NKR24 - PICO5 - Schizophrenia: Familyintervention vs TAU

Characteristics of studies

Characteristics of included studies

Barrowclough 2001

Methods	Allocation: randomised - computer generated random list. Blindness: assessor blind. Duration: 9 months, with follow up at 12 and 18 months. Setting: Tameside and Glossop, Stockport and Oldham, England
Participants	Diagnosis: comorbid schizophrenia and substance use disorders (ICD 10 and DSM IV) . N = 36. Age: range 17-62 years, mean 30.5. Sex: 33 M, 3 F. History: median duration 4 years, range 1-19 years, informed consent obtained
Interventions	1. Motivational interviewing, cognitive behavioural intervention and family intervention, using individual and combined sessions, in addition to standard care. N = 18 2. Standard care. N = 18. Family intervention consisted of 10-16 sessions and the individual interventions (CBT and motivational intervention) occurred on ~ 29 sessions
Outcomes	Death. Global state: GAF. Mental state: PANSS. Social functioning: SFS. Relapse. Unable to use - Addiction Severity Index: no usable data. The Drugs Attitude Inventory: no usable data. The Leeds Dependence Questionnaire: no usable data. The Alcohol Use Scale: no usable data. Drug Use Scale of the Clinician Rating Scale: no usable data
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised, computer generated
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	Single, untested
Blinding of outcome assessment (detection bias)	Unclear risk	Single, untested
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Bradley 2006

Methods	Allocation: randomised (by a staffmember who drew names froma canister and, without looking at the names). Blindness: single (Independent researcherswhowere blind to study condition, conducted the assessments). Duration: 12 months with 18-month follow up. Setting: Australia.
Participants	Diagnosis: schizophrenia (DSM IV). N = 59*. Age: mean 34. Sex: 15 M, F 35. History: 21 had received hospital treatment before study entry; ten participants had a substance disorder. Inclusion criteria: who had a diagnosis of schizophrenia, schizoaffective disorder, or schizophreniform disorder; who were aged between 18 and 55 years; and who had a minimum of 10 hours of contact with family members each week
Interventions	1. Family intervention therapy plus case management. N = 30. 2. Case management. N = 29.
Outcomes	Leaving the study early. Mental state: BPRS, SANS. QoL.

	Social functioning: HoNOS. Family outcome: Family Burden Scale.
Identification	
Notes	*Nine participants completed the data collection procedure after treatment Family intervention - 26 sessions over 12 months

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised - no further details
Allocation concealment (selection bias)	Unclear risk	Randomised by a staff member who drew names froma canister and,without looking at the names
Blinding of participants and personnel (performance bias)	Unclear risk	Single blind, independent researchers who were blind to study condition, untested
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Low risk	Principally funded by grant 1997-0219 from the Victorian Health Promotion Foundation

Bressi 2008

Methods	**Study design:** **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 29.5 (6.5) ● *Sex (male %)*: 70 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: 101.0 (68.5) ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: 28.6 (7.4) ● *Sex (male %)*: 80 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: 103.6 (97.1) ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** diagnosis of schizophrenia or disorders from the schizophrenicspectrum (delusional disorder, schizophreniformdisorder, schizoaffective disorder, schizoid and schizotyp18 and 65 years of age. Theywere required to have lived in the family of origin for at least 6months, and had face to face contact of at least 35 h a week withthe relatives concerned.patientswere required to be taking an atypical neuroleptic, regardless ofany other medication prescribed. **Excluded criteria:** presence of an organic disorder underlying the psychiatric condition or an IQ lower than 75.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: Milan Systemic Model:The therapeutic process consisted of an assessment phase plusa series of 12 family sessions lasting 1.5 h each, held on a monthlybasis, or more frequently if necessary. The patients undergoing SFTalso received routine psychiatric treatment. Patients attended thesesessions together with the relatives with whom they livedIn the initial phase of SFT, relatives and patients attended psychoeducationalsessions to enhance their knowledge with regardto the most prominent aspects of the illness: symptoms, precipitatingevents, prodromic signs of relapse, and the importance ofcompliance with medical treatment. TAU ● *Description*: This consisted of drug treatment related to a series of clinicalinterviews carried out by the patient's treating psychiatrist (who does not work at the hospital, but is assigned to a given district)in order to investigate the outcome measures established by theExpert Consensus Guidelines for the Treatment of Schizophrenia[11] . The frequency of the interviews varied from case to case,with a minimum of one session per month.
Outcomes	*Continuous*: ● Family burden, FBIS ● Days at hospital ● Carer satisfaction ● QoL ● Social functioning ● Symptoms *Dichotomous*:

	● Clinical relapse ● Crimes ● Imprisoned ● Readmissions
Identification	**Sponsorship source:** Not stated **Country:** Italy **Setting:** **Comments:** **Authors name:** Cinzia Bressi **Institution:** Psychiatric Clinic, Milan State University **Email:** cinzia.bressi@unimi.it **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** *Jesper ØStrup Rasmussen* End of treatment, and 12 mo after end of treatment. relapse defined as:the transition from a nonschizophrenic state to a schizophrenicstate, with the appearance of specific symptoms evaluatedon a standardized scale (PSE), or the marked re-exacerbationof a symptom already present at t0.Days at hospital not reported, but readmissions reported. **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Not described, only randomisation.
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible to blind pt' or personnel
Blinding of outcome assessment (detection bias)	Low risk	Comment: Very little is descibed, but it says: The variables were assessedon a monthly basis and were blind with respect to treatment. Theassessment was made by a single psychiatrist who interviewed thepatients' treating psychiatrists
Incomplete outcome data (attrition bias)	Low risk	Comment: No incompleted participants:All patients completed the therapy prescribed for the12 months in question and were reassessed 12 monthsafter the course of treatment was completed.
Selective reporting (reporting bias)	Unclear risk	Comment: No trial protocol.
Other bias	Low risk	

Buchkremer 1995

Methods	Allocation: 'randomly assigned'. Blindness: not blind. Duration: 10 weeks family therapy, follow up 1 year. Setting: Italy.
Participants	Diagnosis: schizophrenia (DSM-III). N = 99. Age: range 18-48 years, mean 27. Sex: 72 M, 27 F. History: > 2 episodes or clinically deteriorating, mean previous episodes 2.6, mean duration ill 5.5 years. Exclusions: psychiatric secondary diagnoses.
Interventions	1. Therapeutic relative groups: psychoeducational training, problem solving + relatives self-help groups, self-supporting after 6 months, 1 session/2 weeks for 1 year. N = 67 2. Standard care. N = 32.
Outcomes	Death. Relapse. Hospital admission. Unemployed. Independent living. Unable to use - Mental state: AMDP (no usable data). Global state: CGI, GAS (no usable data). Hospitalisation: no usable data. Length of admission: no data reported. Additional medication: no usable data.

	Family experience: CFI, FKI, MFB (no usable data).
Identification	
Notes	The therapeutic relative groups and self help groups are added in this review

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	Not blinded
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Carra 2007

Methods	Allocation: randomised using random number table. Blindness: 'both relatives and clinicians in the IG groups programme were blind as to successive participation to the SG'. Duration 2 years. Setting: Italy.
Participants	Diagnosis: schizophrenia. N = 101. Age: mean 29 years. Sex: 73 M, 28 F. History: clinically stable. Inclusion criteria: relatives living with someone suffering from schizophrenia and had not attended family groups or other support services before the study intervention; the patient was clinically stable (having had no psychiatric hospitalisation or any relapse for six months prior to study entry) and was not receiving any psychosocial or rehabilitative treatment other than standard care; absence of alcohol or drug dependence or organic disease
Interventions	1. Family support programme. N = 26. 2. Information group. N = 50. 3. Treatment as usual. N = 25. All groups received standard antipsychotic care.
Outcomes	Relapse. Hospitalisation. Compliance with standard community care. Objective burden: self-sufficiency, social functioning, worsened. Relatives' EE was evaluated by the CFI.
Identification	
Notes	The family support programme is consists of two components that roughly correspond to the phases of the group. The first phase involves training on communication and coping skills, stress identification and management, and multiple family group-based problem solving, basically derived from the second stage of the psychoeducational multiple family group approach used by McFarlane Weekly sessions composed of 16-18 relatives for 24 sessions (1.75 h per session) and leaflets. The second element comprises weekly meetings for 48 sessions (1.5 h per session) over 2 yearswith a support groupmade up of 8-9 relativeswho have previously attended the information group

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using random numbers table
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	no details
Blinding of outcome assessment (detection bias)	Low risk	Follow-up assessments were carried out by research assistants blind about the treatment assigned, untested
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	no details
Other bias	Low risk	

Chen 2005

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	Study attrition not reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Chien 2004

Methods	Allocation: randomised, computer generated numbers. Blindness: not reported. Duration: 3 months. Setting: Hong Kong, China.
Participants	Diagnosis: schizophrenia (DSM IV). N = 48. Age: range 20-50+ years, mean 40. Sex: 27 M, 21 F. History: illness less than 3 years, with no comorbidity or other mental illness
Interventions	1. Mutual family support: twelve, 2-hour group sessions per week, co-facilitated by a psychiatric nurse. Mutual support included: sharing personal data, fostering dialectical processes, encouraging discussion of taboo areas, fostering a sense of 'all being in the same boat', encouraging mutual support, providing opportunities of individual problem solving and standard care. N = 24. 2. Standard care. N = 24. Standard care, mostly chlorpromazine, haloperidol (88% in the experimental group and 85% in the control group), with > 70% taking the medium dose
Outcomes	Leaving the study early. Global state: hospital admission. Family outcome: family Burden Interview Schedule. Family outcome: family Assessment Device. Family outcome: family Support Service Index..
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomsied, by computer generation
Allocation concealment (selection bias)	Unclear risk	no details
Blinding of participants and personnel (performance bias)	Unclear risk	no details
Blinding of outcome assessment (detection bias)	Unclear risk	no details
Incomplete outcome data (attrition bias)	Unclear risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	no details
Other bias	Unclear risk	no details

Chien 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*:

	● *Sex (male %)*: ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: ● *Sex (male %)*: ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** All the families that met the following inclusioncriteria were invited to participate:a. Families living with and caring for one relative with aprimary diagnosis of schizophrenia, according to criteriaof the Diagnostic and Statistical Manual of MentalDisorders, 4th edition, DSM-IV [38];b. The relative with schizophrenia did not suffer comorbidityof other mental illness during recruitmentto the study and who had been diagnosed withschizophrenia for three years or less; andc. Those were aged 18 years or over and able to understandand read the Chinese language. **Excluded criteria:** Exclusion criteria included those who cared for morethan one family member with mental illness, who themselveshad mental illness, and who were the primary carers for lessthan three months.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: a 36-week program of mutualsupport and the conventional psychiatric outpatient care.The group met on a bi-weekly basis for 18 sessions (overnine months), each lasting about two hours TAU ● *Description*: included medical consultationand advice, individual nursing support and advice onavailable community health care services, social welfare andfinancial services provided by a medical social worker, andcounseling by a clinical psychologist if necessary. At completion,as an ethical move, we invited the participants in theroutine care group to participate in a similar psychoeducationgroup should they wish to do so, as the group interventionwere effective.
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction ● Social functioning ● Symptoms *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** this study was funded by the Deparmental grant of theNethersole School of Nursing, CUHK **Country:** Hong-Kong China **Setting:** Outpatient clinic **Comments:** **Authors name:** Wai Tong Chien **Institution:** The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Shatin, Hong Kong SAR, P.R. China **Email:** wtchien@cuhk.edu.hk **Address:** the Nethersole School of Nursing,7/F., Esther Lee Building, Chung Chi College, The Chinese University ofHong Kong, Shatin, N.T., Hong Kong SAR, P.R. China
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** *Elisabeth Ginnerup-Nielsen* Readmissions er opgivet i continous outcomes som en mean af hele gruppen ved hver assessment **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "They were then selected randomly from the patient list, using a computer-generated random numbers table."

Allocation concealment (selection bias)	Low risk	Quote: "the participants were then asked by the principal researcher to draw a sealed opaque envelope,"
Blinding of participants and personnel (performance bias)	High risk	Quote: "Except for the principal researcher and the group instructor, all other clinic staffs were blinded to treatment allocation." Comment: Patient ptobably not blinded
Blinding of outcome assessment (detection bias)	Low risk	Quote: "clinic staff and an outcome assessor who were blind to the families' allocation of groups; (c)"
Incomplete outcome data (attrition bias)	Low risk	Comment: ITT analysis and only 1/35 and 2/35 repectively dropped out
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Chien 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: ● *Sex (male %)*: ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: ● *Sex (male %)*: ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** Caregivers were eligiblefor the study if they were 18years or older, if they were the maincaregiver for the relative with schizophrenia,and if they lived with the relativewith schizophrenia. Patients hadto be diagnosed as having schizophrenia according to DSM-IV criteria andbe 18 years or older. **Excluded criteria:** Caregivers whohad mental illness themselves orcared for more than one relative withmental illness were excluded.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: The SCMP was composedof 14 two-hour sessions foreach individual patient-caregiverdyad every other week. The programwas based on the family psychoeducationand support programs developedby Chien and colleagues (1,5) andMcFarlane (3) and consisted of sixstages: orientation and engagement,educational workshop about schizophreniacare, caregiving role andtherapeutic communication, experiencesharing and problem solving,community support resources, andtermination of the program. TAU ● *Description*: The usual care group received routinepsychiatric outpatient and familyservices only. These services consistedof monthly medical consultationand treatment planning by the attendingpsychiatrist, nursing adviceon community health care services,and brief family education (two groupsessions) on patients' illness by psychiatricnurses and social workers. Allpatients and their family memberswere invited by the nurse in the clinicto participate in all of the services.
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction SSQ6 ● Social functioning ● Symptoms *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** This research was supported by departmentalresearch grant 2006-07 from the School ofNursing at the Chinese University of HongKong. **Country:** Hog Kong **Setting:** **Comments:** **Authors name:** Wai Tong Chien **Institution:** School of Nursing, Faculty of Health and Social Sciences, Hong Kong Polytechnic University,

	Email: hschien@inet.polyu.edu.hk **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Jesper ØStrup Rasmussen* There were no significantsociodemographic or clinical differencesbetween the two studygroups and the 408 persons who didnot participate in the study. **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Jesper ØStrup Rasmussen* FU: 15 mdr. scalessymptoms: BPRS (higher=better)Functioning: SLOF (Specific Level of Functioning scale; possible scores range from 43 to 215, with higher scores indicating better functioning.)days at hospital last 6 mo.carer satisfaction: SSQ6 (The items are rated on a six-point Likert scale, with a higher total score (ranging from 0 to 6) indicating more satisfactionwith the available social support.) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the par- ticipants were randomly assigned to the usual care or the SCMP group." Comment: Unclear how randomisation was doneIt only says "randomised"
Allocation concealment (selection bias)	Unclear risk	Comment: Not described.
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible to blind patients, therapists or caregivers
Blinding of outcome assessment (detection bias)	Low risk	Comment: One researcher who was blind tothe group assignment administeredthe pretest before the patient-caregiver caregiverdyads were randomly assigned togroups and administered two posttestsat one and 15 months after theintervention.
Incomplete outcome data (attrition bias)	Low risk	Quote: "Data were an- alyzed on an intention-to-treat basis that maintained the advantages of ran- dom allocation" Comment: High FU rates.
Selective reporting (reporting bias)	Low risk	Comment: No protocol but study well done
Other bias	Low risk	

Chien 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 25.2 (7.6) ● *Sex (male %)*: 60.0 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: 26.2 (8.0) ● *Sex (male %)*: 64.4 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** The inclusion criteria of family caregivers and patientswith schizophrenia were those who were: (a) aged 18years or above, speaking in Mandarin/Cantonese; (b) one ofthe main carers who lived with and provided most of thecare for their relative who had a primary diagnosis ofschizophrenia according to the criteria in the Diagnosticand Statistical Manual, DSM-IV (American PsychiatricAssociation, 1994); and (c) patients who did not haveany co-morbidities in terms of other mental disorders atbaseline. **Excluded criteria:** Exclusion criteria included those caregivers whothemselves suffered from mental illness or who had beenthe primary carers for less than three months; and thosepatients who were mentally unstable or who had been rehospitalisedbefore the random assignment of the participantsinto study groups.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: While the introductionand orientation to the group programme and itsobjectives were made during the first two sessions, theother 12 group sessions were mainly conducted by a groupleader (advanced psychiatric nurse) or guest speakers (i.e.,mental health professionals) using didactic teaching todiscuss mental illness and its treatment

	and the servicesthat are available (Sessions 2–5), common and individualissues in family and patient caregiving (Sessions 5–8), thesharing of the caregiving role and the difficulties faced bythe participants and experienced family caregivers (Sessions8–10), training in problem solving and caregivingskills, and behavioural rehearsals conducted by the clinicalpsychologists and the group leader (Sessions 9–12), andthe development of a social network, coping skills, andfuture plans in caregiving (Sessions 12–14). The emphasiswas placed on the importance of the family environmentand relationships and on the demands of caregiving,imparting information about the mental illness and itstreatment and available community services, and discussionson stress management and caregiving skills such aseffective communication, medication compliance, establishinginterpersonal relationships, and crisis intervention. TAU ● *Description*: Forty-five family caregivers in standard care (plus thosein the mutual support and psycho-education groups)received the routine psychiatric outpatient care, consistingof psychiatric consultations and treatment by a psychiatrist(every 4–6 weeks); a brief education session onmental illness and its treatment and services, conducted bypsychiatric nurses (every 1–2 months); training in employmentand social skills, conducted by an occupationaltherapist (when referred by a psychiatrist or socialworker); and social welfare services and counselling,offered by a social worker (every 4–6 weeks after thepsychiatric consultation)
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction SSQ6 ● Social functioning ● Symptoms BPRS ● Symptoms PANNS *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** Health Care and Promotion Fund, Food andHealth Bureau, The HKSAR Government supported theresearch and governed the progress and review of theresearch. **Country:** Hong-Kong China **Setting:** **Comments:** **Authors name:** Wai Tong Chien **Institution:** School of Nursing, Faculty of Health and Social Sciences, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong Special Administrative Region **Email:** wai.tong.chien@polyu.edu.hk **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* *Jesper ØStrup Rasmussen* Time 1=end of treatment, Time 2=længtse FU (24 mdr).skalaer:Socialfunktion: SLOF - socialfunktion subscale (higher=better)Pårørendetilfredshed: SSQ6 (higher=better) **Dichotomous outcomes:** *Elisabeth Ginnerup-Nielsen* Note fjernet igen **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "After completing the pre-test questionnaires after the outpatient clinic follow-up consultation, family caregivers were assigned into groups of three in terms of their patients' dates of follow-up in the clinics and asked by the first author to draw a labelled card (one of three cards respectively labelled: 1 = 'mutual support'; 2 = 'psycho-education';" Comment: Patients primarily diagnosed as suffering from schizophreniawere selected randomly by the first author fromthe patient lists (in alphabetical order of their names) ofthe two outpatient clinics in Hong Kong.
Allocation concealment (selection bias)	Unclear risk	no information
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible to blind pt's or personel
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Unclear if blinded
Incomplete outcome data (attrition bias)	Low risk	Quote: "All of the data were analysed on an intention-to- treat basis" Comment: And only 1/45 and 2/45 dropout

Selective reporting (reporting bias)	Low risk	Quote: "ClinicalTrials.gov (NCT00940394)]" Comment: Outcome in protocol relevant and assessed
Other bias	Low risk	

Chien 2013a

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 26.3 (6.1) ● *Sex (male %)*: 60 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: 28.2 (5.2) ● *Sex (male %)*: 64 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** Inclusion criteria were caregiversliving with and caring for a relativewith a primary diagnosis of schizophreniathat met DSM-IV criteria,patients with no other mental illnessat baseline, age .17 years, and understandingof Mandarin or Cantonese **Excluded criteria:** Exclusion criteria included caregiverswho had mental illness themselves(N=58) or who had been primarycaregivers for less than three months
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: nine-monthFPGP program modified from ourprevious work (1,9,13), which provideda hybrid model of care integratingpeer support and educationinto the context of standard psychiatriccare. The 14 group sessions (eachlasting two hours) were mainly heldevery two to three weeks, and participantswere encouraged to interactand have activities outside of thesegroup sessions TAU ● *Description*: routine outpatientcare.
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction ● Social functioning ● Symptoms *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** This study was supported by grant 216020 fromthe Health Care and Promotion Fund, HospitalAuthority Hong Kong S.A.R. **Country:** China **Setting:** **Comments:** **Authors name:** Wai Tong Chien **Institution:** the School of Nursing and the Faculty of Health and Social Sciences, PQ402, Hong Kong Polytechnic University **Email:** wai.tong.chien@polyu.edu.hk **Address:** the School of Nursing and the Faculty of Health and SocialSciences, PQ402, Hong Kong Polytechnic University, Hung Hom, Kowloon
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* SLOF overall tastet i skemaSLOF social functioning subscale: end of treatment mean (sd) Intervention group: 44.80 (15.8) N=35Control group: 38 (10.1) N=36Longest FUintervention: 53.70 (18.90) N=35control:

	40.50 (7.50) N=36 **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "106 were randomly selected from the patient lists by means of computer-generated num- bers,"
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Participants were assessed at recruitment and again one week (posttest 1), 18 months (posttest 2), and 36 months (posttest 3) after completion of the interventions by a trained research nurse who was independent from the participants' recruitment procedure and blind to their intervention participation."
Incomplete outcome data (attrition bias)	Low risk	Quote: "FPGP (very low dropout rates)."
Selective reporting (reporting bias)	Low risk	Quote: "This trial is registered as NCT00940394 at clinicaltrials.gov." Comment: Outcome from protocol reported
Other bias	Low risk	

Dai 2007

Methods	
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no details
Allocation concealment (selection bias)	Unclear risk	no details
Blinding of participants and personnel (performance bias)	Unclear risk	no details
Blinding of outcome assessment (detection bias)	Unclear risk	no details
Incomplete outcome data (attrition bias)	Unclear risk	no details
Selective reporting (reporting bias)	Unclear risk	no details
Other bias	Unclear risk	no details

Dyck 2002

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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Randomised by pulling papers out of a hat labelled with study group
Allocation concealment (selection bias)	High risk	
Blinding of participants and personnel (performance bias)	High risk	open study
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	High risk	Not all outcome data reported
Other bias	Low risk	

Fallon 1981

Methods	
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Interventions	
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Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Fernandez 1998

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Garety 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 35.0 (12.3) ● *Sex (male %)*: 71,4 ● *Length of illness (years), mean (sd)*: 13.3 (11.8) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: 52.11 (15.89) ● *SOFAS mean (sd)*: TAU ● *Age, mean (sd)*: 35.6 (11.2) ● *Sex (male %)*: 67,9 ● *Length of illness (years), mean (sd)*: 10.5 (8.6) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: 55.21 (14.77) ● *SOFAS mean (sd)*: **Included criteria:** Participants were recruited by approaching consecutive patientswho had recently relapsed, whether or not they had beenadmitted. After this index relapse, patients were screened andinvited to take part as soon as they were

	thought able to giveinformed consent. The inclusion criteria were:(a) a current clinical diagnosis of non-affective psychosis (ICD−10category F2 and DSM−IV);(b) age 18−65 years;(c) a second or subsequent psychotic episode starting not morethan 3 months before they agreed to enter the trial;(d) a rating of at least 4 (moderate severity) for at least onepositive symptom on the Positive and Negative SyndromeScale (PANSS) **Excluded criteria:** Criteria for exclusion from the trial were:(a) a primary diagnosis of alcohol or substance dependency,organic syndrome or intellectual disability;(b) a command of spoken English inadequate for engaging inpsychological therapy;(c) unstable residential arrangements such that the likelihood ofbeing available for the duration of the trial was low.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: Family intervention followed the manual of Kuipers et al21 with anemphasis on improving communication, offering discussion ofup-to-date information about psychosis, problem-solving,reducing criticism and conflict, improving activity, and theemotional processing of grief, loss and anger.9 months. TAU ● *Description*: Treatment as usual consisted of good standard care deliveredaccording to national and local service protocols and guidelines,including the prescription of antipsychotic medication. Thefrequency and nature of service contacts was monitored, as wasthe prescription of medication. Treatment as usual did notpreclude the provision of psychological interventions, althoughin practice this was relatively rare, as reported below.
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL Euroqol ● Days at hospital ● Carer satisfaction ● Social functioning SOFAS higher=better ● Symptoms PANSS total *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** The study was supported by a Wellcome Trust Programme Grant **Country:** UK **Setting:** **Comments:** **Authors name:** Philippa A. Garety **Institution:** Department of Psychology, Institute of Psychiatry **Email:** p.garety@iop.kcl.ac.uk **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Jesper ØStrup Rasmussen* Scales:Symptoms: PANSS (Low=better)Social functioning (high=better) *Elisabeth Ginnerup-Nielsen* Social and occupational functioning is rated on a scale of0−100 by the assessor using the Social and Occupational FunctioningAssessment Scale (SOFAS). Higher scores = better adaptive functioning **Dichotomous outcomes:** *Jesper ØStrup Rasmussen* Definition of relapse: Remission and relapse ratings were made using a publishedmethod employed in a previous randomised controlled trial.1,24Consensus ratings are made by paired members of the researchteam using manualised a priori operationalised definitions, amethod with moderate to good reliability (kappa values of 0.56and 0.71 for the identification of remission and relapse respectivelybetween paired raters) and good validity (independentPANSS ratings were strongly related to the remission/relapseratings of participants).24 Ratings are based on changes in positivepsychotic symptoms. Evidence is required of improvement in (forpartial remission) or absence of (for full remission) positivepsychotic symptoms continuing for at least 4 weeks. Relapseratings are based on evidence of the re-emergence of, or significantdeterioration in, positive psychotic symptoms of at least moderatedegree persisting for at least 2 weeks.Only by 24 mo. Relapse in those with partial or full remission from initial episode. *Elisabeth Ginnerup-Nielsen* Er lidt i tvivl om hvornår dette outcome er rapporteret.. Umiddelbart virker det som om tabel 1 rapporterer ved 12 mdr?? **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was also stratified within each of the five participating centres and within in-patient or out-patient status at the time of relapse. Randomisation schedules were independently generated by a trial randomisation service"

Allocation concealment (selection bias)	Low risk	Quote: "Randomisation schedules were independently generated by a trial randomisation service in a separate location from all trial centres (accessed by telephone)," Comment: Randomisation schedules wereindependently generated by a trial randomisation service in aseparate location from all trial centres (accessed by telephone)
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible to blind pt's and personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Trial research assessors were independent of treatment delivery and every effort was made to ensure they were kept masked to allocation. The primary outcome variable, relapse, was assessed by masked panel evaluation following the procedure" Comment: Trial research assessors were independent of treatment deliveryand every effort was made to ensure they were kept masked toallocation. The primary outcome variable, relapse, was assessedby masked panel evaluation following the procedure describedby Craig et al1 and Bebbington et al
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	Comment: No protocol but relevant outcome assessed
Other bias	Low risk	

Giron 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 30.92 (6.98) ● *Sex (male %)*: 64 ● *Length of illness (years), mean (sd)*: 11.64 (8.91) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: 54.20 (12.97) TAU ● *Age, mean (sd)*: 32.12 (9.05) ● *Sex (male %)*: 84 ● *Length of illness (years), mean (sd)*: 10.36 (5.94) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: 52.20 (14.73) **Included criteria:** (i) schizophreniaor schizophreniform disorder according toDSM-IV criteria (APA, 1994); (ii) to select patients withsevere and persistent disorder but with sufficientstability to allow for establishing a reliable baseline,the following operative criteria were applied: persistingpositive psychotic symptoms for more than 1 yearor a clinical relapse in the previous 2 years, with atleast 2 months of clinical stability, defined as no variationsin two Psychiatric Assessment Scale (PAS) ratingstaken at an interval of 1 month. Patients with suchsevere persistent symptoms that it was not possible toidentify a clinical relapse on the PAS were excluded;(iii) aged 17–55 years; (iv) having lived at home formore than 1 month with a key relative (identified asthe relative with the greatest number of hours of faceto-face contact with the patient) with a critical attitude,measured by means of the Semantic Differential (atleast one item with a positive score under the dimensionof negative evaluation or passivity), or a deficit inempathic capacity (index of empathic capacity o0.5)measured using the Empathy Questionnaire (Giro´n & Go´mez-Beneyto, 1995, 2004); (v) absence of mentalretardation, serious cognitive disorder, abuse or dependenceon toxic substances according to the DSMIVcriteria in the patient and their relative, includingserious mental illness in the latter ; and (vi) familygroup or key relative had not received psychoeducationalfamily intervention lasting for more than3 months. **Excluded criteria:**
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: The family intervention technique of Kuipers et al.(2002) was used. The key elements of the programme were: providing information, active listening and clarificationof emotions, problems and needs, establishinga therapeutic alliance, improving communication,problem-solving techniques, diminishing critical attitudesand overinvolvement, and training in empathy.The intervention team was composed of highly experiencedpsychiatrists, psychologists, social workersand nurses. They were trained specifically in familyintervention by a member of Julian Leff's team. Thesessions were held every fortnight during the first9 months and then monthly for the remaining15 months. TAU ● *Description*: Thestandard treatment included support, home visits,social work, rehabilitation and medication. Individualcounselling consisted of problem-solving and psychologicalsupport given by an experienced psychiatristwho had no training in the family intervention technique
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction ● Social functioning

	● Symptoms PANSS *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** This study was supported by project grant 97/1159from Fondo de Investigaciones Sanitarias, and projectgrant 011010 from Fundacio´ La Marato´ de TV3. Thisstudy was supported by the Associacio´ Valencianade Doce`ncia i Investigacio´ en Salut Mental. **Country:** Spain **Setting:** **Comments:** **Authors name:** M. Giron **Institution:** Department of Clinical Medicine, University Miguel Herna´ndez, Alacant, Spain **Email:** giron@icali.es **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* Family burden was evaluated by means of theSpanish version of the Social Behaviour AssessmentSchedule (SBAS; Plattet al. 1980; Go´mez-Beneyto et al.1986).(the sum ofthe key relative's rating of the level of objective difficultiesin eight areas of his/her life when these are notconsidered in relation to the presence of the patient athome was also used)(the higher the score, the moreburden perceived) *Jesper ØStrup Rasmussen* Interventionperiod: 24 mo. Scales:clinical relapse definition: To establish clinical relapse, the method of Vaughn et al. (1984) was followed. Persisting positive symptoms were definedaccording to criteria described previously (Giro´n &Go´mez-Beneyto, 1995, 2004).Burden: SBAS (Low=better) *Jesper ØStrup Rasmussen* Length if intervention: 24 mo, no FU. Clinical relapse definition: To establish clinical relapse, the method of Vaughn et al. (1984) was followed. Persisting positive symptoms were definedaccording to criteria described previously (Giro´n & Go´mez-Beneyto, 1995, 2004).Family burden: SBAS (low=better) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Carpenter, 1974). Two patients with level 0−1 or level 2−4 on the Quantity of Useful Work scale were randomized to two groups: family intervention+individual counselling+standard treat- ment, or individual counselling+standard treatment." Comment: Not clear how randomisation was achieved?
Allocation concealment (selection bias)	Low risk	Quote: "1974). Two patients with level 0−1 or level 2−4 on the Quantity of Useful Work scale were randomized to two groups: family intervention+individual counselling+standard treat- ment, or individual counselling+standard treatment. The allocation to each group was carried out blind to the identity of the patient." Comment: The allocation to each group was carried out blind tothe identity of the patient.
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible to blid pt's and personnel
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Evaluation was carried out by a psychiatrist who was not involved in the processes of treatment, randomization or allocation. Active mea- sures were taken to guarantee the evaluator's blind- ness to the patient study group."
Incomplete outcome data (attrition bias)	Low risk	Quote: "An intention-to-treat analysis was performed." Comment: And no dropoutHigh FU rates.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Glynn 1992

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Goldstein 1978

Methods	Allocation: randomised, stratified by premorbid psychosocial competence, sex - no further details. Blindness: single - definition of relapse + BPRS, single and non-blind - decision to rehospitalise. Duration: 6 weeks treatment, 6 months follow up. Setting: Ventura, USA. Design: factorial.
Participants	Diagnosis: schizophrenia (New Haven Index > 4). N = 104*. Age: mean 23.4 years. Sex: 57 M, 47 F. History: 'acute', consecutive admissions, 1-2 previous admissions
Interventions	1. Crisis-orientated family therapy: 1 session/week, 6 weeks + standard care, varied treatment thereafter. N=52 2. No family therapy: standard care, varied treatment after 6 weeks. N = 52 Factored with: A. High dose fluphenazine. B. Low dose fluphenazine.
Outcomes	Relapse (full-time admission, partial hospitalisation or substantial change inmedication) . Leaving the study early. Unable to use: Mental state: BPRS (subgroup analysis, no SD). Suicide: N = 2, original allocation unclear. Service use: no usable data.
Identification	
Notes	* total N is 103 in second paper - reasons unclear. Data relating to high and low dose fluphenazine not used in this review. Leaving the study early data is contradictory in different parts of report - first set of data chosen at random

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	Single blind, untested
Blinding of outcome assessment (detection bias)	Unclear risk	Single blind, untested
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Guo 2007

Methods	
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Herz 2000

Methods	
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Hogarty 1986

Methods	
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Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Hogarty 1997

Methods	Allocation: randomised. Blindness: not blind. Duration: 3 years treatment, 3 years follow up. Setting: Pittsburgh, USA. Design: factorial.
Participants	Diagnosis: schizophrenia + schizo-affective disorders (RDC). N = 97. Age: range 16-55 years, mean 28.6. Sex: 56 M, 41 F. History: acute admissions, mean previous admissions 2.7, mean length of illness 6.2 years. Exclusions: organic brain syndrome, drug or alcohol dependence in past 6 months,

	medical conditions preventing use of antipsychotic medication
Interventions	1. Personal therapy: psychoeducation, relaxation, identification of stressors and prodromal symptoms, social skills training + neuroleptic medication. N = 23 2. Supportive therapy: active listening, empathy and reassurance, advocacy and problem solving + neuroleptic medication. N = 24 3. Family therapy: joining, survival skills training, reintegration into the family and the community + neuroleptic medication. N = 24 4. Personal therapy + family therapy. N = 26. All groups received more than 5 sessions.
Outcomes	Relapse (psychotic). Leaving the study early. Unable to use: Drug compliance: no usable data. Therapeutic alliance: no usable data.
Identification	
Notes	The paper reports two trials (N = 151), one studying patients who lived with families (N = 97) and one studying patients who lived alone. This review only looked at the data from the former trial. For this review supportive therapy is the control arm and family therapy is the intervention

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	Not blinded
Blinding of outcome assessment (detection bias)	High risk	Not blinded
Incomplete outcome data (attrition bias)	Unclear risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Koolaee 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: ● *Sex (male %)*: 72.8 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: ● *Sex (male %)*: 72.8 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 100 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** 1. They were living with and caring for one child with a primary diagnosis of schizophrenia, according to criteria of the DSM-IV (American Psychiatric Association, 1994).2. They were aged 45–65 years.3. They were able to read and write Persian.4. They had the same social-economic status (SES).5. They were resident in the middle-class city of Tehran.6. They had completed a consent-to-participate letter.7. Their schizophrenic child had no other mental illness, and the duration of schizophrenia was three years or less at the time of recruitment. **Excluded criteria:** 1. They had a diagnosis of mental illness.2. They cared for more than one family member with chronic physical or mental illness.3. They had been the primary carer for fewer than three months.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: The programme consisted of 12 weekly two-hour sessions over three months; patients were not included in group sessions.Goals:-Establishment of trusted and explained common goals-Summary of curriculum of family intervention sessions-Education and practising communication skills- Education and practising problem-solving skills-Discussion of themes of earlier sessions TAU ● *Description*: The remaining 19 participants received the routine psychiatric outpatient and family support services. These services varied very little between the two clinics and included: medical consultation and advice; individual nursing support; advice on available community care health services, social welfare and financial services provided

	by a medical social worker; and advice on counselling by a clinical psychologist and counsellor
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction ● Social functioning *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** Not stated. **Country:** Iran **Setting:** **Comments:** **Authors name:** Anahita Khodabakhshi Koolaee **Institution:** Faculty of Counselling and Family, Department of Family Counselling, Social Welfare & Rehabilitation University, Tehran, Iran. **Email:** anna_khodabakhshi@yahoo.com **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Jesper ØStrup Rasmussen* Only for the total sample. **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Jesper ØStrup Rasmussen* Length of intervention: 3 mo. (measurement at baseline (T1), after three months (T2) and after six months (T3)) The FU is then 3 mo, our cutoff is 4 mo. Scales:Burden: FBIS (low=better) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Unclear how randomisation was done
Allocation concealment (selection bias)	Unclear risk	Comment: Nor described.
Blinding of participants and personnel (performance bias)	Low risk	Comment: With the written consent of both patients and mothers, participants received the interventions on two different days of the week; they were therefore unaware of the other intervention methods.
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Following intervention, an independent trained assessor undertook measurement
Incomplete outcome data (attrition bias)	Low risk	Comment: No ITT but relatively small and equal dropout (2/18 and 3/18)
Selective reporting (reporting bias)	High risk	Comment: They write in the measurements section: The number and duration of psychiatric hospital admissions during the preceding three months at T1, T2 and T3 were obtained from the outpatient clinic records.They never present the results.No protocol
Other bias	Low risk	

Kulhara 2009

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 31.1 (11.5) ● *Sex (male %)*: 44.7 ● *Length of illness (years), mean (sd)*: 4.7 (2.6) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: 31.6 (9.8) ● *Sex (male %)*: 65.8

	● *Length of illness (years), mean (sd)*: 5.1 (3.0) ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** a diagnosis of schizophreniaaccording to the Diagnostic and StatisticalManual (28), based on a structuredinterview, a duration of illness of 2–10 yearsand were living with a relative continuously for aperiod of 2 years or more prior to inclusion inthe study. **Excluded criteria:** Patients with comorbid axis I psychiatricdisorders, personality disorders, substanceabuse or dependence (except nicotine), organicbrain syndrome or mental retardation wereexcluded.
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: The structured intervention had two phases.During the engagement, phase attempts weremade to build a positive therapeutic alliance withthe family. Preliminary information (oral⁄printed)about schizophrenia was provided. All this wasdone in a no fault atmosphere i.e. without attachingblame to anyone, especially the family. Thisphase included 1–2 sessions and lasted about amonth. The intervention phase lasted 9 monthsduring which monthly sessions of 40–60 min each,were held with caregivers. The approximate contentof these sessions included education aboutaetiology, symptoms, treatment and prognosis(two sessions); discussion on medication management,alternative treatments, realistic goal setting,substance abuse, marriage and related issues (twosessions); communication training consisting ofimproving clarity of communication, ways ofproviding positive and negative feedback (onesession); problem-solving training consisting ofmanagement of day-to-day problems, non-complianceand stressful life-events (one session); educationabout identification of early signs of relapseand how to seek help (one session); informationabout caring for children, disability benefits,employment opportunities, accessibility to mentalhealth facilities, etc. (one session) and feedback(one session). TAU ● *Description*: out-patient visits, medication management andsupportive counselling of patients and relatives.No other services were available. Specifically,routine treatment did not include structuredpsychoeducational intervention. The duration⁄frequencyof sessions and length of treatment wascomparable with those of structured interventionpackage.
Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction higher=better ● Social functioning *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** This study was funded by the WHO-SEARO, India **Country:** India **Setting:** outpatients **Comments:** **Authors name:** Kulhara P, **Institution:** Department of Psychiatry, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India **Email:** param_kulhara@yahoo.co.in **Address:** Department of Psychiatry, PGIMER,Chandigarh-160012, India.
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Jesper ØStrup Rasmussen* Scales:Carer satisfaction: Satisfaction with treatment among caregivers was rated using the Patient Satisfaction Questionnaire (33), slightly modified for use among caregivers. This four-item scale with scores ranging from 0 to 12 has been found to be a valid index of quality of care in a psychiatric service.Family burden: Burden on caregivers was assessed using the Family Burden Interview Schedule, FBIS (Low=better)resultat: F = 1.74; df = 1, 74; P > 0.05Relapse definition: Relapse was defined as either the presence of psychotic symptoms (delusions, hallucinations, gross-behavioural disturbances)for 2 weeks or more, or re-hospitalisation. *Elisabeth Ginnerup-Nielsen* Carer satisfaction assessed via: Patient Satisfaction Questionnaire modified for use among caregivers. higher scoresindicate greater satisfaction with the aspect of careFamily burden assessed with F values? Probably not usable **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients (and caregivers) were randomly allocated"
Allocation concealment (selection bias)	Low risk	Comment: Patients (and caregivers) were randomly allocatedto the structured psychoeducational intervention,or the routine-care group, using a spss-basedcomputer program.
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible
Blinding of outcome assessment (detection bias)	Low risk	Quote: "This was a blind rating done by one consultant psychiatrist trained in the use of PANSS, based on information from the patient supplemented by the caregiver." Comment: probably all assesments were blinded. First assesment also most important
Incomplete outcome data (attrition bias)	High risk	Quote: "Results of the repeated measures manova were significant for both the Ôintent-to treatÕ sample and the ÔcompletersÕ sub- sample. This indicated that structured-intervention" Comment: But dropout 39 %
Selective reporting (reporting bias)	High risk	Comment: Table 4, much more reported for baseline, than end of treatment.No protocol
Other bias	Low risk	

Leff 1982

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Leff 2001

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Li 2004

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Li 2005

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Linszen 1996

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Liu 2007

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Unclear risk	No details
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Luping 2007

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Unclear risk	No details
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Lv 2003

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Merinder 1999

Methods	Allocation: block randomisation. Blindness: single. Duration: follow up 1 year. Setting: Aarhus, Denmark.
Participants	Diagnosis: schizophrenia (ICD-10). N = 46. Age: range 30.3 - 39.6 years, mean 35.9. Sex: 24 M, 22 F. History: receiving treatment at time of inclusion in community psychiatric centres
Interventions	1. Eight-intervention session using mainly a didactic interactive method with the patient and care interventions performed in separate sessions. N = 23 2. Standard care with psychosocial rehabilitation and supportive psychotherapy. N = 23
Outcomes	Relapse. Leaving the study early. Global state: GAF. Mental state: BPRS, IS. Service satisfaction: VSSS. Knowledge of schizophrenia.
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised by block, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	Single, untested
Blinding of outcome assessment (detection bias)	Unclear risk	Single, untested
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Navidian 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Familyintervention ● *Age, mean (sd)*: 34 (13.14) ● *Sex (male %)*: 58 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 50 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: TAU ● *Age, mean (sd)*: 34 (13.14) ● *Sex (male %)*: 58 ● *Length of illness (years), mean (sd)*: ● *Length of illness (month), mean (sd)*: ● *Schizophrenia, Schizoaffective, schizofreniform (%)*: 50 ● *Level of functioning (GAF, GAS) at baseline, mean (sd)*: **Included criteria:** family caregivers of patientswith schizophrenia **Excluded criteria:**
Interventions	**Intervention Characteristics** Familyintervention ● *Description*: of a weekly, 4-session psycho-educationalgroup intervention for caregivers of patients with mentaldisorders over a period of three monthsfour 120-min sessions held duringfour consecutive weeks with one session each week. Sixpsycho-educational groups of eight or nine caregivers(three groups for schizophrenia and three groups formood disorders) were arranged with the same content,and the program was conducted by a mental healthnurse or psychiatrist. TAU ● *Description*:

Outcomes	*Continuous*: ● Family burden, FBIS ● QoL ● Days at hospital ● Carer satisfaction ● Social functioning ● Symptoms ● Caregiver burden ZBI 0-88 lower=better *Dichotomous*: ● Clinical relapse ● Readmissions ● Imprisoned ● Crimes
Identification	**Sponsorship source:** Behavioral Sciences Research Center provided the research grant for this study. **Country:** Iran **Setting:** **Comments:** **Authors name:** Ali Navidian **Institution:** Department of Mental Health & Psychiatric Nursing, Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, Iran **Email:** alinavidian@gmail.com **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Elisabeth Ginnerup-Nielsen* percentage of males in both groups: 58 *Jesper ØStrup Rasmussen* 50% of the patients had schizophrenia, and 50% mood disoirders. The characteristics are for the total sample, but the results are presented for each condition. **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Jesper ØStrup Rasmussen* Results only for the sample with schizophrenia. Lengst of intervention: 3 mo, FU period is 3 month, our cutoff is 4 mo. Scales:family burden: ZBI (The items are answered on a five-point scale ranging from 0 (never) to 4 (always). Scores were calculated by summing up the total chosen statement whichranges from 0 to 88, that higher scores implying greater perceived caregiver burden.) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: unclear how
Allocation concealment (selection bias)	High risk	Comment: Not described - probably not done
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible.
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Not described.
Incomplete outcome data (attrition bias)	Low risk	Comment: Dropout not described. No itt analysis. but Intervenion relatively shortHigh FU rates.
Selective reporting (reporting bias)	Low risk	Quote: "Clinical" Comment: Main outcome meassure - burden - reported in protocol
Other bias	Low risk	

Qui 2002

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Ran 2003

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Shi 2000

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Tan 2007

Methods	Allocation: randomised. Blindness: open study. Duration: three years. Setting: China.
Participants	Diagnosis: chronic schizophrenia (CCMD-3, ICD-10). N = 150. Age: 18-55 years. Sex: men and women. History: no details.
Interventions	1. Family intervention: 1.5 hour/session, once a month. N = 75. 2. Medication. N = 75.

Outcomes	Relapse. Social functioning: Social Disability Screening Schedule
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	Open study
Blinding of outcome assessment (detection bias)	High risk	Open study
Incomplete outcome data (attrition bias)	High risk	Study attrition not reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Tarrier 1988

Methods	Allocation: 'randomly allocated' - method not described, stratified by first/multiple episode, presence/absence of residual symptoms and EE. Blindness: single - CFI, PSE, relapse. Duration: 9 months treatment, 8 years follow up. Setting: Salford, UK.
Participants	Diagnosis: schizophrenia (PSE). N = 83*. Age: range 16-64 years, mean 35.3. Sex: 29 M, 54 F. History: acutely ill, hospital admissions, to be discharged to family having lived with them > 3 months, mean past admissions ~ 3, mean duration ill ~ 6 yrs. Excluded: organic illness.
Interventions	1. Enactive programme: active participation of families including role play. N = 16 2. Symbolic programme: advice and verbal instructions to families. N = 16 Education only: 2 sessions with family. N = 16* high EE, 9 low EE. Control: routine multidisciplinary care in OPD. N = 16* high EE, 10 low EE More than 5 sessions.
Outcomes	Death. Relapse (recurrence/worsening of psychotic symptoms over 1 week, PSE). Hospital admission. Leaving the study early. Family experience: CFI. Unable to use: Contact with services: no data. Use of medication: no data.
Identification	
Notes	Intervention group 1+2 both involved psychoeducational involvement of families undertaken by multidisciplinary team in clinics, 2 sessions of educational programme, 3 of stress management, and 8 of goal setting. These groups added for this analysis. Groups 3+4 not split in data reporting and used as comparison for this analysis *Only the 64 people fromhigh EE families were randomised to group 1+2 vs group 3+4, and are used in this analysis. 19 from low EE families were allocated to groups 3+4 only and are not included in this analysis

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	Single, untested
Blinding of outcome assessment (detection bias)	Unclear risk	Single, untested
Incomplete outcome data (attrition bias)	Low risk	Study attrition reported
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Vaughan 1992

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Low risk	single blind
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Wang 2006

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Xiang 2005

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	Unclear risk	No details
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Xiong 1994

Methods	Allocation: 'randomly assigned' - no further details. Blindness: assessments blinded. Duration: 18 months treatment, 18 months follow up. Setting: Shashi & Jingzhou, China.
Participants	Diagnosis: schizophrenia (DSM-III-R). N = 63*. Age: range 17-54 years, mean 31. Sex: 43 M, 20 F. History: mean previous admissions ~ 4, mean duration ill ~ 7.5 years, participants living with family
Interventions	1. Family-educational supportive sessions (group and individual sessions: initially monthly then sessions every 2-3 months. N = 34 2. Standard care: no clinic follow up + medication. N = 28.
Outcomes	Death. Relapse. Global state: GAF. Mental state: BPRS-R, SAPS-CV, SANS-CV . Hospital admission. Drug compliance. Family burden.
Identification	
Notes	*One participant not accounted for.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details
Allocation concealment (selection bias)	Unclear risk	no details
Blinding of participants and personnel (performance bias)	Unclear risk	Single blind, untested
Blinding of outcome assessment (detection bias)	Unclear risk	Single blind, untested
Incomplete outcome data (attrition bias)	High risk	Study attrition not reported
Selective reporting (reporting bias)	Unclear risk	no details
Other bias	Unclear risk	no details

Zhang 2006 a

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Zhang 2006 b

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Zhou 2007

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details
Allocation concealment (selection bias)	Unclear risk	No details
Blinding of participants and personnel (performance bias)	Unclear risk	No details
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	No details
Other bias	Unclear risk	No details

Footnotes

Characteristics of excluded studies

Bademli 2014

Reason for exclusion	Wrong outcomes

Chien 2008a

Reason for exclusion	dublet

Chien 2013b

Reason for exclusion	dublet

Dixon 2011

Reason for exclusion	Wrong study design

Fiorillo 2011

Reason for exclusion	Wrong outcomes

Gleeson 2010

Reason for exclusion	Wrong intervention

Gleeson 2013

Reason for exclusion	Wrong intervention

Gutierrez Maldonado 2009

Reason for exclusion	Wrong outcomes

Kopelowicz 2012

Reason for exclusion	Wrong outcomes

Lobban 2013

Reason for exclusion	Wrong outcomes

Moxon 2008

Reason for exclusion	Wrong outcomes

WaiTong 2013

Reason for exclusion	dublet

Weidong 2010

Reason for exclusion	Wrong study design

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Barrowclough 2001

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Bradley 2006

[Empty]

Bressi 2008

Bressi,C.; Manenti,S.; Frongia,P.; Porcellana,M.; Invernizzi,G.. Systemic family therapy in schizophrenia: a randomized clinical trial of effectiveness. Psychotherapy and psychosomatics 2008;77(1):43-49. [DOI: 000110059 [pii]]

Buchkremer 1995

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Carra 2007

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Chen 2005

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Chien 2004

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Chien 2008

Chien,W. T.. Effectiveness of psychoeducation and mutual support group program for family caregivers of chinese people with schizophrenia.. The Open Nursing Journal 2008;2(Journal Article):28-39. [DOI:]

Chien 2010

Chien,W. T.; Lee,I. Y.. The schizophrenia care management program for family caregivers of Chinese patients with schizophrenia.. Psychiatric Services 2010;61(3):317-320. [DOI:]

Chien 2013

Chien,Wai Tong; Chan,Sally W. C.. The effectiveness of mutual support group intervention for Chinese families of people with schizophrenia: A randomised controlled trial with 24-month follow-up.. International journal of nursing studies 2013;50(10):1326-1340. [DOI:]

Chien 2013a

Chien,Wai Tong; Thompson,David R.. An RCT with three-year follow-up of peer support groups for Chinese families of persons with schizophrenia.. Psychiatric Services 2013;64(10):997-1005. [DOI:]

Dai 2007

[Empty]

Dyck 2002

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Fallon 1981

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Fernandez 1998

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Garety 2008

Garety,P. A.; Fowler,D. G.; Freeman,D.; Bebbington,P.; Dunn,G.; Kuipers,E.. Cognitive--behavioural therapy and family intervention for relapse prevention and symptom reduction in psychosis: randomised controlled trial. The British journal of psychiatry : the journal of mental science 2008;192(6):412-423. [DOI: 10.1192/bjp.bp.107.043570 [doi]]

Giron 2010

Giron,M.; Fernandez-Yanez,A.; Mana-Alvarenga,S.; Molina-Habas,A.; Nolasco,A.; Gomez-Beneyto,M.. Efficacy and effectiveness of individual family intervention on social and clinical functioning and family burden in severe schizophrenia: a 2-year randomized controlled study.. Psychological medicine 2010;40(1):73-84. [DOI:]

Glynn 1992

[Empty]

Goldstein 1978

[Empty]

Guo 2007

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Herz 2000

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Hogarty 1986

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Hogarty 1997

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Koolaee 2010

Koolaee,A. K.; Etemadi,A.. The outcome of family interventions for the mothers of schizophrenia patients in Iran.. International Journal of Social Psychiatry 2010;56(6):634-646. [DOI:]

Kulhara 2009

Kulhara,P.; Chakrabarti,S.; Avasthi,A.; Sharma,A.; Sharma,S.. Psychoeducational intervention for caregivers of Indian patients with schizophrenia: a randomised-controlled trial.. Acta Psychiatrica Scandinavica 2009;119(6):472-483. [DOI:]

Leff 1982

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Leff 2001

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Li 2004

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Li 2005

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Linszen 1996

[Empty]

Liu 2007

[Empty]

Luping 2007

[Empty]

Lv 2003

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Merinder 1999

[Empty]

Navidian 2012

Navidian,A.; Kermansaravi,F.; Rigi,S. N.. The effectiveness of a group psycho-educational program on family caregiver burden of patients with mental disorders.. BMC Research Notes 2012;5(Journal Article):399. [DOI:]

Qui 2002

[Empty]

Ran 2003

[Empty]

Shi 2000

[Empty]

Tan 2007

[Empty]

Tarrier 1988

[Empty]

Vaughan 1992

[Empty]

Wang 2006

[Empty]

Xiang 2005

[Empty]

Xiong 1994

[Empty]

Zhang 2006 a

[Empty]

Zhang 2006 b

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Zhou 2007

[Empty]

Excluded studies

Bademli 2014

Bademli,K.; Duman,Z. C.. Effects of a Family-to-Family Support Program on the Mental Health and Coping Strategies of Caregivers of Adults With Mental Illness: A Randomized Controlled Study.. Archives of Psychiatric Nursing 2014;28(6):392-398. [DOI:]

Chien 2008a

Chien,W. T.; Thompson,D. R.; Norman,I.. Evaluation of a peer-led mutual support group for Chinese families of people with schizophrenia.. American Journal of Community Psychology 2008;42(1-2):122-134. [DOI:]

Chien 2013b

Chien,W. T.; Chan,S. W.. The effectiveness of mutual support group intervention for Chinese families of people with schizophrenia: a randomised controlled trial with 24-month follow-up.. International journal of nursing studies 2013;50(10):1326-1340. [DOI:]

Dixon 2011

Dixon,L.; Lucksted,A.; Burland,J.; Stewart,B.; Medoff,D.; Lehman,A.; Sturm,V.; Fang,L.. A Randomized trial of the effectiveness of the nami family to family education program.. Schizophrenia bulletin 2011;37(Journal Article):97-98. [DOI:]

Fiorillo 2011

Fiorillo,A.; Bassi,M.; de Girolamo,G.; Catapano,F.; Romeo,F.. The impact of a psychoeducational intervention on family members' views about schizophrenia: results from the OASIS Italian multi-centre study.. International Journal of Social Psychiatry 2011;57(6):596-603. [DOI:]

Gleeson 2010

Gleeson,J. F.; Cotton,S. M.; Alvarez-Jimenez,M.; Wade,D.; Crisp,K.; Newman,B.; Spiliotacopoulos,D.; McGorry,P. D.. Family outcomes from a randomized control trial of relapse prevention therapy in first-episode psychosis.. Journal of Clinical Psychiatry 2010;71(4):475-483. [DOI:]

Gleeson 2013

Gleeson,J. F.; Cotton,S. M.; Alvarez-Jimenez,M.; Wade,D.; Gee,D.; Crisp,K.; Pearce,T.; Spiliotacopoulos,D.; Newman,B.; McGorry,P. D.. A randomized controlled trial of relapse prevention therapy for first-episode psychosis patients: outcome at 30-month follow-up.. Schizophrenia bulletin 2013;39(2):436-448. [DOI:]

Gutierrez Maldonado 2009

Gutierrez-Maldonado,J.; Caqueo-Urizar,A.; Ferrer-Garcia,M.. Effects of a psychoeducational intervention program on the attitudes and health perceptions of relatives of patients with schizophrenia.. Social Psychiatry & Psychiatric Epidemiology 2009;44(5):343-348. [DOI: http://dx.doi.org/10.1007/s00127-008-0451-9]

Kopelowicz 2012

Kopelowicz,A.; Zarate,R.; Wallace,C. J.; Liberman,R. P.; Lopez,S. R.; Mintz,J.. The ability of multifamily groups to improve treatment adherence in Mexican Americans with schizophrenia.. Archives of General Psychiatry 2012;69(3):265-273. [DOI:]

Lobban 2013

Lobban,F.; Glentworth,D.; Chapman,L.; Wainwright,L.; Postlethwaite,A.; Dunn,G.; Pinfold,V.; Larkin,W.; Haddock,G.. Feasibility of a supported self-management intervention for relatives of people with recent-onset psychosis: REACT study.. British Journal of Psychiatry 2013;203(5):366-372. [DOI:]

Moxon 2008

Moxon,A. M.; Ronan,K. R.. Providing information to relatives and patients about expressed emotion and schizophrenia in a community-support setting: A randomized, controlled trial.. Clinical Schizophrenia and Related Psychoses 2008;2(1):47-58. [DOI:]

WaiTong 2013

Wai Tong,Chien; Sally,W. C. Chan. The effectiveness of mutual support group intervention for Chinese families of people with schizophrenia: A randomised controlled trial with 24-month follow-up. International journal of nursing studies 2013;50(10):1326-1340. [DOI: 10.1016/j.ijnurstu.2013.01.004]

Weidong 2010

Weidong,J.; Guoquan,Z.; Wenli,F.; Yunqing,G.; Meizheng,G.; Jun,W.; Jianhong,S.. A randomized controlled trial on the efficacy of group psychoeducation family intervention for carers of persons with schizophrenia in Shanghai.. European Psychiatry 2010;25(Journal Article). [DOI:]

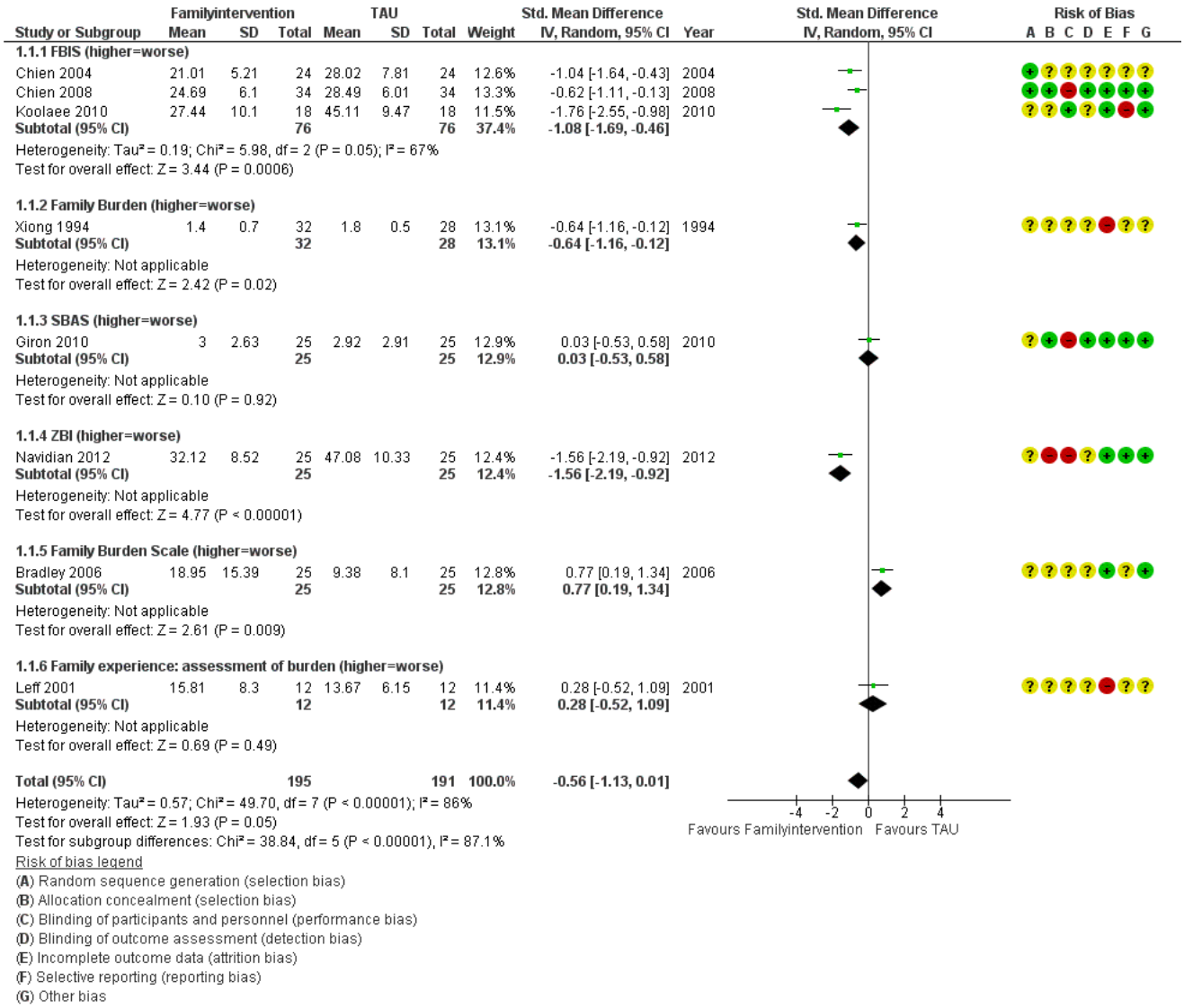
Data and analyses

1 Familyintervention vs TAU

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Family burden, end of treatment	8	386	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-1.13, 0.01]
1.1.1 FBIS (higher=worse)	3	152	Std. Mean Difference (IV, Random, 95% CI)	-1.08 [-1.69, -0.46]
1.1.2 Family Burden (higher=worse)	1	60	Std. Mean Difference (IV, Random, 95% CI)	-0.64 [-1.16, -0.12]
1.1.3 SBAS (higher=worse)	1	50	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.53, 0.58]
1.1.4 ZBI (higher=worse)	1	50	Std. Mean Difference (IV, Random, 95% CI)	-1.56 [-2.19, -0.92]
1.1.5 Family Burden Scale (higher=worse)	1	50	Std. Mean Difference (IV, Random, 95% CI)	0.77 [0.19, 1.34]
1.1.6 Family experience: assessment of burden (higher=worse)	1	24	Std. Mean Difference (IV, Random, 95% CI)	0.28 [-0.52, 1.09]
1.2 Clinical relapse, end of treatment	34	2760	Risk Ratio (IV, Random, 95% CI)	0.55 [0.47, 0.65]
1.3 Clinical relapse, longest FU	11	634	Risk Ratio (IV, Random, 95% CI)	0.77 [0.60, 0.98]
1.4 Days at hospital, end of treatment	8	533	Mean Difference (IV, Random, 95% CI)	-3.20 [-4.54, -1.86]
1.5 Carer satisfaction (higher=better), end of treatment	4	275	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.63, -0.05]
1.5.1 SSQ6	2	182	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.84, 0.28]
1.5.2 modified Patient Satisfaction Questionnaire	1	76	Std. Mean Difference (IV, Random, 95% CI)	-0.47 [-0.93, -0.02]
1.5.3 VSSS, mean change	1	17	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-1.30, 0.65]
1.6 QoL (higher=better), end of treatment	2	263	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.75, -0.25]
1.6.1 final scores	1	213	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-0.83, -0.28]
1.6.2 mean change	1	50	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.82, 0.29]
1.7 Social functioning, end of treatment	10	670	Std. Mean Difference (IV, Random, 95% CI)	-0.42 [-0.70, -0.15]
1.7.1 Specific Level of Functioning scale (higher=better)	3	253	Std. Mean Difference (IV, Random, 95% CI)	-0.46 [-0.86, -0.05]
1.7.2 SFS (higher=better)	3	90	Std. Mean Difference (IV, Random, 95% CI)	-0.70 [-1.25, -0.15]
1.7.3 SOFAS (higher=better)	1	47	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.74, 0.41]
1.7.5 SDSS (higher=worse)	2	230	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-1.32, 0.20]
1.7.6 HoNOS (higher=worse)	1	50	Std. Mean Difference (IV, Random, 95% CI)	0.33 [-0.23, 0.89]
1.8 Crimes (imprisonment), longest FU	1	39	Risk Ratio (IV, Random, 95% CI)	0.95 [0.22, 4.14]
1.9 Family burden, longest FU	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

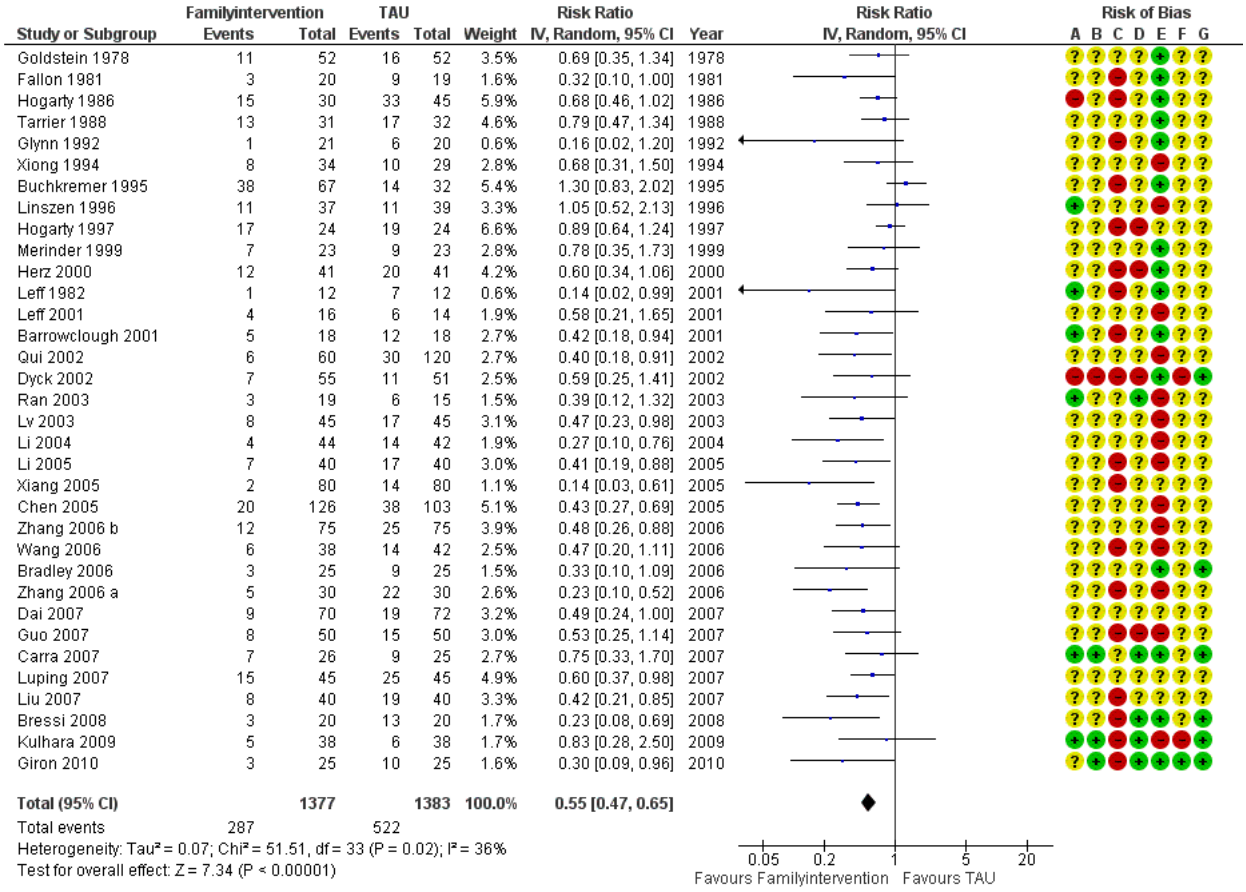
Figures

Figure 1 (Analysis 1.1)



Forest plot of comparison: 1 Familyintervention vs TAU, outcome: 1.1 Family burden, end of treatment.

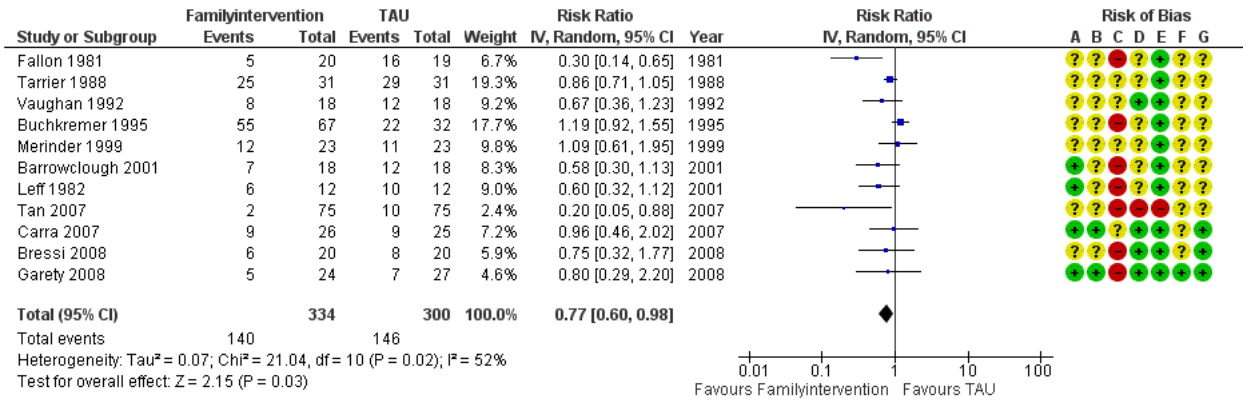
Figure 2 (Analysis 1.2)



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: 1 Familyintervention vs TAU, outcome: 1.2 Clinical relapse, end of treatment.

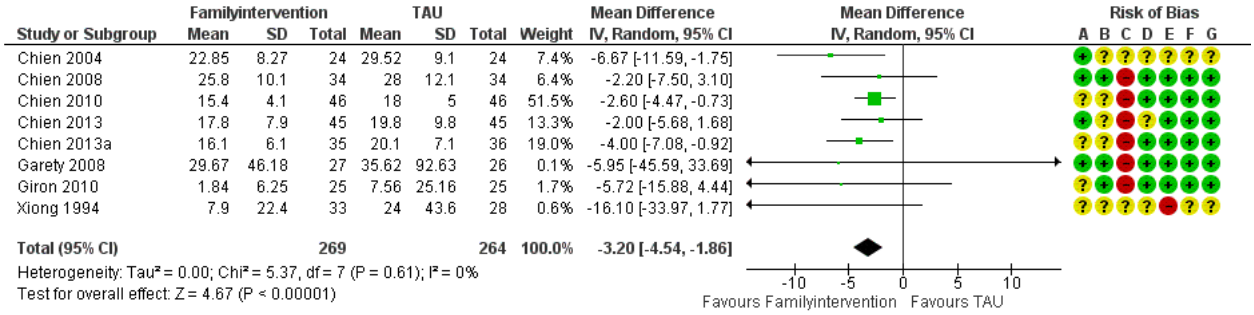
Figure 3 (Analysis 1.3)



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: 1 Familyintervention vs TAU, outcome: 1.3 Clinical relapse, longest FU.

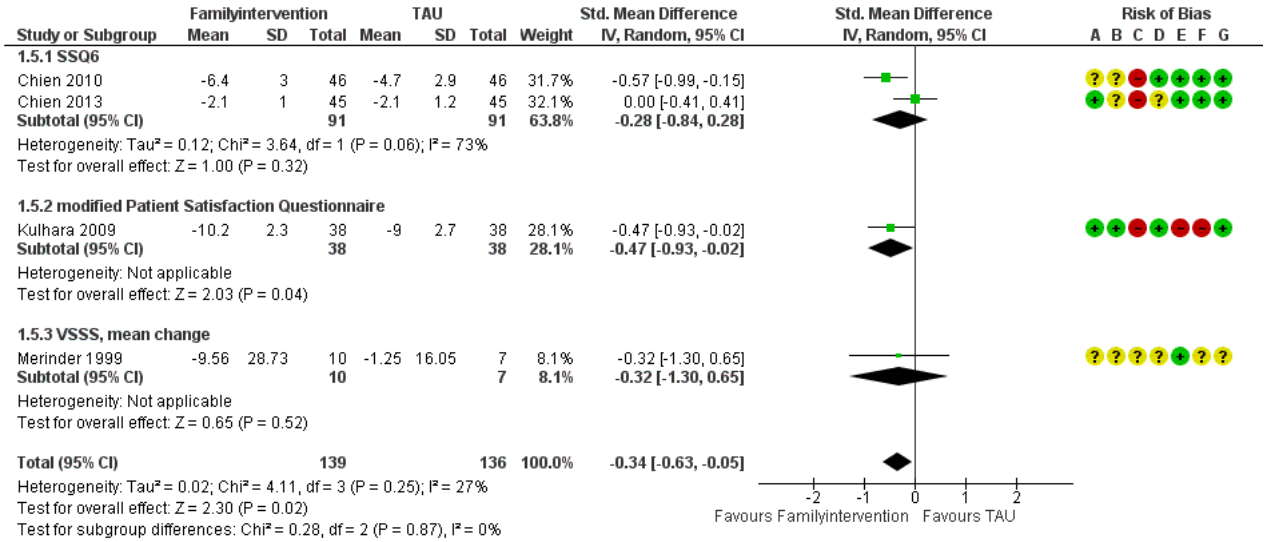
Figure 4 (Analysis 1.4)



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: 1 Familyintervention vs TAU, outcome: 1.4 Days at hospital, end of treatment.

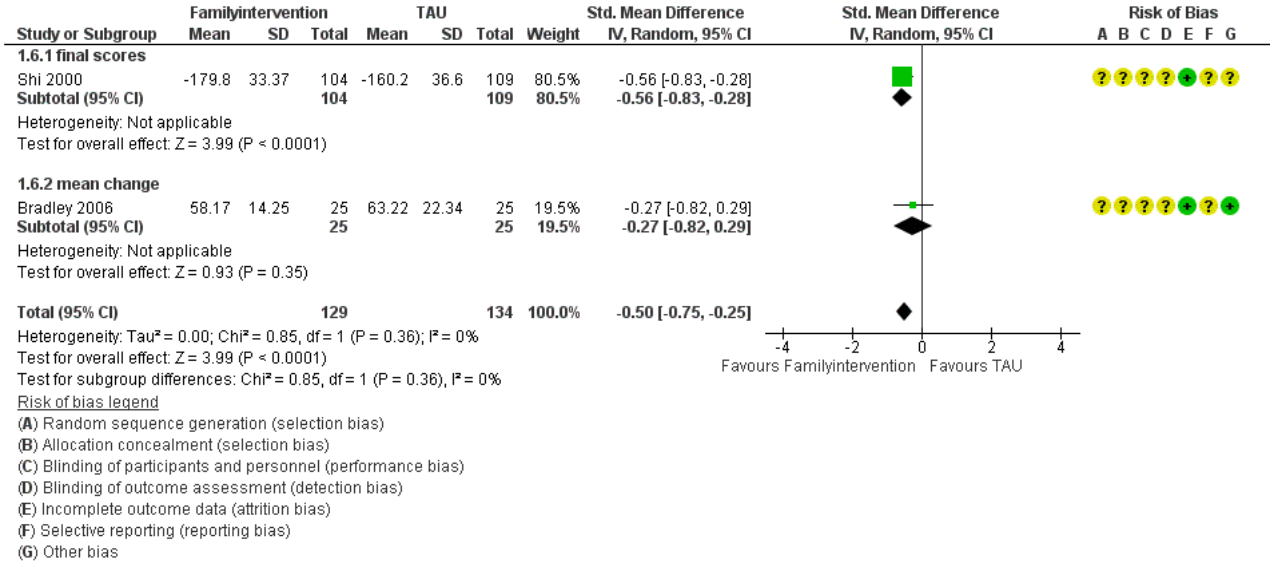
Figure 5 (Analysis 1.5)



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

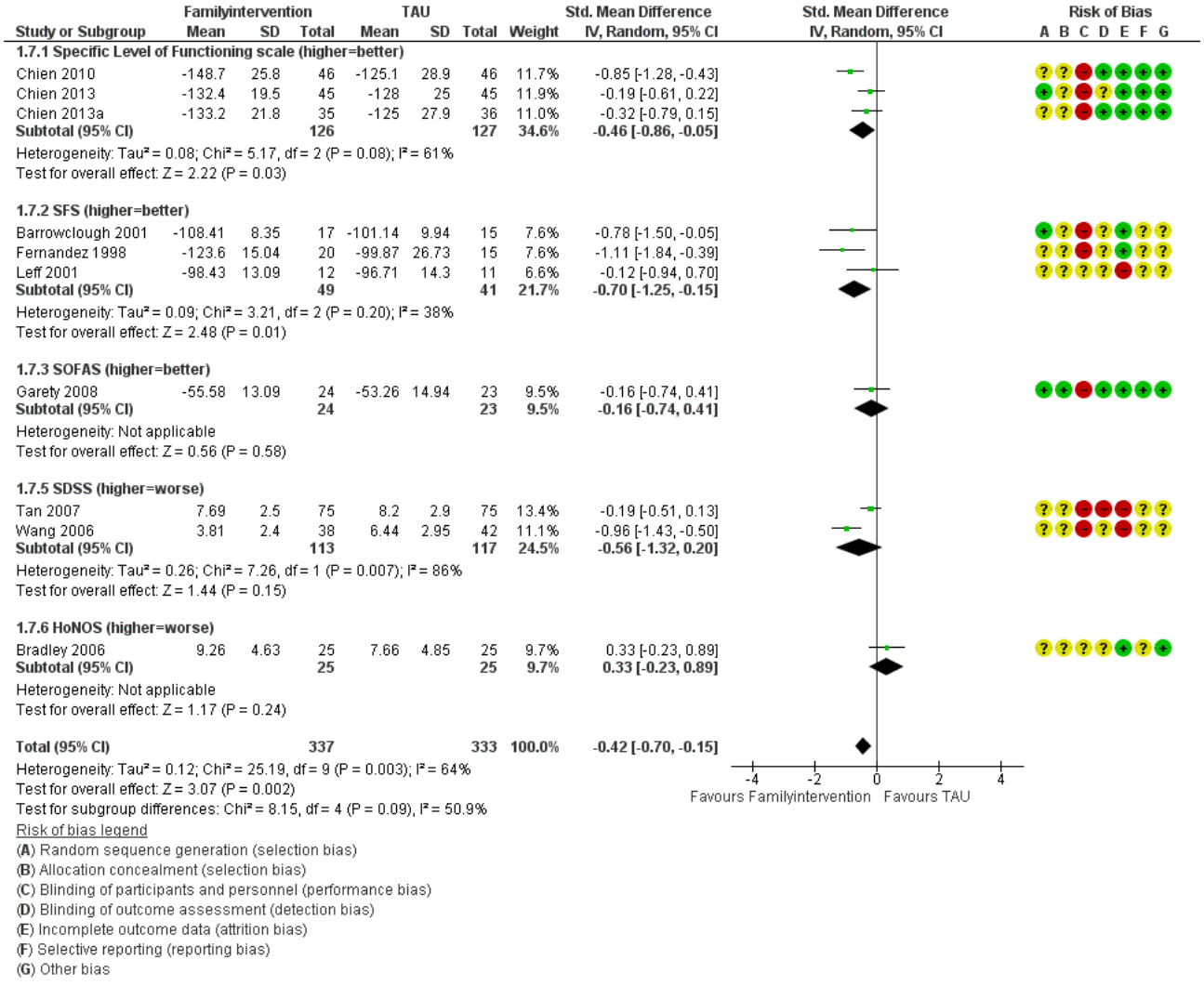
Forest plot of comparison: 1 Familyintervention vs TAU, outcome: 1.5 Carer satisfaction (higher=better), end of treatment.

Figure 6 (Analysis 1.6)



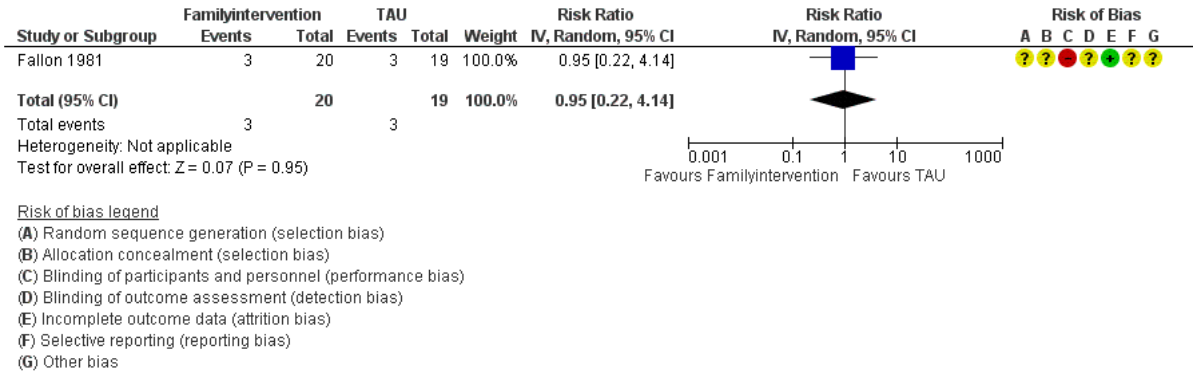
Forest plot of comparison: 1 Familyintervention vs TAU, outcome: 1.6 QoL (higher=better), end of treatment.

Figure 7 (Analysis 1.7)



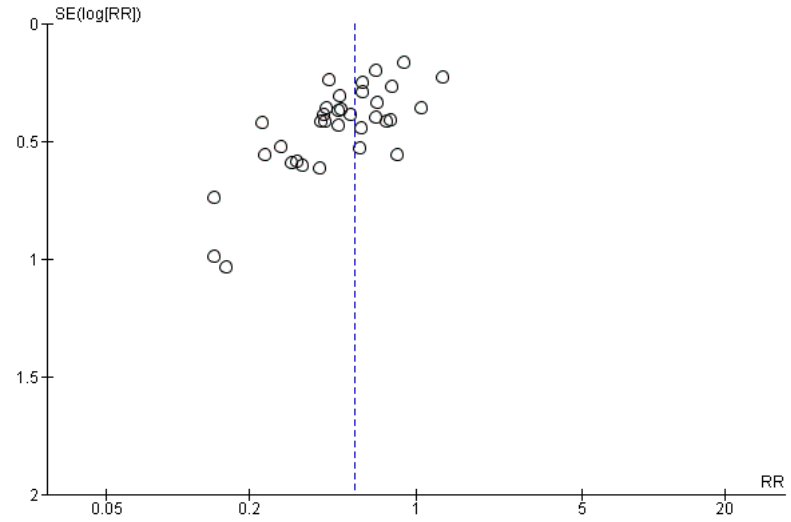
Forest plot of comparison: 1 Familyintervention vs TAU, outcome: 1.7 Social functioning, end of treatment.

Figure 8 (Analysis 1.8)



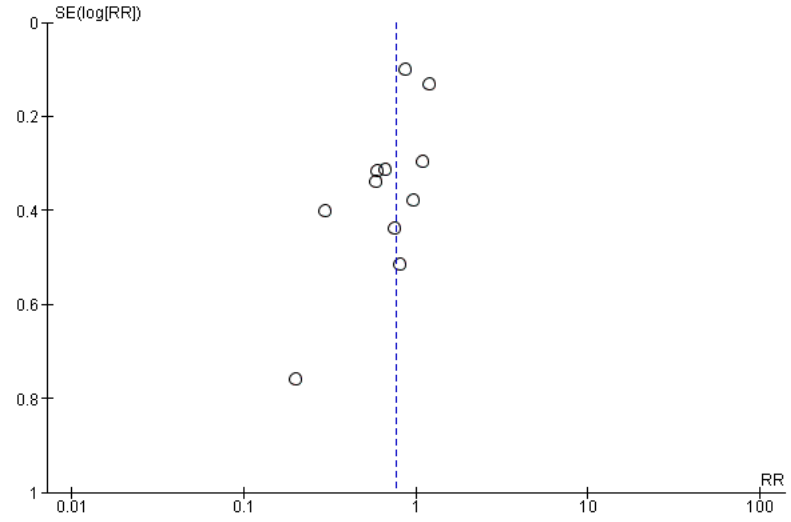
Forest plot of comparison: 1 Familyintervention vs TAU, outcome: 1.8 Crimes (imprisonment), longest FU.

Figure 9 (Analysis 1.2)



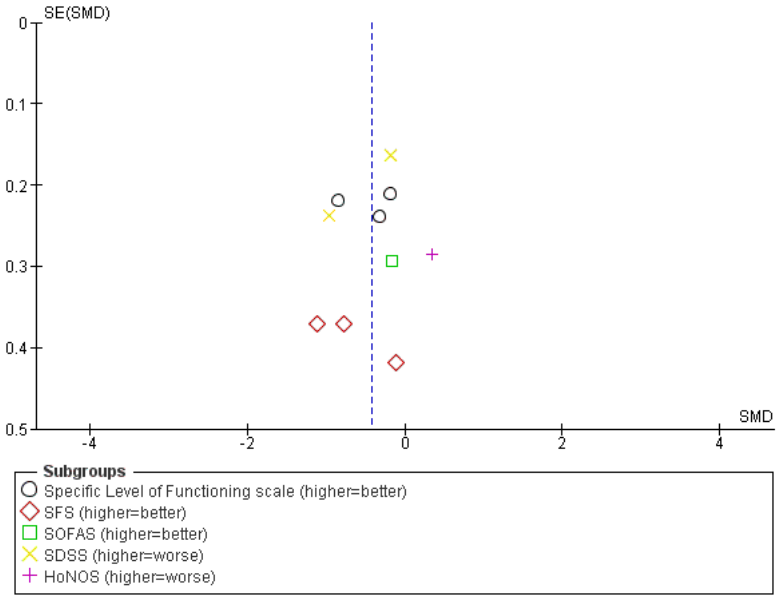
Funnel plot of comparison: 1 Familyintervention vs TAU, outcome: 1.2 Clinical relapse, end of treatment.

Figure 10 (Analysis 1.3)



Funnel plot of comparison: 1 Familyintervention vs TAU, outcome: 1.3 Clinical relapse, longest FU.

Figure 11 (Analysis 1.7)



Funnel plot of comparison: 1 Familyintervention vs TAU, outcome: 1.7 Social functioning, end of treatment.