# APPENDIX 13B: CLINICAL EVIDENCE STUDY CHARACTERISTICS TABLES:

## PSYCHOLOGICAL AND PSYCHOSOCIAL INTERVENTIONS

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## **Abbreviations**

ACE active cognitive therapy for early psychosis BPRS (-P) Brief Psychiatric Rating Scale (Psychotic Subscale)

CBT cognitive behavioural therapy

DSM (-III-R, -IV) Diagnostic and Statistical Manual of Mental Disorders – 3rd edition

revised, 4th edition

ECT electroconvulsive therapy

EPPIC Early Psychosis Prevention and Intervention Centre, Australia

ITT intention to treat
N/A not applicable
QLS Quality of Life Scale

RCT randomised controlled trial

SANS Scale for the Assessment of Negative Symptoms

sd standard deviation

SOFAS Social and Occupational Functioning Assessment Scale

STOPP systematic treatment of persistent psychosis

## **Included studies**

Study ID	APTER1978
Bibliographic reference	Apter, A., Sharir, I., Tyano, S., et al. (1978) Movement therapy with psychotic adolescents. <i>British Journal of Medical Psychology</i> , 51, 155-159.
General information	Funding source: Not reported.
	Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.
	Type of analysis: Not reported.
	Blindness: Only raters blind.
	Duration: Number of weeks of treatment – 12 weeks; length of follow-up – 12 weeks.
	Raters: Only raters blind.
	Design: Single site RCT, unclear location – 'The work was carried out while the authors were at Geha Psychiatric Hospital, Patah-Tiqvah, Israel.'
	Number of people screened, excluded and reasons: Not reported – 30 randomised.
	Notes about study methods: The adolescent unit at Geha Psychiatric Hospital is designed for the treatment of severely disturbed
	patients in a 'closed' setting. In addition to biological treatment (psychotropic drugs and electroconvulsive therapy [ECT]) there is
	a very active milieu programme that includes large and small group therapies, psychodrama, occupational and recreational
	therapies and in the last 2 years, movement therapy.
Participants	Diagnosis: Acute psychosis (bipolar disorder not specified).
	Diagnostic tool: Not reported.
	Inclusion criteria:
	• aged 13 to 18 years
	admission to the closed inpatient ward.
	Exclusion criteria: Not reported.
	Total sample size: Number randomised = 30.
	Gender: 50% male.
	Age: Not reported.
	Ethnicity: Not reported.
	Setting: Acute inpatient unit.
Interventions	Intervention: Group 1: individual movement therapy, 1 hour three times a week, N = 10; Group 2: group movement therapy, 1
	hour three times a week, $N = 10$ ; Group 3: group non-specific dance therapy and gymnastic activities in the ward, $N = 10$ .
	Notes about the interventions: Movement therapy: The idea of movement therapy is that the patient becomes 'aware' of their body,
	is able to know the full limits of their physical potential and is able to realise their potential completely. The main foci of attention

	are body stability, improving body image, coordination, expression of body energy, organisation and planning of body movements and non-verbal communication and expression.
Extractable outcomes	None.
Quality	Sequence generation: Unclear risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome assessors blinded: Low risk.
	Missing outcome data: Unclear risk.
	Selective outcome reporting: High risk.
	Other bias: Low risk.
Related publications	None.

Study ID	EDWARDS2011
Bibliographic reference	Edwards, J. Cocks, J. Burnett, P., et al. (2011) Randomized controlled trial of clozapine and CBT for first-episode psychosis with
	enduring positive symptoms: a pilot study. Schizophrenia Research and Treatment, Article ID: 394896. DOI: 10.1155/2011/394896.
General information	Funding source: Victorian Government's Health Promotion Foundation (Australia) and NOVARTIS.
	Published or unpublished data: Published.
Method	Type of study: Single-blind randomised trial.
	Type of analysis: Intention to treat (ITT).
	Blindness: Single-blind (unclear if participants, providers or outcome assessors are blind).
	Duration: Number of weeks of treatment – 12 weeks; length of follow-up – 24 weeks.
	Raters: Not reported.
	Design: Single site randomised controlled trial (RCT), Melbourne, Australia.
	Number of people screened, excluded and reasons: 1,456 individuals were referred to the Early Psychosis Prevention and
	Intervention Centre (EPPIC), 89 met study criteria, 41 refused research participation, 48 agreed to participation. 48 participants
	were randomised.
	Notes about study methods: 64.3% of clozapine group were male compared with 90.9% of the clozapine + cognitive behavioural
	therapy (CBT) group.
Participants	Diagnosis: people with first episode psychosis with enduring positive symptoms.
·	Diagnostic tool: <i>Diagnostic and Statistical Manual of Mental Disorders</i> – 4th edition (DSM-IV).
	Inclusion criteria:
	people with first episode psychosis meeting the DSM-IV criteria for a diagnosis of schizophrenia, schizophreniform
	disorder, delusional disorder, or psychotic disorder not otherwise specified
	aged 15 to 29 years

	<ul> <li>patients 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), 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</li> <li>participants were sourced from consecutive admissions to EPPIC at the Orygen Youth Health Centre for Youth Mental Health in Melbourne, Australia.</li> <li>Exclusion criteria:         <ul> <li>an organic mental disorder</li> <li>pregnancy or lactation</li> <li>requiring antidepressant medication</li> <li>a mood stabiliser or ECT</li> <li>a history of drug-induced granulocytopenia.</li> <li>Total sample size: Number randomised = 48.</li> <li>Gender: 71% male.</li> <li>Age: Mean 21.4 years (range not reported).</li> <li>Ethnicity: Not reported.</li> </ul> </li> </ul>
	Setting: EPPIC.
Interventions	Intervention: Group 1: clozapine 12.5 mg/day titrated up to a maximum dose of 300 mg/day for 12 weeks, N = 14; group 2: clozapine 12.5 mg/day titrated up to a maximum dose of 300 mg/day + CBT (the manualised programme, systematic treatment of persistent psychosis [STOPP]) for 12 weeks, N = 11.  Notes about the interventions: Data were extracted for two out of four treatment arms because thioridazine is not included in the research protocol. Average daily dose of clozapine was 44.8 mg/day higher in the clozapine only group than the clozapine+CBT group.For CBT, a manualised programme (STOPP) was used. Therapy was conducted twice weekly for 12 weeks, with a minimum attendance of 15 sessions required. All participants received routine clinical care, including access to a 24-hour mobile assessment and treatment team, inpatient service, case management and psychiatric review. Patients were seen weekly by a psychiatrist/psychiatry registrar for the duration of the trial. All participants not receiving CBT attended weekly case management sessions.
Extractable outcomes	Mental state: BPRS-P, Beck Depression Inventory, Scale for the Assessment of Negative Symptoms (SANS), Clinical Global Impression.  Social functioning: Social and Occupational Functioning Assessment Scale (SOFAS).  Quality of life: Quality of Life Scale (QLS).  Leaving the study early: Not reported.
Quality	Sequence generation: Unclear risk. Allocation concealment: Unclear risk. Participants blinded: Unclear risk.

	Providers blinded: Unclear risk.
	Outcome assessors blinded: Unclear risk.
	Missing outcome data: Low risk.
	Selective outcome reporting: Unclear risk.
	Other bias: Low risk.
Related publications	None.

Study ID	GLEESON2009
Bibliographic reference	Gleeson, J. F., Cotton, S. M., Alvarez-Jiménez, M., et al. (2009) A randomized controlled trial of relapse prevention therapy for first-
	episode psychosis patients. <i>Journal of Clinical Psychiatry</i> , 70, 477-486.
General information	Funding source: Eli Lilly, Colonial Foundation, National Health and Medical Research Council of Australia and Marqués de
	Valdecilla Public Foundation.
	Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.
	Type of analysis: ITT with last observation carried forward.
	Blindness: Only raters blind.
	Duration: Number of weeks of treatment – 30.33 weeks; length of follow-up – 30.33 weeks.
	Raters: Independent of treatment.
	Design: Single centre RCT -EPPIC, Melbourne, Australia.
	Number of people screened, excluded and reasons: 399 assessed for eligibility, 127 refused to participate, 186 did not meet
	inclusion criteria and four did not meet inclusion criteria at baseline.
	Notes about study methods: None.
Participants	Diagnosis: First episode psychosis (4% bipolar) in remission.
	Diagnostic tool: DSM-IV (automated in clinic).
	Inclusion criteria:
	DSM-IV diagnosis of first episode psychotic disorder
	<6 months of prior treatment with antipsychotic medication
	• age 15 to 25 years
	• remission on positive symptoms (defined as 4 weeks or more of scores of 3 [mild] or below on the subscale items hallucinations, unusual thought disorder, conceptual disorganisation, and suspiciousness on the expanded version of the BPRS).
	Exclusion criteria:
	<ul> <li>ongoing active positive symptoms of psychosis</li> </ul>
	severe intellectual disability

	inability to converse in English
	participation in previous CBT trials.
	Total sample size: Number randomised = 82.
	Gender: 63% male.
	Age: 20.1 years (range not reported).
	Ethnicity: Not reported.
	Setting: Specialist centre (EPPIC).
Interventions	Intervention: Group 1: combined individual and family CBT for relapse prevention + EPPIC treatment as usual, mean (sd) number of individual therapy sessions completed was $8.51(4.87)$ and family sessions $10.2(4.6)$ , $N = 41$ ; Group 2: EPPIC Treatment as usual, $N = 41$ .
	N = 41. Notes about the interventions:
	Combined individual and family CBT for relapse prevention: Key differences with treatment as usual are the shared written individualised formulation regarding relapse risk; systematic and phased approach to relapse prevention via a range of CBT interventions; the parallel individual and family sessions focused on relapse prevention; and supervision focused on relapse
	prevention.
	EPPIC treatment as usual: Participants had access to home-based treatment and a range of psychosocial interventions. At entry to
	the service, all families were routinely offered access to a brief family psychoeducation group and EPPIC families had access to a
	family peer support service.
Extractable outcomes	Relapse (BPRS): Number of people.
	Relapse (BPRS): Time in days.
	Mental state: BPRS, SANS, Montgomery-Åsberg Depression Rating Scale.
	Quality of life: World Health Organisation Quality of Life Assessment.
	Social functioning: SOFAS.
	Leaving the study early: Leaving due to any reason.
Quality	Sequence generation: Low risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome Assessors blinded: Low risk.
	Missing outcome data: Low risk.
	Selective outcome reporting: Low risk.
	Other bias: Low risk.
Related publications	None.

Study ID	HADDOCK2006
Bibliographic reference	Haddock, G., Lewis, S., Bentall, R., et al. (2006) Influence of age on outcome of psychological treatments in first-episode psychosis.
	The British Journal of Psychiatry, 188, 250-254.
General information	Funding source: UK Medical Research Council.
	Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.
	Type of analysis: ITT.
	Blindness: Only raters blind.
	Duration: Number of weeks of treatment – 5 weeks; length of follow-up – 78 weeks.
	Raters: Only raters blind.
	Design: Multi-site RCT, Manchester/Salford, Liverpool and north Nottinghamshire, England.
	Number of people screened, excluded and reasons: 433 individuals screened, 63 ineligible, 370 eligible. 45 refused randomisation, 10 unable to consent, 315 randomised, six excluded within 7 days owing to diagnostic change.
	Notes about study methods: 71 participants were aged ≤ 21 years and 238 were aged >21 years. Baseline data were compared
	according to age using a cut-off point of age 21 years (that is, 'over 21' and '21 years and under'). This cut-off was considered to be
	a pragmatic developmental point at which to divide the groups. It also allowed sufficient numbers of participants in both groups
	to ensure that the appropriate comparisons could be made.
Participants	Diagnosis: schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychosis not otherwise
	specified.
	Diagnostic tool: DSM-IV
	Inclusion criteria:
	<ul> <li>either first or second admission (within 2 years of a first admission) to inpatient or day patient unit for treatment of psychosis</li> </ul>
	<ul> <li>DSM-IV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychosis not otherwise specified</li> </ul>
	<ul> <li>positive psychotic symptoms for 4 weeks or more; a score of 4 or more on Positive and Negative Syndrome Scale target</li> </ul>
	item for either delusions (P1) or hallucinations (P3).
	Exclusion criteria:
	substance misuse or organic disorder judged to be the main cause of psychotic symptoms.
	Total sample size: Number randomised = 309.
	Gender: 70% male (77% male aged ≤ 21 years).
	Age: 27.4 (19.6 aged ≤ 21) years.
	Ethnicity: 85% white.
T , , , ,	Setting: Inpatient/ day patient.
Interventions	Intervention – Group 1: CBT plus routine care, 15 to 20 hours within 5 weeks, N = 101; Group 2: supportive counselling plus

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	routine care, 15 to 20 hours within 5 weeks, $N = 106$ ; Group 3: routine care, $N = 102$ .
	Notes about the interventions:
	CBT: Manual-based and conducted by one of five therapists trained in CBT in psychosis, supervised by experienced cognitive
	therapists. 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.
	Supportive counselling: A comparison intervention to control for non-specific elements of therapist exposure. It was delivered in
	the same 5-week format with three boosters, with the aim of matching the duration of total therapist contact time to that in the
	CBT arm. The supportive counselling was also manual-based and supervised by an experienced counsellor.
	The same five research therapists administered both CBT and supportive counselling interventions, according to randomisation.
	Routine care: Not reported.
Extractable outcomes	None.
Quality	Sequence generation: Low risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome assessors blinded: Low risk.
	Missing outcome data: Unclear risk.
	Selective outcome reporting: High risk.
	Other bias: Low risk.
Related publications	Lewis, S., Tarrier, N., Haddock, G., et al. (2002) Randomised controlled trial of cognitive-behavioural therapy in early
	schizophrenia: acute-phase outcomes. British Journal of Psychiatry, 181 (Suppl.), s91-97.

Study ID	JACKSON2008
Bibliographic reference	Jackson, H. J., McGorry, P. D., Killackey, E., <i>et al.</i> (2008) Acute-phase and 1-year follow-up results of a randomized controlled trial of CBT versus befriending for first-episode psychosis: the ACE project. <i>Psychological Medicine</i> , <i>38</i> , 725-735.
General information	Funding source: National Health and Medical Research Council project grant. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.  Type of analysis: Missing values in each of the outcome measures for any individual at time points subsequent to baseline were assumed to have occurred at random, given observed pre-treatment scores. Ten multiply imputed datasets were generated using the 'PAN' package in the R statistical software program to deal with these missing responses.  Blindness: Only raters blind.  Duration: Number of weeks of treatment – 14 weeks; length of follow-up – 52 weeks.  Raters: Independent of treatment  Design: Single centre RCT –EPPIC, Melbourne, Australia.  Number of people screened, excluded and reasons: 427 people screened, 316 were eligible. 126 could not be approached within
	4 weeks (for example, no response to telephone calls/letters, non-attendance at appointments) and were excluded because the trial required therapy to start within 6 weeks of admission. Therefore, 190 individuals were approached for inclusion in the study, but 128 people refused participation. 62 were randomised.  Notes about study methods: 5% of the sample had received ECT.
Participants	Diagnosis: First episode psychosis (21% bipolar). Diagnostic tool: Not reported (automated in clinic). Inclusion criteria:  • first episode psychosis • aged 15 to 25 years. Exclusion criteria:  • inability to speak English • intellectual disability (IQ <70) • psychosis due to a medical condition • change to a non-psychotic diagnosis • left the EPPIC catchment area • treatment from a private psychiatrist/psychologist • participating in a first-episode mania trial • exhibiting violent behaviour • being incarcerated. Total sample size: Number randomised = 62. Gender: 73% male.

	Age: 22.3 years (range not reported).
	Ethnicity: Not reported.
	Setting: Specialist centre (EPPIC).
Interventions	Intervention: Group 1: active cognitive therapy for early psychosis (ACE), a maximum of 20 sessions over 14 weeks, N = 31;
	Group 2: befriending, a maximum of 20 sessions over 14 weeks, N = 31.
	Both in addition to EPPIC treatment as usual: A comprehensive treatment service for 15- to 25-year-olds experiencing a first
	episode of psychosis. It includes a 16-bed inpatient unit, an outpatient case management system, family work, accommodation,
	prolonged recovery programmes and tailored group programmes. Medication is administered in line with a low-dose protocol.
	Notes about the interventions:
	ACE: Assessment of the presenting psychotic and non-psychotic complaints followed by a formulation of the relationship between
	these complaints and the participant's life history. Problems were prioritised according to a flowchart that directed the ACE
	therapy. Each area of difficulty was treated from a broadly cognitive behavioural perspective.
	Befriending: Aimed to control for time in therapy, participant expectations and positive experiences of therapy. Based on the
	befriending therapy used by Sensky and colleagues (Sensky, T., Turkington, D., Kingdon, D., et al. (2000) A randomized controlled
	trial of cognitive-behavioral therapy for persistent symptoms in schizophrenia resistant to medication. Archives of General
	Psychiatry, 57, 165-172), it consisted of talking about neutral topics that interested the participant, such as music, sport, books,
	cooking and pets. If the participant found verbal interaction difficult, the participant and therapist engaged in activities such as
	board games, walking or playing sport, with a view to using the activity as a tool to engage the participant in further neutral
	conversation during and after the activity.
Extractable outcomes	Mental state: BPRS, SANS.
	Social functioning: SOFAS.
	Number of hospitalisations.
	Mortality: Number of people who died by suicide.
	Leaving the study early: Leaving due to any reason.
Quality	Sequence generation: Low risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome assessors blinded: Low risk.
	Missing outcome data: Low risk.
	Selective outcome reporting: Unclear risk.
	Other bias: Low risk.
Related publications	None.

Study ID	JACKSON2009	
Bibliographic reference	Jackson, C., Trower, P., Reid, I., <i>et al.</i> (2009) Improving psychological adjustment following a first episode of psychosis: a randomised controlled trial of cognitive therapy to reduce post psychotic trauma symptoms. <i>Behaviour Research and Therapy</i> , 47, 454-462.	
General information	Funding source: Department of Health Published or unpublished data: Published	
Method	Type of study: Individual randomised trial Type of analysis: Available case analysis. Blindness: Only raters blind. Duration: Number of weeks of treatment – 26 weeks; length of follow-up – 52 weeks. Raters: Independent of treatment. Design: Multi-site RCT – four mental health services across the West Midlands, Great Britain. Number of people screened, excluded and reasons: 357 individuals were screened, 166 patients met the inclusion criteria. Of these, 60 (37%) refused consent; 25 could not be contacted and 11 were thought to be unsuitable to be contacted by their care teams at the time of the study. This left a sample of 70 consenting to randomisation. One person then withdrew their consent, two were deported and one person no longer fulfilled the criteria for the trial (their diagnosis was changed). In total 66 people were randomised to the two conditions. Notes about study methods: No changes were made to medication regimes in either the experimental or control conditions. The majority of participants having CBT and treatment as usual (90% versus 92%, respectively) were prescribed atypical neuroleptic medication.	
Participants	Diagnosis: First episode psychosis (excluding bipolar).  Diagnostic tool: International Classification of Diseases, 10th revision (ICD-10).  Inclusion criteria:  • a first episode of psychosis within the previous 6–18 months  • aged between 16 and 35 years.  Exclusion criteria:  • unable to speak English.  • unable to give informed consent.  Total sample size: Number randomised = 70.  Gender: 74% male.  Age: Mean 23.3 years (range: 16 to 38).  Ethnicity: 71% white.  Setting: Not reported.	

Interventions	Intervention – Group 1: cognitive therapy-based recovery intervention + treatment as usual, a maximum of 26 sessions over
	26 weeks, N = 36; Group 2: treatment as usual from their local mental health services, N = 30.
	Notes about the interventions:
	Cognitive therapy-based recovery intervention: There were three key components: (1) engagement and formulation; (2) trauma
	processing; and (3) appraisals of psychotic illness (shame, loss and entrapment). The intervention was not just designed for those
	who could be described as 'traumatised' by their experiences of psychosis but was intended to be helpful for all people adjusting
	to and recovering from a first episode of psychosis.
	Treatment as usual: although the treatment as usual interventions across the four sites were not standardised, they were closely
	monitored and documented. In both conditions (control and cognitive therapy-based recovery intervention), treatment as usual
	usually consisted of a combination of case management and antipsychotic medication.
Extractable outcomes	Mental state: Calgary Depression Scale for Schizophrenia.
	Leaving the study early: Leaving due to any reason.
Quality	Sequence generation: Low risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome assessors blinded: Low risk.
	Missing outcome data: High risk.
	Selective outcome reporting: Unclear risk.
	Other bias: Low risk.
Related publications	None.
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Study ID	LINSZEN1996	
Bibliographic reference	Linszen, D., Dingemans, P., Van der Does, J. W., et al. (1996) Treatment, expressed emotion and relapse in recent onset	
	schizophrenic disorders. Psychological Medicine, 26, 333-342.	
General information	Funding source: Not reported.	
	Published or unpublished data: Published.	
Method	Type of study: Individual randomised trial.	
	Type of analysis: Not reported.	
	Blindness: Only raters blind.	
	Duration: Number of weeks of treatment - 65.8 weeks; mean number of weeks of inpatient treatment: 13.8 and outpatient	
	treatment: 52; length of follow-up – 5 years.	
	Raters: Independent of treatment.	
	Design: Single centre RCT- psychiatric inpatient, Amsterdam, The Netherlands.	

	Number of people screened, excluded and reasons: Not reported.
	Notes about study methods: Randomisation of participants to the specific outpatient intervention was performed on completion of
	inpatient treatment.
Participants	Diagnosis: schizophrenia (55%), schizoaffective disorders (21%), schizophreniform disorder (13%) and other psychotic disorders,
	for example, delusional disorder and atypical psychosis (11 %)
	Diagnostic tool: DSM-III-R
	Inclusion criteria:
	confirmed diagnosis of schizophrenia or a related disorder
	in need of continuous antipsychotic medication
	<ul> <li>between 15 and 26 years and living with parents or other relatives or in close contact with them.</li> </ul>
	Exclusion criteria:
	<ul> <li>patients with primary alcohol or drug dependence or brief drug-related psychoses who needed detoxification.</li> </ul>
	Total sample size: Number randomised = 76.
	Gender: 70% male.
	Age: Mean 20.6 years (range not reported).
	Ethnicity: Not reported.
	Setting: Inpatient and outpatient.
Interventions	Intervention: Group 1: Inpatient psychosocial and behavioural family intervention, 18 family therapy sessions over a maximum of
	12 months, N = 37; Group 2: inpatient psychosocial intervention, 18 sessions over a maximum of 12 months, N = 39.
	Notes about the interventions:
	Inpatient psychosocial and behavioural family intervention: A behavioural family intervention was added to the inpatient
	psychosocial intervention. The family treatment was based on the behavioural family management approach as developed by
	Falloon and colleagues (Falloon, I. R. H., Boyd, J. L. & McGill, C. W. (1984) Family Care of Schizophrenia. Guildford Press: New York,
	NY). Psychoeducation, communication training and the development of problem solving skills were the main components; the
	methods include instruction, role rehearsal and modelling.
	Inpatient psychosocial intervention: Acted as a control condition. As during inpatient treatment, patients were taught about their
	illness including recognisable psychotic, negative, affective and residual symptoms and prodromal signs. Patients were also
	supported with seeking employment, education and financial help.
Extractable outcomes	Relapse (BPRS): Number of people.
	Leaving the study early: Leaving due to any reason.
Quality	Sequence generation: Unclear risk.
	Allocation concealment: Unclear risk.
	Participants blinded: High risk.
	Providers blinded: High risk.
	Outcome assessors blinded: Low risk.

	Missing outcome data: High risk.
	Selective outcome reporting: High risk.
	Other bias: Low risk.
Related publications Lenior, M., Dingemans, P., Linszen, D., et al. (2001) Social functioning and the course of early-onset schizoph	
	follow-up of a psychosocial intervention. British Journal of Psychiatry, 179, 53–58.
	Linszen, D., Dingemans, P., Scholte, W., et al. (1998) Early recognition, intensive intervention and other protective and risk factors
	for psychotic relapse in patients with first psychotic episodes in schizophrenia. International Clinical Psychopharmacology, 13
	(Suppl. 1), S7–S12.
	Nugter, A., Dingemans, P., Van der Does, J., et al. (1997) Family treatment, expressed emotion and relapse in recent onset
	schizophrenia. Psychiatry Research, 72, 23–31.

Study ID	MAK2007
Bibliographic reference	Mak, G. K. L., Li, F. W. S. & Lee, P. W. H. (2007) A pilot study on psychological interventions with Chinese young adults with
	schizophrenia. Hong Kong Journal of Psychiatry, 17, 17-23.
General information Funding source: Zee Foundation.	
	Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.
	Type of analysis: Available case.
	Blindness: Only raters blind.
	Duration: Number of weeks of treatment – 39 weeks; length of follow-up – 65 weeks.
	Raters: Independent of treatment.
	Design: Single-site RCT, Hong Kong, China.
	Number of people screened, excluded and reasons: 53 patients interviewed and screened. 48 patients randomised.
	Notes about study methods: N/A.
Participants	Diagnosis: Schizophrenia.
	Diagnostic tool: DSM-IV.
	Inclusion criteria:
	schizophrenia according to DSM-IV criteria
	aged 15 to 32 years
	Cantonese speaking
	<ul> <li>willing to participate in the study and attend the specified follow-up treatments.</li> </ul>
	consent to continue seeing their psychiatrist for ongoing psychiatric treatment.
	the absence of any other psychiatric and medical comorbidity.
	Exclusion criteria: Not reported.

	Total cample circu Number randomicad = 49	
	Total sample size: Number randomised = 48.	
	Gender: 56% male.	
	Age: Mean 24 years (range 15 to 32).	
	Ethnicity: Not reported.	
	Setting: Non-specified psychiatric setting.	
Interventions	Intervention: Group 1: psychotherapy over 65 weeks, N = 23; Group 2: waitlist over 65 weeks, N = 13.	
	Notes about the interventions:	
	Psychotherapy: Psychological treatment was based on clinical assessments of the subjects' presenting problems and needs; the	
	orientation being cognitive-behavioural. The two project psychologists had periodic case consultations with each other to ensure	
	their therapy coverage and approach were compatible. Each patient was seen at least once (about 1 hour) every 2 weeks during the	
	treatment period. Patients with extra needs were allocated more treatment sessions, after the basic psychological treatment	
	package.	
Extractable outcomes	None.	
Quality	Sequence generation: Unclear risk.	
•	Allocation concealment: Unclear risk.	
	Participants blinded: High risk.	
	Providers blinded: High risk.	
	Outcome assessors blinded: Low risk.	
	Missing outcome data: High risk.	
	Selective outcome reporting: High risk.	
	Other bias: Low risk.	
Related publications	None.	

Study ID	POWER2003	
Bibliographic reference	Power, P. J., Bell, R. J., Mills, R., et al. (2003) Suicide prevention in first episode psychosis: the development of a randomised	
	controlled trial of cognitive therapy for acutely suicidal patients with early psychosis. Australian and New Zealand Journal of	
	Psychiatry, 37, 414-420.	
General information	Funding source: Commonwealth Department of Health and Family Services.	
	Published or unpublished data: Published.	
Method	Type of study: Individual randomised trial.	
	Type of analysis: Not reported.	
	Blindness: Only raters blind.	
	Duration: Number of weeks of treatment – 10 weeks; length of follow-up – 6 months.	
	Raters: Independent of treatment.	
	Design: Single centre RCT -EPPIC, Melbourne, Australia.	

	Number of people screened, excluded and reasons: 92 people were referred and met criteria for the trial, 36 refused to participate and the remaining 56 were randomised.  Notes about study methods: N/A.	
Participants	Diagnosis: Acutely suicidal first episode psychosis (bipolar not specified).  Diagnostic tool: Automated in clinic. Inclusion criteria:  • first episode psychosis • aged 15 to 29 years • all patients at EPPIC who were rated between 4 and 7 on the Expanded Version 4 of the BPRS Suicidality subscore were referred for consideration of LifeSPAN therapy. A score of 4 equates to 'suicidal thoughts frequent, without intent or plan' and 7 equated to a 'specific suicidal plan and intent or suicide attempt'.  Exclusion criteria: Not reported.  Total sample size: Number randomised = 56.  Gender: Not reported.  Age: Estimated mean 22 years (inclusion range 15 to 29).  Ethnicity: Not reported.  Setting: Specialist centre (EPPIC).	
Interventions	Intervention: Group 1: LifeSPAN therapy (cognitive orientated therapy for suicide behaviour) + EPPIC treatment as usual, eight to ten individual sessions, over 10 weeks, N = 31; Group 2: EPPIC treatment as usual, N = 25.  Notes about the interventions:  LifeSPAN therapy: Draws on the experience at EPPIC with cognitive oriented therapy for early psychosis (COPE) and suicide prevention manuals such as 'Choosing to live' and 'Cognitive therapy of suicide behaviour: a manual for treatment'. There were four phases: (1) initial engagement; (2) suicide risk assessment/formulation; (3) cognitive modules; and (4) final closure/handover. EPPIC treatment as usual: An early intervention programme for young people (aged 15–29) presenting with first episode psychosis. EPPIC's services include an early detection and crisis assessment team, an acute inpatient unit, an outpatient group programme, assertive follow-up teams and an intensive outreach mobile support team. Approximately 250 new patients are accepted into the EPPIC service each year. Treatments are provided via an integrated bio-psychosocial model with a strong emphasis on low-dose medication and cognitive-orientated individual, group and family therapies. Follow-up is provided for 18 months.	
Extractable outcomes	Mortality: Number of people dying by suicide. Quality of life: QLS. Leaving the study early: Leaving due to any reason.	
Quality	Sequence generation: Unclear risk. Allocation concealment: Unclear risk. Participants blinded: High risk.	

	Providers blinded: High risk.	
	Outcome assessors blinded: Low risk.	
	Missing outcome data: High risk.	
	Selective outcome reporting: High risk.	
	Other bias: Low risk.	
Related publications	None.	

## **Excluded studies**

Study	Reason for exclusion
ADDINGTON2011A	Not relevant to this section. Included in Chapter 5, 'At risk
	mental states for psychosis and schizophrenia in children and
	young people'.
AGHOTOR2010	Adult population.
ALARAISANEN2007	Design: non-RCT
ALVAREZ-JIMÉNEZ2009	Design: non-RCT
ARCHIE2003	Adult population.
BAKER2010	Design: non-RCT.
BARROWCLOUGH2001	Adult population.
BARROWCLOUGH2009	Adult population.
BEAUCHAMP2011	Adult population.
BECHDOLF2004A	Adult population.
BECHDOLF2005	Adult population.
BECHDOLF2007	Outcomes not of interest.
BECHDOLF2009	Conference abstract.
BECHDOLF2010A	Adult population.
BECHDOLF2011	Conference abstract.
BECHDOLF2012	Not relevant to this section. Included in Chapter 5, 'At risk
	mental states for psychosis and schizophrenia in children and
	young people'.
BECKER1997	Adult population.
BECKER1998	Design: non-RCT.
BEEBE2001	Adult population.
BIRCHWOOD2011	Design: protocol only.
BOLA2006	Intervention not included in the scope.
BORA2009	Outcomes not of interest.
BOWIE2011	Conference abstract.
BRADSHAW2000	Adult population.
BRESSI2008	Adult population.
BUCCISBAKER2010	Intervention not included in the review protocol.
CAMPBELL2011	Non-clinical population.
CARPENTER1987	Adult population.
CATHER2005	Adult population.
CATTY2008	Adult population.
CATTY2010	Adult population.
CHAMORRO2008	Not in English.
CHOI2006	Adult population.
CHOI2009	Adult population.
CHONG2009	Adult population.
CHRISTODOULIDES2008	Design: non-RCT.
COLE1967	Paper unavailable.
COMBS2011	Adult population.
CORCORAN2005	Design: discussion on prodromal interventions for
	schizophrenia.
CORELL2004	Adult population
CUNNINGHAMOWENS2001	Adult population.
DAPRATI2005	Adult population.
DAUMIT2010	Conference abstract.
DAVIS1972	Adult population.

DIAMOND2001	Design: non-RCT.
DIXON1999	Adult population.
DOANE1985	Adult population.
DOERINGSMULLER1998	Adult population.
DURHAM2003	Adult population.
EACK2007	Adult population.
EACK2009	Not relevant to this section. Included in Chapter 8, 'Cognition,
Enteresory	employment and education'.
EACK2011A	Outcomes not of interest
EACK2011B	Not relevant to this section. Included in Chapter 8, 'Cognition,
2.101 20112	employment and education'.
EDWARDS2003	Conference abstract.
ERICKSON1998	Design: cohort.
ERICKSON2010	Adult population.
FALLOON1982	Adult population.
FALLOON1985	Adult population.
FALLOON1987	Adult population.
FAZEL2011	Outcomes not of interest.
FENTON1979	Adult population.
FJELL2007	Design: discussion.
FOWLER2009	Adult population.
FRANK1990	Adult population.
FRAZIER2007	Design: cohort.
GALLAS2010	Conference abstract.
GARETY2008	Adult population
GARRETT2011	Secondary analysis.
GASTAL2010	Not in English.
GLEESON2008	Design: protocol only.
GLEESON2010	Outcomes not included in the review protocol.
GLICK1985	Adult population.
GLICK2011	Adult population.
GLICKSOHN2000	Adult population.
GOLDSTEIN1978	Intervention not included in the review protocol.
GOULET1993A	Not in English.
GRANHOLM2009	Adult population.
GRAWE2006	Adult population.
GUANG2005	Not in English.
GUMLEY2006	Adult population.
GUO2007	Design: protocol only.
GUO2010	Adult population.
GUPTA2011	Conference abstract.
GUTTGEMANNS2011	Not in English.
HAMANN2006	Adult population.
HAN2004	Not in English.
HENGGLER1999	8% of the sample had a diagnosis of thought disorder/
	schizophrenia.
HERVIEUX2009	Not in English.
HJORTHO2008	Design: protocol only.
HODGE2010	Adult population.
HOGARTY1979	Adult population.
HOGARTY1997A	Adult population.
HOGARTY1997B	Adult population.
HOLLOWAY1996	Conference abstract.
HOULT1984B	Intervention not included in the review protocol.
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JACKSON2001	Design: cohort.
JACKSON2005A	Design: Non-RCT.
JAUGEY2012	Conference abstract.
JENNER2001	Design: Non-RCT.
JENNER2004	Adult population.
JOHNSON2008	Adult population.
JOLLEY2003	Adult population.
JONES2001	Adult population.
KARON1969	Adult population.
KEMP2007	Intervention not included in the review protocol.
KILLACKEY2008	Not relevant to this section. Included in Chapter 8, 'Cognition,
Tubblicite 12000	employment and education'.
KLINGBERGSWITTO2010	Design: protocol only.
KOIKE2011	Design: protocol only.
LANDA2012	Conference abstract.
LARGE2011	Outcomes not of interest.
LARSEN2007	Design: non-experimental.
LEAVEY2004	Outcomes not included in the review protocol.
LECARDEUR2009	Adult population.
LECOMTE1999	Adult population.  Adult population.
LEFF1984	Adult population.  Adult population.
LEFF1989	Adult population.  Adult population.
LEFF2002	Adult population.  Adult population.
LEHTINEN2000	Adult population. Adult population.
LENIOR2002	Design: non-RCT.
LENIOR2005	Adult population.
LENZENWEGER2002	Non-clinical population.
LI2005A	Adult population.
LIBERMAN2005	Non-clinical population.
LINSZEN1993	1 1
	Not in English.
LIU2010A LOBBAN2011	Design: non-RCT.  Focuses on carers.
MALM1982	
	Adult population.
MARTIN2005 MCCAY2007	Adult population.
	Adult population.
MCCAY2006	Adult population.
MCFARLANE1996	Adult population.
MCGLIBK2007	Adult population.
MCGURK2007	Adult population.
MELAU2011	Adult population.
MIKLOWITZ2004	Design: non-RCT.
MILLER2004	Adult population.
MORGAN2011	Adult population.
MORRISON2002	Design: cohort.
MORRISON2004	Not relevant to this section. Included in Chapter 5, 'At risk
	mental states for psychosis and schizophrenia in children and
MODDICON 2007	young people'.
MORRISON2007	Not relevant to this section. Included in the Chapter 5, 'At risk
	mental states for psychosis and schizophrenia in children and
MODDICONIO014	young people'.
MORRISON2011	Not relevant to this section. Included in Chapter 5, 'At risk
	mental states for psychosis and schizophrenia in children and
MODDICONI2012	young people'.
MORRISON2012	Not relevant to this section. Included in Chapter 5, 'At risk

	mental states for psychosis and schizophrenia in children and
	young people'.
NAEEM2005	Adult population.
NAEEM2006	Design: non-RCT.
NAEEM2008	Adult population.
NAOKI2003	Not in English.
NORMAN2002	Adult population.
NUGTER1997	Outcomes not included in the review protocol.
OBRIEN2007	Design: non-RCT.
ODONNELL2003	Adult population.
PARK2011	Adult population.
PATRASKAR2011	Adult population.
PAWELCZYK2009	Adult population.
PENN2005	Systematic review: no new useable data.
PENN2009	Adult population.
PETERS2010	Adult population.
PILLING2002A	Systematic review – adult population.
PILLING2002B	Systematic review – adult population.
PITSCHEL-WALZ2001	Adult population.
POPOV2011	Adult population.
POSNER1992	Adult population.
PUIG2009	Conference abstract.
RAJJI2009	Systematic review of non-RCTs.
RAZALI2000	Adult population.
RICHARD-DEVANTOY2011A	Conference abstract.
RICHARD-DEVANTOY2011B	Systematic review of non-RCTs.
RIETDIJK2010	Design: protocol only.
ROLLINSON2008	Design: non-RCT.
ROSENBAUM2005	Design: non-RCT.
ROSS2011A	Adult population.
ROTONDI2005	Adult population.
RUHRMANN2009	Design: cohort.
RUND1994	Design: Non-RCT.
SAHA2007	Systematic review of non-RCTs.
SCHMIDT2011	Systematic review of non-RCTs.
SEMPLE2005	Systematic review of non-RCTs.
SENSKY2000	Adult population.
SHIMODERA2000	Adult population.
STAIN2010	Conference abstract.
STAIN2011	Conference abstract.
SUNGUR2003	Not in English.
SVENSSON1999	Design: non-RCT.
TANG1994	Adult population.
TARBOX2008	Systematic review of non-RCTs.
TARRIER1988	Adult population.
TARRIER1999	Adult population.
TAS2012	Adult population.
TIFFIN2007	Design: non-RCT.
TROWER2004	Adult population.
TURKINGTON2000	Adult population.
TURKINGTON2002	Adult population.
UELAND2004	Not relevant to this section. Included in Chapter 8, 'Cognition, employment and education'.
UELAND2005	Not relevant to this section. Included in Chapter 8, 'Cognition,
OLLAINDZUUJ	Thou resevant to this section, included in Chapter o, Cognition,

	employment and education'.
UZENOFF2008	Adult population.
VALENCIA2007	Adult population.
VALMAGGIA2005	Adult population.
VANDERGAAG2011	Conference abstract.
VELLIGAN2008	Adult population.
VELTRO2011	Adult population.
VESTERAGER2011	Adult population.
WARING1986	Design: review.
WRIGHT2012	Design: protocol only.
WYKES2003	Adult population.
WYKES2007A	Adult population.
WYKES2007B	Not relevant to this section. Included in Chapter 8, 'Cognition,
	employment and education'.
WYKES2009	Adult population.
WYKES2011	Adult population.
XIONG1994	Adult population.
ZASTOWNY1992	Adult population.
ZHANG1994	Conference abstract.
ZHANG2005	Not in English.

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