allocated to either condition'

Moniz-Cook 2008a *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Randomisation procedure not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Level of blinding of participants and personnel not reported. A protocol was in place. Only two CMHNs adhered to the 4 consecutive family treatment sessions. Despite protocol-led recommendations no relaxation or anxiety management occurred. Only two CMHNs sustained clinical supervision, noted as 'poor adherence' in the text.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers conducted baseline measures.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for withdrawal were reported (1 neighbour disengaged, 18 caregivers disengaged, 3 carers relocated, 3 spouse deceased care provided by a child).
Selective reporting (reporting bias)	Low risk	All outcome results at each time period reported.
Other bias	Low risk	Authors supervised CMHNs.

Proctor 1999

Methods	Randomised controlled trial. Study duration: 6 months.
Participants	105 subjects, 12 nursing and residential homes. Residents had a mean age of 83.1. Staff selected 10 residents in each home whose behavioural problems made them difficult to care for.
Interventions	Staff training and Education Intervention including psychosocial management of resident's behavioural problems. Control Primary aim of intervention: To assess quality of care, resident depression and organic symptoms and resident behavioural characteristics. (See Table 2)
Outcomes	Crichton Royal Behavioural Rating Scale (CRBRS) Automatic Geriatric Examination for Assisted Taxonomy (AGECAT) (depression & organic symptoms) (See Table 3)
Notes	Country of origin: Manchester, UK Seven 1 hour seminars plus individual visits from a member of the hospital outreach team. An experienced psychiatric nurse then visited each residential home every week to provide support to individual staff in development of care planning skills.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Residential homes were randomised to the control or intervention group'

Proctor 1999 *(Continued)*

Allocation concealment (selection bias)	Low risk	10 residential homes and 2 nursing homes were paired according to size and accreditation status. Computer generated random numbers used independently of the researchers to assign one of each pair of homes to intervention or control. Ten residents in each home were selected by staff independently of the researchers.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Residents were unaware of carer allocation. However, 'Staff that received the training were aware of the intervention'.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The paper does not report who conducted the outcome assessments and whether they were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All reported (11 died, 2 transferred and 3 withdrew consent).
Selective reporting (reporting bias)	Low risk	All results reported.
Other bias	Unclear risk	Staff who received training were aware of intervention and may have had expectations about the effects of the programme.

Teri 2000

Methods	Randomised placebo controlled clinical trial. Study duration: 12 months.
Participants	149 care recipients (CR) with Alzheimer's disease and their caregiver (CG). CRs had a mean age of 74.8 years, whilst CGs had a mean age of 65.6 and were predominantly the CR's spouses.
Interventions	Caregiver Behaviour Management Techniques Intervention Haloperidol Trazodone Placebo Primary aim of intervention: To decrease CR agitated behaviours (See Table 2)
Outcomes	Clinical Impression of Change (ADCS) The Consortium to Establish a Registry for Alzheimers Disease (CERAD) Behavioural Rating Scale for Dementia (BRSD) Revised Memory and Behaviour Problem Checklist (RMBPC) Cohen Mansfield Agitation Inventory (CMAI) Physical Self Maintenance (PSM) Agitated Behaviour Inventory for Dementia (ABID) Cognitive Function (MMSE)

Teri 2000 *(Continued)*

	(See Table 3)
Notes	Country of origin: America BMT intervention delivered over 8 weekly and 3 biweekly sessions providing information about AD, strategies for decreasing agitated behaviours, assignments and videotape training program, conducted by a therapist with masters degree.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Subjects were randomly allocated'
Allocation concealment (selection bias)	Low risk	'Subjects were allocated to four study arms. Ten sites had patients randomised to medications or placebo. Eleven sites had patients randomised to medications, placebo or BMT. Treatments were assigned in randomised blocks of nine or 12'. Randomisation was concealed.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The intervention had a protocol. Ongoing training, inter-rater reliability checks and quality control were performed to ensure standardisation. 'To insure interviewers remained blind to treatment assignment, caregivers did not discuss any aspects of treatment with the interviewer '.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Paper reports that in no instance was blinding compromised. Assessments conducted by blind interviewers.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The paper reports number of patients who withdrew and reasons and adverse effects (57 discontinued, major reasons for dropout included increased agitation in the trazodone arm (59%), unacceptable adverse effects in the haloperidol arm (43%), and caregiver difficulties or increased agitation in the BMT arm (35%)).
Selective reporting (reporting bias)	Low risk	The paper reports only total frequency score for the RMBPC but not reaction. The paper reports post-treatment data only.
Other bias	Low risk	Clinicians had a treatment protocol but allowed discretion in strategies to employ and when; therefore, intervention not wholly standardised.

Teri 2003

Methods	Randomised controlled trial. Study duration: 24 months.
Participants	153 community dwelling care recipients (CR) meeting criteria for Alzheimer's disease and their caregiver (CG). CRs had a mean age of 78 years, with an average MMSE score of 16.8 and were predominantly male. CGs had a mean age of 70, and were predominantly female.
Interventions	Caregiver training in behavioural management techniques with home-based exercise program - Reducing Disability in Alzheimers disease (RDAD) Control (routine medical care) Primary aim of intervention: CG management of CR problem behaviours and decreasing CR frailty and behavioural impairment.

Teri 2003 *(Continued)*

	(See Table 2)
Outcomes	Physical Health and Function (SF36) Affective Status - Hamilton Depression Rating Scale (HDRS) & Cornell Scale for Depression in Dementia CR Physical Health & Function Revised Memory and Behaviour Problem Checklist (RMBPC) (See Table 3)
Notes	Country of origin: Washington, USA. RDAD: In own home, 12 x 1 hour sessions, 2 per week for the first 3 weeks, followed by 1 for the next 4 weeks and biweekly sessions over the following 4 weeks. Followed by 3 sessions over the next 3 months conducted by health professionals experienced in dementia care.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Patient caregiver dyads were randomly assigned to exercise plus behavioural management techniques or routine medical care'
Allocation concealment (selection bias)	Low risk	The random allocation sequence was obtained from a computer program that blocked groups of 8 patients. Dyads were randomised after baseline assessment by research coordinators.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	A manual was used. Treatment adherence maintained and monitored through weekly supervision. Treatment sessions were videotaped and reviewed by independent reviewers. Unsure as to the level of blinding of other personnel and participants other than outcome assessment interviewers.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessments conducted by blind interviewers.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All reported (43 institutionalised, 2 declined to continue, 2 caregivers were ill, 2 moved, 5 caregivers declined to continue, 9 patients died and 1 caregiver died).
Selective reporting (reporting bias)	Unclear risk	Behavioural data not reported.
Other bias	Unclear risk	Training by authors

Teri 2005a

Methods	Randomised controlled trial. Study duration: 6 months.
Participants	95 care recipients (CR) with Alzheimer's disease and family caregivers (CG). CR mean age: 79.95 with an average MMSE score of 14.0. CR were required to have three or more agitated or depressed behaviour problems. CG ages ranged from 22 to 91 years. CR were predominantly female.
Interventions	Community Consultants Training program (STAR- Caregivers) Control (routine medical care)

Teri 2005a *(Continued)*

	Primary aim of intervention: To train community consultants to teach CGs a systematic behavioural approach for reducing mood and behaviour problems of their CR. (See Table 2)
Outcomes	Center for Epidemiologic Studies Depression Scale (CES-D) for CG Hamilton Depression Rating Scale (HDRS) for CG Perceived Stress Scale (PSS) Caregiver Sleep Questionnaire Screen for Caregiver Burden (SCB) Short Sense of Competence Questionnaire (SSCQ) Neuropsychiatric Inventory (NPI) Revised Memory and Behaviour Problem Checklist (RMBPC) The quality of Life in Alzheimers disease (QOL-AD) (See Table 3)
Notes	Country of origin: Washington, USA. Counsultant training consisted of an initial 2 hour orientation with supervising gero-psychologist. A standardised treatment manual that included instructions to consultants was disseminated and discussed. Consultants met the CGs in their home over 8 weekly sessions followed by four monthly phone calls.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomly assigned caregivers and care recipients to the intervention or control'
Allocation concealment (selection bias)	Unclear risk	The randomisation procedure is not reported; therefore, whether adequate allocation concealment was achieved is unclear.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Follow-up was conducted by interviewers blind to treatment assignment. Unsure as to the level of blinding of participants. A manual was used and adherence to the manual was monitored through audio taping treatment sessions and weekly supervision. (Consultants also had to successfully complete a pilot case).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers blind to treatment assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported withdrawal, however, some specific reasons are not recorded (3 care recipients hospitalised, 9 caregivers declined due to non-specific reasons)
Selective reporting (reporting bias)	Low risk	The paper does not report RMBPC data for frequency at 6 months.
Other bias	Unclear risk	Ratings of consultant adherence not done by independent raters.

Teri 2005b

Methods	Randomised controlled trial. Study duration: 2 months.
Participants	31 residents and 25 staff from four assisted living residences. Residents were predominantly female, had a mean age of 85.8 years and a MMSE mean score of 16.0. The mean age of staff was 37.4 years.
Interventions	Staff Training in Assisted Living Residences (STAR) based on a manual. Control - usual onsite training Primary aim of intervention: Dementia specific training program to teach direct care staff to improve care and reduce problems in residents with dementia. (See Table 2)
Outcomes	Geriatric Depression Scale (GDP) Clinical Anxiety Scale (CAS) Revised Memory and Behaviour Problem Checklist (RMBPC) Agitated Behaviours in Dementia (ABID) Neuropsychiatric Inventory (NPI) Short Sence of Competence Questionnaire (SSCQ) (See Table 3)
Notes	Country of origin: Seattle, Washington, USA. STAR is conducted over 2 months, through 2 half day group workshops and four individualised sessions.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Four assisted living residences were randomly assigned to intervention or control'
Allocation concealment (selection bias)	Unclear risk	Randomisation procedure not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	A training manual and protocol were used. Opportunities to discuss site specific issues that might hinder implementation or sustainability were provided. Unclear as to the level of blinding of participants and staff other than outcome assessors.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers blind to treatment condition conducted pre-training and post-training assessments
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition to report.
Selective reporting (reporting bias)	Unclear risk	No RMBPC frequency data reported. Doesent state the number of participants in each group, this information had to be sought by authors.

Teri 2005b *(Continued)*

Other bias	Low risk	Training by authors.

Weiner 2002

Methods	Randomised controlled trial
Participants	76 Care recipients with data available at 12 month follow-up.
Interventions	See Teri 2000 and Table 2
Outcomes	Agitated Behaviours in Dementia (ABID) (SeeTable 3)
Notes	Reports the maintenance effects of Teri 2000 paper.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised placebo controlled clinical trial.
Allocation concealment (selection bias)	Low risk	'Subjects were allocated to four study arms. Ten sites had patients randomised to medications or placebo. Eleven sites had patients randomised to medications, placebo or BMT. Treatments were assigned in randomised blocks of nine or 12'.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	'To insure Interviewers remained blind to treatment assignment, caregivers did not discuss any aspects of treatment with the interviewer'. Clinicians had a treatment protocol.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Paper reports that in no instance was blinding compromised.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not state dropout, however, this is reported in the previous paper.
Selective reporting (reporting bias)	Unclear risk	The paper only reports ABID data, however, other outcome measures were used.
Other bias	Low risk	No other forms of bias noted.

Zarit 1987

Methods	Randomised controlled trial - wait list control. Study duration: 24 months.
Participants	184 dementia care recipients (CR) living in the community and their primary caregivers (CG). CR mean age was 75.72 with an average MMSE score of 14.42. Mean age of CG was 62.02. 119 completed treatment.

Zarit 1987 *(Continued)*

Interventions	Caregiver Support Group Intervention (SG) Caregiver Individual Family Counselling Intervention (IFC) Wait list Control Group Primary aim of intervention: To test the effectiveness of a stress-management approach in reducing CG stress and burden. CG changes in reports of stress, improvement in management of the CR's problem behaviours, CG increased use of social support and CG perception of treatment benefits. (See Table 2)
Outcomes	Brief Symptom Inventory (BSI) Burden Interview (BI) Memory and Behaviour Problems Checklist (MBPC) Caregiver Change Interview Social Support Caregiver adequacy of support (See Table 3)
Notes	Country of origin: USA Only one experimental condition offered at a time at each site (2 sites). Subjects at one site randomly assigned to either IFC or wait list, other site randomly assigned to SG or wait list. For the purposes of this review SG was compared with wait list control. The interventions were delivered over 8 sessions (8 weeks).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomly assigned to either IFC, SG or wait list control"
Allocation concealment (selection bias)	Unclear risk	Crossover. 1st year of study one site received intervention and then assigned to a wait list. In the 2nd year, this was reversed. Does not state actual procedure of how sites assigned, e.g. blocks
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and staff not reported. The first author monitored sessions using audiotapes and supervision sessions to ensure that therapists implemented the treatment approach.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The paper does not report who conducted the assessments.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout numbers reported, but specific reasons not reported
Selective reporting (reporting bias)	Low risk	One year outcome data not reported, only post-intervention
Other bias	High risk	Crossover trial

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

Study	Reason for exclusion
Alessi 1999	Physical activity and environmental intervention to improve sleep and agitation.
Ashaye 2003	Assessment of CANE measurement scale. No behavioural outcomes.
Assal 2004	Pharmacological intervention only.
Ayalon 2006	This paper is a systematic review.
Ayalon 2009	Not an RCT, the paper reports a case series using problem solving for the management of depression and agitation in long term care.
Baillon 2002	Review paper of multi-sensory therapy in psychiatric care.
Baillon 2004	Snoezelen or Reminiscence therapy intervention.
Baillon 2005	Snoezelen or Reminiscence intervention
Baker 2001	Snoezelen & Activity intervention
Baker 2003	Snoezelen intervention
Baker 2006	Case series.
Baldelli 2007	Occupational Therapy intervention
Ballard 2009	Period of BPST not randomised, only pharmacotherapy part of trial randomised (information supplied by Author)
Beauchamp 2005	Worksite based Internet multi-media program. No behavioural component, predominantly focused on carer stress and coping
Belle 2006	Enhancing Quality of life through proving education and skills
Bellelli 2004	This paper reports on the maintenance effects of the CRONOS project.
Bird 2007	Not an RCT, naturalistic controlled trial with repeated measures
Buchanan 2002	Case Series
Burgener 1998	Instructional intervention for Caregivers on bathing and specific activities.
Burgio 2001	Communication improvement intervention using memory books, no behavioural analysis
Burns 2003	This paper reports the effects of the Reach study 2 year outcomes. No behavioural outcomes.
Callahan 2006	Behavioural intervention, however from intervention description there is no evidence of functional analysis.
Cohen-Mansfield 2006	Identity specific intervention regarding retention of self identity and the impact of role based treatment

Study	Reason for exclusion
Cohen-Mansfield 2007	This was not a fully randomised controlled trial, due to only some of the care homes being randomly assigned
Conti 2008	Recreational activities intervention
Coyne 1997	Therapies were standardised not individually tailored, intervention involved the use of verbal prompts for eating behaviour
Davison 2007	Not an RCT, participants were referred into the study
Deudon 2009	Education and coaching intervention to provide ideas of interventions to reduce and avoid BPSD but did not involve analysis of behaviour
Dias 2008	Support & education Intervention to predominantly reduce caregiver burden
Dwyer-Moore 2007	Case Series
Elliot 2010	Psycho-education and caregiver health intervention
Farran 2007	Reports on a subgroup only from previous randomised controlled trial, full RUSH trial is included in the review
Feeney 2003	Interactive voice response intervention.Behavioural management advice provided over the phone.
Finnema 2005	Emotion oriented care intervention training staff to use an emotion oriented approach
Gallagher-Thompson 2008	Cognitive behavioural intervention to reduce depression in family caregivers
Garilova 2009	Education only intervention involving two day training on problem behaviours.
Gerritsen 2005	Cross sectional study in care homes to investigate the relationship between apathy and quality of life.
Gitlin 2001	Home Environmental intervention proving occupational therapy to improve the environment.
Gitlin 2005	Paper reports the maintenance effects of included study Gitlin 2003, however the results have not been reported in the same format and therefore this data could not be included in the review.
Gitlin 2007	This paper reports on the design and method of projectACT3, however the results for this study are not yet published.
Gitlin 2008	Physical activity intervention, not functional analysis
Graff 2006	Occupational therapy based intervention
Graff 2007	Occupational therapy based intervention.
Graff 2008	Occupational therapy based intervention.
Grant 2007	Initial elucidation of unmet need or cause not by trained professional as this study is distance based. All contact with a trained professional is via the telephone
Heard 1999	Case Series

Study	Reason for exclusion
Hepburn 2001	Psychodeuctional and coaching group intervention, providing role training to help caregivers assume a more clinical belief set about care giving
Hepburn 2003	Reports only on the development and testing of the Savvy Caregiver Program.
Hepburn 2005	Psychoeducational intervention to deal with caregiver distress using activity, OT and music
Herbert 2003	Psycho-educational group program for caregivers to look at caregiver appraisal of stress and problem solving
Hinchliffe 1995	Primary outcome data not reported in continuous format (reported as dichotomous) therefore it could not be included in the meta-analysis.
Hochhalter 2007	Observational study.
Hoeffer 2006	No behavioural outcome e.g. NPI or CMAI. Behaviour rated through 'hassle' scale only. Specific bathing intervention.
Hoehn-Anderson 1992	Psychosocial intervention to involve families in care to evoke positive responses from residents when provided with items of interest
Javadpour 2009	Psychoeducational intervention. Randomisation unclear
Kolanowski 2001	Therapeutic recreational activities intervention. The paper is a review with a report of a small pilot crossover experimental design
Kolanowski 2005	Recreational Activities intervention, not functional analysis.
Kolanowski 2006	Specific agitation study, not an RCT, cross sectional design with repeated measures
Koltai 2001	Memory and coping program specifically for improving cognition not behaviour.
Konnert 2009	Cognitive behavioural therapy intervention
Kovach 1996	Therapeutic activities intervention, to promote comfort, QOL and dignity.
Kovach 2006	Serial Trial Intervention, needs assessed but not in terms of what functions behaviours served or what where the antecedents and causes.
Kuiper 2009	Dementia care mapping intervention
Kurz 2003	Pharmacological intervention.
Lam 2010	Activities based intervention.
Lavertsky 2006	Review paper.
Lawton 1998	Stimulation intervention
Litchenburg 2005	Pleasant events intervention, brainstorming and activity programming
Lovheim 2006	Cross sectional study to discover factors associated with the use of anti-psychotics
Low 2004	Cross sectional study to investigate the relationship between self destructive behaviours and nursing home environments

Study	Reason for exclusion
Lucero 2002	Review/discussion paper of exit seeking wandering behaviour intervention strategies.
Magai 2002	Increasing sensitivity to non verbal signals to improve psychological well-being of caregiver.
Marriot 2000	Cognitive behavioural therapy intervention, involving role play and problem solving.
Martin 2007	Activity based intervention to improve sleep/wake patterns.
Mayer 1991	Specific observational wandering intervention to assess the use of mirror.
McCallion 1999	Intervention to improve communication between carer and resident by observing interactions.
McCurry 1998	Specific Sleep intervention, did analyse behaviour however excluded due to targeting only night time behaviour.
McCurry 2005	Sleep Education intervention to deal with nighttime insomnia only.
McGilton 2003	Way-finding intervention
Melis 2008	No behavioural outcomes.
Mittleman 2004	Support and education intervention where caregivers dictated sessions.
Mittleman 2006	Counselling and support intervention with management of behaviours however from the description of the intervention it was not apparent functional analysis was utilised.
Moniz-Cook 2001	Case Series
Moniz-Cook 2003	Case Series, not a randomised controlled trial
Montgomery 2004	Systematic review of pharmacological therapies for sleep problems in later life
Narayan 2000	Reports 6 month data from an NIH-funded study, decision making educational intervention.
Onder 2005	Reality orientation intervention
Opie 1999	Systematic Literature Review paper looking at the efficacy of psychosocial approaches
Opie 2002	Randomised controlled trial lasted only 3 days where subjects acted as own controls (early group controls for late group).
Ostwald 1999	Psychoeducational intervention only.
Ouslander 2006	Sleep improvement intervention involving increasing daytime physical activity, bright light exposure and social interactions
Palese 2009	Observational study.
Politis 2004	Kit based activity intervention to reduce apathy and improve quality of life.
Poon 2005	Cognitive intervention to test the efficacy of telemedicine vs face to face treatment
Qazi 2003	Case series regarding managing anxiety in people with dementia.
Rasin 2007	Qualitative study.

Study	Reason for exclusion
Reeve 1985	Reality orientation. Not a randomised controlled trial.
Reuben 2003	Discussion paper.
Richards 2005	Social Activity Intervention.
Robinson 1994	Only secondary outcomes reported. No extractable data for Primary outcomes.
Robinson 2007	Psychoeducational and communication facilitation intervention.
Rolland 2007	Physical Activity intervention to improve ADL's & physical performance
Rosendahl 2006	High intensity Functional exercise program to improve gait.
Scholzel-Dorenbos 2010	Review paper.
Schrijnemaekers 2002	Emotion-oriented care intervention providing education on dementia
Schulz 2003	Overview of REACH project, site specific outcomes and future directions.
Sink 2006	Cross sectional study on caregiver characteristics and which are associated with neuropsychiatric symptoms
Sival 1997	Activities intervention, case study of three participants with dementia.
Sloane 2004	Intervention specifically tailored to behaviours experienced during showering/bathing
Sung 2006	Group music with movement intervention
Teri 1994	Review paper
Teri 1998	Qualitative study reporting cases from a previous randomised controlled trial.
Thal 2000	Pharmacological intervention.
Thal 2003	Pharmacological intervention.
Tibaldi 2004	Home hospital intervention. Reviewers could not determine a sufficient dosage of Functional Analysis to include this paper
Torta 2004	Review paper
Tung 2005	Physical activity intervention
Van de Winckel 2004	Music based exercise intervention.
Van Weert 2005a	Snoezelen Intervention
Van Weert 2005b	Snoezelen Intervention
Vespa 2002	Role of social relationships in psychosocial and psycho-cognitive behaviour
Visser 2008	No extractable data as only sub scale means reported. Author contacted- data unavailable
Williams 1987	Reality orientation and environmental intervention

Study	Reason for exclusion
Zanetti 1998	Psychoeducational intervention

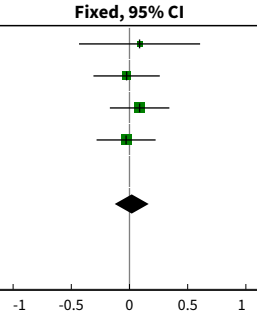
DATA AND ANALYSES

Comparison 1. Functional analysis versus usual care - primary outcomes at post-intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of problem behaviours - family care only	4	722	Std. Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.13, 0.17]
2 Frequency of problem behaviours	12	1551	Std. Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.20, -0.00]
2.1 Family care	10	1046	Std. Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.17, 0.07]
2.2 Residential care	2	505	Std. Mean Difference (IV, Fixed, 95% CI)	-0.21 [-0.39, -0.03]
3 Severity of problem behaviours	5	449	Std. Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.29, 0.08]
3.1 Family care	2	142	Std. Mean Difference (IV, Fixed, 95% CI)	-0.25 [-0.58, 0.08]
3.2 Residential care	3	307	Std. Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.26, 0.19]
4 Patient depression	3	480	Std. Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.33, 0.03]
4.1 Family care	2	375	Std. Mean Difference (IV, Fixed, 95% CI)	-0.08 [-0.29, 0.12]
4.2 Residential care	1	105	Std. Mean Difference (IV, Fixed, 95% CI)	-0.38 [-0.77, 0.00]

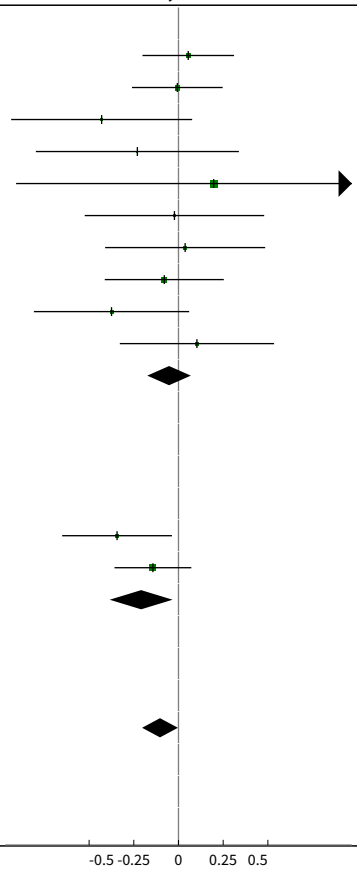
Analysis 1.1. Comparison 1 Functional analysis versus usual care - primary outcomes at post-intervention, Outcome 1 Incidence of problem behaviours - family care only.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Burgio 2003	27	-1.1 (4.8)	30	-1.6 (5.8)		7.89%	0.09[-0.43,0.61]
Farran 2004	89	-0.3 (2.2)	101	-0.2 (2.6)		26.28%	-0.02[-0.31,0.26]
Gitlin 2003	124	-0.5 (5.5)	112	-0.9 (5)		32.66%	0.09[-0.17,0.34]
Gitlin 2010	117	-1.2 (5.7)	122	-1.1 (5.9)		33.17%	-0.03[-0.28,0.22]
Total ***	**357**		**365**			**100%**	**0.02[-0.13,0.17]**
Heterogeneity: Tau^2=0; Chi^2=0.57, df=3(P=0.9); I^2=0%							
Test for overall effect: Z=0.26(P=0.8)							



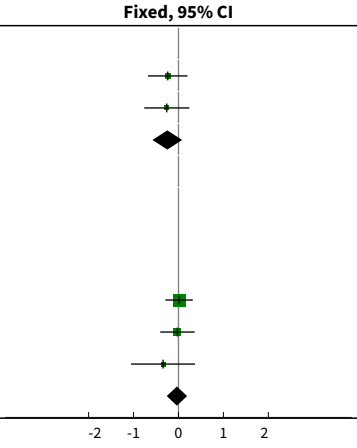
Analysis 1.2. Comparison 1 Functional analysis versus usual care - primary outcomes at post-intervention, Outcome 2 Frequency of problem behaviours.

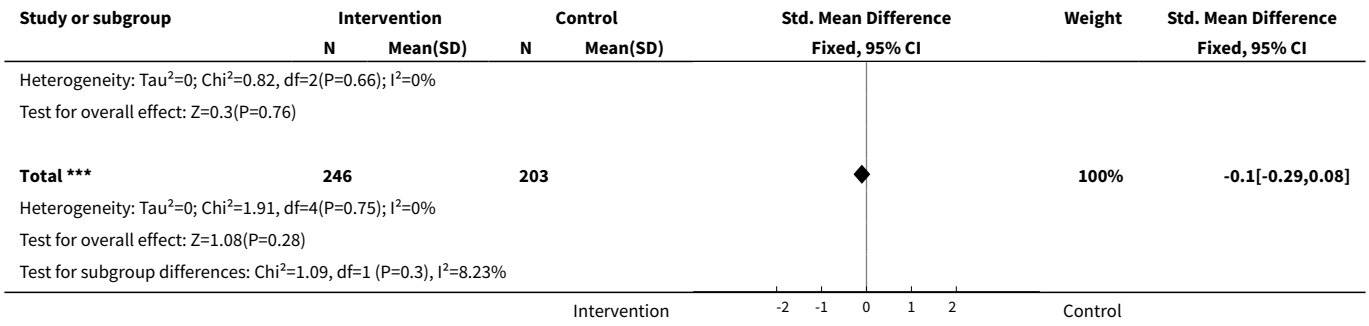
Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
1.2.1 Family care							
Farran 2004	124	-1.1 (13.9)	111	-1.9 (13.4)		15.31%	0.05[-0.2,0.31]
Gitlin 2010	117	-0.5 (19)	122	-0.4 (17.7)		15.62%	-0.01[-0.26,0.25]
Gormley 2001	34	-2.5 (5.2)	28	-0.2 (5.4)		3.92%	-0.43[-0.94,0.08]
Huang 2003	24	-7.5 (49.6)	24	2.3 (32.4)		3.12%	-0.23[-0.8,0.34]
Losada-Baltar 2004	15	4.7 (21.8)	4	0 (26.9)		0.82%	0.2[-0.91,1.3]
Moniz-Cook 2008a	30	3.6 (22.2)	31	4.2 (29.5)		3.99%	-0.02[-0.52,0.48]
Teri 2000	41	-0.1 (0.5)	36	-0.1 (0.5)		5.01%	0.04[-0.41,0.49]
Teri 2003	67	-0.4 (2.4)	72	-0.2 (2.6)		9.07%	-0.08[-0.41,0.25]
Teri 2005a	42	-1 (2.4)	41	-0.1 (2.4)		5.33%	-0.37[-0.81,0.06]
Zarit 1987	44	2.1 (29.8)	39	-1 (28.5)		5.4%	0.1[-0.33,0.53]
Subtotal ***	**538**		**508**			**67.58%**	**-0.05[-0.17,0.07]**
Heterogeneity: Tau^2=0; Chi^2=6.31, df=9(P=0.71); I^2=0%							
Test for overall effect: Z=0.85(P=0.4)							
1.2.2 Residential care							
Chenoweth 2009	101	-1 (22.8)	70	7.6 (27.7)		10.66%	-0.34[-0.65,-0.04]
Fossey 2006	172	1.2 (23.9)	162	4.6 (23)		21.76%	-0.14[-0.36,0.07]
Subtotal ***	**273**		**232**			**32.42%**	**-0.21[-0.39,-0.03]**
Heterogeneity: Tau^2=0; Chi^2=1.1, df=1(P=0.29); I^2=9.12%							
Test for overall effect: Z=2.33(P=0.02)							
Total ***	**811**		**740**			**100%**	**-0.1[-0.2,-0]**
Heterogeneity: Tau^2=0; Chi^2=9.46, df=11(P=0.58); I^2=0%							
Test for overall effect: Z=2.02(P=0.04)							
Test for subgroup differences: Chi^2=2.04, df=1 (P=0.15), I^2=51.1%							



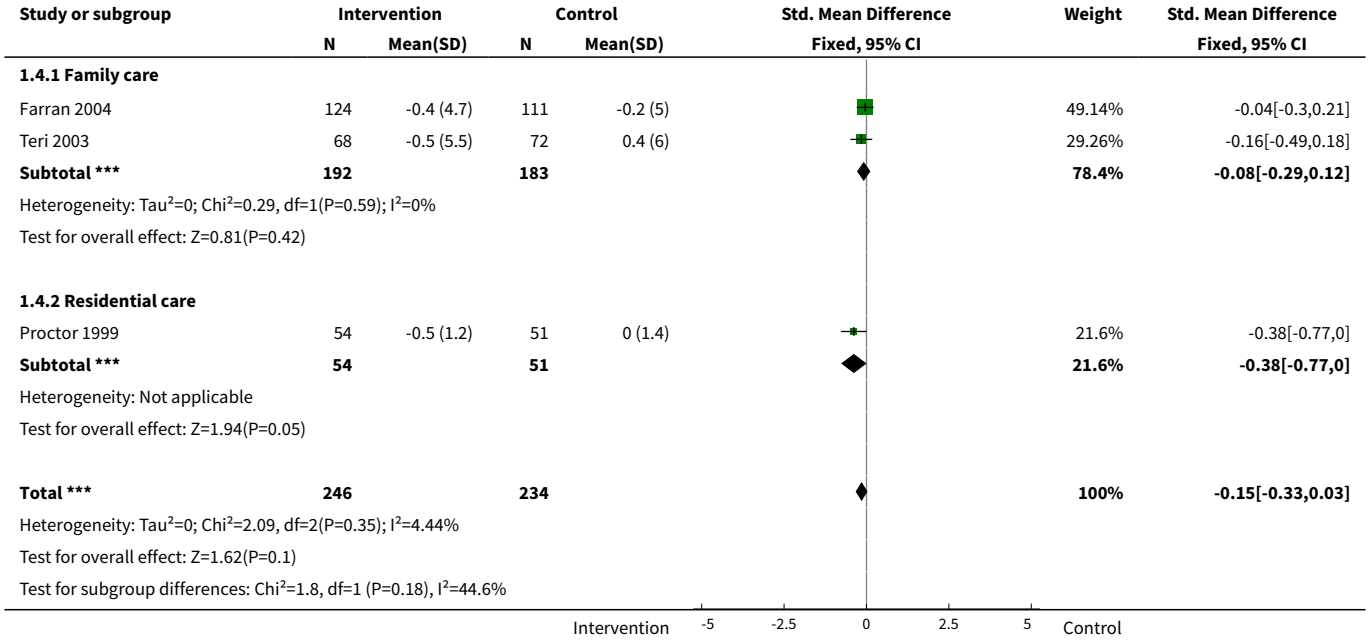
Analysis 1.3. Comparison 1 Functional analysis versus usual care - primary outcomes at post-intervention, Outcome 3 Severity of problem behaviours.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
1.3.1 Family care							
Gonyea 2006	40	-6.5 (16.5)	40	-2.3 (17.8)		18.02%	-0.24[-0.68,0.2]
Gormley 2001	34	-1.5 (4.6)	28	-0.2 (5.3)		13.81%	-0.26[-0.76,0.24]
Subtotal ***	**74**		**68**			**31.83%**	**-0.25[-0.58,0.08]**
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.95); I^2=0%							
Test for overall effect: Z=1.47(P=0.14)							
1.3.2 Residential care							
Chenoweth 2009	101	1.1 (7.2)	70	1 (7.1)		37.52%	0.01[-0.29,0.32]
Proctor 1999	54	1.1 (26.7)	51	1.6 (14)		23.8%	-0.02[-0.41,0.36]
Teri 2005b	17	-0.6 (6)	14	1.5 (5.9)		6.85%	-0.34[-1.06,0.37]
Subtotal ***	**172**		**135**			**68.17%**	**-0.03[-0.26,0.19]**





Analysis 1.4. Comparison 1 Functional analysis versus usual care - primary outcomes at post-intervention, Outcome 4 Patient depression.



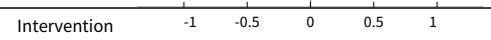
Comparison 2. Functional analysis versus usual care - primary outcomes at follow-up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of problem behaviours - family care only at 6 month follow-up	2	436	Std. Mean Difference (IV, Fixed, 95% CI)	0.08 [-0.11, 0.27]
2 Frequency of problem behaviours at 6 month follow-up	4	627	Std. Mean Difference (IV, Fixed, 95% CI)	0.00 [-0.16, 0.16]
3 Frequency of problem behaviours at 12 month follow-up	3	266	Std. Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.22, 0.27]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Family care	3	266	Std. Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.22, 0.27]

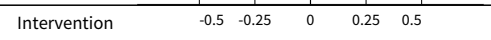
Analysis 2.1. Comparison 2 Functional analysis versus usual care - primary outcomes at follow-up, Outcome 1 Incidence of problem behaviours - family care only at 6 month follow-up.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Farran 2004	120	-0.5 (5.7)	96	-0.9 (5.1)		49.27%	0.08[-0.19,0.34]
Gitlin 2010	106	-1.1 (5.9)	114	-1.6 (5.8)		50.73%	0.08[-0.18,0.35]
Total ***	**226**		**210**			**100%**	**0.08[-0.11,0.27]**
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.96); I^2=0%							
Test for overall effect: Z=0.83(P=0.41)							



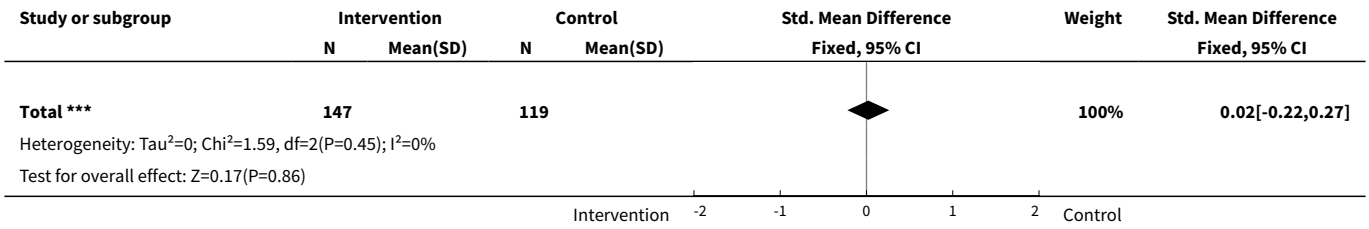
Analysis 2.2. Comparison 2 Functional analysis versus usual care - primary outcomes at follow-up, Outcome 2 Frequency of problem behaviours at 6 month follow-up.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Farran 2004	120	-1.2 (14)	96	-2.1 (13.5)		34.21%	0.07[-0.2,0.33]
Gitlin 2010	106	0.5 (22.9)	114	-0.4 (22)		35.24%	0.04[-0.22,0.31]
Teri 2003	61	-0.1 (2.5)	64	0.1 (2.5)		20.03%	-0.08[-0.43,0.27]
Teri 2005a	32	-0.8 (2.3)	34	-0.3 (2.7)		10.52%	-0.2[-0.68,0.29]
Total ***	**319**		**308**			**100%**	**0[-0.16,0.16]**
Heterogeneity: Tau^2=0; Chi^2=1.16, df=3(P=0.76); I^2=0%							
Test for overall effect: Z=0.01(P=0.99)							



Analysis 2.3. Comparison 2 Functional analysis versus usual care - primary outcomes at follow-up, Outcome 3 Frequency of problem behaviours at 12 month follow-up.

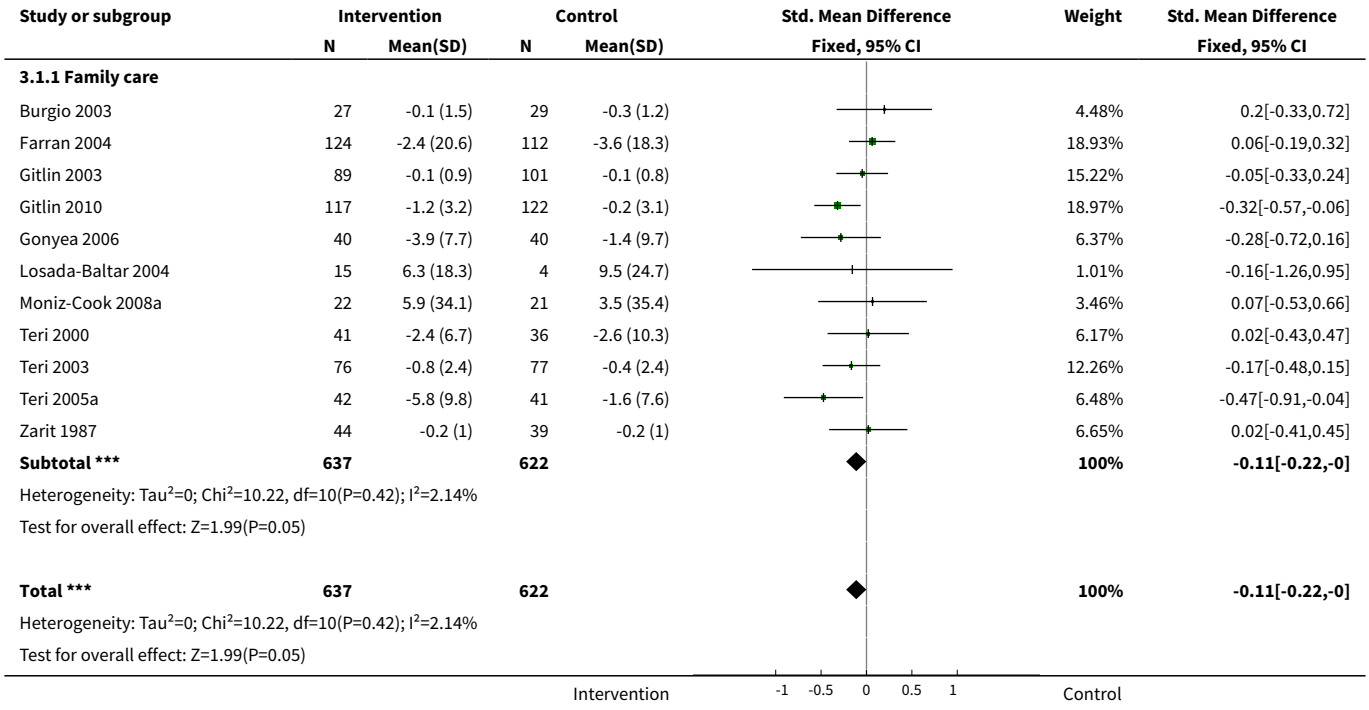
Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
2.3.1 Family care							
Farran 2004	108	-2 (12.4)	77	-1.9 (15.6)		69.3%	-0.01[-0.3,0.29]
Moniz-Cook 2008a	22	1 (23.9)	21	5 (23.5)		16.5%	-0.16[-0.76,0.43]
Teri 2000	17	0.9 (14)	21	-5.4 (18)		14.2%	0.38[-0.27,1.02]
Subtotal ***	**147**		**119**			**100%**	**0.02[-0.22,0.27]**
Heterogeneity: Tau^2=0; Chi^2=1.59, df=2(P=0.45); I^2=0%							
Test for overall effect: Z=0.17(P=0.86)							



Comparison 3. Functional analysis versus usual care - secondary outcomes at post-intervention

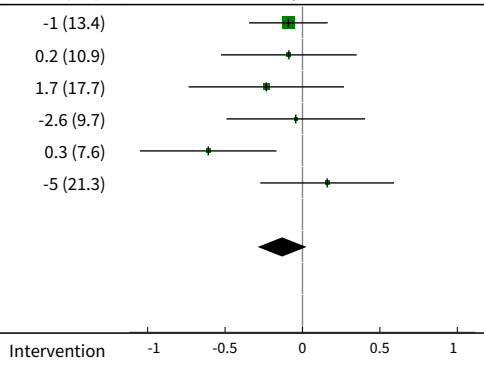
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caregiver reaction	11	1259	Std. Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.22, -0.00]
1.1 Family care	11	1259	Std. Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.22, -0.00]
2 Caregiver burden	6	624	Std. Mean Difference (IV, Fixed, 95% CI)	-0.13 [-0.29, 0.03]
3 Caregiver well-being (depression)	5	473	Std. Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.30, 0.06]

Analysis 3.1. Comparison 3 Functional analysis versus usual care - secondary outcomes at post-intervention, Outcome 1 Caregiver reaction.



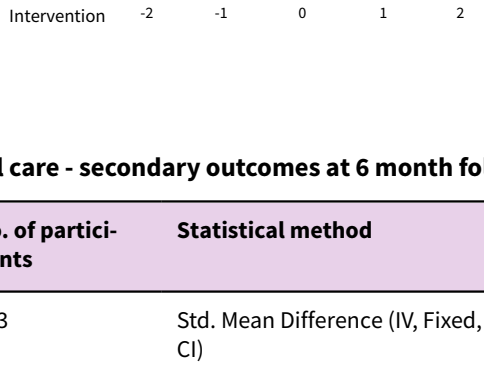
Analysis 3.2. Comparison 3 Functional analysis versus usual care - secondary outcomes at post-intervention, Outcome 2 Caregiver burden.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Gitlin 2010	117	-2.2 (12.8)	122	-1 (13.4)		38.63%	-0.09[-0.34,0.16]
Gonyea 2006	40	-0.8 (11.1)	40	0.2 (10.9)		12.94%	-0.09[-0.53,0.35]
Gormley 2001	34	-2.6 (18.6)	28	1.7 (17.7)		9.87%	-0.23[-0.74,0.27]
Teri 2000	41	-2.9 (7.3)	36	-2.6 (9.7)		12.41%	-0.04[-0.49,0.4]
Teri 2005a	42	-4.4 (7.7)	41	0.3 (7.6)		12.81%	-0.61[-1.05,-0.17]
Zarit 1987	44	-1.9 (16.8)	39	-5 (21.3)		13.34%	0.16[-0.27,0.59]
Total ***	**318**		**306**			**100%**	**-0.13[-0.29,0.03]**
Heterogeneity: Tau^2=0; Chi^2=6.69, df=5(P=0.24); I^2=25.28%							
Test for overall effect: Z=1.64(P=0.1)							



Analysis 3.3. Comparison 3 Functional analysis versus usual care - secondary outcomes at post-intervention, Outcome 3 Caregiver well-being (depression).

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Burgio 2003	36	-2.4 (14.6)	34	0.6 (12.7)		14.97%	-0.22[-0.69,0.25]
Farran 2004	127	-0.2 (6.6)	113	0.2 (6.1)		51.49%	-0.06[-0.31,0.19]
Losada-Baltar 2004	15	-1.3 (14.5)	4	7.8 (20.3)		2.64%	-0.55[-1.67,0.57]
Moniz-Cook 2008a	30	0.1 (5.9)	31	0.1 (5)		13.14%	0.01[-0.5,0.51]
Teri 2005a	42	-2.4 (12.1)	41	0.4 (13.2)		17.76%	-0.22[-0.65,0.21]
Total ***	**250**		**223**			**100%**	**-0.12[-0.3,0.06]**
Heterogeneity: Tau^2=0; Chi^2=1.39, df=4(P=0.85); I^2=0%							
Test for overall effect: Z=1.26(P=0.21)							



Comparison 4. Functional analysis versus usual care - secondary outcomes at 6 month follow-up

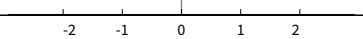
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caregiver reaction	4	653	Std. Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.27, 0.04]
2 Caregiver burden	2	286	Std. Mean Difference (IV, Fixed, 95% CI)	-0.14 [-0.38, 0.09]
3 Caregiver well-being (depression)	2	290	Mean Difference (IV, Fixed, 95% CI)	-0.93 [-2.56, 0.70]

Analysis 4.1. Comparison 4 Functional analysis versus usual care - secondary outcomes at 6 month follow-up, Outcome 1 Caregiver reaction.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Farran 2004	118	-2.6 (20.5)	96	-3.6 (20.2)		32.65%	0.05[-0.22,0.32]
Gitlin 2010	106	-1.2 (4.3)	114	-0.3 (4.5)		33.71%	-0.2[-0.47,0.06]
Teri 2003	76	-0.8 (2.4)	77	-0.4 (2.3)		23.51%	-0.17[-0.49,0.15]
Teri 2005a	32	-6.2 (24.7)	34	-1.6 (22.7)		10.12%	-0.19[-0.68,0.29]
Total ***	**332**		**321**			**100%**	**-0.11[-0.27,0.04]**
Heterogeneity: $Tau^2=0$; $Chi^2=2.04$, df=3(P=0.56); $I^2=0\%$							
Test for overall effect: Z=1.43(P=0.15)							

Analysis 4.2. Comparison 4 Functional analysis versus usual care - secondary outcomes at 6 month follow-up, Outcome 2 Caregiver burden.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Gitlin 2010	106	-2.1 (13.4)	114	-0.7 (14)		77.08%	-0.1[-0.37,0.16]
Teri 2005a	32	-3.3 (19.6)	34	2.4 (20.3)		22.92%	-0.28[-0.77,0.2]
Total ***	**138**		**148**			**100%**	**-0.14[-0.38,0.09]**
Heterogeneity: $Tau^2=0$; $Chi^2=0.41$, df=1(P=0.52); $I^2=0\%$							
Test for overall effect: Z=1.21(P=0.23)							



Analysis 4.3. Comparison 4 Functional analysis versus usual care - secondary outcomes at 6 month follow-up, Outcome 3 Caregiver well-being (depression).

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Farran 2004	122	-0.4 (6.6)	102	0.3 (6.2)		94.23%	-0.69[-2.37,0.99]
Teri 2005a	32	-2.3 (13)	34	2.6 (15.1)		5.77%	-4.9[-11.69,1.89]
Total ***	**154**		**136**			**100%**	**-0.93[-2.56,0.7]**
Heterogeneity: $Tau^2=0$; $Chi^2=1.39$, df=1(P=0.24); $I^2=28.23\%$							
Test for overall effect: Z=1.12(P=0.26)							

Comparison 5. Functional analysis versus usual care - outcomes for behaviour management studies only at post-intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of problem behaviours at post-intervention	2	139	Std. Mean Difference (IV, Fixed, 95% CI)	-0.17 [-0.50, 0.17]
2 Severity of problem behaviours at post-intervention	2	176	Std. Mean Difference (IV, Fixed, 95% CI)	0.33 [0.02, 0.63]
3 Caregiver burden at post-intervention	2	139	Std. Mean Difference (IV, Fixed, 95% CI)	-0.13 [-0.46, 0.21]

Analysis 5.1. Comparison 5 Functional analysis versus usual care - outcomes for behaviour management studies only at post-intervention, Outcome 1 Frequency of problem behaviours at post-intervention.

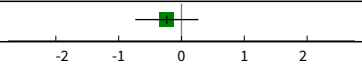
Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Gormley 2001	34	-2.5 (5.2)	28	-0.2 (5.4)		43.89%	-0.43[-0.94,0.08]
Teri 2000	41	-0.1 (0.5)	36	-0.1 (0.5)		56.11%	0.04[-0.41,0.49]
Total ***	**75**		**64**			**100%**	**-0.17[-0.5,0.17]**
Heterogeneity: Tau²=0; Chi²=1.84, df=1(P=0.18); I²=45.5%							
Test for overall effect: Z=0.98(P=0.33)							

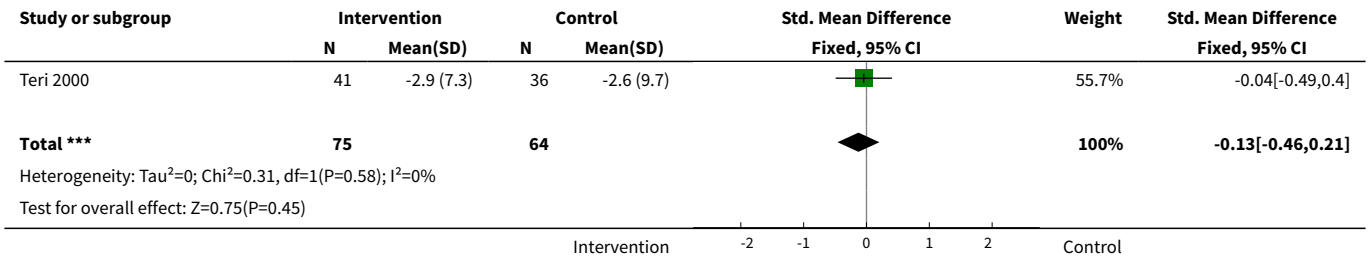
Analysis 5.2. Comparison 5 Functional analysis versus usual care - outcomes for behaviour management studies only at post-intervention, Outcome 2 Severity of problem behaviours at post-intervention.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Mador 2004	36	-1.7 (0.6)	35	-2.2 (0.5)		37.96%	0.89[0.41,1.38]
Proctor 1999	54	1.1 (26.7)	51	1.6 (14)		62.04%	-0.02[-0.41,0.36]
Total ***	**90**		**86**			**100%**	**0.33[0.02,0.63]**
Heterogeneity: Tau²=0; Chi²=8.38, df=1(P=0); I²=88.07%							
Test for overall effect: Z=2.11(P=0.03)							

Analysis 5.3. Comparison 5 Functional analysis versus usual care - outcomes for behaviour management studies only at post-intervention, Outcome 3 Caregiver burden at post-intervention.

Study or subgroup	Intervention N	Intervention Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Gormley 2001	34	-2.6 (18.6)	28	1.7 (17.7)		44.3%	-0.23[-0.74,0.27]





ADDITIONAL TABLES

Table 1. Table 1. Description of primary and secondary outcome measures

Table 1 **:Description of primary and secondary outcome measures**

Outcome	Name of measure	Source	Description	Eighteen trials	
				Family	**Residential /Assisted Living/Hospital**
Primary outcomes: Care recipient					
Patient behaviour	Revised Memory & Behaviour Problem Checklist (**RMBPC**)	Teri 1992	Assessment of behavioural problems in people with dementia. A 24-item checklist which provides one total score and 3 sub scores for the following problems: memory (7 items), depression (9 items) and disruption (8) items. Measures caregiver reports of Incidence (0-24), Frequency and Reaction (0-96) to each of the 24 problems. It was developed to measure reports of behavioural concerns by family caregivers in the US.	**Frequency:** Farran 2000 Gitlin 2010 (2 items) Teri 2003 Teri 2005a Teri 2000 Zarit 1987(non revised version) **Incidence:** Gitlin 2003 (disruptive behaviour only) Burgio 2003	Teri 2005b

Table 1. Table 1. Description of primary and secondary outcome measures *(Continued)*

	Rating Scale for Aggressive Behaviour in the Elderly (**RAGE**)	Patel 1992	Measures aggressive behaviours in the elderly ranging from being uncooperative to physical violence. A 21-items scale where for 17 items ratings are made for the frequency of behaviour over the past 3 days on a Likert scale of 0 (never) to 3 (more than once every day in past 3 days). Items 18-21 have descriptions for severity ratings of 0-3 or yes /no. Scores range from 0-62. Developed for staff working on psycho-geriatric wards.	Gormley 2001	
	Cohen Mansfield Agitation Inventory (**CMAI**)	Cohen-Mansfield 1989	Measures reported agitated behaviours in patients with cognitive impairment. A 29-item scale of verbally/physically aggressive behaviour and verbal/physical non–aggressive behaviour. Each item is rated for frequency 'since the last visit' on a 7 point scale (1–7) ranging from ''never'' to ''several times an hour.'' A total score is obtained by summing the 29 individual frequency scores, yielding a total score that ranges from 29 to 203. Developed in care home settings. **Chinese version:** assess 43 behavioural problems; each item is scored according to the frequency ranging from 1 (never happened) to 7 (several times an hour). Scores can range from 42-294.	Huang 2003 (Chinese Version)	Fossey 2006 Chenoweth 2009
	Problem Checklist (**PC**)	Agar 1997	Assessment of problems experienced by family carers of patients with dementia. The 34-Item Problem Checklist (Gilleard 1984) was adapted to include a further 5 items. Ratings are made for reported frequency (0-2) - scores ranging 0 ± 78 and management difficulty/coping (0-2) - score ranging 0 ± 78. Developed with family caregivers in the UK.	Moniz-Cook 2008a	
Severity of Problem Behaviours	Crichton Royal Behavioural Scale (**CRBRS**)	Wilkin 1989	Assessment of psycho-geriatric patients. The 11-item scale requires ratings for each item on a 1-5 point scale where each point has a severity description. Items are: mobility, memory, orientation, cooperation, restlessness, dressing, feeding, hearing, continence, sleep and subjective and objective mood. Scores range from 0-55		Proctor 1999
	Neuropsychiatric Inventory (**NPI**)	Cummings 1994	Assessment of Behavioural and Psychological Symptoms of Dementia (BPSD) using a caregiver interview, with ratings of the frequency and severity of 10 or 12 neuropsychiatric domains (according to the version). Available versions include for Family / community settings and Nursing homes. Both the frequency (F) and severi-	Gonyea 2006	Chenoweth 2009 Teri 2005b

Table 1. Table 1. Description of primary and secondary outcome measures *(Continued)*

			ty (S) of each symptom are rated on a four - (1–4) and three-point (1–3) Likert scale, respectively. A separate score can be calculated for each symptom by multiplying the frequency and severity scores, resulting values ranging from 0 to 12 for each symptom. A total score can be obtained by summing the 12 F_S scores, yielding total scores that range from 0 to 144. A separate rating of caregiver distress can be made on a five point scale from 0 - no distress, 1 - minimal, 2 - mild, 3 - moderate, 4 - moderately severe, 5 - very severe or extreme; distress ranges 0-60.		
	Pittsburgh Agitation Scale (**PAS**)	Rosen 1994	Measures the severity of disruptive behaviours within four behavioural groups: aberrant vocalisations; motor agitation, aggressiveness & resisting care. Scored from 0-4 with a maximum score 16. The score reflects the most disruptive of severe behaviour within each group.		Mador 2004
	Behavioural Pathology in Alzheimer's Disease Rating Scale (**Behave-AD**)	Rosen 1994	Assessment of behavioural symptoms in Alzheimer's disease. A 25-item scale with Likert scale of 0-4 covering paranoid and delusional ideation (7 items), hallucination (5 items), activity disturbances (3 items), aggression (3 items), diurnal variation (1 item), affective disturbance (2 items), and anxieties (4 items). Ratings range (0-75) and a global rating of the trouble that the various behaviours are to the caregiver is also recorded (0-3).	Gormley 2001	
Patient mood (depression)	Cornell Scale for Depression in Dementia **(CSDD)**	Alexopoulos 1988	Assessment of depression in patients with a dementia syndrome administered by a clinician. The interview takes 20 minutes with the carer and 10 minutes with the patient. A 19-item measure covering mood (4 items), behavioural disturbance (4 items), physical signs (3 items), cyclical functions (4 items), ideational disturbance (4 items). Items are rated on a 3 point scale: absent, mild or intermittent, and severe. Ratings are based on the week prior to the interview and range from 0-38.	Teri 2003	
	Automatic Geriatric Examination for Computer Assisted Taxonomy **(AGECAT)**	Copeland 1986	Measures organic and depression symptoms. Ratings are made from 1 & 2 = subclinical to 5 = severe. It provides syndrome diagnoses of: organicity, schizophrenia, mania, depression, anxiety, obsessional disorder, phobia, and hypochondriasis.		Proctor 1999
	Revised Memory & Behaviour	Teri 1992	Depression Subscale. Measures reported incidence (0-9), frequency (0-36) and caregiver reaction depression (0-36).	Farran 2004	Teri 2005b

Table 1. Table 1. Description of primary and secondary outcome measures *(Continued)*

	Problem Checklist (**RMBPC**)				
Secondary outcomes: Caregiver					
Mood (depression)	Centre for Epidemiological Studies — Depression scale (**CES-D**)	Radloff 1977	Detects depressive symptoms, particularly for use in research or screening. A 20-item scale with scores ranging 0-60. A score of 16 = mild depression and 23 and above is indicative of significant depression. Items are rated as occurring Rarely (< 1 day), Some (1-2 days), Occasionally (3-4 days) and Most (5-7 days).	Farran 2004 Teri 2005a Burgio 2003 Losa-da-Baltar 2004	
	Hospital and Anxiety Depression Scale (**HADs**)	Zigmond 1983	Assessment of mood. A 14 item measure with two sub scales: anxiety and depression. Each item is rated on a four-point Likert scale, giving maximum scores of 21 each for anxiety and depression. Scores of 11 or more on either sub scale are considered to be a significant 'case' of psychological morbidity, while scores of 8–10 represents 'borderline' and 0–7 'normal'	Moniz-Cook 2008a	
Reaction	Revised Memory & Behaviour Problem Checklist (**RMBPC**)	Teri 1992	Assessment of behavioural problems in people with dementia. A 24 item checklist which provides one total score and 3 subscores for the following problems: Memory (7 items), Depression (9 items) and Disruption (8 items). Measures caregiver reports of Incidence (0-24), Frequency and Reaction (0-96) to each of the 24 problems. Developed to measure reports of behavioural concerns by family caregivers in the US.	Farran 2004 Gitlin 2003 Gitlin 2010 Teri 2003 Teri 2005a Zarit 1987 Burgio 2003	Teri 2005b
	Agitated Behaviour in Dementia Scale (**ABID**)	Logsdon 1999	A measure of agitation in an outpatient sample of patients with mild to moderate Alzheimer's disease. A 16-item measure of frequency and caregiver reaction to common agitated behaviours in community residing dementia patients. Scored on a scale of 0-3, rated in the past 2 weeks where: 0 = did not occur during the week, 1 = occurred once or twice, 2 = occurred 3-6 times in the week, 3 = daily or more often.	Teri 2000	
	Neuropsychiatric Inventory (**NPI**) Distress	Cummings 1994	The NPI distress scale has an additional question on each of the 10 or 12 (depend-	Gonyea 2006	

Table 1. Table 1. Description of primary and secondary outcome measures *(Continued)*

			ing on version) domains specifically addressing the level of distress caused to carers by each symptom. Available versions include for Family / community settings and Nursing homes. Ratings are on a five point scale from 0 - no distress, 1- minimal, 2 - mild, 3 - moderate, 4 - moderately severe, 5 - very severe or extreme. Total distress ranges from 0-60.	
	Problem Checklist (**PC**)	Agar 1997	Assessment of problems experienced by family carers of patients with dementia. The 34-item Problem Checklist (Gilleard 1984) was adapted to include a further 5 items. Ratings are made for reported frequency (0-2) - scores ranging 0 ± 78 and management difficulty /coping (0-2) - score ranging 0 ± 78. Developed for use with family caregivers in the UK.	Moniz-Cook 2008a
Burden	Zarit Burden Interview (**ZBI**) First described as the Burden Interview	Zarit 1980	Assessment of the feelings of burden of caregivers in caring for an older person with dementia. A 29-item scale where scores are interpreted as follows: 0-21 = little or no burden, 21-20 = mild to moderate, 21-40 = mild to moderate, 41-60 = moderate to severe burden and 61-88 = severe burden.	Gitlin 2010 Gormley 2001 Zarit 1987
	The Screen for Caregiver Burden (**SCB**)	Vitaliano 1991	Assessment of perceived burden of caring for a person with Alzheimer's disease. A 25-item scale with scores for objective and subjective burden. Objective = the number of caregiver experiences occurring independently of their distress. Subjective = overall distress.	Teri 2005a Teri 2000

Table 2. Table 2. Description of interventions and quality of included studies

Table 2 . **Description of interventions and quality of included studies**

Trial setting	Trial	Study duration from baseline	Intervention duration	Follow-up assessments	Details of intervention sessions & format	Intervention type, aims and components	Delivered by	Intervention dosage[1] Minimal 1-2 sessions Moderate 3-5 Medium High 6-10 High > 10 Behaviour Management[2] = BM	Intervention Information to enable replication of trial. 1. Procedural clarity 2. Manual /protocol 3. Treatment fidelity assessments 4. Follow-up
Family Care	Teri 2003	24 months	3 months	Post intervention = 3 months. Follow-up data for: Problem Behaviour (PB) Frequency & Caregiver (CG) Reaction = 6 months; Patient Depression = 6, 12, 18 & 24.	12 x 1 hour sessions, 2 per week for 3 weeks, Weekly for 4 weeks and biweekly for 4 weeks, plus 3 follow-up sessions	**CG Skills Training Intervention** Aims: CGs taught to identify and modify patient behaviours that impaired day-to-day function and adversely affected CR/CG interactions. Taught how to reduce the occurrences of PB, learn skills to identify and modify precipitants of patient distress. Exercise and Education	Health care professionals delivered sessions (doesn't state how many) Trainers supervised by clinical geropsychologist (received weekly supervision).	**High**	1. Reported what components were included in the intervention; but detail on which components were addressed in each hour long session is absent. 2. Treatment protocol/manual 3. Treatment adherence was monitored by weekly supervision of each trainer by a clinical geropsychologist. Protocol sessions videotaped and reviewed by independent raters 4. Followed up to 24 months.

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

Zarit 1987	24 months	2 months	Post-intervention = 2 months Follow-up = 12 months (data not available)	8 sessions, the last used for Post-intervention assessment	**CG Support Intervention** Aims: Stress- Coping Model. Training teach CG to modify situations linked to stress, increase understanding of patient disease, improve management of PBs and identify useful formal and informal supports	2 Therapists for each group.	**Medium High**	1. The paper reports what usually occurred in the second session of the intervention, but does not state each session's agenda. 2. Conceived from a stress-management approach treatment model, but no mention of a manual. 3. Interventions monitored using audiotapes and supervision sessions to ensure therapists implemented treatment approach. 4. 2 Year longitudinal study but only post-intervention (2 month) data available.
Gitlin 2003	12 months	6 months	Post-intervention = 6 months Follow-up = 12 months (data not extractable)	Active phase: First 6 months, 5 (90 min) home contacts, 1 (30 min) telephone contact. Maintenance Phase: Subsequent 6 months	**CG Skills Training Intervention** Problem solving Intervention Includes: modifying home environments and simplifying daily tasks to address CG concerns; Education, Problem solving, Use of environmental strategies	Occupational therapist (does not state how many)	**Moderate**	1. The paper reports what happens in each intervention session as run by the OT. 2. Protocol 3. Interventions monitored using case review, feedback, checklist & telephone interviews to evaluate satisfaction 4. The paper reports 6 month post-intervention assessment, but not the results of the 12 month follow-up.
Farran 2004	18 months	3 months	Post-intervention = 3 months Follow-up = 6, 9, 12 & 18 months	12 x weekly sessions (5 group, 7 individual) 2 group booster sessions at 6 & 12 months + as needed	**CG Skills Training Intervention** Aims: Improve CG skill in dealing with PB. Content included: Potential causes/contributors to behavioural symptoms, preven-	Trained professionals (nurses, social workers) trained for 40 hours. 4 peo-	**High**	1. Paper reports contents of intervention but not each session in detail. 2. Detailed manual of prescribed material for each session 3. Project director and principal investigator supervised

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

				telephone contacts	tion & management of BPSD, building self efficacy.	ple functioned as intervention staff at any one time.		implementation & provided corrective feedback on a weekly basis. Group sessions were taped and randomly selected for review. 4. All follow-up data up to 18 months available.
Moniz-Cook 2008a	18 months	18 months	Post-intervention = 6 Follow-up = 12 & 18 months	4 consecutive weekly in home visits + clinical judgement for future contact & attend in-service clinical supervision for the 18 month duration. (Interventions were taught prior to the study over 5 half days)	**CG Support Intervention** Aims: To train community mental health nurses (CMHNs) to help family carers manage behavioural changes. Includes: Problem solving approaches, Stress-coping interventions and Functional analysis.	9 CMHNs (usual group 20 CMHNs) - 20 hrs training initially plus supervision 2 hrs per week for 1st 6 months, 1 per fortnight for next 6 months, 1 per month for last 5 months.	**High**	1. The total number of sessions or content of the sessions is not reported. 2. Protocol for CMHNs to conduct 4 in-home visits & attend supervision. No manual. 3. Only two CMHNs with dementia specific caseloads completed the ongoing supervision and adhered to the four consecutive family treatment sessions. 4. Follow-up data for 6, 12 & 18 months
Burgio 2003	18 months	12 months	Post-intervention = 6 months Follow-up data not available	16 in-home treatment sessions (over 12 month period). Skill Training condition vs. Minimal Support Condition. 3 hour workshop, 4 weekly in home visits for 1 month & 2 in the second month. In the	**CG Skills Training** Aims: To establish a knowledge base for CGs in behaviour management, problem solving, & cognitive restructuring. Basic information in behaviour management techniques (BMT) & support on the application of behavioural and environmental treatments.	11 REACH interventionists.	**High**	1. Reports the intervention procedure & components covered. 2. Manual guided intervention based on common needs and cultural preferences of American family caregivers. Manual available from authors. 3. Research personnel functioned as both interventionists and assessors. Feedback on accuracy was provided in weekly clinical case review meetings. All therapeutic con-

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

				following 10 months home visits were alternated.	Individual behaviour prescriptions.			tacts were audio taped to check accuracy of delivery. 4. Only 6 month data reported.
Teri 2000/ Weiner 2002	12 months	4 months	Post-intervention = 4 months Follow-up = 12 months (Weiner 2002)	BMT 8 weekly and 3 biweekly sessions. 16 week parallel design requiring 11 clinical visits. Randomisation to medication, BMT or placebo.	**Behaviour Management** Aims: Compare Behaviour Management Techniques – BMT-with pharmacological treatments for agitation. BMT included: information about AD, strategies for decreasing agitated behaviours.	Therapists with a master's degree and 1 year clinical experience (doesn't state how many therapists)	**High** **BM**	1. BMT intervention sessions not reported in detail. Paper only reports number and components of sessions. 2. Protocol 3. Raters participated in ongoing training to assure standardisation. All were trained prior to starting the trial. 4. Post-treatment data only reported; Weiner 2002 reports 12 month follow-up.
Gitlin 2010	6 months	4 months	Post-intervention = 4 months Follow-up = 6 months	Up to 11 home & telephone contacts over 16 weeks. Up to 9 occupational therapy (OT) sessions, two nursing home (one home and one telephone) and a maintenance phase of 3 brief OT telephone contacts.	**CG Support Intervention** Aims: To help eliminate, reduce or prevent problem behaviours within 3 interacting domains: - Patient based (unmet need, discomfort, pain), Caregiver based (stress & communication style) & Environment based (clutter, hazards).	10 OTs & 2 practice nurses received 35 hours training	**High**	1. Reports what took place during the intervention but not a specific outline for each session. 2. No mention of a manual. 3. Treatment fidelity maintained through twice monthly meetings & audiotapes of 10% of home sessions. Each home session was documented in terms of time spent & content covered. 4. Four and six month follow-up.
Teri 2005a	6 months	2 months	Post-intervention = 2 months	8 weekly sessions followed by 4 monthly phone calls	**CG Support Intervention** Aims: To teach family CGs a systematic behavioural approach for	5 community consultants – trained by clinical gero-psy-	**High**	1. Paper reports on the contents of each treatment session 2.Treatment manual

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

			Follow-up = 6 months		reducing mood and behaviour problems in persons with AD. Teaching ABC rationale and use Improving CG communication Increasing pleasant events, enhancing CG support.	chologist. - 2 hour orientation, 2nd training session & pilot case.		3. Protocol, Audio taped treatment sessions and rated quality 4. Post-test and 6 month follow-up.
Huang 2003	12 Weeks	3 Weeks (main phase)	Post-intervention = 3 weeks Follow-up = 12 weeks	2 in home sessions over 3 weeks, plus telephone calls every 2 weeks.	**CG Skills Training Intervention** Aims: Conceptually built around the Progressively Lowered Stress Threshold (PLST) model. Helping CGs identify the timing & frequency of behavioural problems & explore the causative stressors. Plan environmental and daily schedule modifications. Nurse caregiver collaboration with individualised training to develop individual plans of care.	Investigator – Experienced Gerontological nurse	**Minimal**	1. The paper reports what was conducted by the investigator on each visit. 2. Manual developed by research team as a guide for the training program 3. It is not reported whether there were any checks to insure adherence to the manual, however the principal investigator wrote the manual and conducted the intervention. 4. Followed 12 weeks from baseline.
Gormley 2001	10 Weeks	8 Weeks	Post-intervention = 10 weeks No follow-up	4 sessions conducted over 8 weeks.	**Behaviour Management Training** Aims: To train CGs in: Dementia education & the development of behavioural interventions by behavioural analysis. CGs taught to identify the precipitat-	Conducted by author.	**Moderate** **BM**	1. The paper reports what the 1st, 2nd and subsequent sessions focused on. 2. No mention of manual, the program was developed following a review of guidelines and descriptive studies

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

						ing & maintaining factors of behaviour.			3. The paper does not report information on treatment fidelity checks. 4. No follow-up
	Losada-Baltar 2004	5 months	2months	Post-intervention = 2 months Follow-up = 5 months	8 Sessions, 2 hours per week (16 hour in total)	**CG Skills Training Intervention** Aims: To train CGs in modifying behavioural problems of their relative through: Managing challenging behaviours, defining & identifying the problems, possible causes (ABC) and develop strategies and solutions.	Two psychologists	**Medium High**	1. States the components of the intervention but not which components were implemented in each session. 2. Due to difficulty translating the paper we are unsure if a manual was used. 3. Unsure regarding treatment fidelity checks 4. Followed up 5 months from Baseline.
	Gonyea 2006	6 Weeks	5 Weeks	Post-intervention = 6 weeks No follow-up	5 weekly group sessions (90 mins) including 15 minutes of individual time.	**CG Support Intervention** Aims: CG multi-component behavioural intervention to reduce CG distress through: Behavioural management (identifying ABC), Pleasant events & Relaxation.	Therapists (16-20 hours training).	**Moderate**	1. Session topics outlined 2. Highly structured groups with 5 main themes documented in the paper. 3. To monitor treatment fidelity the principle investigator consulted with therapists on a regular basis to review the group session experience and assess group progress. 4. No follow-up
Assisted Living	Teri 2005b	2 months	2 months	Post-intervention = 2 months No follow-up	2 half day group workshops and 4 individualised sessions	**CG Skills Training Intervention** Aims: To reinforce values of dignity and respect for residents, improve staff responsiveness to resident needs, build specific staff skills to enhance resident care, improve	Clinical psychologist & graduate student in nursing.	**Medium High**	1. The paper reports all the essential components and features of the intervention. 2. Manual detailing all specific aspects of training. 3. Three separate meetings were held to discuss site specific issues that might hinder

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

						job skill and satisfaction.			implementation or sustainability. 4. No follow-up.
Residential Care	Fossey 2006	12 months	10 months	Post-intervention = 12 months No follow-up	Trial clinician worked with homes 2 days a week over 10 months	**CG Skills Training Intervention** Aims: Training in the delivery of Person-centred care and Skills development training. Included: skills training, behavioural management techniques (ABC) and ongoing training and support	Psychologist, occupational therapist or nurse – supervised weekly by authors.	**High**	1. Reports the components of the intervention but detail of each session. 2. No mention of a manual just reference to a specific 'package' of components. 3. Staff offered supervision but no report assessing treatment fidelity. Reports the intervention took a consultation approach. 4. 10 month intervention with 12 month follow-up (for the purposes of this review classed as post-intervention assessment). No other follow-ups.
	Chenoweth 2009	8 months	4 months	Post-intervention = 4 months Follow-up = 8 months	Training was delivered to 2 care staff selected by managers for 6 hours per day over 2 days, trained staff then helped their colleagues to implement care plans over the 4 month intervention period	**Dementia Care Mapping and Caregiver Skills Training** Aims: Person centred care Need-driven behaviour model. where staff are educated to Included: Understand behaviour as a form of communication; recognise that feelings persist despite cognitive impairment; behaviour is a way of expressing needs; understand the impact of staff actions and use of ABC	3 authors trained by Bradford University led training.	**High**	1. Details of the interventions components are reported, but additional information was required from the author to clarify the intervention content before this trial could be included into the review. 2. Bradford University training manual 3. No detail on checking adherence to the manual or treatment fidelity. 4. Follow-up at 8 months from baseline.

Table 2. Table 2. Description of interventions and quality of included studies *(Continued)*

	Proctor 1999	6 months	6 months	Post-intervention = 6 months No follow-up	7 x 1 hour seminars delivered by hospital outreach team. An experienced psychiatric nurse visited every week to give advice and support individual workers in care planning.	**Behaviour Management** Aims: Staff training and psychosocial management of residents PB. Includes: Formulation of detailed and specific care plans & increasing the interval between non-contingent interactions (not in response to need)	Hospital outreach team & psychiatric nurse	**Medium High** **BM**	1. The paper reports only the components of each of the seminars 2.No report of a manual 3. No reports of checking treatment fidelity or adherence. 4. No follow-up.
Hospital Care	Mador 2004	9 Days	9 Days	Post-intervention = 9 days No follow-up	Extended Practice Nurse (EPN) saw patients within 24 hours of randomisation and formulation of a non-pharmacological management plan of strategies to manage challenging behaviour. Assumption that Control condition Geriatric assessment was also	**Behaviour Management** Aims: Specialist support and education to the ward nursing staff to enable them to facilitate behaviour strategies. Included: Understanding patients needs, patient safety, minimising restraint usage, communication, nursing care & targeted behavioural strategies.	? Geriatrician review as in Control Group + Extended practice nurse and ward staff.	**High** **BM**	1. The paper reports the components of the intervention only. 2. No mention of a manual 3. No reporting of assessments of treatment fidelity and adherence 4. No long-term follow-up

[1] = Intervention dosage is based on the number of contact sessions, not the amount of functional analysis

[2] = Intervention focused on Behaviour Management with relatively few other components

Table 3. Table 3. Overview of outcome measures

Table 3 . **Overview of outcome measures**

Trial	Setting	Outcomes **Author's description of care recipient (CR) & caregiver (CG) outcomes**	Assessment Tools **◊ Measure abbreviated after one full description** **∞ Outcome measure not a rating scale** **Δ Inadequate number of equivalent instruments for data aggregation** **□ Instrument not relevant or alternative measure used**
Burgio 2003	Family	Care Recipient (CR) Behaviour & Caregiver (CG) Reaction	Revised Memory and Behaviour Problem Checklist (RMBPC) (incidence only) & RMBPC 'bother or upset'
		CG Appraisal of benefits from Caregiving	Δ Positive Aspects of Caregiving (PAC) (developed by REACH investigators)
		CG Social Support	Δ Lubben Social Network Index (LSNI) 28 item measure (Berkman 1979 adapted scale)
		CG Leisure Time satisfaction	Δ 6-item scale developed by interventionists
		CG Mood	Δ State-trait personality inventory (anxiety sub scale 10 items)
			The Centre for Epidemiologic studies –Depression Scale (CES-D)
		CG Desire to institutionalise	□ 7 Item scale by Morycz 1985
Farran 2004	Family	CR Behaviour/CG Depression	◊ RMBPC
		CG Mood	◊ CES-D
		CG Skill	Δ Behavioural Management Skill –Revised (BMS-R)
		Time to institutionalisation	∞ Interval from Baseline to initial entry into long-term care Facility
Gitlin 2003	Family	CR Behaviour	◊ RMBPC (incidence only)
		CR Level of ADL assistance required	□ Functional Independence Measure (FIM)
		CG Objective & Subjective Burden	∞ Vigilance, Total hours of ADL help & Help received for ADLs.
			◊ RMBPC (upset sub scale)
		CG Perceived Mastery	Δ Care-giving Mastery Index (CMI)
		CG Skill Enhancement	Δ Task Management Strategy Index (TMSI)
		CG Wellbeing	Δ Perceived Change Index (PCI)

Table 3. Table 3. Overview of outcome measures *(Continued)*

		CR Cognitive Ability	□ Mini Mental State Exam (MMSE)
Gitlin 2010	Family	CR Behaviour & CG Reaction (upset)	16-item Agitated Behaviors in Dementia Scale and 2 items (repetitive questioning, hiding/hoarding) from RMBPC, plus 3 other items (wandering, incontinence, shadowing).
		CG Mood	◊ CES-D
		CG Burden	Zarit Burden Interview (ZBI)
		CG Skill enhancement	Δ ◊ TMSI
		CG Perceived Benefits	Δ 11 item survey developed by investigators.
		CG change	Δ ◊ PCI
Gonyea 2006	Family	CR behaviour (Severity & Frequency) & CG Distress	Neuropsychiatric Inventory (NPI)
		CG Burden	◊ ZBI
		CR Functional Impairment	□ Activities of Daily Living (ADL)
Gormley 2001	Family	CR Behaviour (Severity & Frequency)	Behavioural Pathology in Alzheimer's disease scale (BEHAVE-AD)
			Rating Scale for Aggressive Behaviour in the Elderly (RAGE)
		CG Burden	◊ ZBI
		CR Cognitive Ability	□ ◊ MMSE
		CR Functional Ability	□ Blessed Dementia Rating Scale
Huang 2003	Family	CR Behaviour	Cohen Mansfield Agitation Inventory (CMAI)
		CG self efficacy for managing agitation	Δ Agitation Management Self Efficacy Scale (AMSS)
		CR Cognitive Ability	□ ◊ MMSE
		CR Dementia Severity	□ Clinical Dementia Rating (CDR)
		CR Activities of Daily Living	□ Barthel Index
Losada-Baltar 2004	Family	CR Behaviour & CG reaction (upset)	Memory & Behaviour Checklist (MBCL-A & MBCL-B)
		CG Dysfunctional thoughts about care	Δ Beliefs about Care-giving Questionnaire (BACS)
		CG Mood	◊ CES-D
		CG Perceived Support	Δ Perceived Support Questionnaire (PSQ)

Table 3. Table 3. Overview of outcome measures *(Continued)*

		CG Perceived Stress	Δ Perceived Stress Scale (PSS)
Moniz-Cook 2008a	Family	CR Behaviour & CG Management/difficulty coping	Problem Checklist (PC)
		CR Global Dependency	☐ Global Deterioration Scale (GDS)
		CG psychiatric morbidity	Δ General Health Questionnaire (GHQ)
		CG Mood	Hospital Anxiety and Depression Scale (HADS)
Teri 2000	Family	Clinically meaningful change in CR	☐ ADCS Clinical Global Impression of Change scale (ADCS-CGIC)
		CR function (physical and cognitive)	☐ Physical Self maintenance (PSM)
			☐ Instrumental activities of daily living (IADL)
			☐ MMSE
		CG Burden & Reactivity to specific disruptive behaviours	Screen for Caregiver Burden (SCB)
			◊ RMBPC reaction (not reported)
		CR behaviour	☐ Consortium to establish a registry for Alzheimer's disease (CERAD)
			☐ Behavioural Rating scale for Dementia (BRSD)
			◊ RMBPC (Frequency)
			☐ ◊ CMAI (Frequency)
			Agitated behaviour in dementia scale (ABID) (Frequency & Reaction)
Teri 2003	Family	CR Behaviour & CG distress	◊ RMBPC
		CR Physical Health and Function	☐ Short Form Health Survey (SF-36)
			☐ Sickness Impact Profile Mobility (SIP)
		CR Mood	Cornell Depression in Dementia Scale (CDDS)
			☐ Hamilton Depression Scale (HDRS)
		CR Cognitive Ability	◊ MMSE
		Other outcomes:	∞ CR walking speed, functional reach and standing balance.
Teri 2005a	Family	CR Behaviour	◊ RMBPC
			◊ NPI

Table 3. Table 3. Overview of outcome measures *(Continued)*

		CR Quality of life	□ Quality of Life in Alzheimer's disease scale (QOL-AD)
		CG Mood	◊ CES-D
		CG Mood	□ ◊ HDRS
		CG Perceived Stress	Δ ◊ PSS
		CG Burden	◊ SCB
		CG Sleep Problems	Δ Caregiver Sleep questionnaire
		CG Feelings of Competence	Δ Short sense of Competence Questionnaire (SSCQ)
		CR Cognitive status	□ ◊ MMSE
		Adverse reactions	∞
Zarit 1987	Family	CR Behaviour & CG distress	Memory and Behaviour Problem Checklist (MBPC)
		CG Stress associated with care giving	Burden Interview (BI)
		CR Frequency of psychiatric symptoms	□ Brief Symptom Inventory (BSI)
		Social Support	∞ Amount of interaction with informal support network, amount of assistance by others & caregiver rating of adequacy of social support.
		Therapeutic dimensions of Intervention	Δ Caregiver Change Interview (CCI)
		CG Perception of intervention	Δ Global rating of situation improvement
		CR Cognitive Ability	□ ◊ MMSE
Chenoweth 2009	Residential	CR Behaviour	◊ CMAI
			◊ NPI
		CR Quality of life in later stage dementia	□ Quality of Life Index (QUALID)
		Amount of physical restraint	□ Quality of Interaction Schedule (QUIS) observations
		CR Global Dependency	□ ◊ GDS
		Other outcomes:	∞ Antipsychotics & benzodiazepine doses, incidents and admissions to hospital. Also conducted an economic analysis.
Fossey 2006	Residential	CR Behaviour	◊ CMAI
		CR Dementia Severity	□ ◊ CDR

Table 3. Table 3. Overview of outcome measures *(Continued)*

		Neuroleptic use	∞ Daily chlorpromazine amounts to national formulary
		CR Falls	∞ Observations
		CR Quality of life and well-being	Measurement scale not reported.
Proctor 1999	Residential	CR Behaviour	Crichton Royal Behavioural Rating Scale
		CR Organic and Depressive symptoms	Automatic Geriatric Examination for Computer assisted taxonomy (AGECAT)
		CR Activities of daily living	□ Barthel Index
Teri 2005b	Assisted Living	CR Behaviour & CG Reaction	◊ RMBPC
			□ ◊ ABID
			◊ NPI
		CR Mood	RMBPC sub scale
			□ Geriatric Depression Scale
			□ Clinical Anxiety Scale (CAS)
		Staff feelings on capability to provide care for a person with dementia	Δ ◊ SSCQ
		CR Cognitive ability	□ ◊ MMSE
Mador 2004	Hospital	CR Behaviour (severity)	Pittsburgh Agitation Scale (PAS)
		Appropriateness of psychotropic medication	□ Medication Appropriateness Index (MAI)
		Other outcomes	∞ Total daily doses of benzodiazepines and antipsychotics administered, length of stay, discharge destination, number of falls, nursing satisfaction, next of kin (NOK) satisfaction with care.

APPENDICES

Appendix 1. Pre-publication search: March 2011

Source	Search strategy	Hits retrieved

(Continued)

1. ALOIS (www.medicine.ox.ac.uk/alois)	Advanced search Intervention: (contains any): "functional analysis" OR mapping OR "care management" OR psychosocial OR behavioural. Date added to ALOIS between Jan 2010 and March 2011	36
2. MEDLINE In-process and other non-indexed citations and MEDLINE 1950-present (Ovid SP)	1. behavio*.mp. 2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp. 7. anxious*.mp. 8. depress*.mp. 9. apath*.mp. 10. wandering.mp. 11. disinhibit*.mp. 12. confused.mp. 13. confusion.mp. 14. vocal*.mp. 15. BPSD.mp. 16. neuropsychiatr*.mp. 17. or/1-16 18. ("functional analy*" or "dementia care map*" or "person-centred care").mp. 19. (behavio* and (intervention* or manag* or modif* or chang* or analys*)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier] 20. 18 or 19 21. 17 and 20 22. Dementia/ 23. Dementia, Multi-Infarct/ 24. Dementia, Vascular/ 25. Alzheimer Disease/ 26. Lewy Body Disease/ 27. Delirium/ 28. Huntington Disease/ 29. "Pick Disease of the Brain"/	156

(Continued)

30. Kluver-Bucy Syndrome/

31. Wernicke Encephalopathy/

32. Creutzfeldt-Jakob Syndrome/

33. Delirium, Dementia, Amnestic, Cognitive Disorders/

34. dement*.mp.

35. Alzheimer*.mp.

36. (lewy* adj2 bod*).mp.

37. deliri*.mp.

38. ("organic brain disease" or "organic brain syndrome").mp.

39. "supranuclear palsy".mp.

40. (pick* adj2 disease).mp.

41. (creutzfeldt or jcd or cjd).mp.

42. huntington*.mp.

43. binswanger*.mp.

44. korsako*.mp.

45. arteriosclerosis.mp.

46. "cerebrovascular disorder*".mp.

47. "cerebr* deteriorat*".mp.

48. "cerebr* insufficien*".mp.

49. or/22-48

50. 49 and 21

51. randomized controlled trial.pt.

52. controlled clinical trial.pt.

53. random*.ab.

54. placebo.ab.

55. trial.ab.

56. groups.ab.

57. or/51-56

58. (animals not (humans and animals)).sh.

59. 57 not 58

60. 50 and 59

61. (201004* or 201005* or 201006* or 201007* or 201008* or 201009* or 201010* or 201011* or 201012*).ed.

62. 2011*.ed.

63. 61 or 62

(Continued)

	64. 60 and 63	
3. EMBASE 1980-2011 week 8 (Ovid SP)	1. behavio*.mp. 2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp. 7. anxious*.mp. 8. depress*.mp. 9. apath*.mp. 10. wandering.mp. 11. disinhibit*.mp. 12. confused.mp. 13. confusion.mp. 14. vocal*.mp. 15. BPSD.mp. 16. neuropsychiatr*.mp. 17. or/1-16 18. ("functional analy*" or "dementia care map*" or "person centred car*" or "person centered car*").mp. 19. (behavio* adj3 (intervention* or manag* or modif* or chang* or analys*)).mp. 20. 18 or 19 21. 17 and 20 22. presenile dementia/ or "mixed depression and dementia"/ or semantic dementia/ or frontotemporal dementia/ or senile dementia/ or frontal variant frontotemporal dementia/ or multiinfarct dementia/ or exp dementia/ or Pick presenile dementia/ 23. Alzheimer disease/ 24. diffuse Lewy body disease/ 25. delirium/ 26. Huntington chorea/ 27. Kluver Bucy syndrome/ 28. Wernicke encephalopathy/ 29. Creutzfeldt Jakob disease/ 30. dement*.mp.	108

(Continued)

	31. Alzheimer*.mp. 32. (lewy* adj2 bod*).mp. 33. deliri*.mp. 34. ("organic brain disease" or "organic brain syndrome").mp. 35. "supranuclear palsy".mp. 36. (pick* adj2 disease).mp. 37. (creutzfeldt or jcd or cjd).mp. 38. huntington*.mp. 39. binswanger*.mp. 40. korsako*.mp. 41. arteriosclerosis.mp. 42. "cerebrovascular disorder*".mp. 43. "cerebr* deteriorat*".mp. 44. "cerebr* insufficien*".mp. 45. or/22-44 46. 45 and 21 47. randomized controlled trial/ 48. clinical trial/ 49. random*.ti,ab. 50. trial.ti,ab. 51. groups.ab. 52. ("treatment as usual" or "treatment as before").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer] 53. placebo.ab. 54. or/47-53 55. 46 and 54 56. (2010* or 2011*).em. 57. 55 and 56	
4. PSYCINFO 1806-March week 1 2011 (Ovid SP)	1. behavio*.mp. 2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp.	57

(Continued)

7. anxious*.mp.

8. depress*.mp.

9. apath*.mp.

10. wandering.mp.

11. disinhibit*.mp.

12. confused.mp.

13. confusion.mp.

14. vocal*.mp.

15. BPSD.mp.

16. neuropsychiatr*.mp.

17. or/1-16

18. ("functional analy*" or "dementia care map*" or "person centred care" or "person centered care").mp.

19. (behavio* adj3 (intervention* or manag* or modif* or chang* or analys*)).mp.

20. 18 or 19

21. 17 and 20

22. exp Dementia/ or exp Senile Dementia/ or exp Presenile Dementia/ or exp Dementia with Lewy Bodies/ or exp Vascular Dementia/

23. exp Alzheimers Disease/

24. exp Dementia with Lewy Bodies/

25. exp Delirium/

26. Huntingtons Disease/

27. Picks Disease/

28. Kluver Bucy Syndrome/

29. Wernickes Syndrome/

30. Creutzfeldt Jakob Syndrome/

31. dement*.mp.

32. Alzheimer*.mp.

33. (lewy* adj2 bod*).mp.

34. deliri*.mp.

35. ("organic brain disease" or "organic brain syndrome").mp.

36. "supranuclear palsy".mp.

37. (pick* adj2 disease).mp.

38. (creutzfeldt or jcd or cjd).mp.

39. huntington*.mp.

(Continued)

	40. binswanger*.mp.	
	41. korsako*.mp.	
	42. arteriosclerosis.mp.	
	43. "cerebrovascular disorder*".mp.	
	44. "cerebr* deteriorat*".mp.	
	45. "cerebr* insufficien*".mp.	
	46. or/22-45	
	47. 21 and 46	
	48. random*.ti,ab.	
	49. trial*.ti,ab.	
	50. exp Clinical Trials/	
	51. groups*.ab.	
	52. ("treatment as before" or "treatment as usual").mp.	
	53. "control group".ab.	
	54. or/48-53	
	55. 47 and 54	
	56. (2010* or 2011*).up.	
	57. 55 and 56	
5. CINAHL (EBSCOhost)	S1 TX behavio*	48
	S2 TX agitat*	
	S3 TX aggressi*	
	S4 TX delusion*	
	S5 TX hallucinat*	
	S6 TX anxiety	
	S7 TX anxious*	
	S8 TX depress*	
	S9 TX apath*	
	S10 TX wandering	
	S11 TX disinhibit*	
	S12 TX confused	
	S13 TX confusion	
	S14 TX vocal*	
	S15 TX BPSD	
	S16 TX neuropsychiatr*	

(Continued)

S17 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

S18 TX "functional analy*" OR “dementia care mapping”

S19 TX behavio* N3 intervention*

S20 TX behavio* N3 manag*

S21 TX behavio* N3 modif*

S22 TX behavio* N3 chang*

S23 TX behavio* N3 analys*

S24 S18 or S19 or S20 or S21 or S22 or S23

S25 S17 and S24

S26 (MH "Dementia+") or (MH "Dementia, Vascular") or (MH "Delirium, Dementia, Amnestic, Cognitive Disorders") or (MH "Dementia, Multi-Infarct") or (MH "Dementia, Presenile") or (MH "Dementia, Senile")

S27 (MH "Alzheimer's Disease")

S28 (MH "Huntington's Disease")

S29 (MH "Pick Disease of the Brain")

S30 Kluver-Bucy

S31 (MH "Wernicke's Encephalopathy")

S32 (MH "Creutzfeldt-Jakob Syndrome")

S33 TX dement*

S34 TX Alzheimer*

S35 TX lewy* N2 bod*

S36 TX "organic brain disease" or "organic brain syndrome"

S37 TX "supranuclear palsy"

S38 TX pick* N2 disease

S39 TX creutzfeldt or jcd or cjd

S40 TX huntington*

S41 TX binswanger*

S42 TX korsako*

S43 TX arteriosclerosis

S44 TX "cerebr* deteriorat*"

S45 TX "cerebr* insufficien*"

S46 S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45

S47 S25 and S46

S48 TX random*

(Continued)

	S49 TX trial* S50 TX study S51 TX group S52 (MH "Clinical Trials+") S53 S48 or S49 or S50 or S51 or S52 S54 S47 and S53 S55 EM 2010 S56 EM 2011 S57 S55 OR S56 S58 S54 AND S57	
6. Web of Science (1945-present) with conference proceedings	Topic=(Dement* OR Alzheimer* OR "Lewy bod*" OR Huntington* OR "Kluver Bucy" OR "Pick* disease" OR delirium OR "cerebrovascular disorder*" OR "Wernicke encephalopathy" OR "Korsakoff psychosis") AND Topic=(((BPSD OR neuropsychiatr* OR behavio*) AND ("functional analy*" OR "dementia care mapping" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*))))) AND Topic=(random* OR trial* OR "double-blind" OR "crossover" OR "cross-over" OR "cluster rct") AND Year Published=(2010-2011) Timespan=All Years.	235
7. LILACS (BIREME)	Behave$ AND demen$	28
8. CENTRAL (*The Cochrane Library*) (Issue 1 of 4, Jan 2011)	#1 behavio* #2 agitat* #3 aggressi* #4 delusion* #5 hallucinat* #6 anxiety #7 anxious* #8 depress* #9 apath* #10 wandering #11 disinhibit* #12 confused #13 confusion #14 vocal* #15 BPSD #16 neuropsychiatr*	44

(Continued)

#17 (#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)

#18 "functional analy*"

#19 (behavio* and (intervention* or manag* or modif* or chang* or analys*))

#20 (#18 OR #19)

#21 (#17 AND #20)

#22 MeSH descriptor Dementia explode all trees

#23 MeSH descriptor Alzheimer Disease explode all trees

#24 MeSH descriptor Lewy Body Disease explode all trees

#25 dement*

#26 alzheimer*

#27 lewy* adj2 bod*

#28 deliri*

#29 "organic brain disease" or "organic brain syndrome"

#30 "supranuclear palsy"

#31 pick* adj2 disease

#32 creutzfeldt or jcd or cjd

#33 huntington*

#34 binswanger*

#35 korsako*

#36 arterioscerosis

#37 "cerebrovascular disorder*"

#38 "cerebr* deteriorat*"

#39 "cerebr* insufficien*"

#40 (#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 OR #35 OR #36 OR #37 OR #38 OR #39)

#41 (#21 AND #40), from 2010 to 2011

TOTAL before de-duplication	712
TOTAL after de-dupe and first-assess	165

Appendix 2. Second search: April 2010

Source	Search strategy	Hits

(Continued)

MEDLINE In-process and other non-indexed citations and MEDLINE 1950-present (Ovid SP)	1. behavio*.mp. 2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp. 7. anxious*.mp. 8. depress*.mp. 9. apath*.mp. 10. wandering.mp. 11. disinhibit*.mp. 12. confused.mp. 13. confusion.mp. 14. vocal*.mp. 15. BPSD.mp. 16. neuropsychiatr*.mp. 17. or/1-16 18. ("functional analy*" OR “dementia-care map*” OR “person centred care” OR “person centered care”).mp. 19. (behavio* and (intervention* or manag* or modif* or chang* or analys*)).mp. 20. 18 or 19 21. 17 and 20 22. Dementia/ 23. Dementia, Multi-Infarct/ 24. Dementia, Vascular/ 25. Alzheimer Disease/ 26. Lewy Body Disease/ 27. Delirium/ 28. Huntington Disease/ 29. "Pick Disease of the Brain"/ 30. Kluver-Bucy Syndrome/ 31. Wernicke Encephalopathy/ 32. Creutzfeldt-Jakob Syndrome/ 33. Delirium, Dementia, Amnestic, Cognitive Disorders/	389

(Continued)

	34. dement*.mp.	
	35. Alzheimer*.mp.	
	36. (lewy* adj2 bod*).mp.	
	37. deliri*.mp.	
	38. ("organic brain disease" or "organic brain syndrome").mp.	
	39. "supranuclear palsy".mp.	
	40. (pick* adj2 disease).mp.	
	41. (creutzfeldt or jcd or cjd).mp.	
	42. huntington*.mp.	
	43. binswanger*.mp.	
	44. korsako*.mp.	
	45. arteriosclerosis.mp.	
	46. "cerebrovascular disorder*".mp.	
	47. "cerebr* deteriorat*".mp.	
	48. "cerebr* insufficien*".mp.	
	49. or/22-48	
	50. 49 and 21	
	51. randomized controlled trial.pt.	
	52. controlled clinical trial.pt.	
	53. random*.ab.	
	54. placebo.ab.	
	55. trial.ab.	
	56. groups.ab.	
	57. or/51-56	
	58. (animals not (humans and animals)).sh.	
	59. 57 not 58	
	60. 50 and 59	
	61. (200709* or 200710* or 200711* or 200712*).ed.	
	62. 2008*.ed.	
	63. 2009*.ed.	
	64. 2010*.ed.	
	65. or/61-64	
	66. 60 and 65	
EMBASE (Ovid SP)	1. behavio*.mp.	199

(Continued)

1980-2010 week 13	2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp. 7. anxious*.mp. 8. depress*.mp. 9. apath*.mp. 10. wandering.mp. 11. disinhibit*.mp. 12. confused.mp. 13. confusion.mp. 14. vocal*.mp. 15. BPSD.mp. 16. neuropsychiatr*.mp. 17. or/1-16 18. ("functional analy*" OR “dementia care map*” OR “person centered car*” OR “person centred car*”).mp. 19. (behavio* adj3 (intervention* or manag* or modif* or chang* or analys*)).mp. 20. 18 or 19 21. 17 and 20 22. presenile dementia/ or "mixed depression and dementia"/ or semantic dementia/ or frontotemporal dementia/ or senile dementia/ or frontal variant frontotemporal dementia/ or multiinfarct dementia/ or exp dementia/ or Pick presenile dementia/ 23. Alzheimer disease/ 24. diffuse Lewy body disease/ 25. delirium/ 26. Huntington chorea/ 27. Kluver Bucy syndrome/ 28. Wernicke encephalopathy/ 29. Creutzfeldt Jakob disease/ 30. dement*.mp. 31. Alzheimer*.mp. 32. (lewy* adj2 bod*).mp.

(Continued)

	33. deliri*.mp.	
	34. ("organic brain disease" or "organic brain syndrome").mp.	
	35. "supranuclear palsy".mp.	
	36. (pick* adj2 disease).mp.	
	37. (creutzfeldt or jcd or cjd).mp.	
	38. huntington*.mp.	
	39. binswanger*.mp.	
	40. korsako*.mp.	
	41. arteriosclerosis.mp.	
	42. "cerebrovascular disorder*".mp.	
	43. "cerebr* deteriorat*".mp.	
	44. "cerebr* insufficien*".mp.	
	45. or/22-44	
	46. 45 and 21	
	47. randomized controlled trial/	
	48. clinical trial/	
	49. random*.ti,ab.	
	50. trial.ti,ab.	
	51. groups.ab.	
	52. ("treatment as usual" or "treatment as before").mp.	
	53. placebo.ab.	
	54. or/47-53	
	55. 46 and 54	
	56. (2007* or 2008* or 2009* or 2010*).em.	
	57. 55 and 56	
PSYCINFO (Ovid SP) 1806-April week 1 2010	1. behavio*.mp. 2. agitat*.mp. 3. aggressi*.mp. 4. delusion*.mp. 5. hallucinat*.mp. 6. anxiety.mp. 7. anxious*.mp. 8. depress*.mp. 9. apath*.mp.	104

(Continued)

10. wandering.mp.

11. disinhibit*.mp.

12. confused.mp.

13. confusion.mp.

14. vocal*.mp.

15. BPSD.mp.

16. neuropsychiatr*.mp.

17. or/1-16

18. ("functional analy*" OR “dementia care mapping” OR “person centred care” OR “person centered care”).mp.

19. (behavio* adj3 (intervention* or manag* or modif* or chang* or analys*)).mp.

20. 18 or 19

21. 17 and 20

22. exp Dementia/ or exp Senile Dementia/ or exp Presenile Dementia/ or exp Dementia with Lewy Bodies/ or exp Vascular Dementia/

23. exp Alzheimers Disease/

24. exp Dementia with Lewy Bodies/

25. exp Delirium/

26. Huntingtons Disease/

27. Picks Disease/

28. Kluver Bucy Syndrome/

29. Wernickes Syndrome/

30. Creutzfeldt Jakob Syndrome/

31. dement*.mp.

32. Alzheimer*.mp.

33. (lewy* adj2 bod*).mp.

34. deliri*.mp.

35. ("organic brain disease" or "organic brain syndrome").mp.

36. "supranuclear palsy".mp.

37. (pick* adj2 disease).mp.

38. (creutzfeldt or jcd or cjd).mp.

39. huntington*.mp.

40. binswanger*.mp.

41. korsako*.mp.

42. arteriosclerosis.mp.

(Continued)

	43. "cerebrovascular disorder*".mp. 44. "cerebr* deteriorat*".mp. 45. "cerebr* insufficien*".mp. 46. or/22-45 47. 21 and 46 48. random*.ti,ab. 49. trial*.ti,ab. 50. exp Clinical Trials/ 51. groups*.ab. 52. ("treatment as before" or "treatment as usual").mp. 53. "control group".ab. 54. or/48-53 55. 47 and 54 56. (2007* or 2008* or 2009* or 2010*).up. 57. 55 and 56	
CINAHL (EBSCOhost)	S1 TX behavio* S2 TX agitat* S3 TX aggressi* S4 TX delusion* S5 TX hallucinat* S6 TX anxiety S7 TX anxious* S8 TX depress* S9 TX apath* S10 TX wandering S11 TX disinhibit* S12 TX confused S13 TX confusion S14 TX vocal* S15 TX BPSD S16 TX neuropsychiatr* S17 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 S18 TX "functional analy*" OR “dementia care mapping”	251

(Continued)

S19 TX behavio* N3 intervention*

S20 TX behavio* N3 manag*

S21 TX behavio* N3 modif*

S22 TX behavio* N3 chang*

S23 TX behavio* N3 analys*

S24 S18 or S19 or S20 or S21 or S22 or S23

S25 S17 and S24

S26 (MH "Dementia+") or (MH "Dementia, Vascular") or (MH "Delirium, Dementia, Amnestic, Cognitive Disorders") or (MH "Dementia, Multi-Infarct") or (MH "Dementia, Presenile") or (MH "Dementia, Senile")

S27 (MH "Alzheimer's Disease")

S28 (MH "Huntington's Disease")

S29 (MH "Pick Disease of the Brain")

S30 Kluver-Bucy

S31 (MH "Wernicke's Encephalopathy")

S32 (MH "Creutzfeldt-Jakob Syndrome")

S33 TX dement*

S34 TX Alzheimer*

S35 TX lewy* N2 bod*

S36 TX "organic brain disease" or "organic brain syndrome"

S37 TX "supranuclear palsy"

S38 TX pick* N2 disease

S39 TX creutzfeldt or jcd or cjd

S40 TX huntington*

S41 TX binswanger*

S42 TX korsako*

S43 TX arteriosclerosis

S44 TX "cerebr* deteriorat*"

S45 TX "cerebr* insufficien*"

S46 S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45

S47 S25 and S46

S48 TX random*

S49 TX trial*

S50 TX study

S51 TX group

(Continued)

	S52 (MH "Clinical Trials+") S53 S48 or S49 or S50 or S51 or S52 S54 S47 and S53 S55 EM 2007 S56 EM 2008 S57 EM 2009 S58 EM 2010 S59 S55 or S56 or S57 or S58 S60 S54 and S59	
Web of Science with Conference Proceedings (1945 to present)	Topic=((Dementia OR Alzheimer* OR (Lewy body) OR arteriosclerosis OR (Huntington disease) OR (Kluver Bucy) OR (Pick disease) OR delirium OR (cerebrovascular disorder*) OR (Wernicke encephalopathy) OR (Korsakoff psychosis))) AND Topic=(((BPSD OR neuropsychiatr* OR behavio*) AND ("functional analy*" OR "dementia care mapping" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*))))) AND Topic=((random* OR trial* OR "double-blind" OR "crossover" OR "cross-over")) AND Year Published=((2007-2010)) Timespan=2007-2010. Databases=SCI-EXPANDED, CPCI-S	595
LILACS (BIREME)	**(dement$ OR alzheimer$) AND (behavior$ OR agitate$ OR aggressi$ OR delusion$ OR hallucinate$ OR anxiety OR anxious$ OR depress$ OR apath$ OR wandering OR disinhibit$ OR confused OR confusion OR vocal$) OR (BPSD) OR neuropsychiatr$) [Words] and "functional analy$" OR "dementia care map$" OR (behavior$ AND (intervention$ OR manag$ OR modif$ OR chang$ OR analys$) [Words] and 2007 OR 2008 OR 2009 OR 2010 [Country, year publication]**	34
ALOIS (www.medicine.ox.ac.uk/alois)	Advanced search: [Intervention: Contains any word: functional analysis mapping]	1
Umin (Clinical Trial register of Japan) (www.umin.ac.jp/ctr/)	Condition: dementia	8
CENTRAL (*The Cochrane Library*)	#1 behavio* #2 agitat* #3 aggressi* #4 delusion* #5 hallucinat* #6 anxiety #7 anxious* #8 depress* #9 apath* #10 wandering	200

(Continued)

#11 disinhibit*	
#12 confused	
#13 confusion	
#14 vocal*	
#15 BPSD	
#16 neuropsychiatr*	
#17 (#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)	
#18 "functional analy*"	
#19 (behavio* and (intervention* or manag* or modif* or chang* or analys*))	
#20 (#18 OR #19)	
#21 (#17 AND #20)	
#22 MeSH descriptor Dementia explode all trees	
#23 MeSH descriptor Alzheimer Disease explode all trees	
#24 MeSH descriptor Lewy Body Disease explode all trees	
#25 dement*	
#26 alzheimer*	
#27 lewy* adj2 bod*	
#28 deliri*	
#29 "organic brain disease" or "organic brain syndrome"	
#30 "supranuclear palsy"	
#31 pick* adj2 disease	
#32 creutzfeldt or jcd or cjd	
#33 huntington*	
#34 binswanger*	
#35 korsako*	
#36 arterioscerosis	
#37 "cerebrovascular disorder*"	
#38 "cerebr* deteriorat*"	
#39 "cerebr* insufficien*"	
#40 (#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 OR #35 OR #36 OR #37 OR #38 OR #39)	
#41 (#21 AND #40), from 2007 to 2010	
Total	1781

(Continued)

Total after deduplication	1376

Appendix 3. First search: November 2007

Source	Serach strategy	hits
CDCIG Specialized Register (now ALOIS) [searched 17 Nov 2007]	((behavio* OR agitat* OR aggressi* OR delusion* OR hallucinat* OR anxiety OR anxious* OR depress* OR apath* OR wandering OR disinhibit* OR confused OR confusion OR vocal*) OR (BPSD) OR (neuropsychiatr*)) AND ("functional analy*" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*)))	1091
MEDLINE, EMBASE, PSYCINFO, CINAHL (Ovid SP) [searched 15 Nov 2007]	(all terms were searched as: title, abstract, keyword, controlled vocabulary). ((behavio* OR agitat* OR aggressi* OR delusion* OR hallucinat* OR anxiety OR anxious* OR depress* OR apath* OR wandering OR disinhibit* OR confused OR confusion OR vocal*) OR (BPSD) OR (neuropsychiatr*)) AND ("functional analy*" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*))).” AND (((Dementia OR Alzheimer$ OR (Lewy body) OR arteriosclerosis OR (Huntington disease) OR (Kluver Bucy) OR (Pick disease) OR delirium OR (cerebrovascular disorder$) OR (Wernicke encephalopathy) OR (Korsakoff psychosis) OR ((cognit$ or memory$ or mental$) AND (declin$ or impair$ or los$ or deteriorat$)) OR (cerebr$ deteriorat$) OR (cerebr$ insufficien$) AND Phases 1-3 of the Highly sensitive search strategies for identifying reports of randomized controlled trials in Medline (APPENDIX 5b, Cochrane Handbook, 2006), all terms searched as Title, abstract, keyword, Publication type.	128
LILACS (BIREME) [searched 15 Nov 2007]	((behavio* OR agitat* OR aggressi* OR delusion* OR hallucinat* OR anxiety OR anxious* OR depress* OR apath* OR wandering OR disinhibit* OR confused OR confusion OR vocal*) OR (BPSD) OR (neuropsychiatr*)) AND ("functional analy*" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*))).” AND (LILACS search strategy from “Dementia Group Search strategy for Specialized Register ie dementia terms) + trial terms	0
Science Citation index and Social Science Citation index [searched 18 Nov 2007]	TS = ((behavio* OR agitat* OR aggressi* OR delusion* OR hallucinat* OR anxiety OR anxious* OR depress* OR apath* OR wandering OR disinhibit* OR confused OR confusion OR vocal*) OR (BPSD) OR (neuropsychiatr*)) AND ("functional analy*" OR (behavio* AND (intervention* OR manag* OR modif* OR chang* OR analys*))).” AND TS = (((Dementia OR Alzheimer* OR (Lewy body) OR arteriosclerosis OR (Huntington disease) OR (Kluver Bucy) OR (Pick disease) OR delirium OR (cerebrovascular disorder*) OR (Wernicke encephalopathy) OR (Korsakoff psy-	842

(Continued)

	chosis) OR ((cognit* or memory* or mental*) AND (decline* or impair* or los* or deteriorat*)) OR (cerebr* deteriorat*) OR (cerebr* insufficien*) AND TS = (randomized controlled trial*) OR (randomised controlled trial*) OR (controlled clinical trial*) OR placebo* OR crossover OR cross-over OR (double blind*) OR (single blind*)
Total	1884
Total after de-duplication	1570

HISTORY

Protocol first published: Issue 1, 2008
Review first published: Issue 2, 2012

Date	Event	Description
13 April 2010	New search has been performed	A search was performed for this review on 12 April 2010.

CONTRIBUTIONS OF AUTHORS

E M-C - All correspondence; drafting initial protocol and review versions; selection of trials; interpretation of data analyses; updating review.
KS - Extraction, entry and analysis of data; interpretation of data analyses; drafting review versions; liaising with trial and review authors; updating review.

RM - Statistical advice, guidance and extraction of data.

M dV - Drafting initial protocol and review versions; selection of trials; interpretation of data analyses; updating review.
FV - Drafting initial protocol and review versions; selection of trials; interpretation of data analyses; updating review.
IJ - Drafting initial protocol review versions; selection of trials; interpretation of data analyses; updating review.

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DECLARATIONS OF INTEREST

Esme Moniz-Cook

Prof. Moniz-Cook is an author of a study included in the review (Moniz-Cook 2008a).

Esme Moniz-Cook is chief investigator for two ongoing studies- Challenge DemCare Projects - that relate to this review.

Ian James

Ian James is an author of a study included in the review (Fossey 2006). Ian James is co-investigator for two ongoing studies - Challenge DemCare Projects - that relate to this review.

SOURCES OF SUPPORT

Internal sources

- E M-C: Humber Mental Health Teaching NHS Trust & University of Hull, UK.
- M deV : University of Maastricht, Netherlands.
- F V : University of Maastricht, Netherlands.

- I J: Centre for the Health of the Elderly, Newcastle General Hospital, Northumberland, Tyne and Wear NHS Trust, UK.

External sources

- NIHR Programme Grant: 'Management of Challenging Behaviour in dementia at home and in care homes' awarded to authors E M-C and IJ (2007), UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Addition of authors Katie Roberts-Stride and Reem Malouf to the review.

Addition of Banerjee report 2009 and James 2011 to background text.

INDEX TERMS

Medical Subject Headings (MeSH)

Behavior Therapy [*methods]; Caregivers [*education] [psychology]; Conditioning, Operant [physiology]; Dementia [*psychology]; Depression [therapy]; Motivation [physiology]; Randomized Controlled Trials as Topic; Stress, Psychological [therapy]

MeSH check words

Humans