NKR 53 DEMENS og adfærdsforstyrrelser PICO 1 psykoedukation vs. usual care

Review information

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Characteristics of studies

Characteristics of included studies

Berwig 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age y (SD)*: 72.3 (8.11) Control ● *Age y (SD)*: 73.98 (8.15) **Included criteria:** Eligibility criteria for informal caregivers included thefollowing: age 21 years or older; living with or sharingcooking facilities with the care recipient; providing carefor a relative with a medically diagnosed Alzheimer's dis-ease (AD) or related disorders, vascular dementia (VD)or behavior variant frontotemporal dementia (bvFTD)for at least 4 h per day for at least the past 6 months; in-formal caregiver speaks fluent German. **Excluded criteria:** We excludedcaregivers who were involved in another caregiver inter-vention study, who had an actual psychiatric diagnosis ofmental illness or another illness that would prevent6 months of study participation, or the forthcoming institutionalization of the person being cared for.

	Pretreatment: The baseline characteristics of the informal caregivers and relatives with dementia are presented in Table 1.Informal caregivers in the intervention group showed significantly more somatization, lower psychological health-related quality of life, and stronger reaction in response to the challenging behaviors of the people withdementia than informal caregivers in the control group.There was also a trend for informal caregivers in the intervention group to be more depressed.
Interventions	**Intervention Characteristics** Intervention ● *Description*: This German version of the original REACH II program(DE-REACH) had the same number of sessions and dur-ation (6 months) and addressed the same care domainsas REACH II. Likewise, the intervention has beentailored to the needs of each participant on the basis ofhis/her responses in the risk appraisal (see Fig. 2) andwas delivered through active teaching techniques to thecaregivers. The latter are techniques whereby the learner,or in our case the caregiver, is actively involved. Thismeans, for example, that the caregiver actively transfersthe learning contents of the counseling sessions to theireveryday lives (e.g. relaxation technique strategies forcoping with challenging behavior, etc.). We used most ofthe REACH II's intervention and assessment protocols.A research assistant with outstanding English skills con-ducted the translations. The REACH II intervention isessentially based on the fundamentals and the repertoireof behavioral therapy. This approach to psychotherapy isvery scientifically oriented and therefore to be seen asmore or less culture-free. In other words, there is nospecific German behavioral therapy. For this reason, wewere of the opinion that an elaborate back-translationprocedure could be dispensed with.There were, however, three major differences betweenREACH II and this German version. First, accompanyingstructured telephone support group sessions and thespecialized computer-integrated telephone system werenot adopted because of technical and cost reasons.Results of three translational studies of REACH IIshowed that the intervention is effective even withouteither of these intervention components [22–24]. Tocompensate for the omission of the telephone-basedsupport groups of the original REACH II intervention,we requested that each of the participants of the inter-vention group visit a local support group for informalcaregivers of people with dementia. Another major dif-ference consists in the fact that in Germany are othersupport measures that are financially supported by thesocial insurance system in Germany than those in theUSA. In addition, the care advisory possibilities are orga-nized differently. These were important details, whichhad to be adapted for the DE-REACH intervention.Therefore, in the consultation process of REACH II andin the caregiver notebook (see below) other help and of-fers of support were referenced.Minor modifications were that the duration of the in-home sessions was reduced from 1.5 h to 1 h only (theduration of the half-hour telephone sessions was notchanged) and that the required qualification for DE-REACH interventionists was a completed three-yearhealth-care traineeship (e.g. occupational therapists,nurses) and professional experience in dementia care(requirements for interventionists of the originalREACH II program see section"Description of the ori-ginal

	REACH II program").Based on the caregiver notebook of REACH II, the re-search team produced an adapted version of the caregivernotebook for use by interventionists and informal care-givers during and beyond the intervention period. ● *Duration of treatment*: 6 months ● *Length of follow-up after end of treatment*: 3 months Control ● *Description*: Usual care. Services of usual carecorresponded to the available care services determinedby the actual version of the German Care Insurance Law(e.g. caregiver counseling, utilization of day care, low-threshold care services, short-term or prevention care) ● *Duration of treatment*: 6 months ● *Length of follow-up after end of treatment*: 3 months
Outcomes	*BPSD (revised memory an behavior problem checklist (disruptive) SD. Change* ● **Outcome type**: ContinuousOutcome *Caregivers burden (ZBI revised 22 item), SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We used a central randomization via randomization lists realized by an on- line procedure of the Medical Faculty of the Ludwig Maximilians University of Munich [20]."
Allocation concealment (selection bias)	Low risk	Quote: "To obtain the same number of subjects in the intervention and the control group, we used a randomized block design [21]."
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The outcome rater was not informed about the randomization code of a participant before opening a sealed envelope with the code inside after completion of the baseline assessment."

Incomplete outcome data (attrition bias)	Low risk	Quote: "Several methods with missing value imputation were used, including expectation maximization method and the multiple imputations strategy implemented in the Statis- tical Packages for Social Sciences (SPSS) software version 20.0. Secondary analyses of the primary outcome variable were performed on patients treated per protocol (PP population). Secondary" Judgement Comment: Dropput accounted for and equivalent across groups
Selective reporting (reporting bias)	Low risk	Quote: "Clinical trial registration: NCT01690117. Registered September 17, 2012." Judgement Comment: Matches study protocol and the study appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: There were significant differences between the groups on severeal baseline characterisstics, including challanging behavior, reaction (RBMBC), but otherwise no other apparent sources of bias

Chien 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Overall ● *Age y (SD)*: 43.6 (9.2) ● *Male (%)*: 36% **Included criteria:** The inclusion criteria for familycaregivers included being 18 years orolder and living with and caring for arelative who was diagnosed as having a type of dementia caused byAlzheimer's disease, according toDSM-IVcriteria. **Excluded criteria:** Caregivers who had mental illness themselves or whohad cared for their family member for less than three months were ex-cluded. **Pretreatment:** There were no differences between the study groups with respect to their sociodemographic characteristics, types and dosages of medications, or mean scores on the baseline measures when Student's t tests or chi square tests were used

Interventions	**Intervention Characteristics** Intervention ● *Description*: Dementia care mangement ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: 6 months Control ● *Description*: Usual care ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: 6 months
Outcomes	*BPSD (NPI), SD* ● **Outcome type**: ContinuousOutcome *Caregivers burden (familiy caregiving burden inventory), SD* ● **Outcome type**: ContinuousOutcome *Institutionalisation, SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "total of 88 of 200 pairs of eligible patients and their primary caregivers were selected randomly from a list of patients who attended one of the two dementia centers." Judgement Comment: Insufficient information on sequence generation
Allocation concealment (selection bias)	Low risk	Quote: "In order to conceal the inter- vention of interest for family care- givers, six monthly education sessions on dementia care were provided to the standard care group."
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel

Blinding of outcome assessment (detection bias)	Low risk	Quote: "One researcher who was blind to the group assignment administered the pretest before randomization and the two posttests at six and 12 months after the start of the intervention."
Incomplete outcome data (attrition bias)	Low risk	Quote: "The data analysis used an intention-to-treat design that maintained the advantages of ran- dom allocation (15). In" Judgement Comment: However the 5% dropout in the intervention group were not specified.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to study protocol, but appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias.

Chien 2011

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** **Included criteria:** SampleThe participants in this study were family members caring fora relative with dementia at home, and they were recruitedfrom the two largest dementia resources centres, which hadabout 1500 clients primarily diagnosed with dementia,representing 8% of this client population in Hong Kong(Hospital Authority, Hong Kong 2006). Participants wereeligible for inclusion if:●They were aged at least 18 years and could speak and readChinese;●They lived with a relative who was diagnosed as having theAlzheimer's type of dementia (mild or moderate illnessstage) according to the criteria of the Diagnostic and Sta-tistical Manual of Mental Disorders, 4th edition (AmericanPsychiatric Association 1994), and they provided care forat least 4 hours per day; and●Their relative suffered no co-morbidity of other mentalillness during the recruitment period. **Excluded criteria:** They were excluded if they themselves had mental illnessand/or cognitive impairment, or if they had been the primarycarer for3 months.
Interventions	**Intervention Characteristics** Intervention ● *Description*: Dementia familiy care program. For the DFCP, a multi-disciplinary committee including apsychiatrist, a social worker, a case nurse manager from eachcentre, and the researchers, selected 25 intervention goals andobjectives from the recommended dementia guidelines estab-lished in the United States (Cummingset al.2002, Schulzet al.2005). The committee designed an information and psycho-logical support system linking case managers and dementiacare services, health professionals and referrals. One of themain components of the DFCP was the case managers, whoreceived formal training by the research team and coordinatedall levels of family care

of clients with dementia. Each of thefamily participants (n= 46) was assigned one case manager,who conducted weekly home visits, family health and educa-tional needs assessment using the Educational Needs Ques-tionnaire (Chien 2005), and education about dementia care.The case manager, together with another nurse in the centre,then summarized the needs assessment data to generateimportant problem areas in dementia caregiving. In collabo-ration with the caregivers, the case managers prioritized theproblems and formulated an individualized education andsupport programme for effective dementia care for each fam-ily. This preparatory phase lasted about 1 month.After 1 month's needs assessment and preparation, theDFCP was conducted for individual families, lasting about5 months. The family and the case manager met bi-weekly,for a total of 10 two-hour sessions. All family care sessionsconsisted of education, sharing and discussion, psychologicalsupport and problem-solving, in accordance with the com-mon elements found effective in previous studies for caregivers (Townsend 2000, Fung Chien 2002, Brodatyet al.2003, Belleet al.2006). A protocol was specifically designedfor this study, based on evidence from other family interven-tion studies in dementia (Heruet al.2004, Schulzet al.2005,Chien Lee 2008). Seven major themes of family supportivecare programmes identified from the literature were used inthe DFCP along with the results of a needs assessment,including (1) information about the client's illness condition,prognosis, and current treatment and care; (2) the develop-ment of social relationships with close relatives and friends,and thus a satisfactory extended social support network; (3)sharing and adaptation of the emotional impact of caregiv-ing; (4) learning about self-care and motivation; (5) improve-ment of interpersonal relationships between family membersand the client; (6) establishing support from communitygroups and healthcare resources; and (7) improvement ofhome care and finance skills. To strengthen the problem-solving skills within the families, one or two experiencedfamily caregivers were invited to share their personal care-giving problems with the families during the third and fourthsessions. Under the guidance of the case manager, theseproblems were worked on by each family using a six-stepmodel suggested by Zaritet al.(1985). The six steps includeddefining the problem, generation of alternatives, examiningand evaluating each alternative, cognitive rehearsal of actionplan, execution of the plan as homework, and evaluation ofoutcomes.

- *Length of treatment*: 6 months
- *Longest follow-up after end of treatment*: 12 months

Control

- *Description*: Routine care. The routine care group participants (n= 46) received the usualfamily services provided by the dementia resources centres.These services included (1) medical consultation of client andadvice to family on client's illness condition, treatment planand effects of medications provided weekly by a visiting psy-chiatrist; (2) advice and referrals for financial aid and socialwelfare services provided by a social worker in-charge of thecentre; (3) education talks in dementia care conductedmonthly by a registered psychiatric nurse; and (4) social and recreational activities organized weekly by staff at the centre

	● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: 12 months
Outcomes	*BPSD (NPI), SD* ● **Outcome type**: ContinuousOutcome *Caregivers burden, (Caregiver Burden Inventory) SD* ● **Outcome type**: ContinuousOutcome *Institutionalisation, SD.* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "After completion of the baseline measures, the participants were randomly assigned to either the DFCP or routine family support services (control group)." Judgement Comment: Insufficient information on sequence generation
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Insufficient information on allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "A research assistant, who was blind to the subject assignment, administered the pretest before randomization (Time 1), and asked the participants again to complete the outcome measures, including caregivers' bur- den, quality of life, social support, use of family services and client symptom severity scales, for three post-tests at 1 week (Time 2), 12 months (Time 3) and 18 months (Time 4) following the intervention. The"

Incomplete outcome data (attrition bias)	Low risk	Quote: "Analysis of data was on an intention-to-treat basis, thus maintaining the advantages of random sampling and enhanc- ing the validity of the study findings (Montori & Guyatt 2001). Repeated-measures" Judgement Comment: No apperent sources of bias
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to study protocol, but appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Gitlin 2003

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age y (SD)*: 60.4 (13.6) ● *Male (%)*: 24.7 Control ● *Age y (SD)*: 60.5 (13.6) ● *Male (%)*: 22.8 **Included criteria:** To participate in the study, caregivers had to bethe primary caregivers and report at least onelimitation in basic activities of daily living (ADLs;Katz, Ford, Moskowitz, Jackson, Jaffe, 1963) ortwo dependencies in instrumental activities of dailyliving of the care recipient (IADLs; Lawton Brody,1969). Additionally, caregivers had to be at least 21years of age, have been caregiving for at least 6 months, and provide at least 4 hr of care each day. **Excluded criteria:** Caregivers were not eligible if they did not live withthe care recipient, were undergoing chemotherapy orradiation therapy for cancer, had more than threehospitalizations in the past year, or were planning toplace the care recipient in a nursing home within thenext 6 months.
Interventions	**Intervention Characteristics** Intervention ● *Description*: Enviromental Skill-building program ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: None Control

	● *Description*: Usual care ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: None
Outcomes	*BPSD (Revised version of RMBP, disruption-related), SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization schedule used random permuted blocks within each stratum and was prepared by the site biostatistician. Randomization was accomplished by opening opaque sealed envelopes in sequential order for the appro- priate stratum."
Allocation concealment (selection bias)	Low risk	Quote: "The randomization schedule used random permuted blocks within each stratum and was prepared by the site biostatistician."
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of outcome assessors
Incomplete outcome data (attrition bias)	Low risk	Quote: "rate. Twenty subjects were bereaved, 16 had placed their family member in a long-term care facility, 24 missed the follow-up interview, and 7 had dropped out of the study. In accordance with clinical trial research principles, to reduce the number of subjects with missing data, we interpolated scores for 2 subjects who were unavail- able at the 6-month follow-up but participated in the 12-month follow-up interview. The difference be- tween the 12-month follow-up and baseline values was divided by time between follow-up and baseline to obtain a difference per day. This value was then multiplied by 182 (the number of days in 6 months)"
Selective reporting (reporting bias)	Low risk	

Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Koivisto 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age y (SD)*: 75.8 (7.13) ● *Male (%)*: 50.0 Control ● *Age y (SD)*: 75.5 (6.19) ● *Male (%)*: 48.0 **Included criteria:** The inclusion criteria for the present study were asfollows: very mild (Clinical Dementia Rating globalscore [CDR]=0.5) or mild (CDR=1.0) AD at baselineas diagnosed by specialists, the ability to speak and un-derstand Finnish, community-dwelling, free of comor-bid conditions that could have affected cognition atbaseline, capable of performing the CERAD-NB, andthe presence of a family caregiver (Karttunenet al.,2011; Hallikainenet al., 2012; Välimäkiet al., 2014.)
Interventions	**Intervention Characteristics** Intervention ● *Description*: The psychosocial intervention for both persons withAD and their caregivers was provided as rehabilitationcourses in Brain Research and Rehabilitation CenterNeuron. The four courses (total 16days) wereconducted during thefirst 2years after diagnosis. Theintervention aimed to enhance knowledge, to reduce so-cial isolation and caregiver distress, and to supportfunctional ability and managing everyday life situations.Intervention methods included individual assess-ments, individual counseling, education, and bothindividual support and support groups. The life situationof the family was evaluated by interviewing both the per-son with AD and their caregiver, and individual counsel-ing was offered by means to help managing in everydaylife situations. An individual service plan was made toget help after courses. Neurologists and social workersgave lectures to enhance knowledge about AD and socialservices and to information for preparing for the future.Structured group discussions were organized separatelyfor the patients with AD and caregivers to offer socialsupport and reduce social isolation. Multiple creative and social activities were organized tofind ways to

	reducestress and contact with others. Participants were encour-aged to do physical exercise to maintain functional abil-ity. Altogether, 11 course groups were arranged. Amaximum of 10 families were invited to each course ● *Duration of treatment*: 24 months ● *Length of follow-up after end of treatment*: 12 months Control ● *Description*: The control group was also followed up annuallybut did not receive the psychosocial intervention orga-nized by the ALSOVA study. All of the participantsreceived basic counseling about AD by a memorynurse at the time of diagnosis. ● *Duration of treatment*: 24 months ● *Length of follow-up after end of treatment*: 12 months
Outcomes	*BPSD (NPI), SD* ● **Outcome type**: ContinuousOutcome *Institutionalisation* ● **Outcome type**: DichotomousOutcome *Quality of life (Qol-AD), SD* ● **Outcome type**: ContinuousOutcome *Caregivers burden (GHQ), SD* ● **Outcome type**: ContinuousOutcome *ADL (ADCS-ADL), SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The list of randomization numbers and the group sta- tus was created using the computer algorithm, and the study nurse who otherwise took no part in the study in- formed both the participants and the rehabilitation center."
Allocation concealment (selection bias)	Low risk	Quote: "The list of randomization numbers and the group sta- tus was created using the computer algorithm, and the study nurse who otherwise took no part in the study in- formed both the participants and the rehabilitation center. The intervention was provided during the first 2 years"
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Only mentioned as a rater-blinded study
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Another study nurse and a psychologist carried out annual follow-up tests and interviews. They were both blinded to the randomization group and did not partici- pate in providing common health care."
Incomplete outcome data (attrition bias)	High risk	Judgement Comment: There were 30 out of 84 that dropped out in the intervention group (36%).There were 76 out of 152 that dropped out in the control group (50%).There were no statistical analysis that accounted for inclompete outcome data.
Selective reporting (reporting bias)	Low risk	Quote: "The Kuopio University Hospital's ethical committee approved the study protocol (N0. 64/00)." Judgement Comment: Study protocol not available, but the study appears free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Marriott 2000

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age y (SD)*: 69.6 (15.2) Control 1 ● *Age y (SD)*: 58.1 (16.7) Control 2

	● *Age y (SD)*: 63.0 (14.0) **Included criteria:** The inclusion criteria were: patients had to satisfy DSM-III-R on criteria were: primary degenerative dementia of the Alzheimer type and be living in the community with a carer who provided their main support; and the carer had to achieve psychiatric caseness with a score on the General Health Questionnaire score on the General Health of 5 or above, indicating significant psycho-or above, indicating significant psychological morbidity.
Interventions	**Intervention Characteristics** Intervention ● *Description*: Familiy intervention group ● *Length of treatment*: 9 months ● *Longest follow-up after end of treatment*: 3 months Control 1 ● *Description*: No-interview control group ● *Length of treatment*: 9 months ● *Longest follow-up after end of treatment*: 3 months Control 2 ● *Description*: Interview control group ● *Length of treatment*: 9 months ● *Longest follow-up after end of treatment*: 3 months
Outcomes	*BPSD (MOUSE-PAD), SD* ● **Outcome type**: ContinuousOutcome *Depression (Cornell scale for depression dementia), SD* ● **Outcome type**: ContinuousOutcome *Caregivers burden (GHQ), SD* ● **Outcome type**: ContinuousOutcome *ADL, SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects were allocated to one of three Subjects were allocated to one of three groups ± the family intervention group or groups ± the family intervention group or one of the two control groups ± by means one of the two control groups ± by means of random number tables independent of of random number tables independent of the assessor and clinician."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Insufficient information on allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of outcome assessors
Incomplete outcome data (attrition bias)	Low risk	Quote: "One patient and allocated to each group. One patient and carer dropped out of the intervention and carer dropped out of the intervention and were lost to the study. The" Judgement Comment: No apperent sources of bias
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to study protocol, but the study appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Martin-Carrasco 2009

Methods	
Participants	
Interventions	
Outcomes	

Notes	Data obtained from: Jensen M, Agbata IN, Canavan M, McCarthy G. Effectiveness of educational interventions for informal caregivers of individuals with dementiaresiding in the community: systematic review and meta-analysis of randomised controlled trials. Int J Geriatr Psychiatry. 2015 Feb;30(2):130-43. doi: 10.1002/gps.4208.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	reference: Jensen et al., 2015
Allocation concealment (selection bias)	Unclear risk	reference: Jensen et al., 2015
Blinding of participants and personnel (performance bias)	High risk	reference: Jensen et al., 2015
Blinding of outcome assessment (detection bias)	High risk	reference: Jensen et al., 2015
Incomplete outcome data (attrition bias)	Unclear risk	reference: Jensen et al., 2015
Selective reporting (reporting bias)	Low risk	reference: Jensen et al., 2015
Other bias	Low risk	reference: Jensen et al., 2015

Ostwald 1999

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** **Included criteria:** Persons with dementia and their families were re-cruited from local memory loss clinics, the GeriatricResearch, Education, and Clinical Center at the Min-neapolis Veterans Hospital, other senior clinics and healthcenters, the Minneapolis/St. Paul Alzheimer's Associa-tion, and local community hospitals and health andsocial service agencies. To be enrolled in the study,families needed to be caring for a person with a diag-nosis of nonreversible dementia who1. Was living in the community.2. Demonstrated signs of mild to severe dementia;only those who were nonambulatory and requiredtotal care (judged to be at or below a telephone-administered Functional Assessment Staging Test[Reisberg, 1988] score of 7b) were excluded.3. Displayed behavior problems (as perceived by thecaregiver).4. Was able to accompany the caregiver to at leastthe first two weekly intervention sessions.In addition, at least one additional family member,other than the primary caregiver, needed to be will-ing to accompany the caregiver

	ancTpatient to sevenweekly sessions
Interventions	**Intervention Characteristics** Intervention ● *Description*: Minnesota familiy workshop ● *Length of treatment*: 7 weeks ● *Longest follow-up after end of treatment*: 5 months Control ● *Description*: Waiting list ● *Length of treatment*: 7 weeks ● *Longest follow-up after end of treatment*: 5 months
Outcomes	*BPSD (Revised memory and behavior problem checklist), SD* ● **Outcome type**: ContinuousOutcome *Caregivers burden (ZBI revised), SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Once these were done, each family was randomly assigned by a computer program to one of two groups (each family had an equal chance of assignment to either group)."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Insufficient information on allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The workshop faculty had no way of knowing the study status (immediate or waiting list) of workshop participants, except in the first two and the last workshops."

Incomplete outcome data (attrition bias)	Low risk	Quote: "Twelve families discontinued participation in the immediate intervention group (16%) and 11 families dropped out of the waiting list control group (26%). The dropouts and completers (both intervention and waiting list control groups combined) were compared on the basis of their baseline scores on the study's major outcome variables (i.e., caregiver's perception of disruptive behaviors, caregiver's reaction to disruptive behaviors, caregiver burden, and caregiver depres- sion). The two groups were also compared on the basis of demographic variables of caregiver and patient age, caregiver and patient education, caregiver and patient gender, and caregiver and patient income. With the exception of patient age, none of the differences was" Judgement Comment: No apparent sources of bias
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to study protocol, but appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be from other sources of bias

SepeMonti 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age y (SD)*: 57.84 (13.89) ● *Male (%)*: 20 out of 80 Control ● *Age y (SD)*: 59.57 (14.52) ● *Male (%)*: 36 out of 84 **Included criteria:** All patients with a diagnosis of probable or possible AD, acoording to NINCDS-ADRDA criteria, with a known primary caregiver who was responsible for providing informal care to the patient. **Excluded criteria:** Patients affected by other kinds of dementia or included in other non-pharmacological intervention trials and/or in pharmacological clinical trials were excluded. Patients who informal caregiver was unable or refused to participate were excluded.

Interventions	**Intervention Characteristics** Intervention ● *Description*: psycho-educational program for familiy caregivers ● *Duration of treatment*: 8 weeks ● *Length of follow-up after end of treatment*: 18 weeks Control ● *Description*: Program based on providing medical information about AD ● *Duration of treatment*: 8 weeks ● *Length of follow-up after end of treatment*: 18 weeks
Outcomes	*Caregivers burden (caregivers burden inventory), SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: Assigned through computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Judgement Comment: Code as assigned to caregiver and an envelope corresponding to treatment was given.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants and personnel
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: The study was designed as a PROBE (Prospective randomized Open, Blinden Endpoint)
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Dropouts accounted for and equivally distributed among groups.Intention-to treat analysis: multiple imputation method for missing data.

Selective reporting (reporting bias)	Low risk	Judgement Comment: There is no reference to study protocol, but the study appears to be from selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free from other sources of bias

Wang 2011

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Overall ● *Age y (SD)*: 40.63 (8.21) ● *Male (%)*: **Included criteria:** The inclusion criteria of family caregivers were those who were aged‡18 years and living with and caring for the client diagnosed as Alzheimer's type of dementia according to the DSM-IV (American Psychiatric Association, 1994). **Excluded criteria:** Those who had a mental illness themselves or cared for their patientless than two months were excluded.
Interventions	**Intervention Characteristics** Intervention ● *Description*: community-based Family Mutual Support Programme inDementia Care (FMSP-DC) ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: None Control ● *Description*: Standard care ● *Length of treatment*: 6 months ● *Longest follow-up after end of treatment*: None
Outcomes	*Institutionalisation, SD* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Eighty of 400 pairs of eligible patients and their primary family caregivers were selected randomly from the client list of the centre, using the computer-generated random numbers. They were then randomly assigned into either the FMSP-DC or routine care group (control), each consisting of 40 family dyads."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Insufficent information on allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Insufficient information on blinding of participants amd personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "One researcher who was blind to the group assignment administered the outcome measures, including caregivers' burden (Family Caregiving Burden Inventory; Chou, Jiann- Chyun & Chu 2002), quality of life (WHOQOL-BREF; Leung et al. 1997) and social support (Six-item Social Support Questionnaire; Sarason et al. 1987) at baseline before randomisation and at post-test at one week after intervention. The"
Incomplete outcome data (attrition bias)	Low risk	Quote: "Data analysis used an intention-to-treat basis that maintained the advantages of random allocation." Judgement Comment: No apparent sources of bias
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to study protocol, but the study appears to be free of selective outcome reporting
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Footnotes

Characteristics of excluded studies

Akkerman 2004

Reason for exclusion	Wrong intervention

Au 2010

Reason for exclusion	Wrong caregiver population

Beauchamp 2005

Reason for exclusion	Wrong intervention

Bourgeois 2002

Reason for exclusion	Wrong caregiver population

Burgio 2003

Reason for exclusion	Wrong comparator

Burns 2003

Reason for exclusion	Wrong comparator

Castro 2002

Reason for exclusion	Wrong intervention

Coon 2003

Reason for exclusion	Wrong intervention

Davis 2004

Reason for exclusion	Wrong comparator

deRotrou 2011

Reason for exclusion	Wrong caregiver population

DiZazzoMiller 2017

Reason for exclusion	Wrong intervention

Drentea 2006

Reason for exclusion	Wrong intervention

Ducharme 2005

Reason for exclusion	Wrong patient population

Ducharme 2005a

Reason for exclusion	Wrong patient population

Ducharme 2011

Reason for exclusion	Wrong caregiver population

Ducharme 2015

Reason for exclusion	Wrong intervention

Eisdorfer 2003

Reason for exclusion	Wrong intervention

Eloniemi Sulkava 2009

Reason for exclusion	Wrong intervention

Fung 2002

Reason for exclusion	Wrong outcomes

Gallagher Thompson 2003

Reason for exclusion	Wrong comparator

Gallagher Thompson 2007

Reason for exclusion	Wrong comparator

Gaugler 2013

Reason for exclusion	Wrong patient population

Gavrilova 2009

Reason for exclusion	Wrong caregiver population

Gendron 1996

Reason for exclusion	Wrong intervention

Gitlin 2010

Reason for exclusion	Wrong caregiver population

Gonyea 2006

Reason for exclusion	Wrong caregiver population

Gossink 2016

Reason for exclusion	Wrong outcomes

Guerra 2011

Reason for exclusion	Wrong caregiver population

Hebert 1994

Reason for exclusion	Wrong caregiver population

Hebert 1995

Reason for exclusion	Wrong caregiver population

Hebert 2003

Reason for exclusion	Wrong caregiver population

Hepburn 2001

Reason for exclusion	Wrong caregiver population

Hepburn 2006

Reason for exclusion	Wrong caregiver population

Hepburn 2007

Reason for exclusion	Wrong caregiver population

Huang 2013

Reason for exclusion	Wrong intervention

Joling 2012

Reason for exclusion	Wrong intervention

Judge 2013

Reason for exclusion	Wrong caregiver population

King 2002

Reason for exclusion	Wrong intervention

Krystyna 2011

Reason for exclusion	Wrong caregiver population

Kurz 2010

Reason for exclusion	Wrong caregiver population

Livingston 2013

Reason for exclusion	Wrong caregiver population

Livingston 2013a

Reason for exclusion	Wrong patient population

Livingston 2014

Reason for exclusion	Wrong caregiver population

Livingston 2014a

Reason for exclusion	Wrong patient population

Logsdon 2010

Reason for exclusion	Wrong patient population

Losada 2011

Reason for exclusion	Wrong caregiver population

LosadaBaltar 2004

Reason for exclusion	not english

Marquez Gonzalez 2007

Reason for exclusion	Wrong caregiver population

Martin Carrasco 2014

Reason for exclusion	Wrong caregiver population

Martin Cook 2003

Reason for exclusion	Wrong caregiver population

McCurry 1998

Reason for exclusion	Wrong outcomes

Menn 2012

Reason for exclusion	Wrong caregiver population

Moniz Cook 2008

Reason for exclusion	Wrong caregiver population

Nichols 2008

Reason for exclusion	Wrong outcomes

Pahlavanzadeh 2010

Reason for exclusion	Wrong caregiver population

Perkins 1990

Reason for exclusion	Wrong patient population

Perren 2006

Reason for exclusion	Wrong comparator

Phung 2013

Reason for exclusion	Wrong study design

Phung 2013a

Reason for exclusion	Wrong patient population

Prick 2015

Reason for exclusion	Wrong intervention

Roberts 1999

Reason for exclusion	Wrong outcomes

Robinson 1994

Reason for exclusion	Wrong study design

Rodriguez Sanchez 2013

Reason for exclusion	Wrong patient population

Schmidt 1988

Reason for exclusion	Wrong intervention

Shata 2017

Reason for exclusion	Wrong setting

Sogaard 2014

Reason for exclusion	Wrong intervention

Steffen 2000

Reason for exclusion	Wrong intervention

Sutcliffe 1988

Reason for exclusion	Wrong study design

Tang 2018

Reason for exclusion	Wrong comparator

Ulstein 2007

Reason for exclusion	Wrong caregiver population

Villars 2014

Reason for exclusion	Wrong patient population

Waldorff 2012

Reason for exclusion	Wrong intervention

Whitlatch 1991

Reason for exclusion	Wrong caregiver population

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Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

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Data and analyses

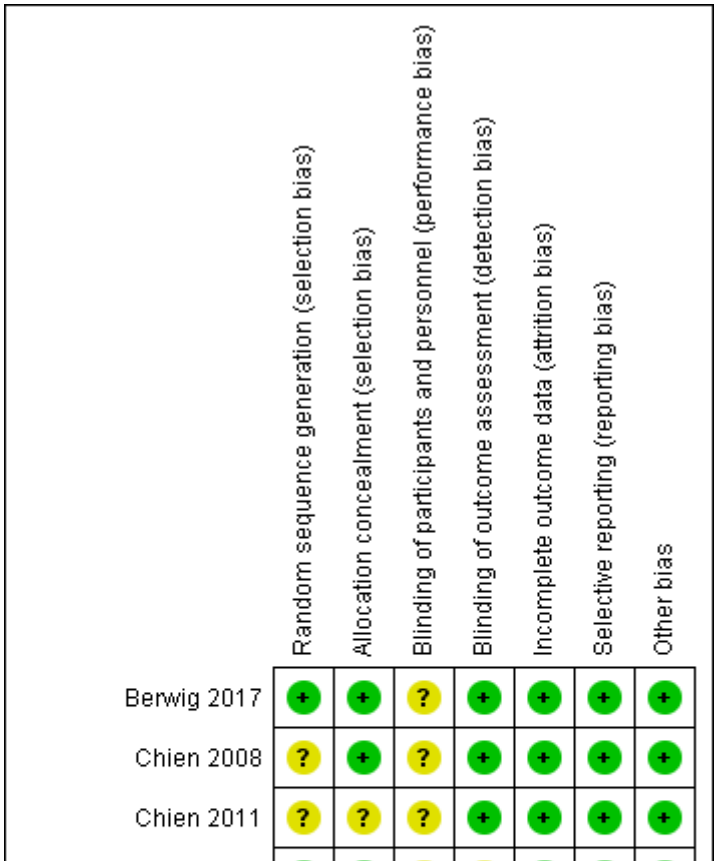
2 Psycho education vs usual care

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 BPSD_longest follow-up max 24 mo	7	598	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.89, 0.08]
2.2 BPSD_end of treatment	7	698	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.71, 0.10]
2.3 Depression_longest follow-up max 24 mo	2	143	Std. Mean Difference (IV, Random, 95% CI)	-0.14 [-0.47, 0.20]
2.4 Caregivers burden_longest follow-up max 24 mo	8	677	Std. Mean Difference (IV, Random, 95% CI)	-0.69 [-1.09, -0.29]
2.5 Institutionalisation_end of treatment, SD	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
2.8 Institutionalisation_longest follow-up max 24 mo	1	130	Risk Ratio (IV, Fixed, 95% CI)	1.06 [0.64, 1.74]
2.11 ADL_longest follow-up max 24 mo	2	171	Mean Difference (IV, Random, 95% CI)	-2.87 [-8.14, 2.40]

2.12 Quality of life_longest follow-up max 24 mo	1	130	Mean Difference (IV, Fixed, 95% CI)	0.40 [-1.77, 2.57]
2.13 Usage of antipsychotic medication_end of treatment	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.14 Usage of antipsychotic medication_longest follow-up max 24 mo	1	164	Risk Ratio (IV, Fixed, 95% CI)	0.10 [0.01, 0.87]

Figures

Figure 1

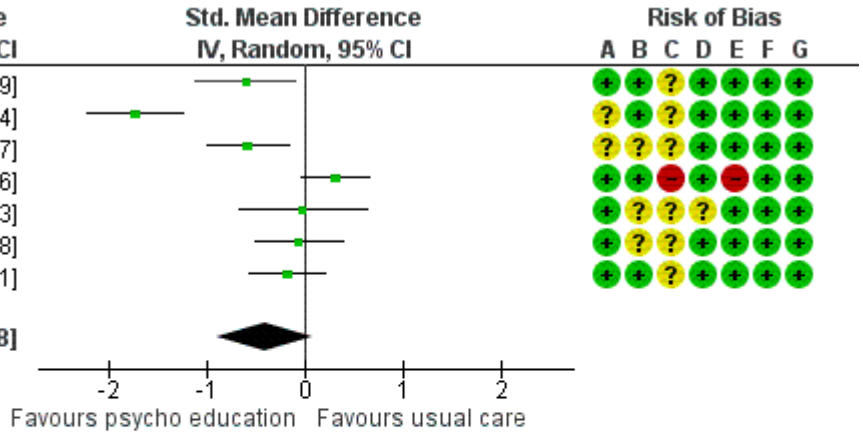


Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 2 (Analysis 2.1)

Study or Subgroup	Psycho education Mean	SD	Total	Usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Berwig 2017 (1)	-1.122	4.569	31	1.505	3.991	31	14.0%	-0.60 [-1.11, -0.09]
Chien 2008 (2)	64.2	11.8	44	85.1	12.1	44	14.1%	-1.73 [-2.23, -1.24]
Chien 2011 (3)	76.5	8.9	46	82.4	11	46	14.7%	-0.58 [-1.00, -0.17]
Koivisto 2016 (4)	17.4	14.1	54	13.2	12.9	76	15.2%	0.31 [-0.04, 0.66]
Marriott 2000 (5)	5.3	2	13	5.35	2.1732	28	12.7%	-0.02 [-0.68, 0.63]
Ostwald 1999 (6)	6.35	5.2	52	6.68	4.5	31	14.5%	-0.07 [-0.51, 0.38]
SepeMonti 2016 (7)	22.2	16.19	55	25.19	16.3	47	14.9%	-0.18 [-0.57, 0.21]
Total (95% CI)			**295**			**303**	**100.0%**	**-0.41 [-0.89, 0.08]**

Heterogeneity: Tau² = 0.37; Chi² = 49.22, df = 6 (P < 0.00001); I² = 88%
Test for overall effect: Z = 1.64 (P = 0.10)



Footnotes
(1) Revised Memory and Behavior ProblemChecklist Frequency (disruptive behavior subscale)
(2) 12 item NPI
(3) NPI-Q
(4) NPI. Measured at 36 months of follow-up.
(5) MOUSE-PAD. The control groups are pooled
(6) Revised Memory and Behavior ProblemChecklist Frequency (disruptive behavior subscale)
(7) NPI

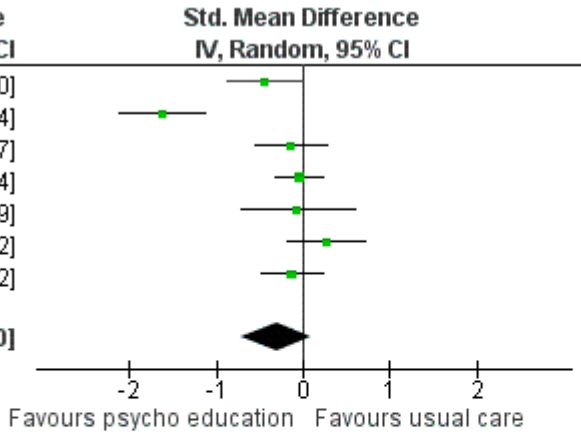
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.1 BPSD_longest follow-up max 24 mo.

Figure 3 (Analysis 2.2)

Study or Subgroup	Psycho education Mean	SD	Total	Usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Berwig 2017 (1)	-1.618	7.213	41	1.286	5.891	40	14.3%	-0.44 [-0.88, 0.00]
Chien 2008 (2)	68.1	10.2	44	84.5	9.8	44	13.8%	-1.63 [-2.11, -1.14]
Chien 2011 (3)	80.1	10.2	46	81.5	9.8	46	14.7%	-0.14 [-0.55, 0.27]
Gitlin 2003 (4)	1.88	1.57	89	1.96	1.88	101	15.9%	-0.05 [-0.33, 0.24]
Marriott 2000 (5)	5.1	2.1	13	5.25	2.3158	28	11.9%	-0.07 [-0.72, 0.59]
Ostwald 1999 (6)	6.16	5.26	52	4.87	3.54	31	14.3%	0.27 [-0.17, 0.72]
SepeMonti 2016 (7)	21.11	12.18	67	22.93	14.61	56	15.2%	-0.14 [-0.49, 0.22]
Total (95% CI)			**352**			**346**	**100.0%**	**-0.30 [-0.71, 0.10]**

Heterogeneity: Tau² = 0.25; Chi² = 39.80, df = 6 (P < 0.00001); I² = 85%
Test for overall effect: Z = 1.47 (P = 0.14)

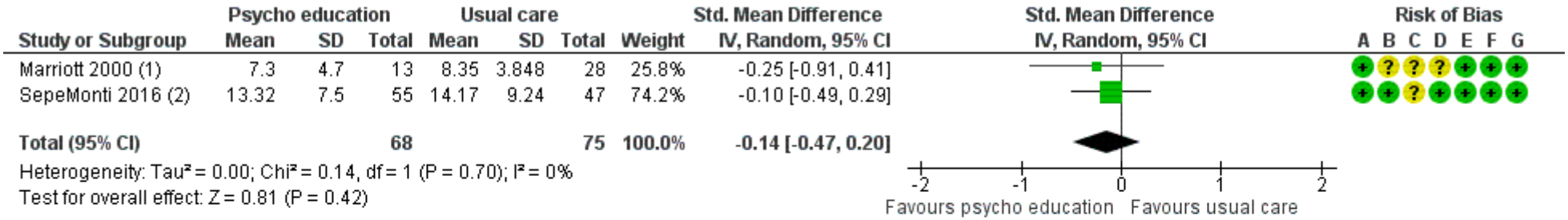


Footnotes
(1) Revised version of RMBP, frequency, disruption-related
(2) NPI
(3) NPI-Q
(4) Revised version of RMBP, disruption-related
(5) MOUSE-PAD. The control groups are pooled
(6) Revised version of RMBP, disruption-related
(7) NPI

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

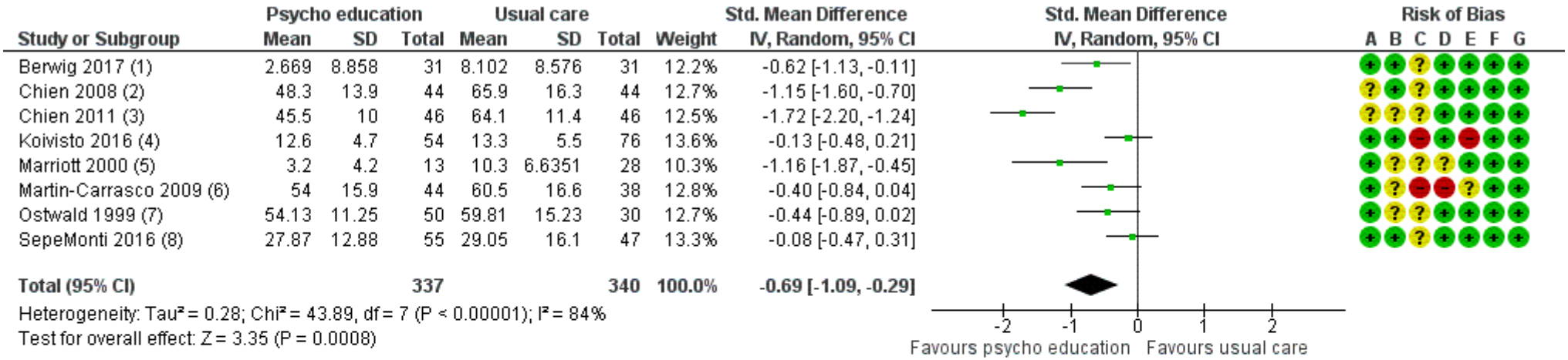
Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.2 BPSD_end of treatment.

Figure 4 (Analysis 2.3)



Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.3 Depression_longest follow-up max 24 mo.

Figure 5 (Analysis 2.4)

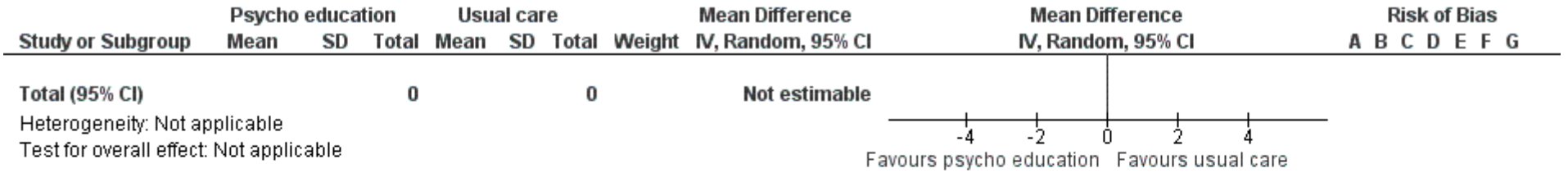


Footnotes
(1) ZBI revised 22-item
(2) Family Caregiving Burden Inventory
(3) Caregiver Burden Inventory
(4) GHQ. Measured at 36 months of follow-up.
(5) GHQ. The control groups are pooled
(6) ZBI 28-item
(7) ZBI revised 22-item
(8) Caregiver Burden Inventory

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

Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.4 Caregivers burden_longest follow-up max 24 mo.

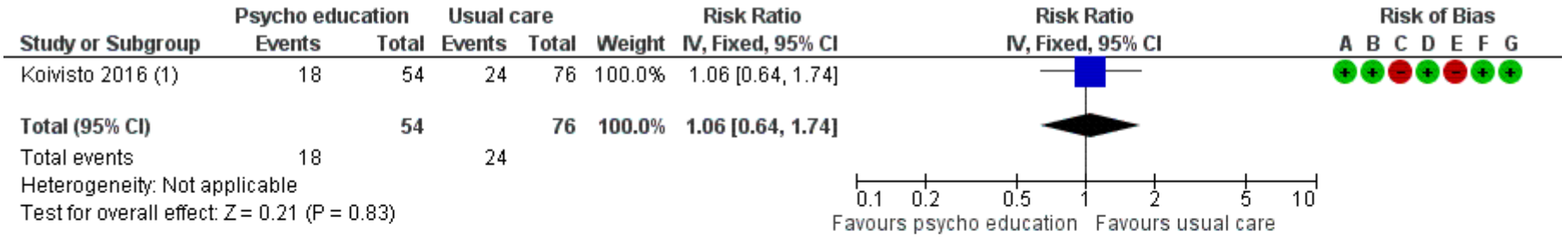
Figure 6 (Analysis 2.5)



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

Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.5 Institutionalisation_end of treatment, SD.

Figure 8 (Analysis 2.8)

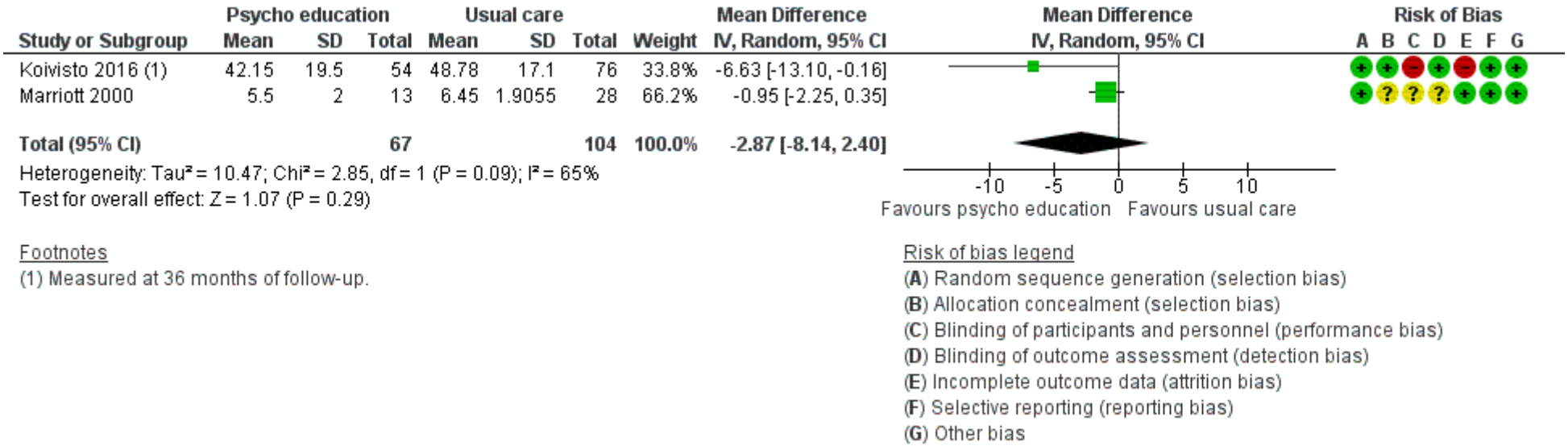


Footnotes
(1) Measured at 36 months of follow-up.

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

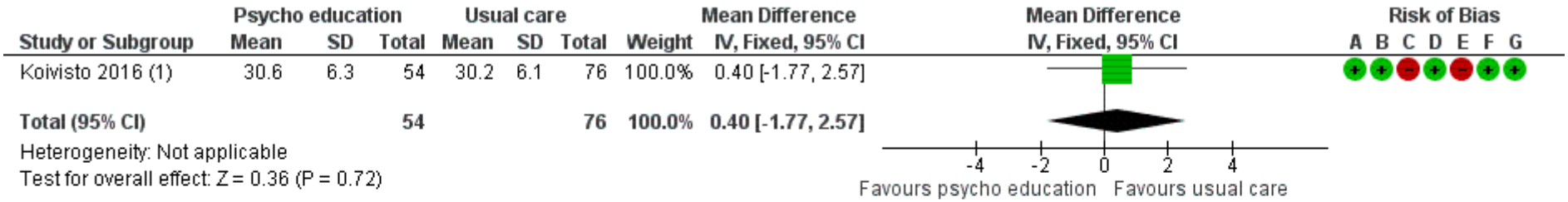
Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.8 Institutionalisation_longest follow-up max 24 mo.

Figure 9 (Analysis 2.11)



Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.11 ADL_longest follow-up max 24 mo.

Figure 10 (Analysis 2.12)

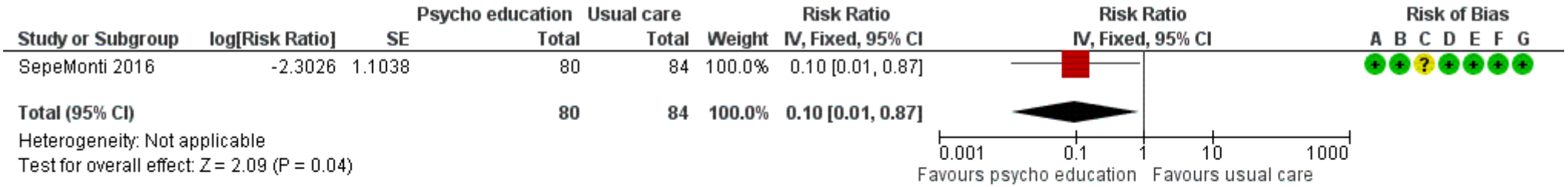


Footnotes
(1) Measured at 36 months of follow-up.

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

Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.12 Quality of life_longest follow-up max 24 mo.

Figure 11 (Analysis 2.14)



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

Forest plot of comparison: 2 Psycho education vs usual care, outcome: 2.14 Usage of antipsychotic medication_longest follow-up max 24 mo.