

NKR24 - PICO8 - schizophrenia: Cognitive Behavioral Therapy

Characteristics of studies

Characteristics of included studies

Barrowclough 2006

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 72,6 ● <i>Alder, mean (sd):</i> 38,83 (8,6) ● <i>Sygdomvarighed (år), mean (sd):</i> 13,67 (7,99) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 72,6 ● <i>Alder, mean (sd):</i> 38,83 (8,6) ● <i>Sygdomvarighed (år), mean (sd):</i> 13,67 (7,99) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 Included criteria: (a) diagnosis of schizophrenia or schizoaffective disorder verified by case note review, using a checklist for DSM-IV (American Psychiatric Association, 1994) criteria; (b) substance misuse and learning disability not identified as the primary problem; (c) age 18-55 years; (d) persistent and clinically significant positive symptoms, i.e. having either item P3 (hallucinatory behaviour) or item P1 (delusions) from the positive subscale of the Positive and Negative Syndrome Scales (PANSS; Kay et al, 1987) scored 4 (moderate) or above, with the symptom having been present at this level for at least 50% of the last 2 months; (e) at least 1 month of stabilisation if the patient had experienced a symptom exacerbation in the last 6 months (i.e. at least 1 month since discharge after an acute admission; no change in psychotropic medication prescribed in the last 4 weeks); (f) informed consent from the patient. Excluded criteria:
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Standard psychiatric care in the UK is based on the care programme approach to case management, and includes maintenance antipsychotic medication, out-patient and community follow-up, and access to community-based rehabilitative activities such as day centres and drop-in centres. CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> The group intervention ran for 6 months, with 18 sessions. Sessions lasted 2 hours including breaks,
Outcomes	Continuous: <ul style="list-style-type: none"> ● <i>Psyk.symp. (notér i noter)</i> ● <i>Negative symptom, anden slala (notér i noter)</i> ● <i>Socialfunktion</i> ● <i>Symptomatisk relapse</i> ● <i>Distress</i> ● <i>QoL</i> ● <i>Indlæggelsesdage</i> ● <i>Pykotiske symptomer, PANSS</i> ● <i>Pykotiske symptomer, SAPS</i> Dichotomous: <ul style="list-style-type: none"> ● <i>Relapse</i>
Identification	Sponsorship source: The study was funded by the National Health Service Executive North West Research and Development Funding and from Pennine Care NHS Trust Research & Development monies. Country: UK Setting: Comments: Authors name: Christine BARROWCLOUGH Institution: School of Psychological Sciences, University of Manchester, UK; Email: christine.barrowclough@manchester.ac.uk Address: School of Psychological Sciences, Rutherford House, Manchester Science Park, Lloyd Street North, Manchester M15 6SZ, UK
Notes	Identification: Participants: Study design: Baseline characteristics: <i>Jesper Østrup Rasmussen</i> Det er for den samlede population, det angives at der ikke er forskel. <i>Louise Klokke Madsen</i> Of the total study sample, 82 (72.6%) were men; the mean age of the participants was 38.83 years (s.d. 8.6); the mean illness duration was 13.67 years (s.d. 7.99); 73 participants were single (64.6%), 19 (16.8%) married or cohabiting and 21 (18.6%) separated or divorced; 48 (42.5%) lived alone, 24 (21.2%) lived with a relative or caregiver, 33 (29.2%) lived in a supported hostel or flat and 7 (6.2%) lived in an unsupported hostel or other accommodation. The majority of participants (101, 89.1%) were diagnosed with schizophrenia and 12 (10.9%) had a diagnosis of schizoaffective disorder.

	<p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes: <i>Jesper Østrup Rasmussen</i> Det angives at interventionen varer 6 mdr, defor er pågørelsen ved 6 mdr afslutning af interventionen, mens 12 mdr FU er 6 mdr efter interventionen. Symptomer: PANNSSocialfunktion: SFSDe angiver i teksten indlæggelsesdage, men kun median og range, kan det bruges til noget?</p> <p><i>Louise Klokke Madsen</i> Relapse, dichotomous data:: At the end of the 12-month followupperiod, 18 members of the CBT group had had at least one relapse (32.7%) compared with 15 (27.3%) in the treatment-as-usual group</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Bradshaw 2000

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd,%):</i> 40 ● <i>Sygdomsvarighed, (år) mean (sd):</i> 11 (6) ● <i>Alder, mean (sd):</i> 32 (7) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd,%):</i> 40 ● <i>Sygdomsvarighed, (år) mean (sd):</i> 11 (6) ● <i>Alder, mean (sd):</i> 32 (7) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 <p>Included criteria: (a) valid diagnosis of schizophrenia based on meeting DSMIV criteria (b) age between 18–60</p> <p>Excluded criteria: (c) persons with mental retardation, organic brain syndrome, or a primary diagnosis of alcoholism or drug abuse were excluded.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Clients in the study participated in the program three days a week from 9:00am–3:00pm. The program consisted of social skill training, independent living skills groups, goal groups, occupational and recreational therapy, prevocational employment training and medication management. <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Clients in this group participated in the regular DTP activities and were also seen for weekly CBT in the DTP for the duration of the treatment period.
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	<p>Sponsorship source: ?</p> <p>Country: USA</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: William Bradshaw</p> <p>Institution: School of Social Work, University of Minnesota, Minneapolis</p> <p>Email: bbradshaw@che1.che.umn.edu</p> <p>Address:</p>

Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics: Jesper Østrup Rasmussen Generelt for hele populationen</p> <p>Intervention characteristics: Jesper Østrup Rasmussen community treatment vs community treatments + CBT</p> <p>Pretreatment:</p> <p>Continuous outcomes: Jesper Østrup Rasmussen Skalaer: Symptomatology was measured by the Global Pathology Index of the Hopkins Psychiatric Rating Scale (Derogatis, 1974). The GPI is an 8 point behaviorally anchored scale that describes severity of symptoms. Psychosocial functioning was measured by the Role Functioning Scale (RFS) (Goodman, et al., 1993). The RFS is made up of four subscales: work, social, family and independent living subscales. Each subscale is a 7 point behaviorally anchored scale. Rehospitalization was measured by the total number of psychiatric hospitalizations clients had during the treatment period.</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Daniels 1998

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Skizofreni eller SKizoaffektiv lidelse (%): 100 ● Sygdomsvarighed, mean (sd): - ● Alder, mean (range): 33.7 (19-61) ● Køn (mænd, %): 67,5 <p>CBT</p> <ul style="list-style-type: none"> ● Skizofreni eller SKizoaffektiv lidelse (%): 100 ● Sygdomsvarighed, mean (sd): - ● Alder, mean (range): 33.7 (19-61) ● Køn (mænd, %): 67,5 <p>Included criteria: All willing patients who met the DSM-IV diagnostic criteria for a schizophrenia or schizoaffective disorder were screened and evaluated by a doctoral-level clinician and experienced diagnostician.</p> <p>Excluded criteria: Patients with medication non-compliance as a current and clinically significant problem or with a history of alcohol/substance abuse or dependence in the preceding year were excluded. Those with a history of moderate to severe neurological impairment or mental retardation as documented in medical records were excluded, as well as those who were significantly psychiatrically unstable as defined by scores of 5 (maximum score per item = 7) or more in any of the following Positive and Negative Syndrome Scale 34 domains: conceptual disorganization, hallucinatory behavior, or unusual thought content.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: Each of the two treatment groups followed a 16-session format, meeting for 50 minutes per session. Each group met twice per week and was led by two leaders. Interactive-Behavioral Training (IBT), a 30-minute approach to social skills training with a combined focus on cognitive-behavioral techniques (such as instruction, modeling, and behavioral rehearsal) and group process strategies.
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage

Identification	<p>Sponsorship source: This article is based on research supported by a grant to the author from the Long Island Jewish Medical Center Faculty Research Competitive Pool Grant Program.</p> <p>Country: USA</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Linda Daniels</p> <p>Institution: Long Island Jewish Medical center</p> <p>Email: -</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants: <i>Jesper Østrup Rasmussen</i> Jeg ser et vis problem i eksklusionskriterierne i fht vores P.</p> <p>Study design:</p> <p>Baseline characteristics: <i>Jesper Østrup Rasmussen</i> For hele populationen generelt. <i>Louise Klokke Madsen</i> 40 patients (27 men and 13 women, mean age = 33.7 years, age range 19–61) were included in the study. Twenty patients were receiving outpatient treatment from the Adult Continuing Day Treatment Program, and 20 were enrolled in the Ambulatory Outpatient Clinic. The total sample (N = 40) included the following diagnostic categories: paranoid schizophrenia (n = 24), schizoaffective (n = 12), undifferentiated schizophrenia (n = 3), and catatonic schizophrenia (n = 1). Mean age of illness onset was 21.56 years (SD = 9.25, range 12–36 years), and total number of hospitalizations was 3.26 (SD = 2.56, range 0–10).</p> <p>Intervention characteristics: <i>Jesper Østrup Rasmussen</i> Interventionen er ikke ren CBT, men en blanding (har forhørt mig hos Lone, interventionen er ok): The present study assesses the efficacy of Interactive-Behavioral Training (IBT) an approach to social skills training with a combined focus on cognitive-behavioral techniques (such as instruction, modeling, and behavioral rehearsal) and group process strategies. The IBT format directly facilitates therapeutic group process and uses established cognitive-behavioral strategies. The blending of cognitive-behavioral and group process interventions is therefore postulated to increase motivation for learning, improve social skills acquisition, and enhance overall social competence. It appears, then, that IBT should improve the effectiveness of current social skills training models, inasmuch as therapeutic group process itself reduces negative symptoms by increasing motivation for social learning. Through the use of cognitive-behavioral and interpersonal group process strategies, group members may learn to participate fully and to act as vehicles for social learning by serving as clarifiers of affect, reality testers, and interpersonal behavioral and problem-solving models. Thus, the combination of cognitive-behavioral and interpersonal group process strategies may offer the most comprehensive and dynamic social skills treatment package. The application of cognitive-behavioral social skills techniques with group process strategies may then fill the current gap in outcome research between social skills and social competence.</p> <p>Pretreatment:</p> <p>Continuous outcomes: <i>Louise Klokke Madsen</i> Six of the 40 participants did not complete the study and were therefore excluded from the following analysis (not stated how many in each group)</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Unclear risk	n.i.
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Durham 2003

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Sygdomsvarighed, mean (range): 10 (2-27) ● Alder, mean (sd): 36 (10.2) ● Skizofreni eller skizoaftaktiv lidelse (%): 95.24 ● Køn (mænd, %): 71 <p>CBT</p> <ul style="list-style-type: none"> ● Sygdomsvarighed, mean (range): 15 (2-31) ● Alder, mean (sd): 36 (10.0) ● Skizofreni eller skizoaftaktiv lidelse (%): 95.45 ● Køn (mænd, %): 68 <p>Included criteria: patients with psychosis and a diagnosis of schizophrenia, schizoaffective disorder or delusional</p>

	<p>disorder, aged 16–65 years who are known to the psychiatric services as suffering from positive symptoms of persistent and distressing hallucinations or delusions, or both, and who have been stabilised on anti-psychotic medication for at least a 6-month period under the care of a consultant psychiatrist.</p> <p>Excluded criteria: Exclusion criteria were: primary diagnosis of alcoholism or drug misuse, evidence of organic brain disease and history of violence</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: 0 <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: max 20 over 9 mdr
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage ● Distress (PSYRATS, hallucinationer) ● Distress, PSYRATS (delusions)
Identification	<p>Sponsorship source: The preparation of this article was made possible by a grant to R.C.D., R.V.M. and D.A.R. by the Chief Scientist Office, Scottish Home and Health Department, Edinburgh, whose financial support is gratefully acknowledged</p> <p>Country: UK</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: ROBERT C. DURHAM,</p> <p>Institution: Department of Psychiatry, Ninewells Hospital & Medical School</p> <p>Email: r.c.durham@dundee.ac.uk</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Jesper Østrup Rasmussen</i> længste FU er efter 3 mdr, så kan jo faktisk ikke indgår, grundet vores cutoff på 4-6 mdr. Social funktion: GAS (higher score indicates a better outcome) <i>Louise Klokke Madsen</i> PSYRATS delusions</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Edwards 2011

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 72.7 ● Alder, mean (sd): 22.5 (3.4) ● Sygdomvarighed (år), mean (sd): ● Skizofreni eller skizoaffektiv lidelse (%): 100 <p>CBT</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 58.3 ● Alder, mean (sd): 22.0 (4.1) ● Sygdomvarighed (år), mean (sd):

	<ul style="list-style-type: none"> ● Skizofreni eller skizoaffektiv lidelse (%): 91.7 <p>Included criteria: experiencing a first treated episode of psychotic disorder that fulfilled the DSM-IV criteria for a diagnosis of schizophrenia, schizophreniform disorder, delusional disorder, or psychotic disorder not otherwise specified; being registered with EPPIC for 12 to 26 weeks; and continuing to experience moderate to severe positive symptoms, defined as a score ≥ 4 on at least one of the hallucinations, unusual thought content, and conceptual disorganisation items of the expanded version of the brief psychiatric rating scale (BPRS; [13]), with a score of not less than 3 on these items for a period of 14 consecutive days or more during the preceding 12 weeks. All participants had been treated with at least one atypical antipsychotic (usually risperidone, olanzapine or quetiapine) at doses up to 500 mg chlorpromazine equivalence (if tolerated), with demonstrated medication compliance for at least the past 4 weeks.</p> <p>Excluded criteria: Exclusion criteria were an organic mental disorder, pregnancy or lactation, requiring antidepressant medication, a mood stabiliser or ECT, and a history of drug-induced granulocytopenia.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: The therapy was conducted twice weekly for 12 weeks, with a minimum attendance of 15 sessions required.
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● Symptomatisk relapse ● Distress ● Indlæggelsesdage ● QoL
Identification	<p>Sponsorship source: The research was supported by the Victorian Government's Health Promotion Foundation and NOVARTIS. NOVARTIS personnel were not involved in the study design, data analysis, or publication. H. P. Yuen performed the statistical analysis and the protocol can be obtained from J. Edwards.</p> <p>Country: Australia</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: J. Edwards</p> <p>Institution: Orygen Youth Health Centre for Youth Mental Health, University of Melbourne</p> <p>Email: j.edwards@unimelb.edu.au</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics: Jesper Østrup Rasmussen Alle er første episode psykoser.</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes: Jesper Østrup Rasmussen FU kan ikke bruges da den ikke er over 4-6 mdr. Skalaer: Psykotiske symp: BPRS-P Negative symptomer: SANS Socialfunktion: SOFAS QoL: QLS</p> <p>Louise Klokke Madsen Mental state was determined with the expanded version of the BPRS [13]. The BPRS psychotic symptoms subscale (BPRS-P) was used to assess positive symptoms, while the scale for the assessment of negative symptoms (SANS; [15]) and the short form of the Beck depression inventory (BDI; [16]) assessed levels of negative symptoms and depression, respectively. The clinical global impression (CGI; [17]) was used to measure the severity of psychotic disorder, as well as the degree of improvement since baseline. Psychosocial functioning was assessed using the social and occupational functioning assessment scale (SOFAS; [18]) and quality of life survey (QLS; [19]).</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Farhall 2009

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 59.6 ● <i>Alder, mean (sd):</i> 33.55 (10.81) ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 78,7 <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 57.8 ● <i>Alder, mean (sd):</i> 32.09 (9.61) ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 64,4 <p>Included criteria: a preliminary DSM-IV diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features; and, in the opinion of their case manager, one or more recovery needs that could potentially be addressed by a component (see later) of the local version of CBTp, 'Recovery Therapy'. Each client accepted from May 2000 to July 2003 who met the criteria was invited to participate.</p> <p>Excluded criteria: Exclusions were patients with a diagnosis of any DSM-IV non-psychotic disorder, brief psychotic disorder, drug-induced psychosis, mood disorder without hallucinations or delusions, or patients with a co-morbid intellectual disability or without conversational English. Those with co-morbid substance use disorders were not excluded.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Therapists work with patients for 12–24 sessions
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	<p>Sponsorship source: The study was funded by the William Buckland Foundation, with additional assistance from La Trobe University and the Department of Human Services, Victoria.</p> <p>Country: Australia</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: John Farhall</p> <p>Institution: 1 School of Psychological Science, La Trobe University, Melbourne, Australia 2 North Western Mental Health, Melbourne, Australia</p> <p>Email: j.farhall@latrobe.edu.au</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Jesper Østrup Rasmussen</i> Det angives at outcomes måles: 1) ved vaskeline 2) ved afslutning af intervention (gn. 9-12 mdr efter baseline) 3) igen 9 mdr efter interventionen. således kan FU godt bruges som længste FU.</p> <p><i>Louise Klokke Madsen</i> PANSS negative + positive, Life Skills Profile</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.

Other bias	Unclear risk	n.i.
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Garety 2008

Methods	Study design: Study grouping: Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 68.8 ● <i>Alder, mean (sd):</i> 37.1 (10.9) ● <i>Sygdomvarighed (år), mean (sd):</i> 9.9 (8.7) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 69.8 ● <i>Alder, mean (sd):</i> 39.1 (10.3) ● <i>Sygdomvarighed (år), mean (sd):</i> 10.9 (8.1) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 98,1 Included criteria: (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).17 Excluded criteria: (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 TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Cognitive-behavioural therapy and family intervention were bothdelivered for 9 months with a planned minimum of 12 and amaximum of 20 sessions.
Outcomes	Continuous: <ul style="list-style-type: none"> ● Indlæggelsesdage ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage ● Distress (PSYRATS hallucinations) ● Distress (PSYRATS, delusions)
Identification	Sponsorship source: The study was supported by a Wellcome Trust Programme Grant (062452) Country: UK Setting: Comments: Authors name: Philippa A. Garety Institution: Department of Psychology, PO77, Institute of Psychiatry, De Crespigny Park, London, SE5 8AF, UK. Email: p.garety@iop.kcl.ac.uk Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: <i>Jesper Østrup Rasmussen</i> End of treatment: 12 mdrFU: 24 mdrIndlæggelsesdage: mellem 0-12 mdrSocialfunktion: SOFASDer er desuden QoL, men kun fo r24 mdr.Symptomer: PANSS Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	

Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Granholt 2005

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 77 ● <i>Alder, mean (sd):</i> 53.1 (7.5) ● <i>Sygdomvarighed (år), mean (sd):</i> 28.4 (10.5) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 70 ● <i>Alder, mean (sd):</i> 54.5 (7.0) ● <i>Sygdomvarighed (år), mean (sd):</i> 30.1 (11.3) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 Included criteria: Schizophrenia or schizoaffective disorder. 42-74 years old. Excluded criteria: disabling medical problems that would interfere with testing, absence of medical records to inform diagnosis, and diagnosis og dependence on substances other than nicotine or caffeine within the past 6 months.
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> 24 weekly group sessions
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	Sponsorship source: Office of Research and Development, Medical Research Service, Department fo Veterans. National Alliance for Reasearch on Schizophrenia and Depression Country: USA Setting: Comments: Authors name: Eric Granholt Institution: San Diego State University Email: egranholt@ucsd.edu Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: <i>Jesper Østrup Rasmussen</i> Jeg ved ikke hvordan dette format sættes ind, Effekt på:- poitive symptomer: F=2,38 df=1, 71 P=0,13 $\eta^2=0,03$ - negative symptomer: F=0,43 df=1, 71 P=0,52 $\eta^2=0,01$ Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.

Other bias	Unclear risk	n.i.
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Grant 2012

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 65.5 ● <i>Alder, mean (sd):</i> 42.9 (10.8) ● <i>Sygdomvarighed (år), mean (sd):</i> 18.0 (12.8) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 67.8 ● <i>Alder, mean (sd):</i> 34.3 (10.9) ● <i>Sygdomvarighed (år), mean (sd):</i> 13.2 (11.0) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 Included criteria: Eligibility criteria included the following: diagnosis of DSM-IV schizophrenia or schizoaffective disorder; prominent negative symptoms (at least moderate severity on 2 Scale for the Assessment of Negative Symptoms 29 global subscales, or marked severity on 1 subscale); aged 18 to 65 years; proficient in English; and able to give informed consent. Excluded criteria: Exclusion criteria included the following: neurologic disease or damage that would compromise cognitive functioning; and physical handicap that would interfere with assessment procedures or therapy attendance.
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Participants in the CT intervention were scheduled to receive up to 18 months of outpatient CT sessions. The sessions typically lasted 50 minutes and were scheduled on a weekly basis;
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	Sponsorship source: Financial Disclosure: Drs Grant, Stolar, and Beck have received royalties from Guilford Press. Funding/Support: This work was supported by a Distinguished Investigator Award from the National Alliance for Research on Schizophrenia and Depression (Dr Beck) and by grants from the Heinz Foundation and the Barbara and Henry Jordan Foundation. Role of the Sponsors: The sponsors had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript. Country: USA Setting: Comments: Authors name: Paul M. Grant Institution: Perelman School of Medicine, University of Pennsylvania, Philadelphia Email: pgrant@mail.med.upenn.edu Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: <i>Louise Klokke Madsen</i> SANS negative symptoms, at 18 months: CT: adjusted mean [SE], 1.66 [0.31] ST: 2.81 [0.34] positive symptoms, at 18 months: CT: adjusted mean [SE], 9.4 [3.3] ST: 18.2 [3.8] GAS, at 18 months: CT: adjusted mean [SE], 58.3 [3.30] ST: 47.9 [3.60] Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	

Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Gumley 2003

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 70.8 ● <i>Alder, mean (sd):</i> 36.7 (10.1) ● <i>Sygdomvarighed (år), mean (sd):</i> 114 (84) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 95.8 <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 75.0 ● <i>Alder, mean (sd):</i> 35.8 (9.6) ● <i>Sygdomvarighed (år), mean (sd):</i> 113 (81) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 98.6 <p>Included criteria: Entry required that patients fulfilled DSM-IV (American Psychiatric Association, 1994) criteria for schizophrenia or a related disorder confirmed by the Structured Clinical Interview for DSM-IV (First et al. 1994), were aged between 18 and 65, were receiving antipsychotic medication, and were considered relapse prone. Patients were considered relapse prone if they had one or more of the following characteristics: (1) a history of relapse in the last 2 years; (2) their keyworker viewed them as living in a stressful environment (e.g. a home environment characterized by high levels of expressed emotion); (3) living alone or socially isolated; (4) nonadherence with antipsychotic medication (where this was viewed as problematic by the participant's keyworker and/or prescribing psychiatrist); and (5) being on a neuroleptic dosage reduction programme.</p> <p>Excluded criteria: Patients were excluded if they were a non-English speaker, had organic brain disorder, presence of significant learning disability, severe positive psychotic symptoms (rating of 5 on the positive scale of the Positive and Negative Syndrome Scale (PANSS) (Kay et al. 1987), a primary drug or alcohol dependence disorder (based on the opinion of the key worker), or being in receipt of a concurrent psychotherapy outside the study.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> 5 sessions i løbet af de første 12 uger. Herefter måles forløbende på patienterne om de er ved at få tilbagefald, i så fald opstartes målrettet CBT, 2-3 om ugen. I gennemsnit får de i løbet af perioden 5 målrettede behandlinger.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: The research was supported by a grant (K/RED/18/13) to Andrew Gumley and Kevin Power from the Chief Scientist Office, Scottish Executive.</p> <p>Country: UK (Scotland)</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: A. Gumley</p> <p>Institution: Department of Psychological Medicine, University of Glasgow</p> <p>Email: -</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics: <i>Louise Klokke Madsen</i> Illness duration in months</p> <p>Intervention characteristics: <i>Jesper Østrup Rasmussen</i> De kommer i gennemsnit lige præcis op på 10 sessioner, hvorfor jeg ikke har ekskluderet den.</p> <p>Pretreatment:</p> <p>Continuous outcomes: <i>Louise Klokke Madsen</i> PANSS positive + negative SFS, Withdrawal <i>Jesper Østrup Rasmussen</i> Skala: PANSS Desuden angives socialfunktion med SFS, skal lige finde ud af hvilket af</p>

domænerne der skal bruges. At 12 months the CBT group showed greater improvement in positive symptoms (-1.10, P=0.028, 95% CI -2.08, -0.12) negative symptoms (-1.89, P=0.016, 95% CI -3.39, -0.35),

Dichotomous outcomes:
 Jesper Østrup Rasmussen Relapse: A total of 13 (18.1%) participants in CBT relapsed compared to 25 (34.7%) in TAU (HR=0.47, P=0.028, 95% CI 0.24, 0.92, NNT=6).

Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Jolley 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)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Unclear risk	n.i.
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Krakvik 2013

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping:</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 65.2 ● <i>Alder, mean (sd):</i> 35.26 (8.89) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 73,9 <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 63.6 ● <i>Alder, mean (sd):</i> 37.50 (11.15) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 86,4 <p>Included criteria: i) suffering from schizophrenia, schizoaffective disorder, or persistent delusional disorder according to ICD-10 (WHO, 1992); ii) residual auditory hallucinations and delusions experienced in the last 6 months, which had caused distress despite the use of neuroleptics; iii) in the age group 18–60 years; and iv) ability to give informed consent to participate in the study.</p> <p>Excluded criteria: i) no perceived distress produced by delusions or hearing voices; and ii) no substance use diagnosis.</p>
Interventions	<p>Intervention Characteristics</p> <p>CBT</p> <ul style="list-style-type: none"> ● <i>Description:</i> Participants received 20 sessions of individual cognitive therapy based on a simplified version of the treatment model developed by Chadwick, Birchwood and Trower (1996). The purpose of the therapy was to reduce the distress that accompanies delusional beliefs and auditory hallucinations by challenging the dysfunctional beliefs of voices and delusions within a cognitive restructuring framework. Particularly for auditory hallucinations, the aim was to challenge beliefs about the power of the voices. The duration and frequency of the sessions were somewhat flexible in

	<p>order to accommodate the needs of individual patients. As a rule, each patient was offered 45 minutes of therapy. There were weekly sessions during the first 8 weeks of treatment. Thereafter, the patients received fortnightly sessions over a period lasting between 4 and 6 months.</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Description:</i> Patients randomly assigned to the waiting list group continued to receive treatment as directed by the referring practitioner. The nature of the TAU interventions included contact with a community case manager, supportive psychosocial interventions delivered from the patients' local therapists, and neuroleptic medication. None of the patients in the waiting list group received systematic and individualized CBTp in the 6-month waiting period.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symp. (notér skala) ● Negative symptomer (notér skala) ● Socialfunktion ● Symptomatisk relapse ● Distress ● QoL ● Indlæggelsesdage <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: The study was supported by the Department of Research and Development at St Olavs University Hospital, Trondheim, Norway.</p> <p>Country: Norway</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Bodil Kråkvik</p> <p>Institution: St. Olavs University Hospital, Trondheim, Norway</p> <p>Email: bodil.krakvik@stolav.no</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Louise Klokke Madsen BPRSSANS GAF function PSYRATS emotional</i></p> <p><i>Jesper Østrup Rasmussen Skalaer: Negative symp.: SANS (low=better) Jeg tænker ikke at PSYRATS kan bruges, da den er opdelt i subskalaer. ved 12 mdr. FU er der kun angivet en effekt, for SANS er den: 12-month N=27 M=7.59 sd=3.63 df=(1,26) F=0.03</i></p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization was administrated by an independent office not involved in the study. In order to avoid potential group bias in the distribution of auditory hallucinations, the participants were stratified with respect to whether or not they had auditory hallucinations. The block design was arranged with different inter-block probabilities of group allocation, which were blind to the assessors."
Allocation concealment (selection bias)	Low risk	Quote: "The randomization was administrated by an independent office not involved in the study. In order to avoid potential group bias in the distribution of auditory hallucinations, the participants were stratified with respect to whether or not they had auditory hallucinations. The block design was arranged with different inter-block probabilities of group allocation, which were blind to the assessors."
Blinding of participants and personnel (performance bias)	High risk	Comment: Waitlist.
Blinding of outcome assessment (detection bias)	High risk	Quote: "All four professionals were trained in the use of assessment measures, but it was not possible to keep them blind to the treatment condition." Comment: All assessments were carried out by three psychologists and one psychiatric nurse, none of which was involved in the patients' therapy. All four professionals were trained in the use of assessment measures, but it was not possible to keep them blind to the treatment condition.
Incomplete outcome data (attrition bias)	Low risk	Quote: "Of the patients allocated to the treatment group, 5 refused to continue the therapy, and 2 patients did not meet for post-treatment. No patients in the waiting list group dropped out during the waiting period. However, when the waiting list group received CBTp + TAU after waiting for 6 months, 6 patients refused to continue the therapy"
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Kuipers 1997

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 71,9 ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 74,1 ● <i>Alder, mean (range):</i> 41.8 (18-63) ● <i>Sygdomsvarighed (år), mean (range):</i> 14 (1-33) CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 53,6 ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 77,8 ● <i>Alder, mean (range):</i> 38.5 (19-65) ● <i>Sygdomsvarighed (år), mean (range):</i> 12.1 (1-26) Included criteria: at least one current positive psychotic symptom (such as delusions or hallucinations) that was distressing, unremitting (at least the past six months) and medication resistant, that had not responded to a previous trial of at least six months of appropriate neuroleptic medication. Clients prescribed clozapine needed to have been stable on this for at least one year (to allow time for all benefits to occur). Excluded criteria: People who had drug, alcohol or organic problems as primary features were excluded.
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Participants randomised into this condition received routine care from their clinical team, which as part of our entry criteria consisted of case management and medication. As above, the research team negotiated with the clinical team to ensure that clients had an allocated keyworker responsible for coordinating their care and setting goals for them. All control group keyworkers were also given feedback from the initial assessments, and were encouraged to review the client's progress every three months. CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Participants randomised into the treatment group received up to nine months of individual CBT for psychosis. Sessions were conducted weekly initially, and then fortnightly, for up to an hour. Therapy was designed to achieve the following aims: (a) to reduce the distress and interference that can arise from the experience of psychotic symptomatology; (b) to reduce emotional disturbance such as depression, anxiety and hopelessness, and to modify dysfunctional schemas if they existed; and (c) to promote the active participation of the individual in the regulation of their risk of relapse and social disability.
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage Dichotomous: <ul style="list-style-type: none"> ● Relapse (20% forværring af symptomscore)
Identification	Sponsorship source: This research was supported by a Research and Development grant from the Department of Health. We are grateful for a charitable donation from Janssen Pharmaceutica. Country: UK Setting: Comments: Authors name: ELIZABETH KUIPERS Institution: Department of Clinical Psychology, Institute of Psychiatry, London Email: - Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: <i>Louise Klokke Madsen BPRS OBS: selective outcome reporting (Change on all other symptom and functioning measures was not significantly different between conditions at this stage of the trial.)</i> Dichotomous outcomes: <i>Jesper Østrup Rasmussen (A five-point change on the BPRS is similar to the criterion of a 20% improvement taken to be an index of clinical response on the BPRS by Breier et al (1994)). In these terms, 6/28 (21%) achieved a large clinical improvement, and a further 8/28 (29%) of the treatment group achieved a reliable clinical improvement. One person of the 28 (3%) in the treatment group showed a reliable worsening of symptoms on the BPRS. In the control group, 1/32 (3%) showed a large clinical improvement and 9/32 (28%) of cases achieved reliable clinical improvements. Three of the 32 (9%) of the control group showed a clinically significant worsening of symptoms over the nine months.</i>

Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Leclerc 2000

Methods	Study design: Study grouping: Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 86.4 ● <i>Alder, mean (sd):</i> 40.6 (10.7) ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> - CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 52.8 ● <i>Alder, mean (sd):</i> 40.6 (10.7) ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> - Included criteria: 1) a diagnosis of schizophrenia, schizo-affectivedisorder, or paranoid psychosis confirmed by the Structured Clinical Interview for DSM-III-R(SCID) (Williams et al., 1992)-SCID IV was not available at the beginning of the study; 2) the ability to speak, read, and write French; and 3) consent from the subject (or trustee, if applicable) to participate in the study Excluded criteria:
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> 2 ugentligt i 12 uger.
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	Sponsorship source: ? Country: Canada Setting: Comments: Authors name: Claude Leclerc Institution: University of Quebec Email: Address:
Notes	Identification: Participants: Study design: Baseline characteristics: <i>Jesper Østrup Rasmussen</i> Alder = hele populationen. <i>Louise Klokke Madsen</i> origin(89.2%). Their mean age was 40.6 years (S B10.7) at the start of the study, and 24.2 years (SB6.8) at first hospitalization; 87.5% were single, and 84.2% unemployed at the start of the study. They had completed a mean of 10.2 years of school(SB3.0). At Time 1, 5.1% lived in an apartment, and 75.9% were psychiatric inpatients. The mean number of years of lifetime hospitalization was 17.83 (SD=11.74) for the experimental group, 11.80 (SB8.65) for the control group, and 11.88 (SD=7.66) for the intent-to-treat group. The mean number of hospitalizations was 4.19 (SO=3.79) for the experimental group, 3.77 (SD=3.95) for the control group, and 4.47 (SB2.50) for the intent-to-treat group. These differences were not significant according to the Student's t-test. Intervention characteristics:

	Pretreatment: Continuous outcomes: <i>Jesper Østrup Rasmussen</i> Time 1: lige efter interventionen Time 2: 6 mdr FU Dichotomous outcomes: Adverse outcomes:
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Lecomte 2008

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 83 ● <i>Alder, mean (sd):</i> 23.10 ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 54.4 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 65 ● <i>Alder, mean (sd):</i> 24.92 ● <i>Sygdomvarighed (år), mean (sd):</i> - ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 53.6 <p>Included criteria: Individuals were eligible if aged between 18 and 35, fluent (verbally as well as reading and writing skills) in one of the official languages (English and French), currently presenting with persistent or fluctuating psychotic symptoms (defined as delusions or hallucinations appearing occasionally, such as in periods of stress), having consulted for the first time a mental health professional for psychotic symptoms in the past 2 years, and being followed by a psychiatrist (and therefore receiving antipsychotic medication). Individuals were only recruited once they had been discharged from the hospital and considered "stabilized" by their psychiatrist. Non-affective psychosis was preferred but individuals with unclear diagnoses at the time of their referral were also accepted.</p> <p>Excluded criteria: Exclusion criteria included suffering from an organic disorder, having already received one of the interventions, and not being able to give informed consent</p>
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Participants received 24 sessions of either treatment, twice a week, for 3 months
Outcomes	Continuous: <ul style="list-style-type: none"> ● Social provision scale ● BPRS positive ● BPRS negative ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	Sponsorship source: Supported by grant 43975 from the Canadian Institutes of Health Research (CIHR; to T.L., C.L., T.W., and C.J.W.). The corresponding author also benefited from a salary award from CIHR to conduct this study. Country: Canada Setting: Comments: Authors name: Tania Lecomte Institution: Department of Psychology, Université de Montréal Email: tania.lecomte@umontreal.ca Address:

Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: <i>Jesper Østrup Rasmussen</i> Da interventionen varer 3 mdr, tager jeg T1 som end of treatment. Dichotomous outcomes: Adverse outcomes:
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Unclear risk	n.i.
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Lewis 2002

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 67,6 ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 87,3 ● <i>Age (median years):</i> ● <i>Alder, median. :</i> 27 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 71,3 ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 87,1 ● <i>Age (median years):</i> ● <i>Alder, median. :</i> 29,1 Included criteria: Inclusion criteria for subjects to enter the trial were: (a) either first or second admission (within 2 years of a first admission) to in-patient or day patient unit for treatment of psychosis; (b) DSM-IV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder or delusional disorder (American Psychiatric Association, 1994); (c) positive psychotic symptoms for 4 weeks or more; (d) score of 4 or more (moderate or severe) on the PANSS (Kay et al, 1989) target item either for delusions (P1) or hallucinations (P3); (e) neither substance misuse nor organic disorder judged to be the major cause of psychotic symptoms. Patients legally detained in hospital were eligible. Excluded criteria:
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> The design of the delivery was to aim for 15–20 hours within a 5-week treatment envelope, plus 'booster' sessions at a further 2 weeks and 1, 2 and 3 months.
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage
Identification	Sponsorship source: The trial was funded as follows: UK Medical Research Council (41%); Northwest England NHSE Office (27%); Trent NHSE Office (7%); the following health authorities: Manchester (8%); Salford and Trafford (2%); Liverpool (3%); Sefton (3%); St Helens and Knowsley (3%); North Nottinghamshire (6%). Country: UK Setting: Comments: Authors name: S. LEWIS

	<p>Institution: School of Psychiatry and Behavioural Sciences, University of Manchester Email: Address:</p>
Notes	<p>Identification: Participants: Study design: Baseline characteristics: <i>Jesper Østrup Rasmussen</i> Jeg har medtaget de skizofreniforme. Intervention characteristics: Pretreatment: Continuous outcomes: <i>Jesper Østrup Rasmussen</i> Five post-baseline assessment visits were scheduled: at 14, 21, 28 and 35 days and the final acute-phase assessment between 42 and 70 days. Behandlingen var 5 uger, med efterfølgende booster, så jeg har taget 35 dage som afslutning af intervention. Dichotomous outcomes: Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Unclear risk	n.i.
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Lincoln 2012

Methods	<p>Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:</p>
Participants	<p>Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> ● <i>Alder, mean (sd):</i> ● <i>Sygdomsvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> ● <i>Alder, mean (sd):</i> ● <i>Sygdomsvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> <p>Included criteria: Patients had to have a diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, or brief psychotic disorder. Furthermore, they had to be at least 16 years old and have sufficient German or English language skills to communicate with the therapist. For ethical reasons, acutely suicidal patients were excluded and referred to psychiatric specialized departments. One patient with acute heroin addiction was required to attend detoxification treatment before beginning therapy. No further criteria were applied. Excluded criteria:</p> </p>
Interventions	<p>Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> </p>
Outcomes	<p>Continuous: <ul style="list-style-type: none"> ● Negative symptom ● Psykotiske symptomer ● Socialfunktion ● Negative symptom ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage Dichotomous: <ul style="list-style-type: none"> ● Relapse </p>

Identification	Sponsorship source: ? Country: Germany Setting: Comments: Authors name: Tania M. Lincoln Institution: Clinical Psychology and Psychotherapy, Department of Psychology, Philipps University Marburg, Marburg, Germany. Email: tania.lincoln@uni-hamburg.de Address:
Notes	Identification: Participants: Study design: Baseline characteristics: <i>Louise Klokke Madsen</i> Sygdomsvarighed= Years of psychosis Intervention characteristics: Pretreatment: Continuous outcomes: <i>Louise Klokke Madsen</i> PANSS-positive, PANSS-negative, RFS-Social II, PDI-distress <i>Jesper Østrup Rasmussen</i> Skalaer: symptomer: PANSSocialfunktion RFS (Self-report scale whereby the total of four sub-scales measures global role functioning. Higher scores indicate better functioning.) Jeg har taget immediate social network. Distress: PDIKan ikke finde 1 year FU, for hver enkelt gruppe, kun samlet: Positive symp: 0.65 [0.33, 0.98] Negative Symp: 0.28 [0.00, 0.55] Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Unclear risk	n.i.
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Unclear risk	n.i.
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Pinninti 2010

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 44 ● <i>Alder, mean (sd):</i> 40 (11) ● <i>Sygdomsvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 CBT <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 44 ● <i>Alder, mean (sd):</i> 40 (11) ● <i>Sygdomsvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 Included criteria: Excluded criteria:
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● <i>CBT sessions:</i> CBT <ul style="list-style-type: none"> ● <i>CBT sessions:</i> 12 weekly individual sessions of cognitive-behavioral therapy
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage Dichotomous:

	● Relapse
Identification	<p>Sponsorship source: This project was funded by a NARSAD</p> <p>Country: USA</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Narsimha R. Pinninti</p> <p>Institution: Department of Psychiatry, University of Medicine and Dentistry, New Jersey, School of Osteopathic Medicine, 2250 Chapel Ave. West, Cherry Hill, NJ 08034</p> <p>Email: narsimha.pinninti@sbcus.us</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants: <i>Louise Klokke Madsen</i> fandt ikke supplementary file</p> <p>Study design:</p> <p>Baseline characteristics: <i>Louise Klokke Madsen</i> For the 25 outpatients who completed pre- and posttest evaluations, 14 (56%) were women and 11 (44%) were men. Twenty (80%) were European Americans, one (4%) was African American, one (4%) was Hispanic American, and three (12%) persons described themselves as of "other" race or ethnicity. Thirteen (52%) had never married, and 22 (88%) were unemployed. The mean ± SD age was 40 ± 11 years. The mean number of years of hospitalization was 3 ± 3. Twenty-two (88%) were diagnosed as having schizoaffective disorder, and three (12%) were diagnosed as having paranoid schizophrenia.</p> <p><i>Jesper Østrup Rasmussen</i> Kun angivet for hele populationen.</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes: <i>Louise Klokke Madsen</i> PSYRATS Auditory hallucinations (possible scores range from 0 to 44, with higher scores indicating greater symptomatology) <i>Jesper Østrup Rasmussen</i> FU: 24 uger PSYRAT (sættes ind i skema i RevMan) Auditory hallucinations Second-generation antipsychotic 14.45 (12.82) Second-generation antipsychotic + CBT 12.71 (13.59) Delusions Second-generation antipsychotic 13.64 (4.84) Second-generation antipsychotic + CBT 9.57 (6.96)</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Rathod 2013

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 59 ● <i>Alder, mean (sd):</i> 35.58 (10.72) ● <i>Sygdomvarighed (år), mean (sd):</i> 12.33 (8.88) ● <i>Skizofreni eller skizoaftaktiv lidelse (%):</i> <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 63 ● <i>Alder, mean (sd):</i> 31.37 (12.43) ● <i>Sygdomvarighed (år), mean (sd):</i> 8.56 (8.24) ● <i>Skizofreni eller skizoaftaktiv lidelse (%):</i> <p>Included criteria: Participants were eligible if they were: 1. Between ages 18 and 65 with a diagnosis of schizophrenia, schizoaffective disorder or delusional disorders using ICD-10 Research Criteria. 2. From the following groups: ● Black British, Black Caribbean or African Caribbean (all three terms usually refer to people of Caribbean origin with Caribbean origin parents and heritage, even if they are born in the UK themselves). ● South Asian Muslim (Pakistani and Bangladeshi—refer to people of Muslim religion who either have their origins in South Asia or their parents and heritage are). 3. Willing to participate in the interview and/or be tape recorded. 4. Had mental capacity to consent and participate. 5. Able to speak English or were willing to participate with interpreters.</p> <p>Excluded criteria: 1. Severe illness which would affect ability to participate in assessments or therapy e.g. very thought disordered or distressed by symptoms. 2. Lacked mental capacity or denied consent. 3. The treating clinical team thought was inappropriate. For e.g. if they were due to receive CBT through their services as standard treatment and being in</p>

	trial could mean they may be randomised to TAU arm.
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: 16 sessions of CaCBTp over a period of 16 to 20 weeks by trained CaCBTp therapists
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: This trial was part funded by the DRE, Clinical Trailblazers programme and Southern Health NHS Foundation Trust and forms part of author PP's doctoral thesis.</p> <p>Country: UK</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Shanaya Rathod</p> <p>Institution: Southern Health NHS Foundation Trust, UK</p> <p>Email: shanayarathod@nhs.net</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p>Jesper Østrup Rasmussen Skalaer: Negative symptomer: BRAIN Hallucinationer og vrangforestillinger: PSYRATS (skal lige finde ud af hvordan de kan tages med under et) 6 mdr FU.</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Rector 2003

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 28 ● Alder, mean (sd): 41.2 (10.9) ● Sygdomvarighed (år), mean (sd): ● Skizofreni eller skizoaffektiv lidelse (%): 100 <p>CBT</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 62 ● Alder, mean (sd): 37.5 (8.3) ● Sygdomvarighed (år), mean (sd): ● Skizofreni eller skizoaffektiv lidelse (%): 100 <p>Included criteria: Participants were included if they met the following criteria: a DSM-IV (American Psychiatric Association, 1994) diagnosis of schizophrenia or schizoaffective disorder based on the Structured Clinical Interview for DSM-IV Axis I Disorders—Version 1 (First et al., 1995); the presence of persistent positive and negative psychotic symptoms in the past 6</p>

	months as determined by the SCID-I interview; stable treatment with antipsychotic medications; age 18–65. Excluded criteria: Patients were excluded from participation on the basis of suspected organic brain pathology; concurrent substance abuse or dependence; and past treatment with either behavioral or cognitive-behavioral therapy in either individual or family format.
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● CBT sessions: CBT <ul style="list-style-type: none"> ● CBT sessions: 6-month period where CBT was delivered on a weekly basis for a total of 20 sessions
Outcomes	Continuous: <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage Dichotomous: <ul style="list-style-type: none"> ● Relapse
Identification	Sponsorship source: This study was funded by the Ontario Mental Health Foundation (OMHF). Country: Canada Setting: Comments: Authors name: Neil A. Rector Institution: Mood and Anxiety Program, Centre for Addiction and Mental Health, Clarke Division, University of Toronto Email: neil_rector@camh.net Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Intervention characteristics: Pretreatment: Continuous outcomes: Jesper Østrup Rasmussen Skala: PANSSFU: 6 mdr Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Sensky 2000

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● Køn (mænd, %): 50 ● Skizofreni eller skizoaffektiv lidelse (%): ● Alder mean (CI 95%): 40 (34-45) ● Sygdomsvarighed (år), mean (CI 95%): 15 (11-18) CBT <ul style="list-style-type: none"> ● Køn (mænd, %): 67 ● Skizofreni eller skizoaffektiv lidelse (%): ● Alder mean (CI 95%): 39 (35-42) ● Sygdomsvarighed (år), mean (CI 95%): 14 (12-17) Included criteria: age 16-60, diagnosis of schizophrenia (ICD-10 + DSM-IV), symptoms causing distress and/or dysfunction for at least 6 months despite medication.

	Excluded criteria:
Interventions	Intervention Characteristics TAU <ul style="list-style-type: none"> ● CBT sessions: Befriending CBT <ul style="list-style-type: none"> ● CBT sessions:
Outcomes	Continuous: <ul style="list-style-type: none"> ● Negative symptom ● Psykotiske symptomer ● Socialfunktion ● Negative symptom ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage Dichotomous: <ul style="list-style-type: none"> ● Relapse
Identification	Sponsorship source: Grant 039243 from the Wellcome Trust, London, England. Further financial support by Hounslow and Spelthorne Community and Mental Health National Health Service Trust. Country: UK Setting: Comments: Authors name: Tom Sensky Institution: Division of Neurosciences and Psychological Medicina, Imperial College School of Medicins, London, England Email: Address:
Notes	Identification: Participants: Study design: Baseline characteristics: Jesper Østrup Rasmussen Skala: SANS Intervention characteristics: Pretreatment: Continuous outcomes: Dichotomous outcomes: Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n.i.
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Shawyer 2012

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics TAU <ul style="list-style-type: none"> ● Køn (mænd, %): 40.9 ● Alder, mean (sd): 39.6 (11.4) ● Sygdomvarighed (år), mean (sd): 15.2 (11.4) ● Skizofreni eller skizoaffektiv lidelse (%): 95.4 CBT <ul style="list-style-type: none"> ● Køn (mænd, %): 71.4 ● Alder, mean (sd): 40.0 (8.5) ● Sygdomvarighed (år), mean (sd): 14.2 (7.9) ● Skizofreni eller skizoaffektiv lidelse (%): 90.4 Included criteria: diagnosis of schizophrenia or related condition based on DSM-IV criteria, aged between 18 and 65 years and having experienced command hallucinations within the previous 6 months that caused distress or dysfunction despite treatment with antipsychotic medication at therapeutic doses

	<p>Excluded criteria: any neurological disorder that may affect cognitive function; insufficient conversational English for meaningful participation; current abuse of alcohol or drugs requiring specific clinical intervention; having a premorbid IQ of less than 70, and inability to give informed consent</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Befriending is a fully manualised control intervention (Bendall, Killackey, Jackson, & Gleeson, 2003) that provides the patient with the same amount of therapist engagement and expectancy as CBT and has similar drop-out rates (Bendall et al., 2006). Befriending involves a series of conversations that are like conversations with a friendly social acquaintance. The sessions focus on neutral topics of interest and enjoyment for the client, such as hobbies, sports, and current affairs (Bendall et al., 2003). An explicit avoidance of discussion of symptoms and problems (redirecting important issues back to the treating clinician if needed) provides the rationale for treatment and is likely to contribute to positive expectancy <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> TORCH comprised three engagement and assessment sessions followed by 12 sessions at weekly intervals. Core modules included belief modification and acceptance-based interventions. Supporting modules included motivational interviewing, personalised psychoeducation, enhancing self-efficacy, relapse prevention, coping, assertion and termination. Homework exercises were given where feasible.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: This research was funded by grants from the National Health and Medical Research Council of Australia (Grant 251730) and the Rebecca L Cooper Medical Research Foundation. Therapist training in mindfulness was funded by grants from Novartis Pharmaceuticals Australia Pty Ltd and Eli Lilly Australia Pty Ltd. These funding sources had no involvement in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication.</p> <p>Country: Australia</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Frances Sawyer</p> <p>Institution: School of Psychological Science, La Trobe University, Victoria 3086, Australia</p> <p>Email: fshawyer@gmail.com</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p>Louise Klokke Madsen PANSS positive PANSS negative Distress (PSYRATS) QOL (feelings) GAF</p> <p>Jesper Østrup Rasmussen FU: 6 mdr Mht. populationen skriver de et interval, jeg har bare taget midt imellem, hhv 18 og 19 Skalaer: symptomer: PANSS Distress: PSYRATS QoL: QLS (jeg har taget: The General Activities subscale measures degree of satisfaction with general activities of life such as work, social relationships and ability to function.) Socialfunktion: GAF</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Startup 2004

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 72,1 ● <i>Alder, mean (sd):</i> 31.3 (9.6) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 78,7 ● <i>Alder, mean (sd):</i> 30.5 (8.7) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 100 <p>Included criteria: aged between 18 and 65years, were resident within the catchment area,had received a clinical diagnosis of schizophrenia,schizophreniform or schizo-affective disorder, appeared to be suffering an acute psychotic episode, were not already receiving psychological treatment, and showed no evidence of organic mental disorder.</p> <p>Excluded criteria: Those who accepted were then excluded if, during a baseline assessment, they were found not to be suffering an acute psychotic episode (N=13), their diagnoses could not be confirmed according to DSM-IV (American Psychiatric Association,1994) criteria (N=7), they had been dependent on alcohol or illicit drugs according to DSM-IV criteria during the past year (N=12), or their IQs, assessed by the Quick Test (Ammons & Ammons, 1962), were below 80 (N=19).</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> max 25
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptom ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p>Dichotomous:</p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: This trial was supported by grant RC012 from the Wales Office of R & D for Health & Social Care and by Conwy & Denbighshire, North-West Wales, and North-East Wales NHS Trust</p> <p>Country: Australia</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Mike Startup</p> <p>Institution: School of Behavioural Sciences, University of Newcastle</p> <p>Email: Mike.Startup@newcastle.edu.au</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Louise Klokke Madsen SANS - psychotic SANS total Social Functioning Scale</i></p> <p><i>Jesper Østrup Rasmussen Da de skriver at interventionen tager 25 uger, tager jeg 6 month som end of treatment og 12 month som 6 mdr FU.</i></p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	

Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Tarrier 1999

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 74 ● <i>Alder, mean (sd):</i> 39.4 (10.9) ● <i>Sygdomvarighed (år), mean (sd):</i> 14.2 (9.9) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 97 <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 74 ● <i>Alder, mean (sd):</i> 39.4 (10.9) ● <i>Sygdomvarighed (år), mean (sd):</i> 14.2 (9.9) ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> 97 <p>Included criteria: a diagnosis of schizophrenia, schizoaffective psychosis or delusional disorder using DSM-111-R (American Psychiatric Association, 1987) criteria; no evidence of organic brain disease; substance abuse was not identified as the primary problem; aged between 18 and 65 years; suffering persistent hallucinations and/or delusions for a minimum of six months, and at least one month of stabilisation if they had suffered an exacerbation during this period; were on stable medication; were not receiving psychological or family intervention; their responsible medical officer had given permission for them to enter the study; and they had given informed consent to participate.</p> <p>Excluded criteria:</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> Routine care consisted of the standard psychiatric management by the clinical team of medication and monitoring through out-patient follow-up and the Care Programme Approach. All patients in the two intervention groups also received routine care <p>CBT</p> <ul style="list-style-type: none"> ● <i>CBT sessions:</i> six hourly sessions, each of which were followed by two summary sessions. Sessions were carried out twice a week and 20 sessions of treatment were carried out over ten weeks.
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Positive symptoms, BPRS (0-6, lower=better) ● Negative symptoms, SANS (0-5, lower=better) ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p>Dichotomous:</p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: The Wellcome Trust</p> <p>Country: UK</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: NICHOLAS TARRIER</p> <p>Institution: University of Manchester</p> <p>Email: nlarrer@frl.wfh.man.</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p><i>Louise Klokke Madsen</i> 52 (74%) were male; they had a mean age of 39.4 (s.d.=10.9) years; 64 (93%) had a diagnosis of schizophrenia, three (4%) a schizoaffective disorder and two (3%) a delusional disorder; they had a mean duration of illness of 14.2 (s.d.=9.9) years</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Jesper Østrup Rasmussen</i> Positive symptom: BPRS (high scores indicate more severe symptoms) negative symptom: SANS (High scores indicate a worse outcome.)</p> <p>Dichotomous outcomes:</p> <p><i>Jesper Østrup Rasmussen</i> Definition of relapse: rehospitalisation for a clinical deterioration that resulted in functional impairment and hospitalisation for at least five days, although not an ideal measure, was chosen as a practical indicator of</p>

relapse
Adverse outcomes:

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Tarrier 2014

Methods	<p>Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>CBT</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 63.3 ● <i>Alder, mean (sd):</i> 32.6 (11.7) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> <p>TAU</p> <ul style="list-style-type: none"> ● <i>Køn (mænd, %):</i> 63.3 ● <i>Alder, mean (sd):</i> 37.3 (14.2) ● <i>Sygdomvarighed (år), mean (sd):</i> ● <i>Skizofreni eller skizoaffektiv lidelse (%):</i> <p>Included criteria: (a) aged between 18 and 65; (b) had a DSM IV diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychotic disorder not otherwise specified; (c) identified as having previous suicide attempts or experiencing current suicidal ideation; (d) under the care of an appropriate clinical team and currently in contact with mental health services; (e) receiving appropriate antipsychotic medication; and, (f) not currently receiving CBT or other empirically validated psychological treatments.</p> <p>Excluded criteria: (a) currently suffered serious suicidal intent and were currently considered a danger to themselves; (b) had a primary diagnosis of bipolar depression or substance induced psychosis; and, (c) suffered from an organic brain disease.</p>
Interventions	<p>Intervention Characteristics</p> <p>CBT</p> <ul style="list-style-type: none"> ● <i>Description:</i> CBSPP was based upon a treatment manual (Tarrier et al., 2008; Tarrier et al., 2013) and was derived from an explanatory model of suicide behaviour; the SAMS (Johnson et al., 2008a). The intervention consisted of three phases to address and change the three components of the SAMS. Modification of: 1) Information processing biases. 2) Appraisals, of defeat, entrapment, social isolation, emotional dysregulation and inter-personal problem solving. 3) Suicide schema. In addition, the sessions focussed on the processes thought to underlie resilience to suicide. The psychological therapy consisted of up to 24 individual therapy sessions delivered twice a week across 12 weeks at a convenient location for the participant (usually their home). Telephone contact or SMS messaging was utilised as appropriate, to support the therapy sessions. <p>TAU</p> <ul style="list-style-type: none"> ● <i>Description:</i>
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Psykotiske symp. (notér skala) ● Negative symptomer (notér skala) ● Symptomatisk relapse ● Socialfunktion ● Distress ● QoL ● Indlæggelsesdage <p>Dichotomous:</p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: This report/article presents independent research commissioned by the National Institute for Health Research (NIHR) UK under its Programme Grants for Applied Research scheme (RP-PG-0606-1086).</p> <p>Country: UK</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Nicholas Tarrier</p> <p>Institution: Department of Psychology, Institute of Psychiatry, London, UK</p> <p>Email:</p>

Notes	<p>Address:</p> <p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics: Jesper Østrup Rasmussen Angives kun for hele populationen.</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes: Louise Klokke Madsen PANSS totalPANSS negativePSYRATS hallucinationsGAF total Jesper Østrup Rasmussen De får behandling i 3 mdr, og der er FU ved 4 mdr, derfor tager jeg denne som end of treatment. 6 mdr er kun 2 mdr herefter og kan derfor ikke indgå. Skalaer:Symptomter: PANSS (low=better)Distress: PSYRATS hallucinations</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "participants were randomised using a clinical data management system" Comment: participants were randomised using a clinical data management system and allocated
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was controlled by staff not directly linked to the trial to ensure independence and blindness to the trial allocation arms."
Blinding of participants and personnel (performance bias)	High risk	Comment: Not possible.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Participants were informed of the randomisation outcome via a letter, which also contained a note reminding them not to disclose any information about their care or treatment during assessments which would break the blind requirement. In cases where the RAs were un-blinded, protocols were followed whereby unblinding was documented and the assessment packs were scored by another RA. Masking was further maintained by ensuring that therapists and RAs were located in different offices so that therapy files and assessment data were stored separately. In addition, clinical staff were repeatedly instructed not to disclose any knowledge of therapy or group allocation to assessors." Comment: Participants were informed of the randomisation outcome via a letter, which also contained a note reminding them not to disclose any information about their care or treatment during assessments which would break the blind requirement. In cases where the RAs were unblinded, protocols were followed whereby unblinding was documented and the assessment packs were scored by another RA. Masking was further maintained by ensuring that therapists and RAs were located in different offices so that therapy files and assessment data were stored separately.
Incomplete outcome data (attrition bias)	Low risk	Quote: "attrition levels at follow up were high. However, attrition from samples that experience severe mental illnesses is often substantial because it is challenging to engage and treat such individuals. Furthermore, apart from delusions measured by the PSYRATS, there were no differential effects of drop out status across the TAU and Treatment conditions."
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Trower 2004

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 70,0 ● Alder, mean (sd): 35.1 (10.4) ● Sygdomvarighed (år), mean (sd): ● Skizofreni eller skizoaffektiv lidelse (%): 80,0 <p>CBT</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 55,6 ● Alder, mean (sd): 36.6 (10.3) ● Sygdomvarighed (år), mean (sd): ● Skizofreni eller skizoaffektiv lidelse (%): 83,3 <p>Included criteria: ICD-10 diagnosis of schizophrenia or related disorder with command hallucinations for at least 6 months (World Health Organization, 1992). Participants were required to have a recent history of compliance with, and a peace of mind of, voices with 'severe' commands, including harm to self, others or major social transgressions.</p> <p>Excluded criteria: Patients were excluded if they had a primary organic or addictive disorder.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: This was delivered by community mental health teams. A detailed breakdown of the services received by the control and treatment groups during the trial and 1 year before the trial are shown in Table 1. This shows that

	<p>TAU was extensive, involving 18 categories of service and admissions. Medication was recorded 12 months before, and during, the trial.</p> <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: median: 16 sessions over 6 mdr.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symptomer ● Socialfunktion ● Negative symptomer ● QoL ● Symptomatisk relapse ● Distress ● Indlæggelsesdage <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Relapse
Identification	<p>Sponsorship source: The research undertaken for this study was supported by a grant from the Department of Health to P.T., M.B. and A.M.</p> <p>Country: UK</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: PETER TROWER</p> <p>Institution: School of Psychology, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK</p> <p>Email: M.J.Birchwood.20@Bham.ac.uk</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Louise Klokke Madsen PSYRATS distress</i></p> <p><i>Jesper Østrup Rasmussen</i> end of treatment ved 6 month, FU ved 12 month. Skalaer: Distress: Psyrats, højere score, dårligere outcome. Symptomerne er rapporteret som den med F: Although change in psychotic symptoms was not predicted, a significant drop occurred in PANSS positive symptoms amounting to 3.7 points in the CTCH group, from a baseline of 21.8, and a small increase occurred in the control group (F=12.6, P<0.001). Similarly, there was a small but consistent reduction in negative symptoms (F=4.8, P=0.001) in the CTCH group. These effects were maintained at 12 months for positive symptoms (F= 14.2, P=0.001), negative symptoms (F=12.3, P=0.002)</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

vanderGaag 2011

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping: Parallel group</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 73 ● Alder, mean (sd): 37.45 (10.61) ● Sygdomvarighed (år), mean (sd): 11.02 (8.37) ● Skizofreni eller skizoaffektiv lidelse (%): 100 <p>CBT</p> <ul style="list-style-type: none"> ● Køn (mænd, %): 69 ● Alder, mean (sd): 36.52 (11.18) ● Sygdomvarighed (år), mean (sd): 10.14 (7.59) ● Skizofreni eller skizoaffektiv lidelse (%): 100 <p>Included criteria: (a) age 18–64; (b) diagnosis of schizophrenia or schizoaffective disorder (DSM-IV-TR, 295.xx)16(c)</p>

	<p>Positive and Negative Syndrome Scale (PANSS)17 scores of delusions 54 OR hallucinations 54 OR suspiciousness54) AND Psychotic Symptoms Rating Scale (PSYRATS)18 scores delusions-suffering 52 AND delusions-impact 52 OR hallucinations-suffering 52 AND hallucinations-impact52;(d) treatment resistance defined as failure of two or more antipsychotic treatments of at least 6 weeks over the past 2 years.</p> <p>Excluded criteria: intellectual disabilities with IQ<50; severe addiction; no competence in the Dutch language; and previous exposure to CBT.</p>
Interventions	<p>Intervention Characteristics</p> <p>TAU</p> <ul style="list-style-type: none"> ● CBT sessions: <p>CBT</p> <ul style="list-style-type: none"> ● CBT sessions: Therapy was provided in weekly sessions for 26 weeks but could end earlier when the participant attained the goals set.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Psykotiske symptomer, PANSS ● Psykotiske symptomer, SAPS ● Psyk.symp. (notér i noter) ● Socialfunktion ● QoL ● Negative symptomer, anden slala (notér i noter) ● Indlæggelsesdage ● Symptomatisk relapse ● Distress <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● normal function (within 95% range of norm by SFS), end of treatment
Identification	<p>Sponsorship source: This study was supported by grant 945-04-406 of the Netherlands Organization for Health Research and Development (ZonMW) and the contributions of the Universities of Groningen and Utrecht and the mental healthcare organisations Lentis, GGZ Drenthe, Mediant, Dimence, Altrecht, Parnassia and the Grote Rivieren.</p> <p>Country: The Netherlands</p> <p>Setting:</p> <p>Comments:</p> <p>Authors name: Mark van der Gaag</p> <p>Institution: VU University and EMGO Institute, Department of Clinical Psychology, Amsterdam and Parnassia Psychiatric Institute, Department of Psychosis Research, The Hague</p> <p>Email: m.van.der.gaag@psy.vu.nl</p> <p>Address:</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p><i>Louise Klokke Madsen</i> QoL=World Health Organization - Quality of Life, total <i>Other outcomes:</i> PANSS total <i>PSYRATS total</i> <i>Jesper Østrup Rasmussen</i> Til symptomer rapporteres kun totalscorer på både PANSS og PSYRATS. <i>QoL: WHO-QOL</i></p> <p>Dichotomous outcomes:</p> <p><i>Jesper Østrup Rasmussen</i> De angiver hvor mange der har et godt funktionsniveau ud fra: the level of social functioning had to be in the 95% range of the normal population (assessed by the Social Functioning Scale (SFS)); 19 there had to be no or minimal suffering from residual symptoms; and there had to be no or minimal affect on daily living of residual symptoms on the PSYRATS. CBT: EoT: 33/109 LFU: 39/109 TAU: EoT: 20/97 LFU 25/97</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	Unclear risk	n.i.
Blinding of outcome assessment (detection bias)	Unclear risk	n.i.
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Unclear risk	n.i.
Other bias	Unclear risk	n.i.

Footnotes

Characteristics of excluded studies

Wang 2003

Reason for exclusion	Fremmedsprog
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Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies**Included studies****Barrowclough 2006**

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[Empty]

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Trower,P.; Birchwood,M.; Meaden,A.; Byrne,S.; Nelson,A.; Ross,K.. Cognitive therapy for command hallucinations: randomised controlled trial. The British journal of psychiatry : the journal of mental science 2004;184(Journal Article):312-320. [DOI:]

vanderGaag 2011

van der Gaag,M.; Stant,A. D.; Wolters,K. J.; Buskens,E.; Wiersma,D.. Cognitive-behavioural therapy for persistent and recurrent psychosis in people with schizophrenia-spectrum disorder: cost-effectiveness analysis.. British Journal of Psychiatry 2011;198(1):59-65. [DOI: 10.1192/bjp.bp.109.071522 [doi]]

Excluded studies**Wang 2003**

Wang.Changhong; Li,Yan; Zhao,Zheng; Pan,M.; Feng,Y.; Sun,F.; Du,B.. Controlled study on long-term effect of cognitive behavior intervention on first episode schizophrenia. Chinese Mental Health Journal 2003;17(3):200-202. [DOI:]

Data and analyses**1 CBT vs TAU**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
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1.1 Psychotic symptoms (higher=worse), end of treatment	15	1078	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-0.58, -0.10]
1.1.1 PANSS positive	10	805	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.31, -0.03]
1.1.2 SAPS	2	126	Std. Mean Difference (IV, Random, 95% CI)	-1.46 [-3.38, 0.47]
1.1.3 BPRS	3	147	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-0.59, 0.10]
1.2 Negative symptoms (higher=worse), end of treatment	18	1214	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.59, -0.04]
1.2.1 PANSS negative	10	765	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.31, 0.08]
1.2.2 SANS	6	333	Std. Mean Difference (IV, Random, 95% CI)	-0.85 [-1.71, 0.01]
1.2.3 BPRS negative	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.39, 0.57]
1.2.4 BRIANS	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.71, 0.73]
1.3 Psychotic symptoms (higher=worse), min 4-6 month FU	10	892	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.38, 0.19]
1.3.1 PANSS positive	7	705	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.22, 0.38]
1.3.2 SAPS	1	63	Std. Mean Difference (IV, Random, 95% CI)	-0.64 [-1.14, -0.14]
1.3.3 BPRS positive	2	124	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.76, -0.01]
1.4 Negative symptoms (higher=worse), min 4-6 month FU	12	1011	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.30, 0.13]
1.4.1 PANSS negative	7	704	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.26, 0.32]
1.4.2 SANS	3	202	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.66, -0.10]
1.4.3 BPRS negative	1	75	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.59, 0.37]
1.4.4 BRIANS	1	30	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.68, 0.76]
1.5 Social function, end of treatment	8	575	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.23, 0.10]
1.5.1 SOFAS (higher=better)	2	203	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.26, 0.29]
1.5.2 Social provision scale (higher=better)	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.37, 0.59]
1.5.3 SFS (higher=better)	2	164	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.68, 0.35]
1.5.4 GAS (higher=worse)	2	99	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.46, 0.33]
1.5.5 GAF (higher=worse)	1	34	Std. Mean Difference (IV, Random, 95% CI)	-0.52 [-1.21, 0.16]
1.6 Distress, PSYRATS (higher=worse)	6	236	Mean Difference (IV, Random, 95% CI)	0.22 [-0.84, 1.28]
1.6.1 Dilusions	1	40	Mean Difference (IV, Random, 95% CI)	6.30 [-0.08, 12.68]
1.6.2 Distress	2	72	Mean Difference (IV, Random, 95% CI)	0.11 [-1.82, 2.03]
1.6.3 Hallucinations	3	124	Mean Difference (IV, Random, 95% CI)	0.70 [-2.87, 4.28]
1.7 Relapse, end of treatment	4	363	Risk Ratio (IV, Random, 95% CI)	0.80 [0.48, 1.32]
1.8 QoL (higher=better), end of treatment	4	297	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.32, 0.38]
1.9 days in hospital, end of treatment	4	425	Mean Difference (IV, Random, 95% CI)	-10.64 [-32.14, 10.86]

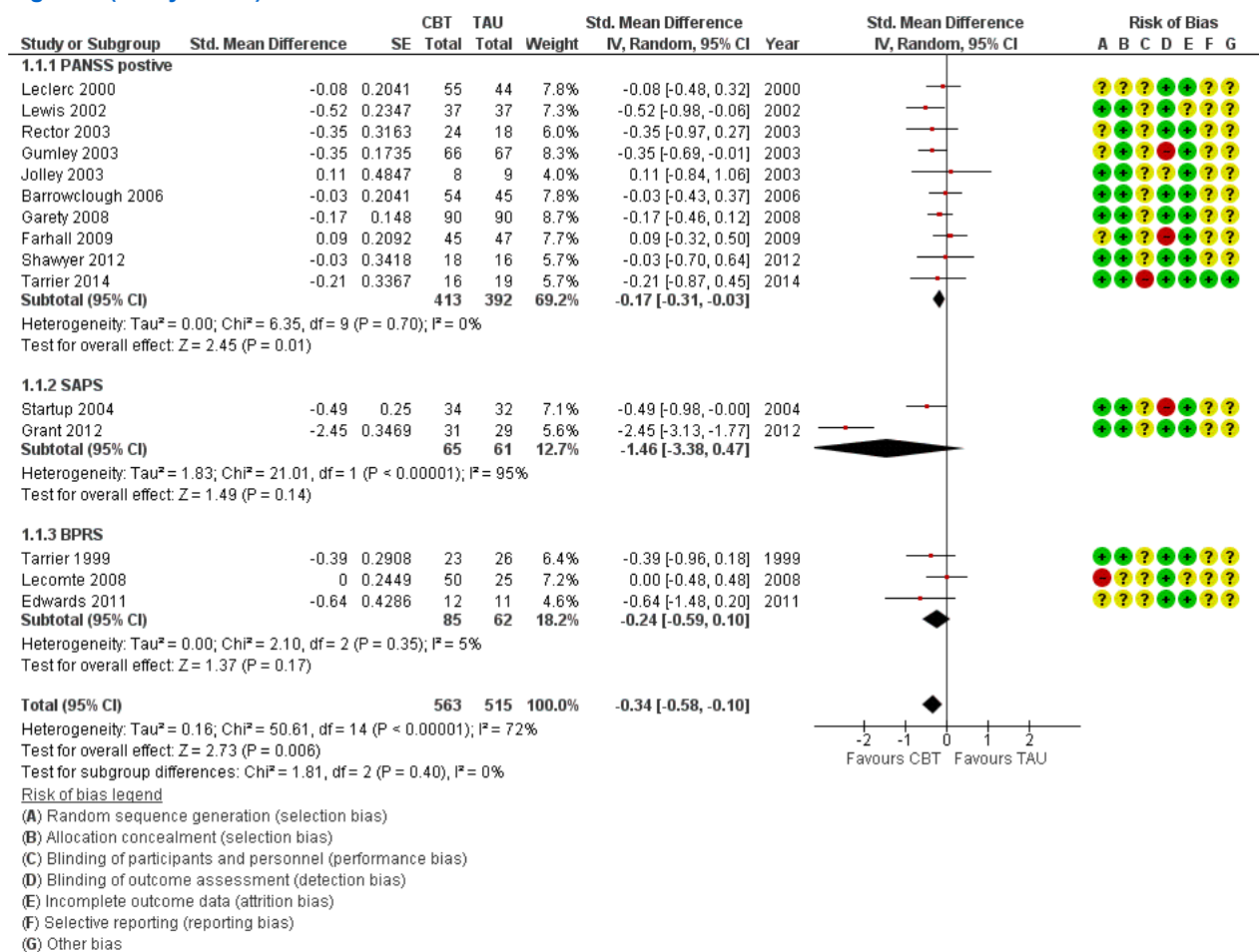
2 CBT vs TAU original data

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Psychotic symptoms (higher=worse), end of treatment	14	1061	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.61, -0.11]
2.1.1 PANSS positive	9	788	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.32, -0.04]
2.1.2 SAPS	2	126	Std. Mean Difference (IV, Random, 95% CI)	-1.45 [-3.37, 0.46]
2.1.3 BPRS positive	3	147	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-0.59, 0.10]
2.2 Negative symptoms (higher=worse), end of treatment	17	1186	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.60, -0.04]
2.2.1 PANSS negative	9	748	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.33, 0.09]
2.2.2 SANS	6	333	Std. Mean Difference (IV, Random, 95% CI)	-0.80 [-1.63, 0.02]
2.2.3 BPRS negative	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.39, 0.57]
2.2.4 BRIANS	1	30	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.71, 0.73]
2.3 Psychotic symptoms (higher=worse), min. 4-6 month FU	8	679	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.34, 0.10]
2.3.1 PANSS positive	5	492	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.12, 0.24]
2.3.2 SAPS	1	63	Std. Mean Difference (IV, Random, 95% CI)	-0.64 [-1.14, -0.13]
2.3.3 BPRS positive	2	124	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.75, -0.01]

2.4 Negative symptoms (higher=worse), min. 4-6 month FU	10	798	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.30, 0.10]
2.4.1 PANSS negative	5	491	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.25, 0.33]
2.4.2 SANS	3	202	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.66, -0.10]
2.4.3 BPRS negative	1	75	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.59, 0.38]
2.4.4 BRIANS	1	30	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.68, 0.76]
2.5 Social function, end of treatment	8	575	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.23, 0.10]
2.5.1 SOFAS (higher=better)	2	203	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.26, 0.29]
2.5.2 Social provision scale (higher=better)	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.37, 0.59]
2.5.3 SFS (higher=better)	2	164	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.68, 0.35]
2.5.4 GAS (higher=worse)	2	99	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.46, 0.33]
2.5.5 GAF (higher=worse)	1	34	Std. Mean Difference (IV, Random, 95% CI)	-0.52 [-1.21, 0.16]
2.6 Distress, PSYRATS (higher=worse)	6	236	Mean Difference (IV, Random, 95% CI)	0.22 [-0.84, 1.28]
2.6.1 Dilusions	1	40	Mean Difference (IV, Random, 95% CI)	6.30 [-0.08, 12.68]
2.6.2 Distress	2	72	Mean Difference (IV, Random, 95% CI)	0.11 [-1.82, 2.03]
2.6.3 Hallucinations	3	124	Mean Difference (IV, Random, 95% CI)	0.70 [-2.87, 4.28]
2.7 Relapse, end of treatment	4	363	Risk Ratio (IV, Random, 95% CI)	0.80 [0.48, 1.32]
2.8 QoL (higher=better), end of treatment	4	297	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.32, 0.38]
2.9 days in hospital, end of treatment	4	425	Mean Difference (IV, Random, 95% CI)	-10.64 [-32.14, 10.86]

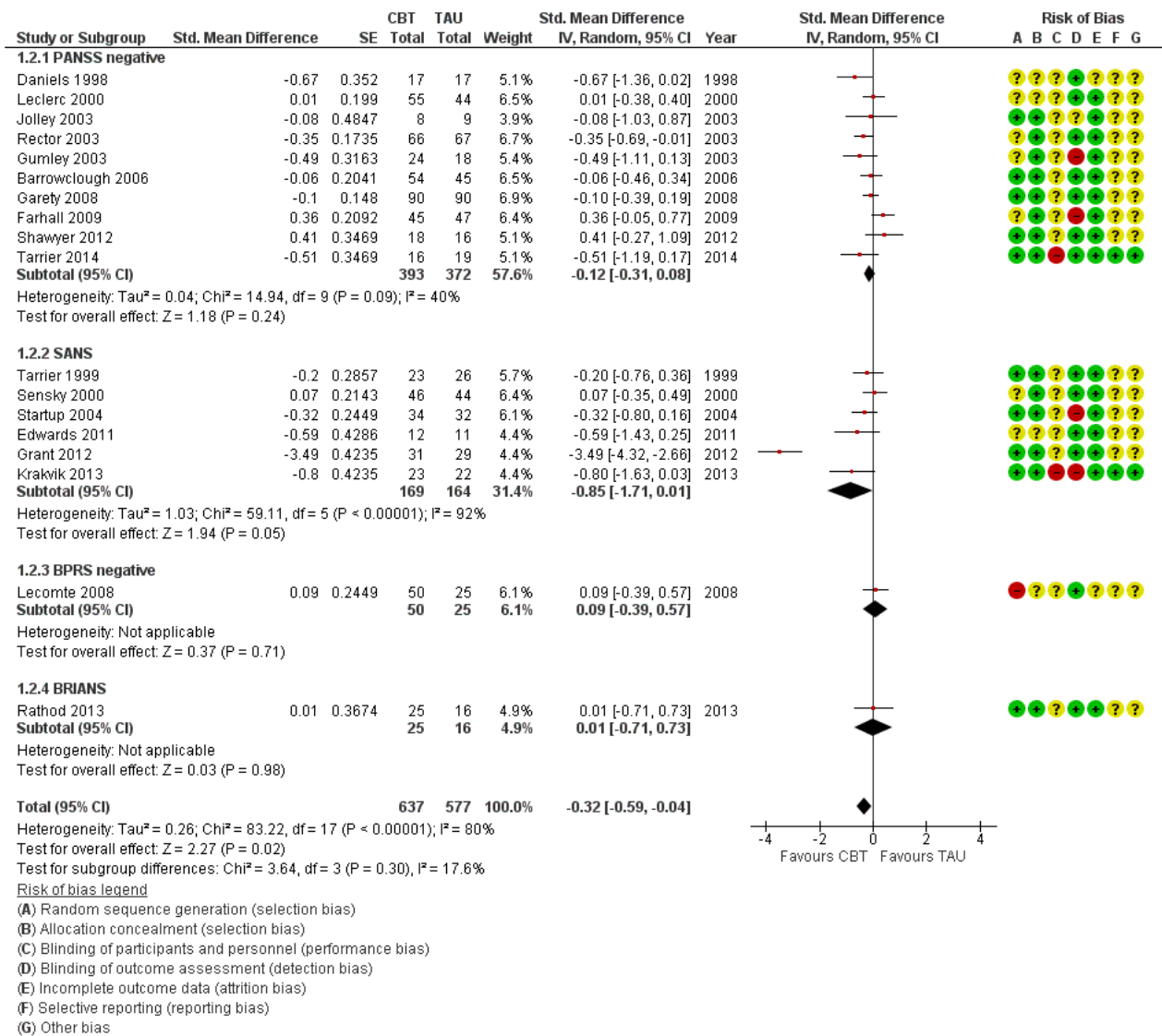
Figures

Figure 1 (Analysis 1.1)



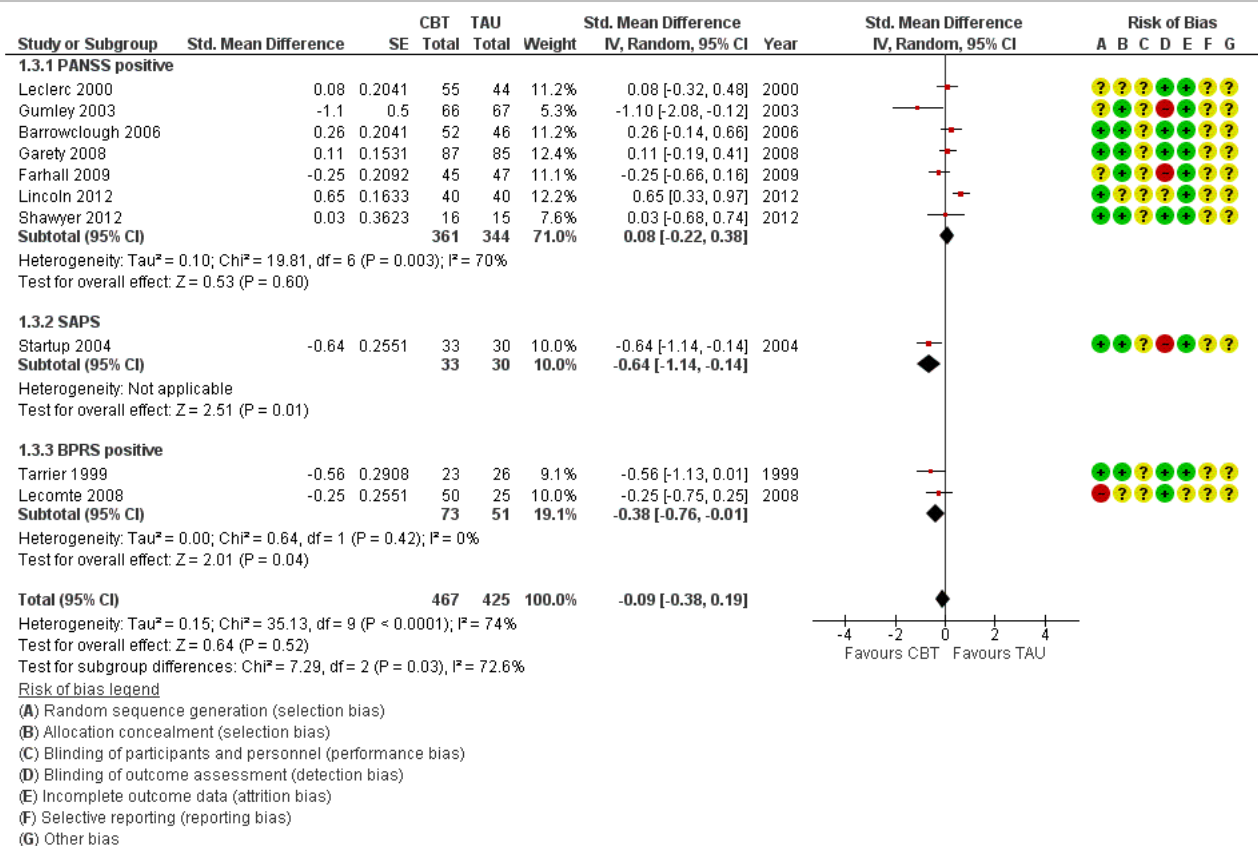
Forest plot of comparison: 1 CBT vs TAU, outcome: 1.1 Psychotic symptoms (higher=worse), end of treatment.

Figure 2 (Analysis 1.2)



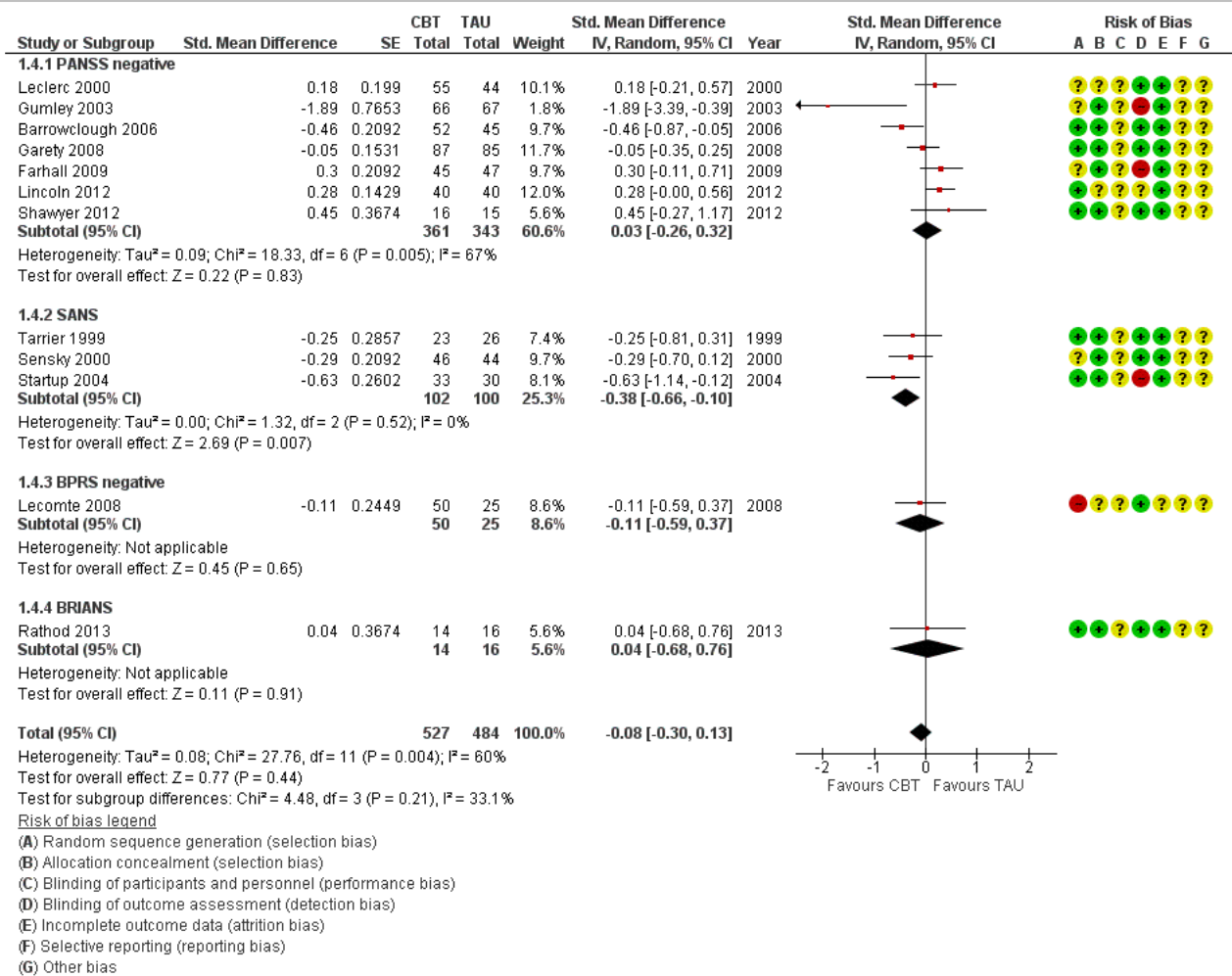
Forest plot of comparison: 1 CBT vs TAU, outcome: 1.2 Negative symptoms (higher=worse), end of treatment.

Figure 3 (Analysis 1.3)



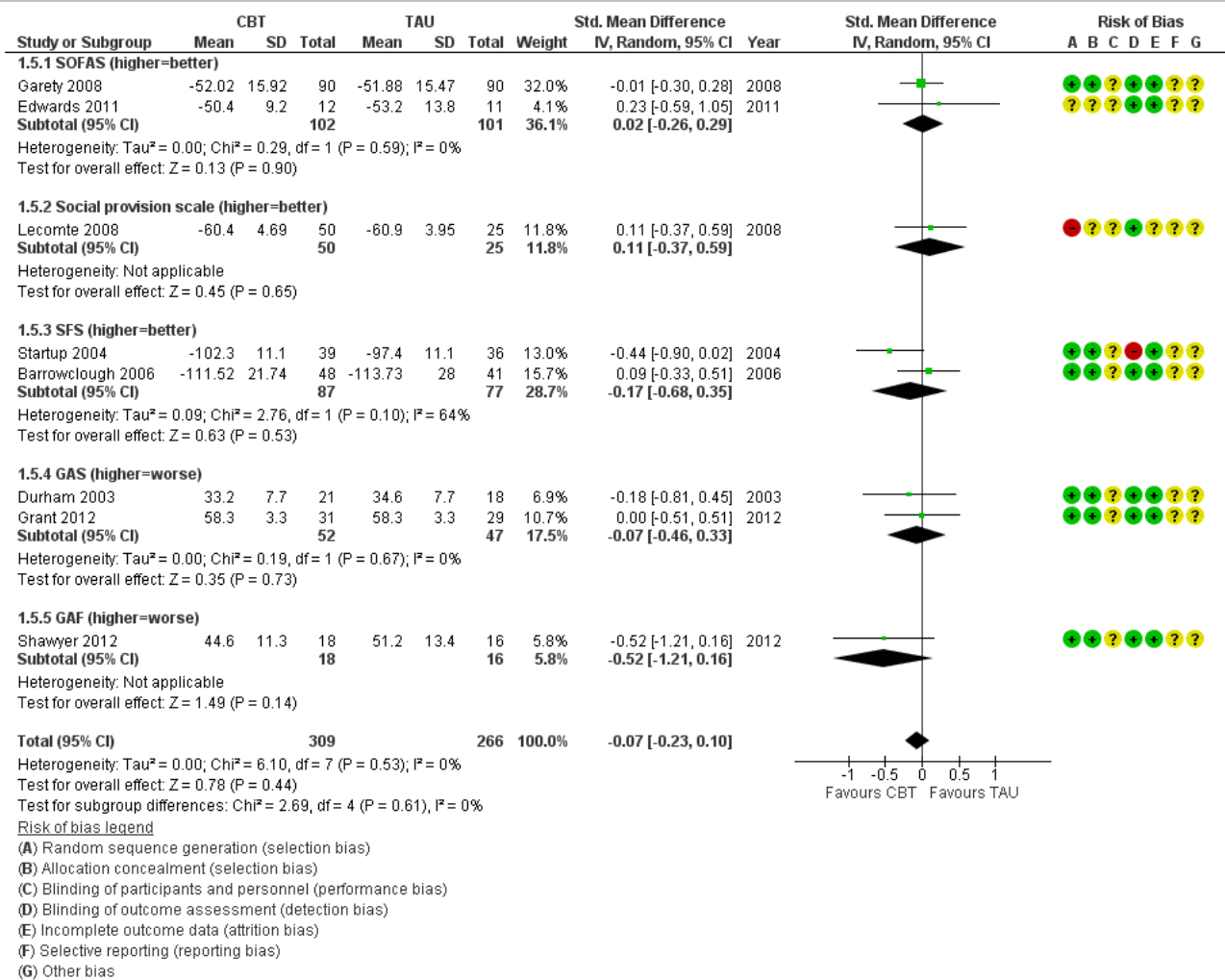
Forest plot of comparison: 1 CBT vs TAU, outcome: 1.3 Psychotic symptoms (higher=worse), min 4-6 month FU.

Figure 4 (Analysis 1.4)



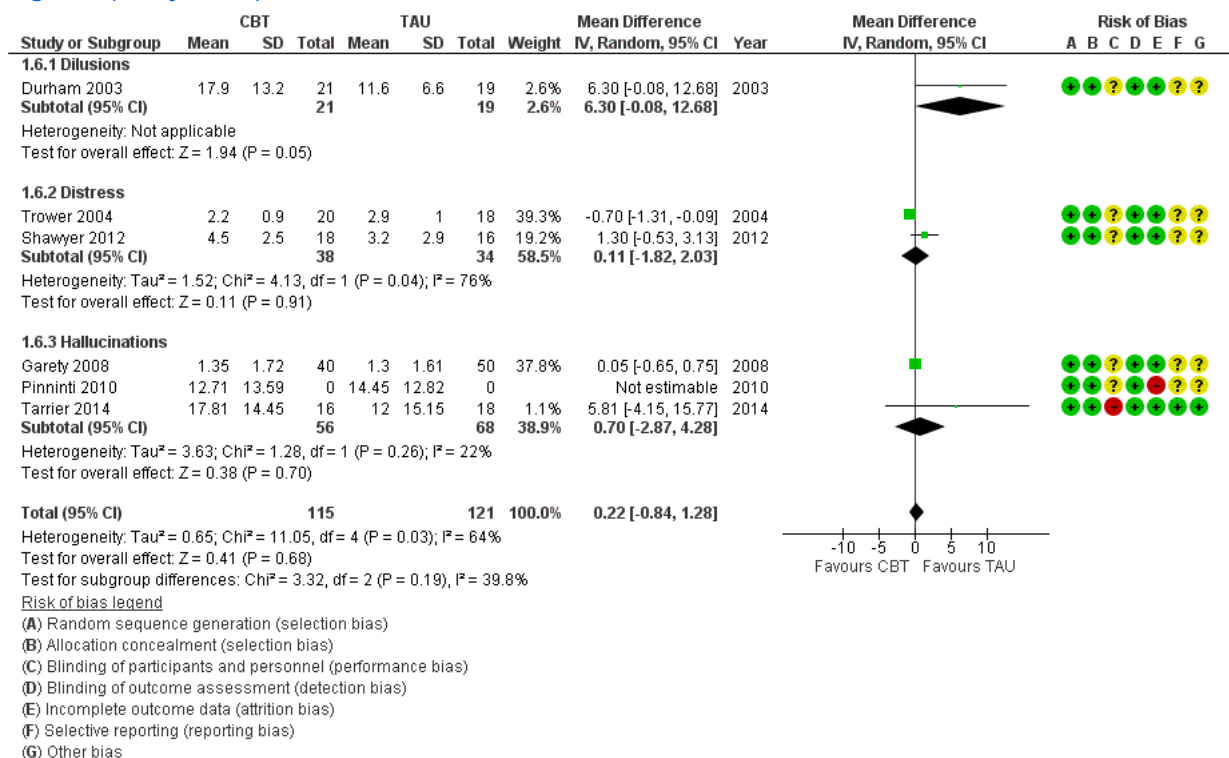
Forest plot of comparison: 1 CBT vs TAU, outcome: 1.4 Negative symptoms (higher=worse), min 4-6 month FU.

Figure 5 (Analysis 1.5)



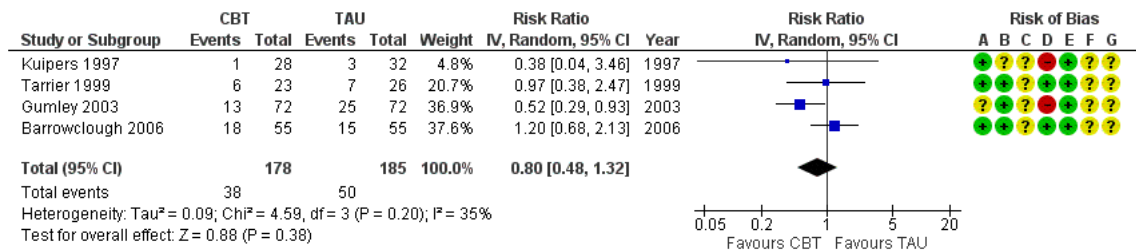
Forest plot of comparison: 1 CBT vs TAU, outcome: 1.5 Social function, end of treatment.

Figure 6 (Analysis 1.6)



Forest plot of comparison: 1 CBT vs TAU, outcome: 1.6 Distress, PSYRATS (higher=worse).

Figure 7 (Analysis 1.7)

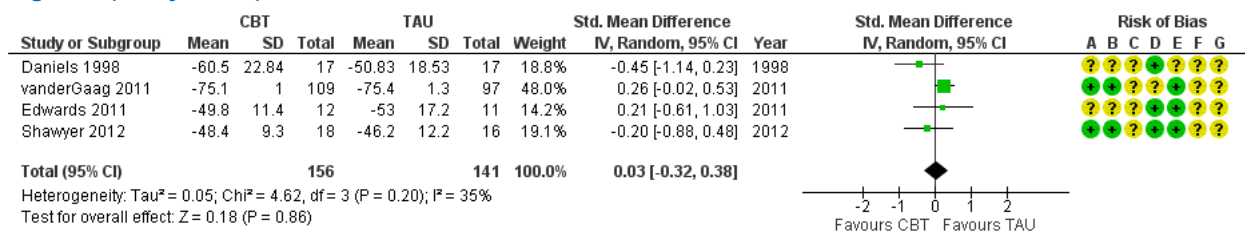


Risk of bias legend

- (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 CBT vs TAU, outcome: 1.7 Relapse, end of treatment.

Figure 8 (Analysis 1.8)

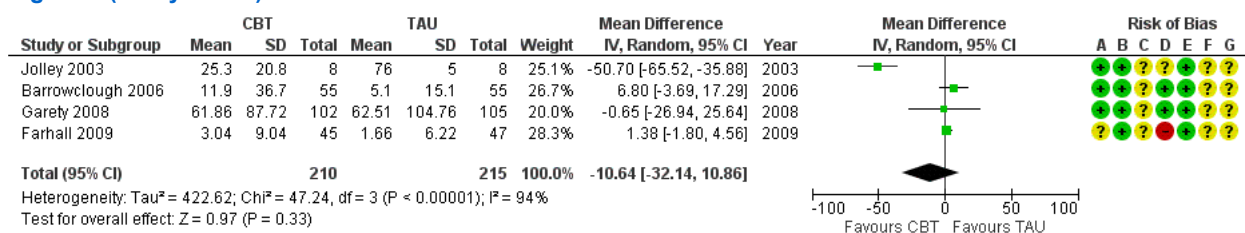


Risk of bias legend

- (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 CBT vs TAU, outcome: 1.8 QoL (higher=better), end of treatment.

Figure 9 (Analysis 1.9)



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 CBT vs TAU, outcome: 1.9 days in hospital, end of treatment.