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Validation therapy for dementia.

Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD001394.

DOI: 10.1002/14651858.CD001394.

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Validation therapy for dementia (Review)

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[Intervention Review]

Validation therapy for dementia

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Editorial group: Cochrane Dementia and Cognitive Improvement Group.

Publication status and date: Edited (no change to conclusions), published in Issue 1, 2009.

Review content assessed as up-to-date: 4 August 2005.

Citation: Neal M, Barton Wright P. Validation therapy for dementia. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Art. No.: CD001394. DOI: 10.1002/14651858.CD001394.

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ABSTRACT

Background

Validation therapy was developed by Naomi Feil between 1963 and 1980 for older people with cognitive impairments. Initially, this did not include those with organically-based dementia, but the approach has subsequently been applied in work with people who have a dementia diagnosis. Feil's own approach classifies individuals with cognitive impairment as having one of four stages in a continuum of dementia: these stages are Mal orientation, Time Confusion, Repetitive Motion and Vegetation. The therapy is based on the general principle of validation, the acceptance of the reality and personal truth of another's experience, and incorporates a range of specific techniques. Validation therapy has attracted a good deal of criticism from researchers who dispute the evidence for some of the beliefs and values of validation therapy, and the appropriateness of the techniques. Feil, however, argues strongly for the effectiveness of validation therapy.

Objectives

To evaluate the effectiveness of validation therapy for people diagnosed as having dementia of any type, or cognitive impairment

Search methods

The trials were identified from the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group (CDCIG) on 5 August 2005 using the terms validation therapy, VTD and emotion-oriented care. The Specialized Register at that time contained records from the following databases: MEDLINE, EMBASE, CINAHL, PSYCLIT, and SIGLE plus many ongoing trials databases.

Selection criteria

All randomised controlled trials (RCTs) examining validation therapy as an intervention for dementia were considered for inclusion in the review. The criteria for inclusion comprised systematic assessment of the quality of study design and the risk of bias.

Data collection and analysis

Data were extracted independently by both reviewers. Authors were contacted for data not provided in the papers. Psychological scales measuring cognition, behaviour, emotional state and activities of daily living were examined.

Validation therapy for dementia (Review)

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Main results

Three studies were identified that met the inclusion criteria (Peoples 1982; Robb 1986; Toseland 1997) incorporating data on a total of 116 patients (42 in experimental groups, and 74 in the control groups (usual care 43 and social contact 21, 10 in reality orientation). It was not possible to pool the data from the 3 included studies, either because of the different lengths of treatment or choice of different control treatments, or because the outcome measures were not comparable.

Two significant results were found:

Peoples 1982 - Validation versus usual care. Behaviour at 6 weeks [MD -5.97, 95% CI (-9.43 to -2.51) P=0.0007, completers analysis] favours validation therapy.

Toseland 1997 - Validation versus social contact. Depression at 12 months (MOSES) [MD -4.01, 95% CI (-7.74 to -0.28) P=0.04, completers analysis] favours validation. There were no statistically significant differences between validation and social contact or between validation and usual therapy. There were no assessments of carers.

Authors' conclusions

There is insufficient evidence from randomised trials to allow any conclusion about the efficacy of validation therapy for people with dementia or cognitive impairment.

PLAIN LANGUAGE SUMMARY

No new evidence of the efficacy of validation therapy for people with dementia or cognitive impairment has been identified. The new study identified Schrijnemaekers 2002 was excluded because it was not deemed to be validation therapy.

Validation therapy is based on the general principle of validation, the acceptance of the reality and personal truth of another's experience. The specific interventions and techniques used within the validation approach bring together behavioural and psychotherapeutic methods to meet the needs of individuals with different stages of dementia. Three studies were identified that met the inclusion criteria. It was not possible to pool the data from the 3 included studies, either because of the different lengths of treatment or choice of different control treatments, or because the outcome measures were not comparable. Two significant results were found but there were no statistically significant differences between validation and social contact or between validation and usual therapy. There were no assessments of carers. All in all there is insufficient evidence from randomised trials to allow any conclusion about the efficacy of validation therapy for people with dementia or cognitive impairment.

BACKGROUND

Validation therapy is described by Feil 1993 as a discrete form of "therapy for communicating with old people who are diagnosed as having Alzheimer's disease and related dementia", which can be clearly distinguished from other types of intervention. Feil's Validation Institute trains and accredits therapists wishing to practice validation therapy.

Validation, as a general term, can be defined as the acceptance of the reality and personal truth of another's experience. This, in itself, is a central element of all humanistically-oriented therapies, and a key aspect of person-centred approaches to dementia care. Validation, in this general sense, can be considered as a kind of

philosophy of care. Within a person-centred approach (Kitwood 1997), validation is identified as providing a high degree of empathy and an attempt to understand a person's entire frame of reference, however disturbed that might be. It is therefore important to try to distinguish between the concept of validation in general and the specific application within validation therapy.

The validation therapy approach was developed by Naomi Feil between 1963 and 1980 (Feil 1982; Feil 1993) in an attempt to address the shortcomings of other approaches, such as reality orientation, used with individuals who have more advanced dementia. Feil developed a model that sought to classify the stage of dementia that an individual has reached according to cognitive and behavioural signs. Its development was the result of an attempt to

provide practical solutions for difficulties experienced by patients and caregivers; it was not developed from a theoretical basis in the way that some other newer psychological therapies have been developed.

Important features of validation therapy are said to include: a means of classifying behaviours; provision of simple, practical techniques that help restore dignity; prevention of deterioration into a vegetative state; provision of an empathic listener; respect and empathy for older adults with Alzheimer's type dementia, who are struggling to resolve unfinished business before they die; and acceptance of the person's reality (Feil 1993). These features are not, however, unique to validation. Feil 1993 identifies a number of beliefs and values that underlie the validation approach, although again many of these are shared by other person-centred approaches:

1. All people are unique and must be treated as individuals.
2. All people are valuable, no matter how disorientated they are.
3. There is reason behind the behaviour of disorientated older people.
4. Behaviour in old age is not merely a function of anatomical changes in the brain, but reflects a combination of physical, social and psychological changes that take place over the life span.
5. Old people cannot be forced to change their behaviours. Behaviours can be changed only if the person wants to change them.
6. Old people must be accepted non-judgementally.
7. Particular life tasks are associated with each stage of life. Failure to complete a task at the appropriate stage of life may lead to psychological problems.
8. When more recent memory fails, older adults try to restore balance to their lives by retrieving earlier memories. When eyesight fails, they use their mind's eye to see. When hearing goes, they listen to sounds from the past.
9. Painful feelings that are expressed, acknowledged, and validated by a trusted listener will diminish. Painful feelings that are ignored or suppressed will gain strength.
10. Empathy builds trust, reduces anxiety, and restores dignity.

The way in which these values are applied to provide specific interventions depends on the severity of dementia in each individual case. Feil has taken an idiosyncratic approach to the diagnosis, classification and staging of dementia and this does not map directly onto medical classification systems. Indeed, early work by Feil stated that validation therapy was not applicable to organic dementia (see Stokes 1990), although she later included Alzheimer's disease within the remit of validation. Feil classifies individuals with cognitive impairment as reflecting one of four stages in a continuum of dementia: these stages are Mal orientation, Time Confusion, Repetitive Motion and Vegetation. Each stage is identified

by specific cognitive and behavioural characteristics. Specific validation therapy interventions address the different cognitive and behavioural features manifested by people with dementia at each of these stages.

The specific interventions and techniques used within the validation approach are based on a synthesis of behavioural and psychotherapeutic methods. The approach was developed through a process of adopting interventions from a variety of sources, to meet the needs of individuals with different stages of dementia. Feil 1982 initially identified the group who most required an alternative approach as being those individuals who were over 85; she described these individuals as the "old - old". Over recent years the approach has been applied to younger individuals with dementia and the term "old - old" is no longer in use in this context. The approach can be used as a structured therapeutic activity in a group setting, running usually for several weeks, or it can be used on an individual basis as part of an ongoing approach to facilitate communication, so supplementing group work.

Validation therapy has at its centre 14 techniques (Feil 1993):

1. Centring in order to focus upon the individual who is to be validated.
2. The use of non-threatening factual words to build trust. These include words such as "who", "what", "where", "when", and "how" - but not the word "why".
3. Rephrasing the person's speech to them.
4. Using polarity - asking the person to think about the most extreme example of their complaint.
5. Imagining the opposite.
6. Reminiscing.
7. Maintaining genuine, close eye contact.
8. Using ambiguity, as in the use of non-specific pronouns such as "they", "he", "she", or "it", in order to respond to the demented person's conversation when they are using non-dictionary words or when what they are saying is not understood.
9. Using a clear, low, loving tone of voice.
10. Observing and matching the person's motions and emotions in order to create trust and establish verbal and non-verbal relationships.
11. Linking behaviour to the unmet human need.
12. Identifying and using the person's preferred sense.
13. Touching - noting that people in the first stage, mal orientation, do not respond well to being touched.
14. Using music in order to trigger early memories and thoughts.

Full explanations of these techniques are given by Naomi Feil (Feil 1993). However, the extent to which some of the techniques are directly relevant to, and appropriate for, the subjective experience of people with dementia has been questioned (e.g. Goudie 1989). In a thorough and critical review of validation therapy Morton described both the theory and the techniques of validation therapy as dubious in formulation and utility (Morton 1999). He also comments on the fact that some of the psychotherapeutic approaches that are adopted within validation are theoretically incompatible. Goudie 1989 similarly find the theory incoherent and unconvincing. They dispute the evidence for some of the beliefs and values of validation therapy, and are critical of the techniques. Nevertheless, the development of the validation approach has been described by some as putting its creator into the 'forefront of the focus on the experience of dementia' (Morton 1997), and others have viewed it as another means to address the 'paucity of nurse-patient interaction' in dementia care (Miller 1995).

Various observational studies have indicated that there are positive effects in using validation therapy in terms of the amount and duration of interactions that participants are able to make during validation groups (Bleathman 1996; Babins 1998). However, other studies (Scanland 1993; Buxton 1996) have found no significant effects of validation therapy.

Feil 1993 argues strongly for the benefits of validation therapy. She sees the benefits for people with dementia as including:

1. restoration of self worth.
2. reduction of the need for chemical and physical restraints.
3. minimization of the degree to which patients withdraw from the outside world.
4. promotion of communication and interaction with other people.
5. reduction of stress and anxiety.
6. stimulation of dormant potential.
7. help in resolving unfinished life tasks.
8. facilitation of independent living for as long as possible.

Possible benefits for families are said to include reduced frustration with their relative, more effective communication, relief in terms of the improvement made by their relative in relation to speech and social functioning, increased visiting, and increased awareness of their own ageing process. Possible benefits for professional caregivers are said to include reduction in frustration, prevention of burn-out, promotion of joy in communicating and increased job satisfaction (Feil 1993). A systematic review of non-randomised studies (Neal 1994) noted that there might potentially be other, more indirect benefits from validation therapy for both patients and staff; for example, validation therapy might help to promote a person-centred approach, thereby improving patient care. Such

benefits would, of course, be highly desirable, but there is a need to demonstrate their presence on the basis of rigorous research yielding strong evidence across a number of well-designed studies.

OBJECTIVES

To determine the efficacy of validation therapy, offered in group or individual format, as an intervention for patients with dementia or cognitive impairment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials were included.

Types of participants

Older people (aged over 65 years) diagnosed with Alzheimer's disease, dementia or other forms of cognitive impairment, according to ICD 10, DSM IV or comparable criteria.

Types of interventions

For the purpose of this review it was decided to examine all studies that reported on the effectiveness of validation therapy as a specific form of psychosocial intervention for people with dementia.

Validation therapy was defined as follows:

- a) Any activity specified as validation therapy that makes reference to, and draws upon the framework identified by Naomi Feil (Feil 1993).
- b) Group programmes with an identified structure using the framework identified in Feil 1982.
- c) Individual validation therapy comprising the intervention techniques identified by Feil 1982, Feil 1993.
- d) Interventions must have a clearly defined time period for which they are to be evaluated, with groups taking place at least once a week.

Control Groups were specified as:

- a) Usual care with no additional activity.
- b) Any activity that differs in content and approach from validation therapy but is additional to usual care; examples include reminiscence groups, reality orientation groups, or social contact groups that do not use the techniques identified as validation.

Types of outcome measures

Outcomes measured were cognition, behaviour, emotional state and activities of daily living. Outcomes of interest include outcomes for both patient and carer.

Search methods for identification of studies

The trials were identified from a search of the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group on 5 August 2005 using the search terms “validation therapy”, VTD, “emotion-oriented therapy”.

The Specialized Register at that time contained records from the following databases:

- CENTRAL: January 2005 (issue 1);
- MEDLINE: 1966 to 2005/02;
- EMBASE: 1980 to 2005/01;
- PsycINFO: 1887 to 2005/01;
- CINAHL: 1982 to 2004/12;
- SIGLE (Grey Literature in Europe): 1980 to 2004/06;
- ISTP (Index to Scientific and Technical Proceedings): to May 2000;
- INSIDE (BL database of Conference Proceedings and Journals): to June 2000;
- Aslib Index to Theses (UK and Ireland theses): 1970 to March 2003;
- Dissertation Abstract (USA): 1861 to March 2003;
- <http://clinicalstudies.info.nih.gov/>;
- National Research Register (issue 2/2005)
- ClinicalTrials.gov: last searched June 2005;
- LILACS: Latin American and Caribbean Health Science Literature: last searched April 2003
- <http://www.forestclinicaltrials.com/CTR/CTRController/CTRHome>: last searched 2 July 2005
- ClinicalStudyResults.org: last searched 1 July 2005
- <http://www.lillytrials.com/index.shtml>: last searched 30 June 2005
- ISRCTN Register: last searched 2 July 2005

The search strategies used to identify relevant records in MEDLINE, EMBASE, PsycINFO, CINAHL and Lilacs can be found in the Group’s module.

Personal contact was made with Naomi Feil at the Validation Institute in the USA and the Validation Institute in Europe.

The reference lists of all papers were searched for further references, and reviewers searched personal holdings of references to reports and trials.

Data collection and analysis

SELECTION OF TRIALS

Reports with titles indicating a possible trial were obtained. The reviewers (MN and PBW) independently reviewed trials and identified those that met the criteria for inclusion. One reviewer rejected all non-relevant reports from the search yields and retained any that were of possible relevance for consideration by the second reviewer. These were then selected or rejected from further consideration, independently by both reviewers, on the basis of study methodology quality criteria designed to assess concealment, blinding and possible bias.

DATA EXTRACTION

Data were extracted from the published reports where possible. When additional data were required, we asked the authors for the relevant information. The summary statistics required 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. Where changes from baseline were not reported, the mean, standard deviation and the number of patients for each treatment group at each time point were extracted.

For each outcome measure, data were sought on every patient assessed. 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 publications, “on-treatment” data of those who completed the trial were extracted and indicated as such.

DATA ANALYSIS

- Outcome measures that are not validated and have not been published were not included as these may be a source of bias. The outcomes measured in clinical trials of dementia and cognitive impairment often arise from ordinal rating scales. Where the rating scales used in the trials had a reasonably large number of categories (more than 10) the data were treated as continuous outcomes arising from a normal distribution.

- Summary statistics (n, mean and standard deviation) were required for each rating scale at each assessment time for each treatment group in each trial for change from baseline. When change from baseline results were not reported, the required summary statistics were calculated from the baseline and assessment time treatment group means and standard deviations. In this case a zero correlation between the measurements at baseline and assessment time was assumed. This method overestimates the standard deviation of the change from baseline, but this conservative approach is considered to be preferable in a meta-analysis.

- Meta-analysis requires the combination of data from the trials that may not use the same rating scale to assess an outcome. The measure of the treatment difference for any outcome would be the weighted mean difference when the pooled trials use the same rating scale or test, and the standardised mean difference, which is the absolute mean difference divided by the pooled standard deviation, when they used different rating scales or tests.

- The duration of the trials may vary considerably. If the range was considered too great to combine all trials into one meta-analysis, it was decided that small time periods would be defined and a separate meta-analysis conducted for each period.
- Overall estimates of the treatment difference are presented.

ASSESSMENT OF QUALITY

Descriptive characteristics (such as quality of randomization, likelihood of bias and blinding) were recorded independently by the two reviewers.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Three studies met the criteria for inclusion. The studies varied in patient characteristics, length of individual validation sessions, number of sessions and duration, nature of the activities defined as validation therapy, the nature of the control condition, and outcome measures. These factors are considered below in turn.

1) STUDY SETTING

Peoples 1982: 225 bed nursing home in a midwestern metropolitan area of the USA.

Robb 1986: 400 bed long term care institution in the USA.

Toseland 1997: four "skilled-care nursing homes" in the USA where average staff to patient ratio was 1:6.7 (range being 1:5.5 to 1:7.3). All four homes were assessed prior to the study using the Sheltered Care Environment Scale (SCES) (**Lemke 1987**), and showed no significant heterogeneity using MANOVA.

2) PATIENT CHARACTERISTICS

Peoples 1982: Patients were over the age of 80 years. The majority of patients were female, widowed, and aged between 81 - 97. Validation group mean age 87 (10 females), reality orientation group mean age 87 (5 female and 3 male), control group mean age 89 (8 female and 3 male). Physical and mental problems were almost evenly distributed amongst the sample groups. Patients were found to be at stages 2 and 3 of Feil's assessment model (**Feil 1982**).

Robb 1986: All residents who were (a) 60 years and older, (b) unlikely to be discharged within the next six months, (c) moderately to severely disorientated, with a dementia diagnosis (but not due to neurological disorders such as Alzheimer's disease, Pick's disease or Huntington's chorea, or cerebrovascular accident within the past six months). Treatment group mean age 80, average length of stay 3.8 years. Control group mean age 81, average length of stay 2.8 years. Patients were selected for the trial by physicians and

head nurses. Out of 398 potential patients 60 were selected, and of these 36 met the criteria for inclusion. All participants were male. **Toseland 1997:** The Short Portable Mental Status Questionnaire (SPMSQ) and the Validation Screening Instrument (VSI) were used to screen patients, who had to display at least a moderate level of dementia, and who also displayed problem behaviours such as physical aggression, verbally abusive behaviours, disruptive vocalisations or motor restlessness. The typical participant was a white female aged 88 years old who had resided in the nursing home for more than 2 years. All three intervention groups had these characteristics.

2) LENGTH AND TYPE OF DURATION OF SESSIONS

Validation therapy group:

Peoples 1982: Two groups with patients assigned randomly, meeting for 30 minutes every weekday morning for 6 weeks.

Robb 1986: twice a week from September to May.

Toseland 1997: 30 minutes, 4 times a week for 52 weeks.

Control group

Peoples 1982: Two control groups: 1) reality orientation group meeting for 30 minutes every weekday afternoon for 6 weeks; 2) usual care.

Robb 1986: Usual care.

Toseland 1997: Two control groups 1) social contact group: 30 minutes, 4 times a week for 52 weeks. 2) Usual care.

3) ACTIVITIES DURING VALIDATION THERAPY

Peoples 1982: The identification of a group leader, song leader or hostess. Discussion on a topic that was previously agreed, singing and movement activity, a closing ritual followed by refreshments. Group work followed the suggested format by **Feil 1982**.

Robb 1986: Not described

Toseland 1997: Groups split into 4 sessions 5-10 minutes long. Session 1. introductions, greetings and singing a song. Session 2. Interaction about a topic of interest, reminiscing encouraged. Session 3. Programme activity, singing or poetry. Session 4. Refreshments and individual good byes.

Throughout the groups, validation therapy techniques, as described in **Feil 1993**, were used, including: non threatening, simple concrete words; speaking in a clear, low, empathic tone of voice; rephrasing and paraphrasing unclear verbal communication; responding to meanings in explicit and implicit verbal and non-verbal communications; and mirroring verbal and non-verbal communications.

4) ACTIVITIES DURING CONTROL GROUPS

Peoples 1982: 1) Reality orientation groups followed a classroom format to facilitate comparison with the validation group. The group followed the guidance of a reality orientation manual. Cues such as flannel boards and calendars were used to promote orientation. The therapist used a guiding approach, and discussion arose when topics were introduced by the patients, the primary focus of responses being to reorientate patients to the present time and place. 2) no treatment or special attention.

Robb 1986: Usual care only.

Toseland 1997: 1) Social contact group. One activity each meeting from the Ringel Institute of Gerontology; activities included music, art, literature, and writing, dance/exercise, games/trivia, holiday and event planning, discussion and other activities. 2) Usual care.

5) OUTCOME MEASURES

- Measures of cognition

Peoples 1982: Tool for Assessing Degree of Confusion in the Elderly (RO Guide 1974). Behaviour Assessment Tool (Feil 1982 and Peoples 1982) Reduction in score = improvement. Ego Integration Tool (Peoples 1982). Locally developed tool without validation; not included in the meta-analysis.

Robb 1986: Mental Status Questionnaire (MSQ; Fishback 1977). Reduction in score = improvement .

Toseland 1997: Mental status - Multi Observational Scale for Elderly Subjects (MOSES; Pruchero 1988). Increase in score = improvement.

- Measures of behaviour

Peoples 1982: Behaviour Assessment Tool (Feil 1982 and Peoples 1982). Reduction in score = improvement.

Robb 1986: Minimal Social Behaviour Scale (MSBS; Farina 1957). Reduction in score = improvement.

Toseland 1997: Cohen Mansfield Agitation Inventory (CMAI; Cohen-Mansfield 1986), carried out as CMAI(N) nurse observed and CMAI(O) non participant observer. Reduction in score = improvement. Geriatric Indices of Positive Behaviour (GIPB). Developed for the study; not used for this review as it lacked validation.

- Measures of emotional state

Toseland 1997: MOSES (as above).

- Measures of activities of daily living

Toseland 1997: MOSES (as above).

Risk of bias in included studies

SELECTION BIAS

Peoples 1982: Randomization was achieved by matching the last two digits of patient number with a table of random numbers.

Toseland 1997: Randomization by an external party not included in the research process.

Robb 1986: Method of randomization unclear.

PERFORMANCE BIAS

With psychological interventions, unlike drug trials, it is impossible to blind patients and staff totally to treatment. Patients will often be aware that they are being treated preferentially, staff involved may have different expectations of treatment groups, and independent assessors may be given clues from patients during the assessments. There may also be contamination between groups, in terms of groups not being held in separate rooms and staff bringing ideas from one group to another. The latter effect can be reduced

to some extent with clear therapeutic protocols (Spector 1999 - b).

The following information was given:

Peoples 1982: Different individuals administered the different therapies. The researcher who administered the validation therapy had previously worked with and undertaken supervised training by Naomi Feil. The person who administered the reality orientation was prepared through the use of literature and through participating in reality orientation groups in other homes.

Robb 1986: Groups were held in a centralized location within the building. No information is provided about who carried out the interventions except that they were salaried nurses and social work staff from the unit. This could have resulted in cross-contamination between the groups.

Toseland 1997: Validation therapy and social contact groups were not conducted on the residential units. Nursing staff were not made aware of which intervention the allocated residents were receiving. End of study monitoring occurred to establish whether the residential staff were able to identify which intervention the residents had been allocated to; they were not able to do so. Non-participant observers were also kept blind to the interventions that the residents were receiving. Validation and social contact group leaders were different, both received additional training. The validation group leaders all received training from Naomi Feil for 4 days, and they were all graduates who had experience of working in residential settings for people with dementia. Each leader received weekly telephone and monthly supervision from the project director. Internal threats to integrity of the study were checked by the random selection of taped recordings of group material to ensure treatment integrity. Social contact group leaders had similar backgrounds and education to the validation group leadership. Social contact leaders were not trained in the use of validation therapy. They received instruction in the use of a social contact manual from the Ringel Institute of Gerontology with specific activities outlined within it. They also received weekly telephone and monthly supervision from the project director. Internal threats to integrity of the study were checked by the random selection of taped recordings of group material to ensure treatment integrity. All study participants continued to participate in the regular social recreational programmes offered within each residential home. A group leader from the validation and social contact groups was allocated to each of the nursing homes.

3) ATTRITION BIAS

Peoples 1982: Reality Orientation group: 2 members dropped out during the study; no data for these individuals were available.

Robb 1986: Control group: 4 out of 16 dropped out. None dropped out thereafter, leaving 12 at post-treatment scoring. Experimental group: 5 dropped out of 20 , thereafter 6 out of the remaining 15 dropped out, 5 due to episodic illness and 1 due to disruptive behaviour during the sessions, leaving 9 at post-treatment scoring. Overall attrition was 9 out of 36; 8 died and 1 had an acute illness. The high death rate of this group indicates that the

patients may have had physical illnesses in addition to dementia. [Toseland 1997](#): 22 out of 88 dropped out. Of these, 18 died, 2 withdrew due to ill health, 2 refused to continue. Validation therapy group: 8 out of 31 dropped out, leaving 23 at post-treatment scoring. Social contact group: 8 out of 29 dropped out, leaving 21 at post-treatment scoring. Usual care group: 6 out of 28 dropped out, leaving 22 at post-treatment scoring.

4) DETECTION BIAS

[Peoples 1982](#): Assessment was completed by the researcher.

[Robb 1986](#): No information was given about who did the pre- or post-test assessments.

[Toseland et al 1997](#): Assessments were made by the residential nursing staff (CMAI-N) and non-participant observers (CMAI-O); all were said to be blinded to the interventions participants had received. It is reported that following the validation and social contact groups participants were often left waiting for up to 15 minutes before being observed again by the nurses and non-participant observers.

Effects of interventions

Most data were derived from sub-scales of the outcome measures. A total of 116 subjects was included, 42 in the experimental and 74 in the control groups. No data were pooled in meta-analyses. [Toseland 1997](#) provided data not previously published. Outcome evaluations focused solely on patients; outcomes for carers were not reported in any study.

- **BEHAVIOUR**: With the exception of behaviour measured at six weeks in the [Peoples 1982](#) study, there were no statistically significant treatment effects for validation therapy compared with usual care or for validation compared with reality orientation, or compared with social contact. [Peoples 1982](#): Validation versus usual care. Behaviour at 6 weeks [MD -5.97, 95% CI (-9.43 to -2.51) P=0.0007, completers analysis] favours validation therapy.

- **COGNITION**: There were no statistically significant differences for validation versus social contact, versus usual therapy or versus reality orientation.

- **EMOTIONAL STATE**: With the exception of depression measured at 12 months in the [Toseland 1997](#) study, there were no significant differences between validation compared with social contact or compared with usual care. [Toseland 1997](#) - Validation versus social contact. Depression at 12 months (MOSES) [MD -4.01, 95% CI (-7.74 to -0.28) P=0.04, completers analysis] favours validation.

- **ACTIVITIES OF DAILY LIVING**: There were no statistically significant differences between validation and social contact or between validation and usual therapy.

There is little information available on the effectiveness of validation therapy. Literature searches revealed only three small randomized trials, with a total of 113 subjects, that were suitable for inclusion. The small numbers in these trials and the inappropriateness of meta-analysis resulted in poor power to detect any effects of this intervention. The limited amount of information available from RCTs means that it is not possible to draw firm conclusions regarding the effectiveness or ineffectiveness of validation therapy. From the analyses that could be undertaken, there were no statistically significant results with the exception of the behavioural improvements identified by [Peoples 1982](#) for validation therapy compared with usual care and a benefit for depression in favour of validation therapy compared with social contact, though not usual therapy, in [Toseland 1997](#).

In relation to these findings, a number of methodological issues warrant further consideration.

- Firstly, there is a lack of clarity in some cases about whether the participants did in fact have dementia, or were experiencing difficulties for other reasons such as physical health problems or excess disability resulting from the effects of institutionalisation. This may relate to the idiosyncratic approach to understanding and classifying dementia adopted by Feil and discussed above. The resulting heterogeneity is likely to make comparisons difficult.

- Secondly, the selection of outcome measures reflects an evaluation of change in limited domains, primarily restricted to participants' cognitive and behavioural functioning, and failing to address any possible impact on caregivers. Other domains that might be relevant, but were not addressed by these studies, include participant and carer well-being and quality of life.

- Thirdly, a number of questions arise regarding the precise nature of the interventions classified here as validation therapy. This is particularly so with respect to [Robb 1986](#), as no description of the intervention is provided and there is no discussion of ways in which therapist adherence to the protocol was monitored. [Pretczynski 1991](#) noted that in their study some staff perceived validation as emotionally demanding, and were unwilling to undertake all the elements of the therapy; if staff do not maintain fidelity to the validation model, this could vitiate attempts at evaluating the efficacy of the therapy. Furthermore, in the absence of clearly-described intervention protocols, it remains unclear whether any observed benefits can be ascribed to those elements and techniques that are specific to validation therapy, or simply result from a broad orientation towards validation, as might be found in the context of person-centred care more generally ([Stokes 1990](#)). Even when there are appropriately prescribed protocols, as in the [Toseland 1997](#) study, the results for non-participant observers conflict with those of participant observers, making interpretation difficult. The constraints that these methodological issues place on

DISCUSSION

interpretation of findings from the included studies are fully acknowledged, in particular by [Robb 1986](#).

The identification and review of the [Schrijnemaekers 2002](#) has not led to any further evidence being identified that demonstrates the effectiveness of validation therapy. The emergence of approaches that combine other approaches may result in requiring extra additional training thereby making the treatment more costly to implement.

Overall, therefore, significant criticisms of the theory and techniques of validation therapy remain to be addressed, and the evidence regarding the effectiveness of validation therapy remains limited and inconclusive.

AUTHORS' CONCLUSIONS

Implications for practice

In the absence of any new large scale trials there is insufficient evidence from randomized trials to draw any reliable conclusions about the efficacy of validation therapy. The inclusion of the [Peoples 1982](#) study shows there may be some positive behavioural benefits from validation, but there remains insufficient evidence for any benefit from an institutional adoption of validation techniques. This is also the position with regard to the evaluation of validation carried out on a one-to-one basis. The potential benefits that have been reported by proponents of the approach might simply reflect changes resulting from any structured group activity or from extra attention given to individuals. The emergence of new approaches that incorporate validation therapy only seek to make decisions about care delivery more complex. The taking of the best elements from multiple approaches may be counter intuitive, as the interventions become more complex to deliver, and clarity as to which elements result in positive outcomes becomes lost.

Implications for research

Any further research on validation therapy must seek to address the

methodological limitations identified in evaluating existing studies, and aim to demonstrate clearly whether any benefits observed can be attributed to the specific nature of the therapy. To date, the randomized studies have focused on a limited range of patient outcomes, and any future research should also seek to evaluate a wider range of participant and caregiver outcomes, including effects on well-being and quality of life, as well as considering the effects on care staff of using this approach.

The use of emergent therapies based upon or incorporating validation therapy provides methodological challenges for further establishing the effectiveness of validation therapy as a discrete intervention. This is compounded when interventions, such as reminiscence therapy are combined with validation to produce new approaches, such as Emotion-Orientated care.

ACKNOWLEDGEMENTS

The reviewers would like to thank the following for their help and co-operation in the process of preparing the initial version of this review:

Naomi Feil, Executive Director of the Validation Training Institute, Cleveland, Ohio, USA

Aimee Spector, Research Fellow, Department of Psychiatry and Behavioural Sciences, University College London

Phillip McCallion, Assistant Professor, Ringel Institute of Gerontology, University at Albany, New York, USA

Professor RW Toseland, Director, Ringel Institute of Gerontology, University at Albany, New York, USA

JP Wattis, Medical Director and Consultant Psychiatrist in Old Age Psychiatry, Leeds Community and Mental Health Services NHS Trust, UK

B Thirkettle, Centre for The Analysis of Nursing Practice, Leeds Community and Mental Health Services NHS Trust and Leeds Metropolitan University, Leeds, UK

Caroline Marshall, CDCIG consumer editor, UK

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Peoples 1982

Methods	Randomized study
Participants	Residents of a 225 bed nursing home in large midwestern metropolitan area USA (31 patients participated, 29 completed). Stage 2 and stage 3 patients utilising Feils criteria
Interventions	Validation Therapy 29 -30 minute weekday sessions over 6 weeks less 1 national holiday Reality Orientation Group 29 - 30 minute week day sessions over 6 weeks less 1 national holiday Usual Care without either of the above interventions
Outcomes	Behaviour Assessment Tool (BAT) Tool for Assessing the Degree of Confusion in the elderly (TADCE)
Notes	Ego integrity was measured using an un validated tool.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Robb 1986

Methods	Single-blind, parallel group, randomized, controlled trial
Participants	Residents of a 400 bed large Veterans Administration medical centre, 36 patients recruited with moderate to severe disorientation and 25 had a diagnosis indicative of dementia. mean age 80.5 years 27 patients completed study (12 control and 9 experiment - 6 partial completion dropped out of the experimental group) Exclusion criteria: Alzheimer's disease, Pick's disease. Huntingdon's chorea, or cerebrovascular accident within last 6 months
Interventions	Validation therapy twice a week for 9 months. Control group received usual treatment e.g. medication
Outcomes	Mental status (MSQ) Morale (PGCMS) Social behaviour (MSBS)
Notes	Analysis by intention-to-treat was done for the partially-treated experimental group including the six participants who dropped out from the experimental group. However this was noted to significantly influence the outcomes for those individuals who had received the full programme, in particular Morale. The issue of the degree of randomization was felt to be unclear. Therefore data is presented without the

Robb 1986 (Continued)

	dropouts included	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Toseland 1997

Methods	Single-blind, parallel group, randomized, controlled study	
Participants	88 patients from 4 nursing homes, diagnosed with at least moderate dementia and with problem behaviours. mean age 87.6 (6.6) years. 66 female 22 male	
Interventions	Validation Therapy four 30 minute meetings per week for 52 weeks Social Care four 30 minute meetings per week for 52 weeks Usual Care	
Outcomes	Cohen Mansfield Agitation Inventory CMAI Multi dimensional Observational Scale for Elderly Subjects MOSES Geriatric Indices of Positive Behaviour GIPB reduced agitation reduced aggression increased sociability Minimum data Set - Resident Assessment Protocol MDS RAP GIPB	
Notes	Non participant observers used CMAI - O to observe Agitation Participant observers used CMAI - N to observe Agitation	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Alprins 1980	
Babins 1988	Concept Analysis
Babins 1998	Study not randomized, case control design
Bleathman 1988	Single Case Experiment design (Pilot Study only), no randomization
Buxton 1996	Not randomized
Canon 1996	Cohort Study, not randomized
Doyle 1992	Qualitative study, not randomized
Dye 1999	Qualitative with case control arm
Esperanza 1987	Not randomized
Feil 1972	Before and after study; no randomization
Fine 1995	Quasi experimental design, no randomization
Fritz 1986	Before and after trial, no randomization
Harris 1995	Single Case Experiment
Morton 1991	Single Case Experiment
Neal 1994	Qualitative Study, not randomized
Pretczynski 1991	Before and after trial, no randomization.
Scanland 1993	Not randomized
Schrijnemaekers 2002	Intervention was not validation therapy - combined with reminiscence therapy
Sharp 1989	Before and after trial
Snow 1990	No randomization

DATA AND ANALYSES

Comparison 1. Validation versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cognition	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Disorientation at 12 months (MOSES)	1	45	Mean Difference (IV, Fixed, 95% CI)	3.04 [-1.37, 7.45]
1.2 Mental Status at 9 months (MSQ)	1	21	Mean Difference (IV, Fixed, 95% CI)	-1.8 [-7.82, 4.22]
1.3 Orientation at 6 weeks (TADCE)	1	21	Mean Difference (IV, Fixed, 95% CI)	-1.22 [-3.92, 1.48]
2 Behaviour	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Irritation at 12 months (MOSES)	1	45	Mean Difference (IV, Fixed, 95% CI)	-0.69 [-2.66, 1.28]
2.2 Social behaviour at 9 months (MSBS)	1	21	Mean Difference (IV, Fixed, 95% CI)	-1.10 [-8.07, 5.87]
2.3 Withdrawal at 12 months (MOSES)	1	45	Mean Difference (IV, Fixed, 95% CI)	-0.58 [-3.93, 2.77]
2.4 Verbally agitated behaviour at 12 months (CMAI-O)	1	45	Mean Difference (IV, Fixed, 95% CI)	3.92 [-2.17, 10.01]
2.5 Verbally agitated behaviour at 12 months (CMAI-N)	1	45	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.38, 0.16]
2.6 Physically non aggressive behaviour at 12 months (CMAI-O)	1	45	Mean Difference (IV, Fixed, 95% CI)	0.61 [-2.05, 3.27]
2.7 Physically non aggressive behaviour at 12 months (CMAI-N)	1	45	Mean Difference (IV, Fixed, 95% CI)	0.1 [-0.10, 0.30]
2.8 Behaviour at 6 weeks (BAT)	1	21	Mean Difference (IV, Fixed, 95% CI)	-5.97 [-9.43, -2.51]
2.9 Aggressive behaviour at 12 months (CMAI -O)	1	45	Mean Difference (IV, Fixed, 95% CI)	0.53 [-0.34, 1.40]
2.10 Aggressive behaviour at 12 months (CMAI -N)	1	45	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.27, 0.17]
3 Emotional state	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Depression at 12 months (MOSES)	1	45	Mean Difference (IV, Fixed, 95% CI)	-0.85 [-4.31, 2.61]
4 Activities of Daily Living	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Self-care functioning at 12 months (MOSES)	1	45	Mean Difference (IV, Fixed, 95% CI)	-1.09 [-2.00, 1.82]

Comparison 2. Validation versus social contact

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cognition	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Disorientation at 12 months (MOSES)	1	44	Mean Difference (IV, Fixed, 95% CI)	0.88 [-3.35, 5.11]
2 Behaviour	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Irritation at 12 months (MOSES)	1	44	Mean Difference (IV, Fixed, 95% CI)	-1.01 [-3.48, 1.46]
2.2 Withdrawal at 12 months (MOSES)	1	44	Mean Difference (IV, Fixed, 95% CI)	-0.72 [-4.19, 2.75]
2.3 Verbally agitated behaviour at 12 months (CMAI-O)	1	44	Mean Difference (IV, Fixed, 95% CI)	6.3 [-0.67, 13.27]
2.4 Verbally agitated behaviour at 12 months (CMAI-N)	1	44	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.29, 0.31]
2.5 Physically non aggressive behaviour at 12 months (CMAI-O)	1	44	Mean Difference (IV, Fixed, 95% CI)	-0.14 [-2.44, 2.16]
2.6 Physically non aggressive behaviour at 12 months (CMAI-N)	1	44	Mean Difference (IV, Fixed, 95% CI)	0.07 [-0.12, 0.26]
2.7 Aggressive behaviour at 12 months (CMAI-O)	1	44	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.65, 1.07]
2.8 Aggressive behaviour at 12 months (CMAI-N)	1	44	Mean Difference (IV, Fixed, 95% CI)	0.08 [-0.15, 0.31]
3 Emotional State	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Depression at 12 months (MOSES)	1	44	Mean Difference (IV, Fixed, 95% CI)	-4.01 [-7.74, -0.28]
4 Activities of Daily Living	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Self-care functioning at 12 months (MOSES)	1	44	Mean Difference (IV, Fixed, 95% CI)	-0.61 [-3.73, 2.51]

Comparison 3. Validation versus reality orientation

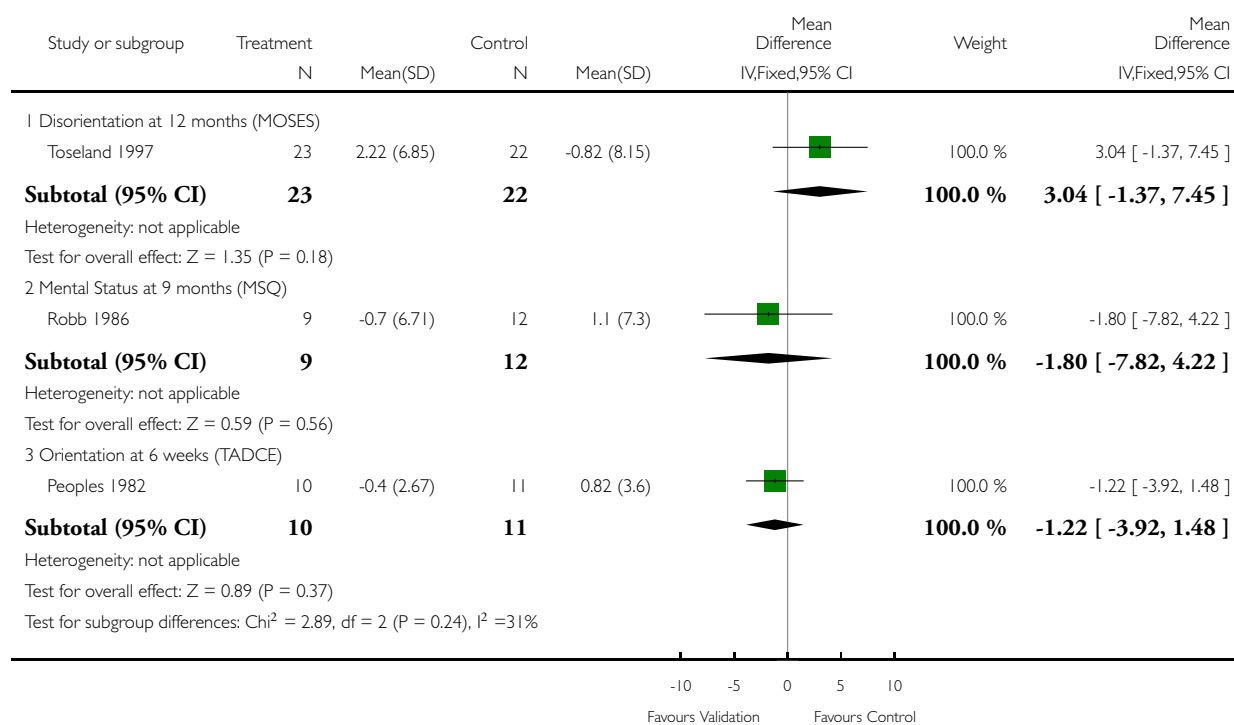
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cognition	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Orientation at 6 weeks (TADCE)	1	18	Mean Difference (IV, Fixed, 95% CI)	0.98 [-1.11, 3.07]
2 Behaviour	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Behaviour at 6 weeks (BAT)	1	18	Mean Difference (IV, Fixed, 95% CI)	-1.95 [-5.04, 1.14]

Analysis 1.1. Comparison 1 Validation versus usual care, Outcome 1 Cognition.

Review: Validation therapy for dementia

Comparison: 1 Validation versus usual care

Outcome: 1 Cognition

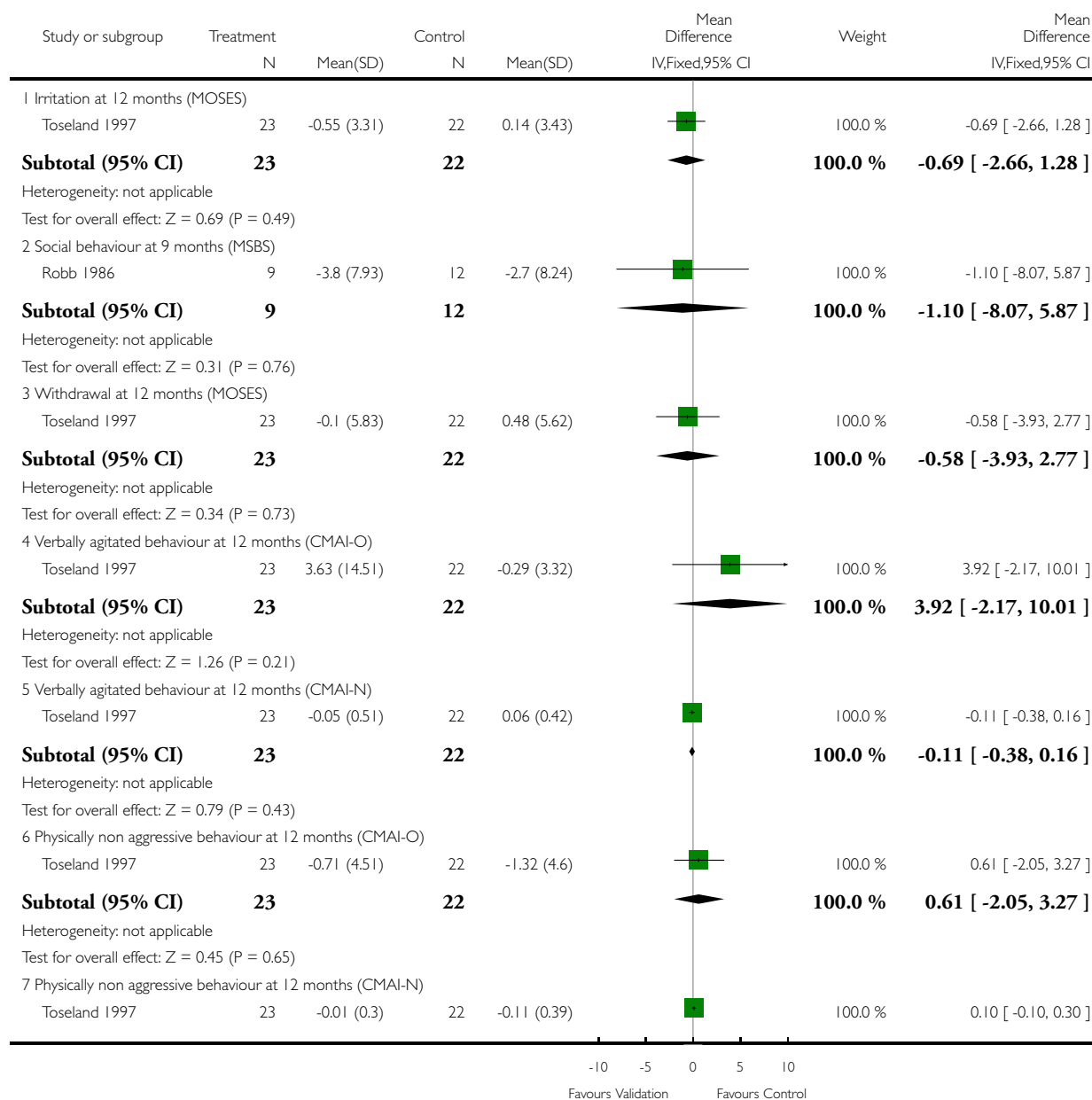


Analysis 1.2. Comparison 1 Validation versus usual care, Outcome 2 Behaviour.

Review: Validation therapy for dementia

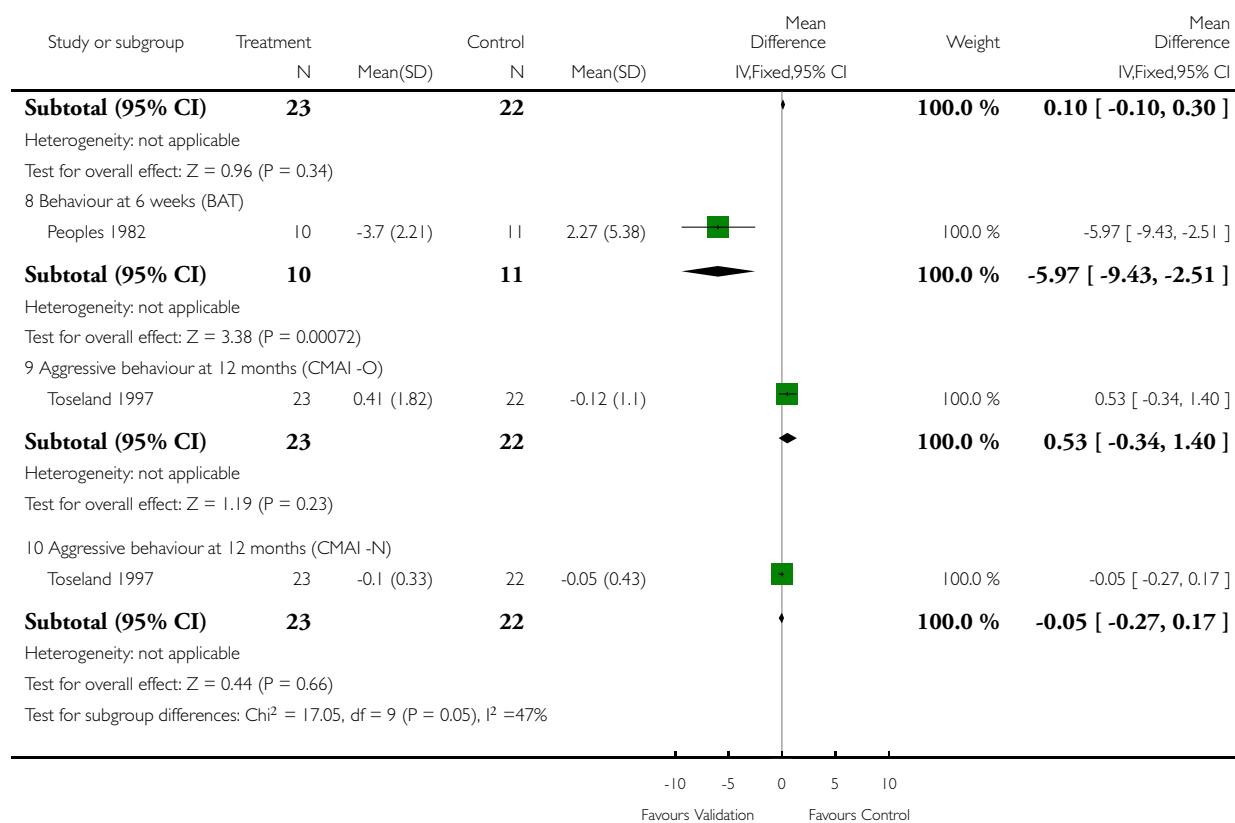
Comparison: 1 Validation versus usual care

Outcome: 2 Behaviour



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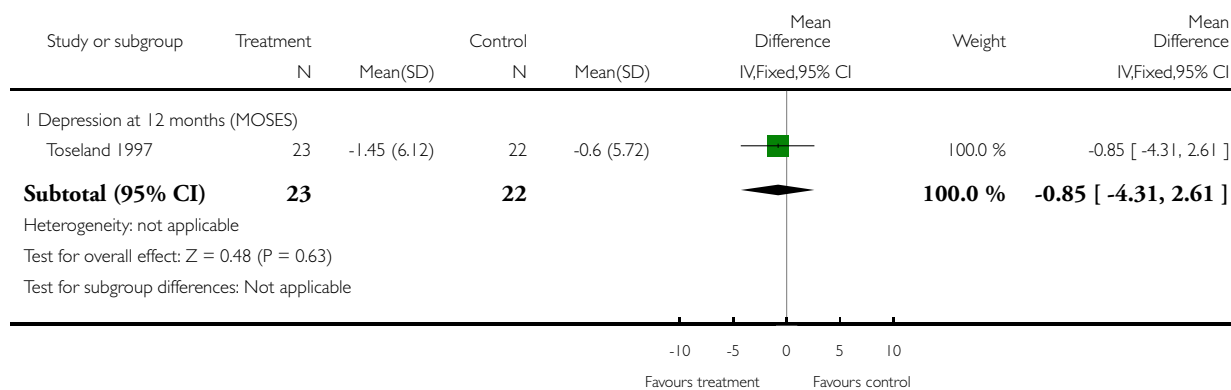


Analysis 1.3. Comparison 1 Validation versus usual care, Outcome 3 Emotional state.

Review: Validation therapy for dementia

Comparison: 1 Validation versus usual care

Outcome: 3 Emotional state

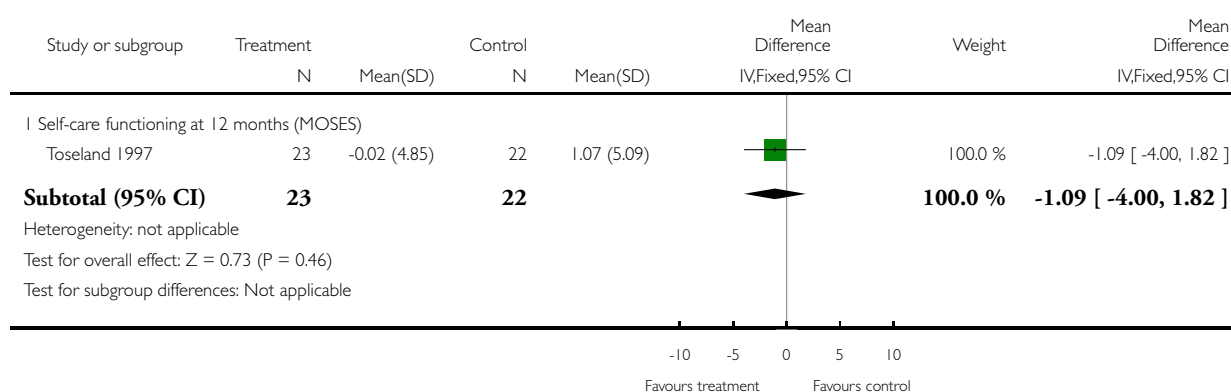


Analysis 1.4. Comparison 1 Validation versus usual care, Outcome 4 Activities of Daily Living.

Review: Validation therapy for dementia

Comparison: 1 Validation versus usual care

Outcome: 4 Activities of Daily Living

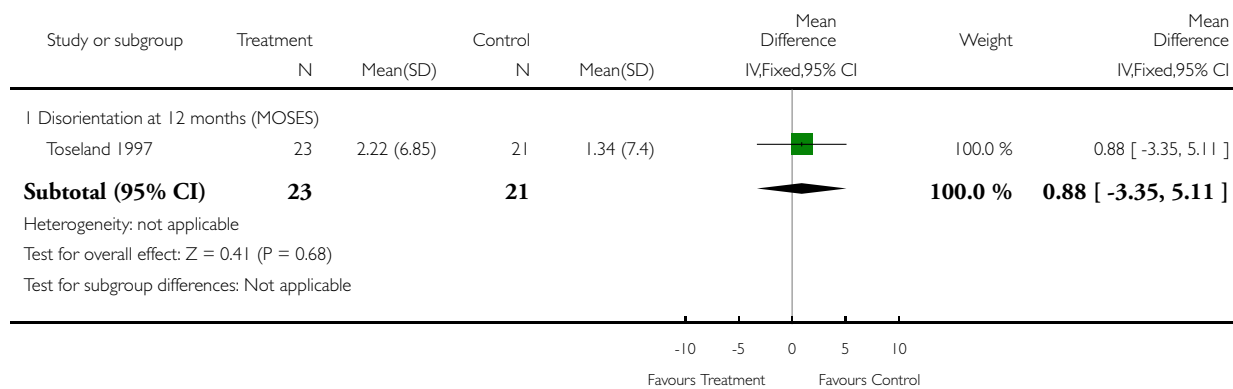


Analysis 2.1. Comparison 2 Validation versus social contact, Outcome 1 Cognition.

Review: Validation therapy for dementia

Comparison: 2 Validation versus social contact

Outcome: 1 Cognition

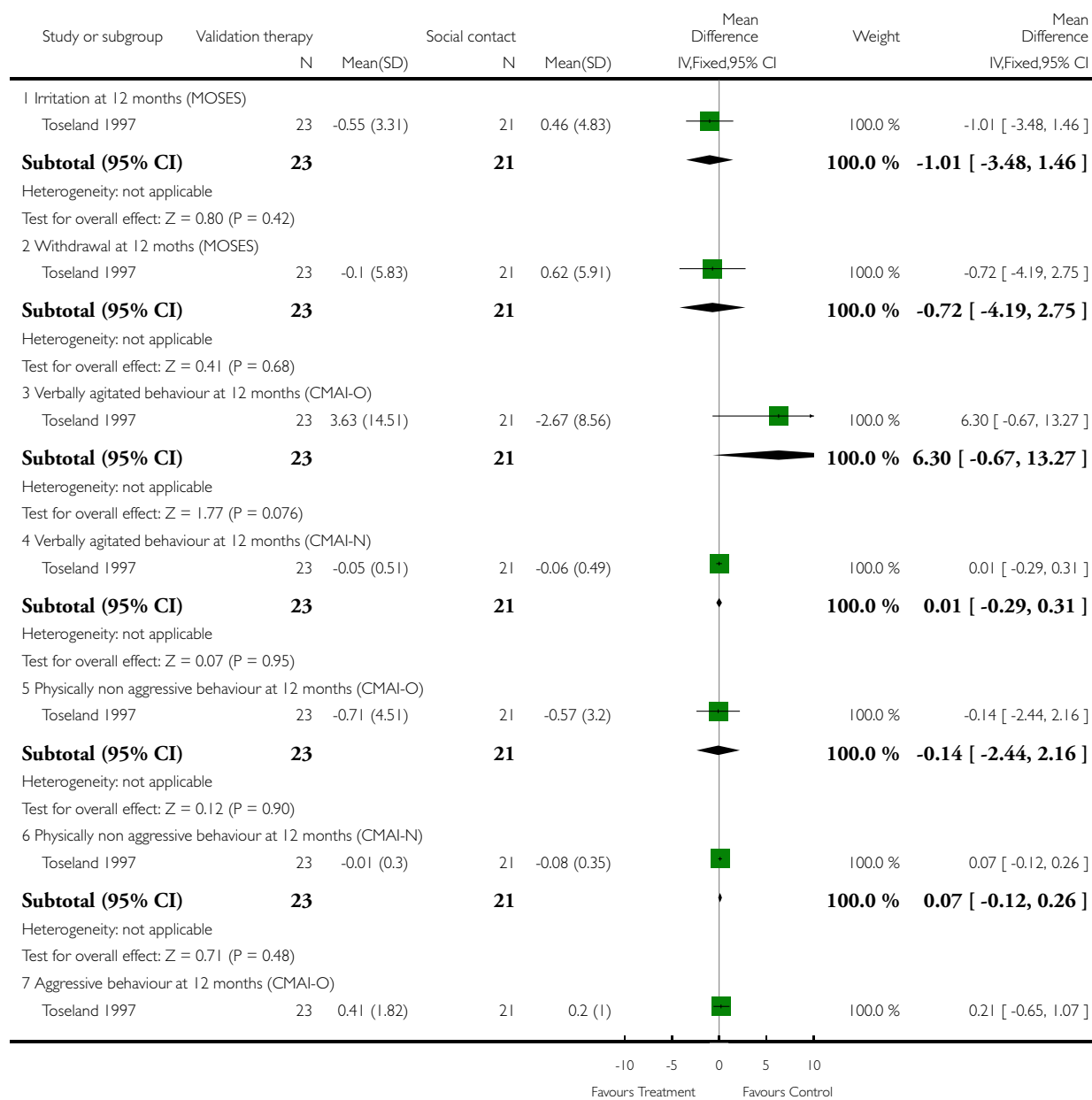


Analysis 2.2. Comparison 2 Validation versus social contact, Outcome 2 Behaviour.

Review: Validation therapy for dementia

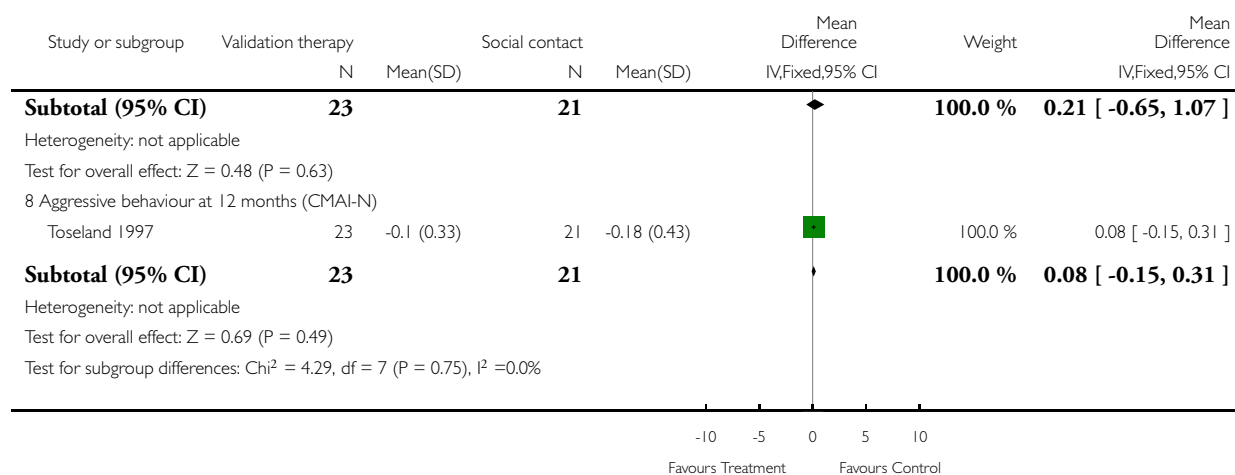
Comparison: 2 Validation versus social contact

Outcome: 2 Behaviour



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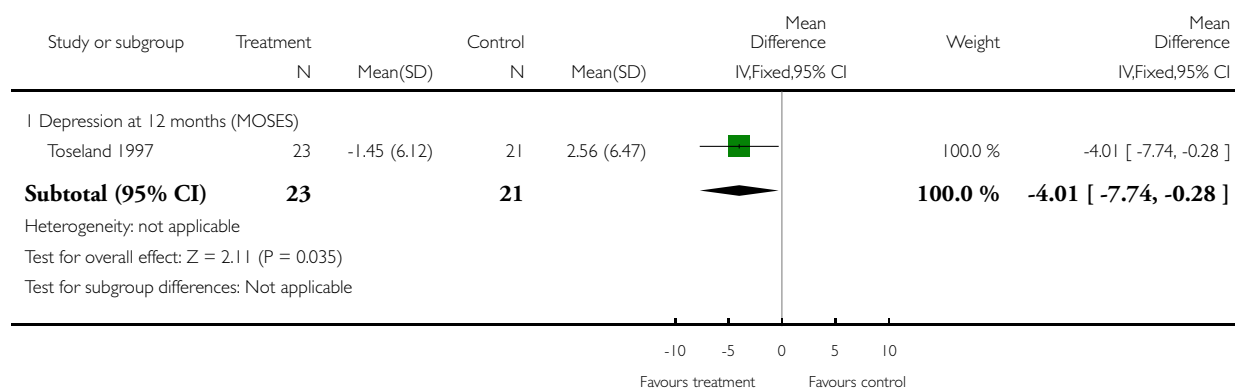


Analysis 2.3. Comparison 2 Validation versus social contact, Outcome 3 Emotional State.

Review: Validation therapy for dementia

Comparison: 2 Validation versus social contact

Outcome: 3 Emotional State

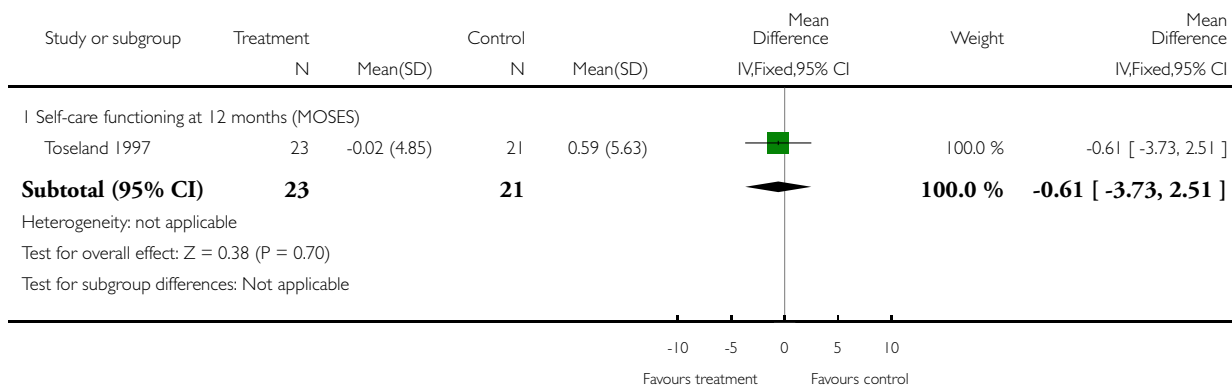


Analysis 2.4. Comparison 2 Validation versus social contact, Outcome 4 Activities of Daily Living.

Review: Validation therapy for dementia

Comparison: 2 Validation versus social contact

Outcome: 4 Activities of Daily Living

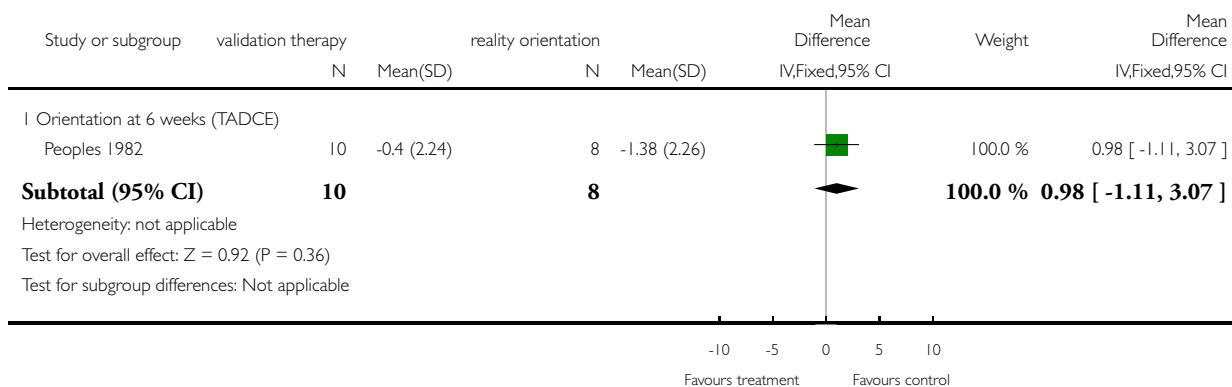


Analysis 3.1. Comparison 3 Validation versus reality orientation, Outcome 1 Cognition.

Review: Validation therapy for dementia

Comparison: 3 Validation versus reality orientation

Outcome: 1 Cognition

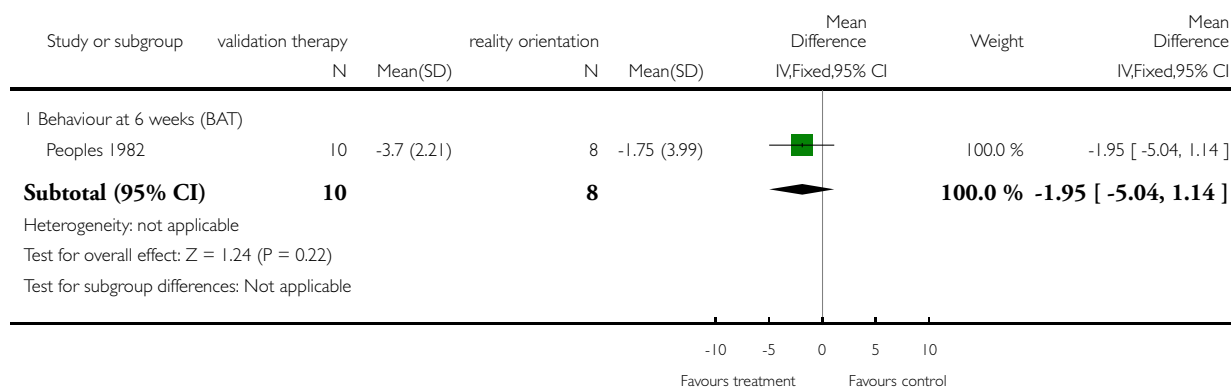


Analysis 3.2. Comparison 3 Validation versus reality orientation, Outcome 2 Behaviour.

Review: Validation therapy for dementia

Comparison: 3 Validation versus reality orientation

Outcome: 2 Behaviour



WHAT'S NEW

Last assessed as up-to-date: 4 August 2005.

Date	Event	Description
7 November 2008	Amended	Converted to new review format.

HISTORY

Review first published: Issue 1, 1999

Date	Event	Description
19 August 2005	New search has been performed	One new study has been identified and reviewed with two separate reports focussing upon behavioural problems with people with cognitive impairment - Schrinjnemekers et al (2002) and work related outcomes for caregivers working with people with cognitive impairment - Schrinjnemekers et al (2003). This trial has been excluded because the intervention, emotion orientated care, is a com-

(Continued)

		bination of validation therapy and other approaches such as reminiscence therapy
9 May 2003	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

MN: drafts of the review, updating, correspondence

PBW: drafts of review and updates

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This review has been peer reviewed anonymously

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Leeds Community & Mental Health Services NHS Teaching Trust, UK.

External sources

- No sources of support supplied

NOTES

August 2003: the review has now been peer reviewed. No changes were made.

INDEX TERMS

Medical Subject Headings (MeSH)

Alzheimer Disease [therapy]; Cognition Disorders [therapy]; Communication; Dementia [*therapy]; Psychotherapy [*methods]; Psychotherapy, Group; Randomized Controlled Trials as Topic

MeSH check words

Aged; Humans