APPENDIX 13C: CLINICAL EVIDENCE STUDY CHARACTERISTICS TABLES:

PHARMACOLOGICAL INTERVENTIONS

Abbreviations

ADHD	attention deficit hyperactivity disorder
AIMS	Abnormal Involuntary Movement Scale
BARS	Barnes Akathisia Rating Scale
b.i.d.	twice a day
BMI	body mass index
BPM	beats per minute
BPRS (-C)	Brief Psychiatric Rating Scale (for Children)
CCMD-II-R	Chinese Classification of Mental Disorders (2nd edition revised)
CDSS	Calgary Depression Scale for Schizophrenia
CGAS	Children's Global Assessment Scale
CGI (-S)	Clinical Global Impression (- Severity) scale
DSM (-III, -IV, -R -TR	*Diagnostic and Statistical Manual of Mental Disorders* (3rd edition, 4th edition, revised, text revision)
ECT	electroconvulsive therapy
HAM-D	Hamilton Depression Rating Scale
h.s.	at bedtime
ITT	intention to treat
K-SADS-PL	Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version
LOCF	last observation carried forward
MADRS	Montgomery-Åsberg Depression Rating Scale
N/A	not applicable
NIMH	National Institute of Mental Health
NOS	not otherwise specified
OCD	obsessive-compulsive disorder
QT, QTc	the interval between Q and T waves in the electrocardiogram
PANSS	Positive and Negative Syndrome Scale
PTSD	post-traumatic stress disorder
RCT	randomised controlled trial
SADS-C	Schedule for Affective Disorders and Schizophrenia – Change Version
SANS	Scale for the Assessment of Negative Symptoms
SAS	Simpson-Angus Extrapyramidal Side Effects Scale
SCID	Structured Clinical Interview for DSM-IV Axis I Disorders
SD	standard deviation
TEOSS	Treatment of Early Onset Schizophrenia Spectrum Disorders Study
TESS	Treatment Emergent Symptoms Scale
TSH	thyroid-stimulating hormone
UKU	Udvalg for Kliniske Undersøgelser
YMRS	Young Mania Rating Scale

APPENDIX 13C (I): INCLUDED STUDIES FOR INITIAL TREATMENT WITH ANTIPSYCHOTIC MEDICATION

Study ID	**ARANGO2009**
Bibliographic reference	Arango, C., Robles, O., Parellada, M., *et al.* (2009) Olanzapine compared to quetiapine in adolescents with a first psychotic episode. *European Child and Adolescent Psychiatry*, *18*, 418-428.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Last observation carried forward (LOCF). Blindness: None (open-label trial). Duration: Number of weeks of treatment 26 weeks; length of follow-up 26 weeks. Raters: Clinical evaluations were performed by one of the four adolescent psychiatrists participating in the research study. Design: Single-centre (Adolescent Unit of Hospital General Universitario Gregorio Marañón, Madrid Spain), open-label, randomised controlled trial (RCT). Number of people screened, excluded and reasons: 53 screened; three excluded (refused to participate in the study). Notes about study methods: • inaccuracies exist in reporting of dropout rates and number of participants assessed • during the run-in/wash-out period all participants were prescribed risperidone 2 to 6 mg (flexible dose at the discretion of the clinician) between 3 and 5 days prior to randomisation.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version (K-SADS-PL); *Diagnostic and Statistical Manual of Mental Disorders* – 4th edition (DSM-IV) Inclusion criteria: • first episode of psychosis before 18 years, lasting less than 1 year after onset of first symptom • aged 12 to 18 years old. Exclusion criteria: • psychotic symptoms appeared to result from acute intoxication or withdrawal • meeting DSM-IV criteria for any substance abuse, learning disabilities, or pervasive developmental disorder • had any organic central nervous system disorder • history of traumatic brain injury with loss of consciousness • pregnant or breast feeding • taking olanzapine or quetiapine before enrolment. Total sample size: Number randomised = 50.

	Gender: 77.5% male. Age: Mean 15.9 years (range not reported). Ethnicity: 78.1% white. Setting: General hospital. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 50% participants were antipsychotic naïve prior to inclusion.
Interventions	Intervention: Group 1: quetiapine, mean dose 438.8 mg/day (variable dose), over 26 weeks, N = 24; Group 2: olanzapine, mean dose 12.11 mg/day (variable dose), over 26 weeks, N = 26. Notes about the interventions: Doses were administered at the discretion of the clinician. Mean treatment time for quetiapine and olanzapine was 143.75 (68) and 144.1 (62.5) days, respectively.
Extractable outcomes	Symptoms: Positive and Negative Syndrome Scale (PANSS; Total, General, Positive, Negative). Depression: Hamilton Depression Rating Scale (HAM-D). Mania: Young Mania Rating Scale (YMRS). Global state: Clinical Global Impression (CGI). Psychosocial functioning: Global Assessment of Functioning. Leaving the study early: Leaving due to any reason. Side effects: Tremor, akathisia, tachycardia (BPM), weight (kg), fasting total cholesterol (mg per dl), fasting high-density lipoprotein cholesterol level (mg per dl).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: High. Providers blinded: High. Outcome assessors blinded: High. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	Robles, O., Zabala, A., Bombin, I., *et al.* (2011) Cognitive efficacy of quetiapine and olanzapine in early-onset first episode psychosis. *Schizophrenia Bulletin*, 37, 405-415.

Study ID	BERGER2008
Bibliographic reference	Berger, G. E., Proffitt, T. M., McConchie, M., *et al.* (2008) Dosing quetiapine in drug-naive first-episode psychosis: a controlled, double-blind, randomized, single-center study investigating efficacy, tolerability, and safety of 200 mg/day vs. 400 mg/day of quetiapine fumarate in 141 patients aged 15 to 25 years. *Journal of Clinical Psychiatry*, *69*, 1702-1714.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case. Blindness: Participants, providers and raters blind during Part 1. In Part 2 only raters blind. Duration: Number of weeks of treatment – Part 1: 4 weeks fixed dose; Part 2: 8 weeks flexible dose; Length of follow-up – 12 weeks. Raters: Independent of treatment. Design: Single-centre ('ORYGEN' Research Centre, Melbourne, Australia) RCT. Number of people screened, excluded and reasons: 443 screened, 302 excluded (ineligible: n = 97; refused to participate: n = 55; other reasons: n = 150) Notes about study methods: Part 1: randomised, double-blind study administering either 200 mg per day or 400 mg per day of quetiapine of 4 weeks' duration. Part 2: single-blind, naturalistic flexible dose study (participants remain in randomised groups) of 8 weeks' duration.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: Structured Clinical Interview for DSM-IV Axis I Disorders (SCID). Inclusion criteria: • 15 to 25 years old • first episode psychosis (one or more of the following symptoms, each present for at least 1 week on a daily basis according to the manual of the extended Brief Psychiatric Rating Scale (BPRS), version 4: somatic concerns (>6), guilt (>6), suspiciousness (>5), hallucinations (>5), unusual thought content (>4), and/or conceptual disorganisation (>4) and meeting one of the following DSM-IV diagnoses: schizophreniform psychosis, schizophrenia, schizoaffective disorder, delusional disorder, major depression with psychotic features, or psychosis not otherwise specified (NOS). Exclusion criteria: • previous treatment with antipsychotic medication • presence of concurrent manic syndrome or learning disability (IQ<70) • organic disorders presenting with a psychotic syndrome • epilepsy • a clinically significant physical illness • history of brain surgery or infarct • concomitant medications that prolong QT interval

	• 20% deviation from normal range laboratory values at baseline • participation in other studies involving investigational or marketed products concomitantly or within 30 days prior to entry into the study • having donated blood or blood products within 4 weeks prior to start of study drug • pregnant or lactating women, or women of child bearing potential not using an acceptable method of contraception. Total sample size: Number randomised = 141. Gender: 67.5% male. Age: Mean 19.3 (range 15 to 24) years. Ethnicity: Not reported Setting: Inpatients and outpatients in a specialist clinic. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 100% participants were antipsychotic naïve prior to inclusion.
Interventions	Intervention: Group 1: quetiapine 200 mg/day over 4 weeks, flexible dose over following 8 weeks, N = 69; Group 2: quetiapine 400 mg/day over 4 weeks, flexible dose over following 8 weeks, N = 72. Notes about the interventions: In both groups (quetiapine 200 mg: 100-mg tablet b.i.d; quetiapine 400 mg: 100 mg tablet in the morning/300 mg tablet at night, each tablet equally sized), the protocol allowed for patients to be started on 200 mg, however most psychiatrists titrated the dose up to 200 mg, typically from a starting dose of 25 to 50 mg. The titration period was never longer than 7 days.
Extractable outcomes	Symptoms: BPRS; response (defined as a 20% reduction in BPRS and a CGI Global Improvement rating of at least minimal improvement); remission (defined as a score of <3 on the BPRS; a CGI-S rating of mild or less and a CGI Global Improvement rating of at least minimal improvement). Depression: Calgary Depression Scale for Schizophrenia (CDSS). Mania: YMRS. Global state: CGI. Psychosocial functioning: GAF. Social functioning: Social and Occupational Functioning Assessment Scale. Side effects: Udvalg for Kliniske Undersøgelser (UKU) Neurologic Subscale Total Score, weight (kg).
Quality	Sequence generation: Low. Allocation concealment: Low. Participants blinded: Part 1: Low; Part 2: High. Providers blinded: Part 1: Low; Part 2: High. Outcome assessors blinded: Low. Missing outcome data: High. Selective outcome reporting: High.

	Other bias: Low.
Related publications	None.

Study ID	**LIEBERMAN2003**
Bibliographic reference	Lieberman, J. A., Tollefson, G., Tohen, M., *et al.* (2003) Comparative efficacy and safety of atypical and conventional antipsychotic drugs in first-episode psychosis: a randomized, double-blind trial of olanzapine versus haloperidol. *The American Journal of Psychiatry*, *160*, 1396-1404.
General information	Funding source: Lilly Research Laboratories. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case (study reports LOCF). Blindness: Unclear. Study reports 'double-blind' conditions, but it is not clear if this refers to the participants, providers or raters. Duration: Number of weeks of treatment 104 weeks; length of follow-up 92 weeks. Raters: Unclear. Design: Multicentre (14 academic medical centres in North America and Western Europe) RCT. Number of people screened, excluded and reasons: Not reported. Notes about study methods: The study was divided into a 12-week acute phase and a 92-week continuation phase (the difference between the two phases was the difference in dose ranges of study medications administered).
Participants	Diagnosis: First episode psychosis. Diagnostic tool: SCID. Inclusion criteria: • 16 to 40 years • onset of psychotic symptoms before age 35 years • met DSM-IV diagnostic criteria for schizophrenia, schizophreniform disorder, or schizoaffective disorder as assessed by the SCID Research Version • experienced psychotic symptoms for at least 1 month but not more than 60 months • scored ≥4 on at least two PANSS psychosis items (P1, P2, P3, P5 or P6) or scored ≥5 on one psychosis item • had a CGI-S score ≥4 (moderately ill) • required treatment with antipsychotic drugs on a clinical basis • has a level of understanding sufficient to communicate with the research staff and to cooperate with all tests and examinations • understood the nature of the study and signed an informed consent document (required of each patient or the patient's authorised legal representative) • female patients of childbearing potential had to have been using a medically accepted means of contraception. Exclusion criteria:

	• previously received antipsychotic drug treatment for more than 16 cumulative weeks • had been treated with clozapine at anytime in their lifetime, or had been treated with an injectable depot neuroleptic within less than three dosing intervals before study entry • pregnant or breastfeeding • serious, unstable medical illnesses or findings from a medical examination that suggested a contraindication to antipsychotic drug treatment • a history of allergic or severe adverse reactions to study medications • met the DSM-IV criteria for substance dependence within 1 month before the first visit • judged clinically to be at suicidal risk too serious to be included in this study • required treatment with anticonvulsants, benzodiazepines (except as allowed for agitation and control of extrapyramidal symptoms), antidepressants, psychostimulants or other antipsychotic drugs concurrently with study medications beyond those permitted as concomitant treatments • had contraindications for neuro-imaging per current regulations of the local regulatory agency • had a past history of any DSM-IV psychotic disorder with recovery (recovery, although based on the clinical impression of the patient's history, was defined as the cessation of positive and negative symptoms and return of functioning for 6 months or longer) • premorbid IQ of ≤70 • had received electroconvulsive therapy (ECT) within 1 month (30 days) before study entry. Total sample size: Number randomised = 263. Gender: 81.8% male. Age: Mean 23.8 years (range not reported). Ethnicity: 52.9% white. Setting: Inpatients and outpatients in a specialist clinic. Mean duration of disorder: 62.5 weeks. Mean age of onset: Not reported. Prior antipsychotic use: 26% participants were antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: olanzapine, mean (range) dose: 10.2 (5 to 20) mg per day, over 104 weeks, N = 131; Group 2: haloperidol, mean (range) dose: 4.82 (2 to 20) mg per day, over 104 weeks, N = 132. Notes about the interventions: • during the 12 weeks' acute phase the initial dose titration ranges for the first 6 weeks were 5 to 10 mg/day for olanzapine and 2 to 5 mg/day for haloperidol • in the second 6 weeks of the acute phase and for the entire continuation phase, the allowed doses were 5 to 20 mg/day of olanzapine and 2 to 20 mg/day of haloperidol.
Extractable outcomes	Symptoms: PANSS (Total, General, Positive, Negative). Depression: Montgomery-Åsberg Depression Rating Scale (MADRS).

	Global state: CGI. Leaving the study early: Leaving due to any reason. Side effects: Weight (kg), prolactin level (mg/dl).
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	Green, A. I., Lieberman, J. A., Hamer, R. M., *et al.* (2006) Olanzapine and haloperidol in first episode psychosis: two-year data. *Schizophrenia Research*, *86*, 234-243.

Study ID	**MCEVOY2007**
Bibliographic reference	McEvoy, J. P., Lieberman, J. A., Perkins, D. O., *et al.* (2007) Efficacy and tolerability of olanzapine, quetiapine, and risperidone in the treatment of early psychosis: a randomized, double-blind 52-week comparison. *The American Journal of Psychiatry*, *164*, 1050-1060.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Efficacy analyses used a modified intention-to-treat (ITT) population (defined as patients who were randomly assigned to a treatment and returned for at least one post-randomisation assessment). Continuous side effect outcomes were analysed using a mixed model similar to the efficacy outcomes. Dichotomous side effect outcomes were analysed using logistic regression. Blindness: Unclear. Study reports 'double-blind' conditions, but it is not clear if this refers to the participants, providers or raters. Duration: Number of weeks of treatment – 52 weeks; length of follow-up – 52 weeks. Raters: Unclear. Design: Multicentre (US and Canada) RCT. Number of people screened, excluded and reasons: 400 screened, exclusions not reported. Notes about study methods: • it is not clear if baseline outcome measures were administered before or after randomisation • 8% of participants in the quetiapine and the risperidone group discontinued due to administrative reasons. • following case-by-case discussions with site investigators nine participants who had been ill for more than 60 months, seven patients who were over 40 years of age and 16 patients who had taken antipsychotics for more than 16 weeks were

	also enrolled into the study.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: SCID. Inclusion criteria: • 16 to 40 years of age • met DSM-IV criteria for schizophrenia, schizophreniform disorder or schizoaffective disorder • first episode of their psychotic illness and had to have been continuously ill for at least 1 month and no more than 5 years • a score of ≥4 on at least one PANSS psychosis item (delusions, conceptual disorganisation, hallucinatory behaviour, grandiosity, or suspiciousness/persecution) • a score of ≥4 (moderately ill) on the severity item of the CGI at the point of maximum severity of illness to date • female participants of childbearing potential had to be using a medically acceptable form of contraception. Exclusion criteria: • a prior psychotic episode had remitted for 3 months or more • prior antipsychotic drug treatment for more than 16 cumulative weeks • not English speaking • history of a learning disability • pregnant or nursing • had a serious, unstable medical illness • had a known allergy to one of the study medications • were at serious risk of suicide • had participated in an investigational drug trial within 30 days before the first treatment visit. Total sample size: Number randomised = 400. Gender: 73% male. Age: Mean 24.5 (range 16 to 40) years. Ethnicity: 51.3% white. Setting: Inpatient and outpatient clinic. Mean duration of disorder: Not reported. Mean age of onset: 23.5 years. Prior antipsychotic use: 96% participants were antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: quetiapine, mean (range) dose: 506 (100 to 800) mg/day, over 52 weeks, N = 134; Group 2: olanzapine, mean (range) dose: 11.7 (2.5 to 20) mg/day, over 52 weeks, N = 133; group 3: risperidone, mean (range) dose: 2.4 (0.5 to -4) mg/day, over 52 weeks, N = 133. Notes about the interventions: • On days 1 and 2, each patient received one capsule of olanzapine (2.5 mg), quetiapine (100 mg) or risperidone (0.5 mg) in the evening. At the treating physician's discretion, the dose could be increased by one capsule every other day.

	• Anticholinergic medications for acute extrapyramidal side effects were permitted for up to a total of 2 weeks over the course of the trial. Clinicians were encouraged to lower the dose of antipsychotic to relieve extrapyramidal side effects. Adjunctive medications and concomitant medications could be used without restriction.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative). Depression: CDSS. Global state: CGI. Quality of Life: QLS – Social and Vocational subscales. Leaving the study early: Leaving due to any reason. Side effects: Weight (kg), BMI (kg/m²), fasting triglycerides (mg/dl), fasting serum glucose level (mg/dl), fasting total cholesterol (mg/dl), high-density lipoprotein cholesterol level (mg/dl), systolic and diastolic blood pressure (mm Hg), prolactin level (mg/dl).
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	Keefe, R. S. E., Sweeney, J. A., Gu, H., *et al.* (2007) Effects of olanzapine, quetiapine and risperidone on neurocognitive function in early psychosis: a randomized, double-blind 52 week comparison. *American Journal of Psychiatry*, *164*, 1061-1071. Patel, J. K., Buckley, P. F., Woolsonet, S., *et al.* (2009) Metabolic profiles of second-generation antipsychotics in early psychosis: findings from the CAFE study. *Schizophrenia Research*, *111*, 9–16. Perkins, D. O., Gu, H., Weiden, P. J., *et al.* (2008) Predictors of treatment discontinuation and medication nonadherence in patients recovering from a first episode of schizophrenia, schizophreniform disorder, or schizoaffective disorder: a randomized, double-blind, flexible-dose, multicenter study. *Journal of Clinical Psychiatry, 69*, 106-113.

Study ID	**ROBINSON2006**
Bibliographic reference	Robinson, D. G., Woerner, M. G., Napolitano, B., *et al.* (2006) Randomized comparison of olanzapine versus risperidone for the treatment of first-episode schizophrenia: 4-month outcomes. *The American Journal of Psychiatry*, *163*, 2096-2102.
General information	Funding source: Non-industry. Published or unpublished data: Published and unpublished.
Method	Type of study: Individual randomised trial. Type of analysis: Available case. Blindness: Only raters were blinded.

	Duration: Number of weeks of acute treatment – 16 weeks, continuation treatment – 156 weeks; length of follow-up – 156 weeks (extractable outcome data during treatment – 16 weeks). Raters: Independent of treatment. Design: Single-centre (The Zucker Hillside Hospital, New York, US) open-label, RCT. Number of people screened, excluded and reasons: 474 screened, 354 excluded (ineligible: n = 282; refused to participate: n = 64; other reasons: n = 8) Notes about study methods: Unclear reporting of number of participants analysed when dropouts taken into consideration. Patients were stratified by sex, current DSM-IV-defined substance abuse or dependence (excluding nicotine and caffeine) and site so it is likely that baseline measures were obtained prior to randomisation.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • current diagnosis of DSM-IV schizophrenia, schizophreniform disorder or schizoaffective disorder • 16 to 40 years • less than 12 weeks of lifetime antipsychotic medication treatment • current positive symptoms evidenced by a rating of 4 or more on the severity of delusions, hallucinations, or thought disorder items of the Schedule for Affective Disorders and Schizophrenia – Change Version (SADS-C) with psychosis and disorganisation items or current negative symptoms demonstrated by a rating of 4 or more on the affective flattening, alogia, avolition, or anhedonia global items of the Hillside Clinical Trials version of the Scale for the Assessment of Negative Symptoms (SANS) • for females, a negative pregnancy test and agreement to use a medically accepted method of birth control • competent and willing to sign informed consent. Exclusion criteria: • meeting DSM-IV criteria for a current substance-induced psychotic disorder, psychotic disorder due to a general medical condition or learning disability • medical condition/treatment known to affect the brain • any medical condition requiring treatment with a medication with psychotropic effects • medical contraindications to treatment with olanzapine or risperidone • significant risk of suicidal or homicidal behaviour. Total sample size: Number randomised = 120. Gender: 70% male. Age: 23.3 years. Ethnicity: 20% white. Setting: General hospital. Mean duration of disorder: 16.5 months.

	Mean age of onset: 20.7 years. Prior antipsychotic use: 78% participants were antipsychotic naïve at study entry.
Interventions	Intervention: Group 1: olanzapine, mean (range) dose: 11.8 (2.5 to 20) mg/day, over 156 weeks, N = 60; Group 2: risperidone, mean (range) dose: 3.9 (1 to 6) mg/day, over 156 weeks, N = 60. Notes about the interventions: • Variable doses: the initial daily dose was 2.5 mg for olanzapine and 1 mg for risperidone. An increasing titration schedule was used: after week 1, dose increases occurred at intervals of 1 to 3 weeks until the subject improved or reached a maximum daily dose of 20 mg of olanzapine or 6 mg of risperidone • Mean length of study participation for participants treated with olanzapine and risperidone was 11.5 and 12.1 weeks.
Extractable outcomes	Symptoms: A rating of mild or better on the SADS-C with psychosis, disorganisation items and positive symptom items plus a CGI rating of much improved or very much improved, maintained for two consecutive visits. Leaving the study early: Leaving due to any reason. Side effects: Parkinsonism, BMI (kg/m^2).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: High. Providers blinded: High. Outcome assessors blinded: Low. Missing outcome data: Low. Selective outcome reporting: High. Other bias: Low.
Related publications	Sevy, S., Robinson, D. G., Sunday, S., *et al.* (2011) Olanzapine vs risperidone in patients with first-episode schizophrenia and a life history of cannabis use disorders: 16-week clinical and substance use outcomes. *Psychiatry Research*, *188*, 310-314.

Study ID	**SCHOOLER2005**
Bibliographic reference	Schooler, N., Rabinowitz, J., Davidson, M., *et al.* (2005) Risperidone and haloperidol in first-episode psychosis: a long-term randomized trial. *The American Journal of Psychiatry*, *162*, 947-953.
General information	Funding source: Johnson and Johnson. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case. Blindness: Unclear. Duration: Number of weeks of treatment – 206 weeks; length of follow-up – not reported. Raters: Unclear Design: Multiple-centre RCT.

	Number of people screened, excluded and reasons: Not reported. Notes about study methods: Three patients assigned to risperidone and one patient assigned to haloperidol did not receive study medication and were therefore excluded from the analysis.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • 16 to 45 years old • met SCID criteria for schizophrenia, schizophreniform disorder or schizoaffective disorder for no more than 1 year during which period they had no more than two psychiatric hospitalisations for psychosis • less than 12 weeks of cumulative exposure to antipsychotics and required antipsychotic treatment upon enrolment into the trial. Exclusion criteria: • met DSM-IV criteria for another axis I diagnosis, including substance dependence or abuse • needed another non-antipsychotic psychotropic medication at enrolment • serious or unstable medical illness. Total sample size: Number randomised = 559. Gender: 71.3% male. Age: Mean 25.5 years (range not reported). Ethnicity: 74.4% white. Setting: Not reported. Mean duration of disorder: Not reported. Mean age of onset: 24.4 years. Prior antipsychotic use: 46.7% participants were antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: risperidone, mean (range) dose: 3.3 (not reported) mg/day, over 206 weeks, N = 281; Group 2: haloperidol mean (range) dose: 2.9 (not reported) mg/day, over 206 weeks, N = 278. Treatment of side effects: Concomitant psychotropic medications addressing extrapyramidal signs and symptoms; chloral hydrate, zolpidem, or flurazepam for sleep; and lorazepam for agitation. Notes about the interventions: • Variable doses: participants in both treatment groups started with a once daily dose of 1 mg that could be increased to 2 mg/day on day 4 and thereafter by 1 mg/day each week, up to a maximum daily dose of 4 mg. • In exceptional cases (insufficient response with not more than mild extrapyramidal signs and symptoms observed at 4 mg/day), dose could be increased further by 1 mg a week up to a maximum daily dose of 8 mg.
Extractable outcomes	Symptoms: PANSS (Total, General, Positive, Negative) Global state: CGI Leaving the study early: Leaving due to any reason.

	Side effects: Extrapyramidal Symptoms Rating Scale, weight (kg), prolactin level (mg/dl).
Quality	Sequence generation: Unclear Allocation concealment: Unclear Participants blinded: Unclear Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	Emsley, R., Rabinowitz, J., Medori, R., *et al.* (2007) Remission in early psychosis: rates, predictors, and clinical and functional outcome correlates. *Schizophrenia Research*, *89*, 129-139.

Study ID	**SIKICH2008**
Bibliographic reference	Sikich, L., Frazier, J. A., McClellan, J., *et al.* (2008) Double-blind comparison of first- and second-generation antipsychotics in early-onset schizophrenia and schizo-affective disorder: findings from the treatment of early-onset schizophrenia spectrum disorders (TEOSS) study. *The American Journal of Psychiatry*, 165, 1420-1431.
General information	Funding source: Non-industry sponsors. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Participants, providers and raters blind. Duration: Number of weeks of treatment – 8 weeks' acute phase plus 44-week double-blind maintenance phase for responders; length of follow-up – 52 weeks. Raters: Clinicians blind to treatment. Design: Multi-centre (University of North Carolina, Chapel Hill, US; McLean Hospital, Belmont, US; University of Washington, US; and Case Western Reserve University, Cleveland, US) RCT. Number of people screened, excluded and reasons: 478 screened, 285 not enrolled in study (reasons not provided). Of 193 enrolled, 74 were excluded (did not meet diagnostic criteria: n = 46; prior treatment with study medication: n = 17; clinical or safety reasons: n = 6; withdrew consent: n = 5). Notes about study methods: Random assignment to olanzapine was discontinued towards the end of the recruitment phase by National Institute of Mental Health's (NIMH) data and safety monitoring board following their review of the interim data, which showed a greater increase in weight with olanzapine than molindone or risperidone, without evidence of greater efficacy. Participants being treated with olanzapine continued their participation and the integrity of the study blind was maintained.
Participants	Diagnosis: First episode psychosis (93%). Diagnostic tool: SCID.

	Inclusion criteria: • 8 to 19 years old (no more than 30% of subjects 16 to 19 years) • score of at least moderate severity on one of the positive psychotic symptom ratings of the PANSS or BPRS-C • met DSM-IV criteria for schizophrenia, schizophreniform or schizoaffective disorder • no depot antipsychotic medication for at least 6 months • good physical health • able to provide informed consent/assent for the study and have a guardian who gives informed written consent. Exclusion criteria: • history of an adequate trial of risperidone, olanzapine or molindone (defined as at least 8 weeks of treatment with the dose during the final 2 weeks of treatment (risperidone 6 mg/day, olanzapine 20 mg/day or molindone 140 mg/day) during current psychotic episode • history of non-response to an adequate trial of the study drug during a prior episode • history of intolerance to risperidone, olanzapine or molindone • bipolar disorder, primary post-traumatic stress disorder (PTSD), primary personality disorder, or psychosis NOS diagnosed by clinician and confirmed by the Structured Clinical Interview for DSM Childhood Diagnoses (KID-SCID) • current major depressive episode • active substance misuse or dependence • premorbid diagnosis of a learning disability • endocrinological or neurological conditions that confound the diagnosis or are a contraindication to treatment • pregnancy or refusal to practice contraception during the study. Total sample size: Number randomised = 119. Gender: 65% male. Age: Mean 13.8 (range 8 to 19) years. Ethnicity: 64% white. Setting: 90% outpatients, 10% inpatients. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 33% antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: risperidone, mean (range) 2.8 (0.5 to 6) mg/day, over 8 weeks, N = 41; Group 2: olanzapine, mean (range) 11.4 (2.5 to 20) mg/day, over 8 weeks, N = 35. Treatment of side effects: Not reported. Notes about the interventions: • Molindone was the third arm of this trial (n = 40), however as it was discontinued by its sole supplier, Endo Pharmaceuticals, on 13 January 2010 only data for risperidone and olanzapine are used in this guideline. • Dose schedules were variable. Medications were initiated at the lowest dose within the range and typically increased to

	the middle of the dose range within 10 days for those participants aged 12 years and older and within 14 days for those aged 8 to 11 years according to age-specific schedules. • When TEOSS began, no antidepressants or mood stabilisers were permitted during the acute treatment phase, however, the protocol changed twice in 2003 in response to safety and enrolment concerns. All of the subjects randomised to molindone received prophylactic benztropine to reduce the risk of extrapyramidal side effects and to protect the blind. Participants randomised to either olanzapine or risperidone received placebo. Study clinicians were allowed to add thymoleptic agents during the maintenance phase.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative), BPRS-C. Global state: CGI, Child and Adolescent Functional Assessment Scale. Leaving the study early: Leaving the study early for any reason. Side effects: Extrapyramidal side effects (Abnormal Involuntary Movement Scale [AIMS], Barnes Akathisia Rating Scale [BARS], Simpson-Angus Extrapyramidal Side Effects Scale [SAS]), weight (kg), BMI (kg/m^2), fasting total cholesterol (mg/dl), fasting triglycerides (mg/dl), fasting high- and low-density lipoprotein cholesterols (mg/dl), prolactin level (µg/l), fasting insulin (mU/L), QT interval (msec), sitting pulse (beats/msec), systolic and diastolic blood pressure (mm Hg).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Low. Providers blinded: Low. Outcome assessors blinded: Low. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	Findling, R. L., Johnson, J. L., McClellan, J., *et al.* (2010) Double-blind maintenance safety and effectiveness findings from the Treatment of Early-Onset Schizophrenia Spectrum (TEOSS) study. *Journal of the American Academy of Child and Adolescent Psychiatry*, *49*, 583-594. Frazier, J. A., McClellan, J., Findling, R. L., *et al.* (2007) Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS): demographic and clinical characteristics. *Journal of the American Academy of Child and Adolescent Psychiatry, 46*, 979-88. McClellan, J., Sikich, L., Findling, R. L., *et al.* (2007) Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS): rationale, design and methods. *Journal of the American Academy of Child and Adolescent Psychiatry*, *46*, 969-978.

Study ID	SWADI2010
Bibliographic reference	Swadi, H. S., Craig, B. J., Pirwani, N. Z., *et al.* (2010) A trial of quetiapine compared with risperidone in the treatment of first onset psychosis among 15- to 18-year-old adolescents. *International Clinical Psychopharmacology*, 25, 1-6.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Only raters were blinded. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Independent of treatment. Design: Single-centre (Princess Margaret Hospital, Christchurch, New Zealand) open-label, RCT. Number of people screened, excluded and reasons: 176 screened, 154 excluded (non-psychotic disorder: n = 149; substance-induced psychosis: n = 3; informed consent refusal: n = 2) Notes about study methods: In the ITT, last measures were taken either at discontinuation or at completion and taken as the final data for comparison. Patients who discontinued because of the need to increase dosage beyond the level stipulated in the protocol after 3 weeks was included in the analysis. Four patients treated with quetiapine had to exceed the maximum 800 mg dose after the third week and had to exit the study. Their data at the point of the exit were included in the analysis.
Participants	Diagnosis: First episode psychosis. Diagnostic tool: DSM-IV (format not reported). Inclusion criteria: • 15-19 years • first onset psychotic disorder or a mood disorder with psychotic features according to DSM-IV criteria. Exclusion criteria: • alcohol or substance dependence not in full remission • earlier treatment with atypical antipsychotic drugs. Total sample size: Number randomised = 22. Gender: Not reported. Age: 16.74 (16 to 19) years Ethnicity: Not reported. Setting: Inpatient clinic. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: Not reported (however, participants who had earlier treatment with atypical antipsychotic drugs were excluded).
Interventions	Intervention – Group 1: quetiapine, mean (range) dose: 607 (100 to 800) mg/day, over 5 weeks, N = 11; Group 2: risperidone mean

	(range) dose: 2.9 (1.5 to 5) mg/day, over 6 weeks, N = 11. Treatment of side effects: Not reported. Notes about the interventions: • Doses were variable. • Four patients treated with quetiapine had to exceed the maximum 800 mg dose after the third week and had to exit the study. • Cognitive behavioural therapy, family work and activity-based interventions (part of the clinic's usual treatment programme) were allowed.
Extractable outcomes	Symptoms: PANSS (Total), BPRS. Depression: HAM-D. Mania: YMRS. Global state: CGI. Leaving the study early: Leaving due to any reason. Side effects: AIMS, BARS, SAS, weight (kg), prolactin level (mg/l).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: High. Providers blinded: High. Outcome assessors blinded: Low. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	None.

Study ID	**VANBRUGGEN2003**
Bibliographic reference	Van Bruggen, J., Tijssen, J., Dingemans, P., *et al.* (2003) Symptom response and side-effects of olanzapine and risperidone in young adults with recent onset schizophrenia. *International Clinical Psychopharmacology*, *18*, 341–346.
General information	Funding source: Eli Lilly and non-industry sponsors. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case. Blindness: Blinding not reported. Duration: Number of weeks of treatment – 6 to 10 weeks; length of follow-up – 6 to 10 weeks. Raters: Not reported. Design: Single-centre (University of Amsterdam, The Netherlands) RCT.

	Number of people screened, excluded and reasons: Not reported. Notes about study methods: • Continuous data are reported dichotomously. • Duration of untreated psychosis was much longer in the olanzapine group (24.9 months) compared with the risperidone group (8.8months). • Duration of prior antipsychotic use was much greater in the risperidone groups (45.5 weeks) than the olanzapine group (15.9 weeks). • Participants who achieved remission (defined using the PANSS) after 6 weeks were discharged from the psychiatric ward and endpoint data were obtained. Participants who were still actively symptomatic at 6 weeks remained on the psychiatric ward for further treatment by switching medication and endpoint data were obtained. Participants who achieved partial remission based on the clinical judgment of their treating psychiatrist, continued study medication for another 4 weeks after which endpoint data were obtained. It is not clear how many participants were considered to have achieved remission at 6 weeks, how many participants were considered to be actively symptomatic at 6 weeks and switched medication, or how many participants were considered to have achieved partial remission and continued treatment for a further 4 weeks.
Participants	Diagnosis: First and second episode psychosis (first episode psychosis 89% and 85% in the risperidone and olanzapine treated groups, respectively). Diagnostic tool: DSM-IV (format not specified). Inclusion criteria: • age 16 to 28 years • first or second psychotic episode according to DSM-IV criteria of schizophrenia, schizophreniform or schizoaffective disorder. Exclusion criteria: • epilepsy • toxic psychosis or infectious disorder • primary diagnosis of substance abuse • learning disability • pregnant or lactating female patients • concomitant use of other antipsychotic agents • treatment with an injectable depot neuroleptic less than one dosing interval before study entry • narrow-angle glaucoma • known hypersensitivity to any ingredient of the tablets containing olanzapine or risperidone • insufficient knowledge of the Dutch language. Total sample size: Number randomised = 44. Gender: 79.6% male.

	Age: Mean 20.8 years (range not reported). Ethnicity: Not reported. Setting: Inpatient clinic. Mean duration of disorder: Not reported Mean age of onset: 17.9 years. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: risperidone, mean (range) dose: 4.4 (1 to 8) mg/day), over 6 to 10 weeks, N = 26; Group 2: olanzapine, mean (range) 15.6 (5 to 30) mg/day, over 6 to 10 weeks, N = 18. Notes about the interventions: • The olanzapine treatment regimen started with 10 mg/day with a flexible titration of 5 mg increments or decrements/day during the first 2 weeks. • The risperidone treatment regimen started with 1 mg/day increased to 2 mg/day after 3 days with a flexible titration of 1 mg increments or decrements/day with the allowed dose range during the first 2 weeks. • The mean (SD) length of treatment in the risperidone and olanzapine groups was 9.8 (6.7) weeks and 6.7 (3.4) weeks, respectively.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative, General, Depression). Leaving the study early: Leaving the study early for any reason. Side effects: Akathisia, parkinsonism, weight (kg).
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: High. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: High. Other bias: High.
Related publications	None.

APPENDIX 13C (II): INCLUDED STUDIES FOR ANTIPSYCHOTICS IN THE TREATMENT OF THE ACUTE EPISODE

Study ID	**AstrazenecaD1441C00112**
Bibliographic reference	AstraZeneca D1441C00112 (unpublished) A 6-week, international, multicenter, randomized, double-blind, parallel-group, placebo-controlled, phase IIIb study of the efficacy and safety of quetiapine fumarate (SEROQUEL™) immediate-release tablets in daily doses of 400 mg and 800 mg compared with placebo in the treatment of adolescents with schizophrenia. Available from: www.astrazenecaclinicaltrials.com/_mshost800325/content/clinical-trials/resources/pdf/8579471 [accessed 6 November 2012].
General information	Funding source: AstraZeneca. Published or unpublished data: Unpublished.
Method	Type of study: Individual randomised trial. Type of analysis: Available case (study reports LOCF). Blindness: Participants, providers and assessors blind. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Independent of treatment. Design: Multicentre (43 international, inpatient and outpatient sites) RCT. Number of people screened, excluded and reasons: 268 screened, 46 excluded (adverse events: 4.3%; eligibility criteria not fulfilled: 91.3%; lack of study drug: 2.2%; sponsor directive 2.2%). Notes about study methods: A medication washout period of 1 to 28 days based on the current medications at screening preceded the study. Results are currently unpublished
Participants	Diagnosis: Schizophrenia. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • provision of written informed consent by one or both parents or by legal guardian prior to any study procedure and have a parent or legal guardian available to accompany the patient at each scheduled study visit, providing reliable information, and responsible for receiving and dispensing study medication; and provision of written assent by the patient prior to any study procedure • aged 13 to 17 years • if female and of childbearing potential, must have used a reliable method of contraception; all female patients needed to have the absence of pregnancy confirmed by a negative β-human chorionic gonadotropin (β-hCG) before randomisation • DSM-IV criteria for schizophrenia • patients with a Social Communication Questionnaire score of ≥15 and who otherwise met entrance criteria must have had a documented history of delusions or hallucinations • PANSS score of ≥60 and a score of 4 or greater on at least one of the following items: delusions (P1), conceptual disorganisations (P2), or hallucinations (P3) at both screening and randomisation (day 1)

	• willingness to agree not to harm self • willingness to adhere to the schedule of assessments. Exclusion criteria: • Secondary DSM-IV Axis I diagnoses of bipolar disorders • premorbid IQ <70 or diagnosis of a learning disability • psychosis judged to be the direct physiological consequence of a medical condition or treatment • psychosis judged to be the direct physiological effect (for example, intoxication, withdrawal) of a misused medication or substance • history of any serious suicide attempt that required medical intervention or current suicidal risk that could not be safely managed as determined by the clinical judgment of the investigator • serious homicidal risk or homicidal behaviours within the past 3 months that resulted in adjudication • known intolerance for or lack of response to quetiapine, as judged by the investigator • contraindications as detailed in country-specific prescribing information for quetiapine • pregnancy or lactation in female patients • substance abuse or dependence including alcohol, as defined in DSM-IV within 1 month prior to screening • inability to discontinue psychoactive medications prior to randomisation • use of haloperidol decanoate, fluphenazine decanoate or risperidone microspheres within 1 dosing interval prior to randomisation • ECT within 30 days prior to screening • use of potent cytochrome P450 (CYP3A4) inhibitors or use of potent CYP3A4 inducers in the 14 days preceding randomisation • thyroid-stimulating hormone (TSH) concentration more than 10% above the upper limit of the normal range • laboratory test results outside the reference range and considered by the investigator to be clinically significant • baseline QTc interval (Fridericia formula) ≥450 milliseconds at baseline • renal, cardiovascular, hepatic, hematologic, endocrinologic, ophthalmologic or other disease or clinical finding that was unstable or that in the opinion of the investigator would be negatively affected by study medication or that would affect study medication • unstable diabetes mellitus with a baseline glycosylated haemoglobin (HbA1c)≥8.5; admission to a hospital for treatment of diabetes or diabetes-related illness in past 12 weeks; not under the care of a physician responsible for the patient's diabetes care; diabetes mellitus that is clinically unstable in the opinion of the physician responsible for the patient's diabetes management at the time of baseline; physician responsible for the patient's diabetes care had not approved the patient's participation in the study • the patient had not been on the same dose of oral hypoglycaemic drug(s) and/or diet for the 4 weeks prior to randomisation • for patients taking insulin whose daily dose on one occasion in the past 4 weeks was more than 10% above or below their

	mean dose in the preceding 4 weeks • patient's complete blood count with white blood cell differential showed an absolute neutrophil count <1.0 x 109/L 24 hours after testing • medical condition that would affect absorption, distribution, metabolism or excretion of study medication • history of seizure disorder, except febrile convulsions • use of experimental drug within 30 days of randomisation • previous participation in this study • significant medical illness that could prevent patient from completing double-blind treatment. Total sample size: Number randomised = 222. Gender: 58.6% male. Age: Mean 15.4 years (range: 13 to 17 years). Ethnicity: 61.4% white. Setting: Inpatient and outpatient. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: quetiapine, mean (range) dose: 400 (not reported) mg/day, over 6 weeks, N = 73; Group 2: quetiapine, mean (range) dose: 800 (not reported) mg/day, over 6 weeks, N = 74; Group 3: placebo (mean dose N/A), over 6 weeks, N = 75. Notes about the interventions: Study treatment was given twice daily and began with an initial dose of 50 mg of quetiapine or matching placebo on the evening of day 1. Patients randomised to the 400 mg/day group reached the target dose of quetiapine or matching placebo by day 5.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative). Depression: PANSS-Depressive Symptoms. Global state: CGI. Psychosocial functioning: Children's Global Assessment Scale (CGAS). Leaving the study early: Leaving due to any reason. Side effects: Tremor, akathisia, dyskinesia, extrapyramidal disorder, tachycardia (BPM), QT interval (msec), fasting serum glucose level (mg/dl), insulin (µU/L), weight (kg), fasting total cholesterol (mg/dl), fasting high-density lipoprotein cholesterol level (mg/dl), fasting low-density lipoprotein cholesterol level (mg/dl), fasting triglycerides, prolactin level, standing pulse (beats/min), sitting pulse (beats/min), systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), BMI (kg/m^2).
Quality	Sequence generation: Low. Allocation concealment: Low. Participants blinded: Low. Providers blinded: Low. Outcome assessors blinded: Unclear.

	Missing outcome data: High. Selective outcome reporting: Low. Other bias: Low.
Related publications	AstraZeneca D1441C00150 (unpublished) A 26-week, international, multicenter, open-label phase IIIb study of the safety and tolerability of quetiapine fumarate (Seroquel™) immediate-release tablets in daily doses of 400 mg to 800 mg in children and adolescents with bipolar I disorder and adolescents with schizophrenia. Available from: www.astrazenecaclinicaltrials.com/_mshost800325/content/clinical-trials/resources/pdf/8579486 [accessed 6 November 2012].

Study ID	**FINDLING2008A**
Bibliographic reference	Findling, R. L., Robb, A., Nyilas, M., *et al.* (2008) A multiple-center, randomized, double-blind, placebo-controlled study of oral aripiprazole for treatment of adolescents with schizophrenia. *The American Journal of Psychiatry*, *165*, 1432-1441.
General information	Funding source: Otsuka Pharmaceuticals. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case (study reports LOCF). Blindness: Unclear. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Unclear. Design: Multicentre (US, Europe, South America, Asia, the Caribbean and South Africa) RCT. Number of people screened, excluded and reasons: Not reported, Notes about study methods: Participants who were deemed appropriate by their treating physicians were screened for eligibility within 4 weeks of baseline.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • male or female • age 13 to 17 years inclusive • DSM-IV axis I primary diagnosis of schizophrenia and confirmation of the schizophrenia diagnosis by an adequately trained clinician (for example, child psychiatrist) at the time of screening by means of the K-SADS-PL (23) and a baseline PANSS score of 70 or higher. Exclusion criteria: • psychiatric comorbidity requiring pharmacotherapy • evidence of suicide risk • history of current diagnosis of schizoaffective disorder • learning disability

	• major depressive episodes • neuroleptic malignant syndrome • any neurologic disorder other that Tourette's syndrome • severe head trauma • any unstable medical condition. Total sample size: Number randomised = 302. Gender: 57% male. Age: Mean 15.5 years (range not reported). Ethnicity: 37% white. Setting: Inpatient and outpatient clinics. Mean duration of disorder: 1.4 years. Mean age of onset: 14.1 years. Prior antipsychotic use: 51.7% participants were antipsychotic naïve before the study.
Interventions	Intervention: Group 1: aripiprazole, mean (range) dose: 10 (2 to 10) mg/day, over 6 weeks, N = 100; Group 2: aripiprazole, mean (range) dose: 30 (2 to 30) mg/day, over 6 weeks, N = 102; Group 3: placebo (mean dose N/A), over 6 weeks, N = 100. Notes about the interventions: • Aripiprazole was administered according to a forces titration schedule. One group started on 2 to 5 mg/day, followed by an increase after day 3 to the target dose of 10 mg/day by day 5. The second group started on 2 mg/day, which was increased every 2 days to 5 mg/day, 10 mg/day, 15 mg/day, 20 mg/day and finally the target dose of 30 mg/day by day 11. • Target doses were maintained for at least 2 weeks. • Participants who experienced unacceptable tolerability problems before day 25 were removed from the study. • After day 25 a dose reduction was permitted, after which point a return to the target dose was not permitted. • Participants were permitted to receive benzodiazepine or anticholinergic medications for relief of transient symptoms.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative). Psychosocial functioning: CGAS. Global state: CGI. Quality of Life: Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire. Leaving the study early: Leaving the study early for any reason. Side effects: Akathisia, dyskinesia, parkinsonism, dystonia, weight (kg), BMI (kg/m^2), fasting serum glucose levels (mg/dl), fasting total cholesterol (mg/dl), fasting triglycerides (mg/dl), fasting high-density lipoprotein cholesterol level (mg/dl), prolactin level (µg/l), QT interval (msec), mortality.
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Unclear.

	Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: Low. Selective outcome reporting: Low. Other bias: Low.
Related publications	Robb, A. S., Carson, W. H., Nyilas, M., *et al.* (2010) Changes in positive and negative syndrome scale-derived hostility factor in adolescents with schizophrenia treated with aripiprazole: posthoc analysis of randomized clinical trial data. *Journal of Child and Adolescent Psychiatry*, *20*, 33-38.

Study ID	**HAAS2009**
Bibliographic reference	Haas, M., Eerdekens, M., Kushner, S., *et al.* (2009) Efficacy, safety and tolerability of two dosing regimens in adolescent schizophrenia: double-blind study. *The British Journal of Psychiatry*, *194*, 158-164.
General information	Funding source: Johnson and Johnson. Published or unpublished data: Published and unpublished.
Method	Type of study: Individual randomised trial. Type of analysis: Available case (study reports LOCF). Blindness: Unclear. Duration: Number of weeks of treatment – 8 weeks; length of follow-up – 8 weeks. Raters: Unclear. Design: Multicentre (Belgium, Bulgaria, Czech Republic, Estonia, Germany, Poland, Romania, US) RCT. Number of people screened, excluded and reasons: 343 screened, 86 excluded (ineligible: n = 51; withdrew consent: n = 7; 'other': n = 5; lost to follow-up: n = 1; following a protocol amendment children under the age of 13 years and those with a schizophreniform disorder: n = 22). Notes about study methods: Reported as a double-blind trial, however 'During the consent process, the difference in the two doses was explained to the patients and their caregivers. It was explained that the lower dose although expected to have some activity, might be an ineffective treatment'. Side effect data were not reported in sufficient detail to allow extraction and analysis.
Participants	Diagnosis: Schizophrenia disorder. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • male and female • age 13 to 17 years • DSM-IV diagnosis of schizophrenia • currently hospitalised for an acute episode (PANSS total score between 60 and 120, inclusive) • negative pregnancy test • inpatients and outpatients experiencing an acute episode with a total PANSS score of 60 to 120, inclusive.

	Exclusion criteria: • significant risk for suicide or violent behaviour during the study • history of neuroleptic malignant syndrome • tardive dyskinesia • known or suspected seizure disorder • BMI<5th percentile or >95th percentile using standardised percentile curves for children and young people. Total sample size: Number randomised = 279. Gender: 56.6% male. Age: Mean 15.6 (range 13 to 17) years. Ethnicity: 84.6% white. Setting: Inpatient and outpatient clinics. Mean duration of disorder: 1.8 years. Mean age of onset: 13.9 years. Prior antipsychotic use: 32% participants were antipsychotic naïve before the study.
Interventions	Intervention: Group 1: risperidone 0.15 to 0.6 mg/day (participants >50 kg: 0.15 to 0.6 mg/day; patients <50 kg: 0.003 to 0.012 mg/kg/day), over 8 weeks, N = 132; Group 2: risperidone 1.5 to 6 mg/day (participants >50 kg: 1.5 to 6 mg/day; patients <50 kg: 0.03 to 0.12 mg/kg/day), over 8 weeks, N = 125. Notes about the interventions: • Administered as an oral solution once or twice daily. • For participants in group 1, starting dose was 0.5 mg/day for participants weighing >50 kg or 0.01 mg/kg/day for participants weighing <50 kg. • For participants in group 2, starting dose was 0.05 mg/day for participants weighing >50 kg or 0.001 mg/kg/day for participants weighing <50 kg. • Upwards titration schedules were adjusted up to the maximum tolerated dose over a period of 12 days. • Dose remained stable during the last 4 weeks of the treatment period.
Extractable Outcomes	Symptoms: PANSS (Total, Positive, Negative). Global state: CGI. Leaving the study early: Leaving the study early for any reason. Side effects: Akathisia, dyskinesia, dystonia, parkinsonism, tremor, weight (kg), fasting total cholesterol (mmol/l), fasting triglycerides (mmol/l), fasting glucose (mmol/l), prolactin level (ng/ml), tachycardia (BPM).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear. Outcome assessors blinded: Unclear.

	Missing outcome data: High. Selective outcome reporting: High . Other bias: Low.
Related publications	None.

Study ID	**HAAS2009B**
Bibliographic reference	Haas, M., Unis, A. S., Armenteros, J., *et al.* (2009) A 6-week, randomized, double-blind, placebo-controlled study of the efficacy and safety of risperidone in adolescents with schizophrenia. *Journal of Child and Adolescent Psychopharmacology*, *19*, 611-621.
General information	Funding source: Johnson and Johnson. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Unclear. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Unclear. Design: Multicentre (23 sites in India, Russia, Ukraine, United States) RCT. Number of people screened, excluded and reasons: 178 screened, 18 excluded (ineligible: n = 16; withdrew consent: n = 2). Notes about study methods: None.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: DSM-IV (interview format not reported). Inclusion criteria: • male and female • aged 13 to 17 years • DSM-IV diagnosis of schizophrenia • inpatients and outpatients experiencing an acute episode with a total PANSS score of 60 to 120 (inclusive) • good physical health • negative pregnancy test. Exclusion criteria: • subjects who met DSM-IV criteria for dissociative disorder, bipolar disorder, major depressive disorder, schizoaffective disorder, schizophreniform disorder, autistic disorder or primary substance-induced psychotic disorder at screening • mild, moderate or severe learning disabilities (IQ <70) • known or suspected substance dependence diagnosed by DSM-IV criteria in the 3 months preceding screening • significant risk of suicide or violent behaviour • subjects failing to respond to adequate treatment with two or more typical or atypical antipsychotics (including risperidone) during the current psychotic episode

	• exhibited hypersensitivity or intolerance to risperidone • history of neuroleptic malignant syndrome or any severe drug allergy or hypersensitivity • depot antipsychotic treatment (within two treatment cycles before baseline) • ECT (in the 4 weeks before baseline) • clozapine (within 2 months before baseline) • use of prohibited concomitant medications that could not be discontinued per the investigator's judgement • use of insight-oriented or cognitive-behavioural psychotherapy during the study; however could receive a limited supportive psychotherapy or psychoeducation. Total sample size: Number randomised = 160. Gender: 64% male. Age: Mean 15.6 (range 13 to 17) years. Ethnicity: 53% white. Setting: Inpatient and outpatient clinics. Mean duration of disorder: 2.5 years. Mean age of onset: 13.1 years. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: risperidone 1 to 3 mg/day, over 6 weeks, N = 55; Group 2: risperidone 4 to 6 mg/day, over 6 weeks, N = 51; group 3: placebo (mean dose N/A), over 6 weeks, N = 54. Notes about the interventions: • Treatment administered once daily. • Doses administered by forced titration from minimum within assigned target ranges by day 7, further increases within the assigned dose range were made by day 14 to maximum tolerated dosage level. • After day 14, doses were maintained at maximally tolerated level for the remainder of the study. • Treatment of side effects included β-adrenergic blocker for treatment-emergent akathisia and anti-parkinsonism medications. • Participants were allowed to receive limited supportive psychotherapy or psychoeducation.
Extractable outcomes	Symptoms: PANSS (Positive, Negative). Psychosocial functioning: CGAS. Leaving the study early: Leaving the study early for any reason. Side effects: Extrapyramidal side effects (AIMS, SAS), extrapyramidal disorder, prolactin level (µg/l), tachycardia (BPM), mortality.
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear.

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

Study ID	**JENSEN2008**
Bibliographic reference	Jensen, J. B., Kumra, S., Leitten, W., *et al.* (2008) A comparative pilot study of second-generation antipsychotics in children and adolescents with schizophrenia-spectrum disorders. *Journal of Child and Adolescent Psychopharmacology, 18*, 317-326.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case reports (LOCF). Blindness: Open-label trial. Duration: Number of weeks of treatment – 12 weeks; length of follow-up – 12 weeks. Raters: Not independent of study. Design: Single-centre (University of Minnesota Medical Centre, US) open-label RCT. Number of people screened, excluded and reasons: 67 screened, 37 excluded (ineligible: n = 37; refused to participate: n = 10). Notes about study methods: To enhance treatment adherence and/or alleviate side effects, the dosing strategy could be modified to twice daily (rather than once daily) based on the discretion of the study physician.
Participants	Diagnosis: Schizophrenic disorder. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • male and female • aged 10 to 18 years • diagnosis of schizophrenia, schizoaffective disorder, schizophreniform or psychotic disorder NOS • at least one positive or negative symptom associated with schizophrenia, present throughout the past 2 weeks of moderate or greater severity on the PANSS • people with a past diagnosis of obsessive-compulsive disorder (OCD), past history of substance misuse or dependence or pervasive developmental disorder were allowed to participate only if their psychotic symptoms were not better accounted for by the comorbid disorder. Exclusion criteria: • learning disability • affective disorder (major depressive disorder or bipolar disorder) with psychotic features • current alcohol or drug dependence or misuse

	• history of serious adverse reactions or non-response to an adequate trial of any of the proposed treatments • pregnant or refused to practice contraception • serious or unstable medical condition • PTSD if the majority of psychotic symptoms were related to the PTSD. Total sample size: Number randomised = 30. Gender: 66.7% male. Age: Mean 15.2 (range 10 to 18) years. Ethnicity: 60% white. Setting: Inpatient and outpatient clinics. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 76.7% participants antipsychotic naïve at study entry.
Interventions	Intervention: Group 1: risperidone, mean (range) dose: 3.4 (1 to 6) mg/day, over 12 weeks, N = 10; Group 2: quetiapine, mean (range) dose: 611 (100 to 800) mg/day, over 12 weeks, N = 10; Group 3: olanzapine, mean (range) dose: 14 (5 to 20) mg/day over 12 weeks, N = 10. Notes about the interventions: • The risperidone dose started at 0.5 mg/day and could be increased in 0.5 to 1 mg increments every 2 to 3 days to a maximum dose of 6 mg/day. • The quetiapine dose started at 100 mg/day and could be increased in 100 mg increments every 2 to 3 days to a maximum dose of 800 mg/day. • The olanzapine dose started at 5 mg/day and could be increased in 5 mg increments every 3 days to a maximum dose of 20 mg/day. • Study medications could be adjusted on the basis of participant response and emergence of treatment-related side effects at the discretion of the study physician. Slower increases in medication were used if the participant had significant side effects. • Diphenhydramine (up to 100 mg/day) was provided if clinically significant side effects were experienced. Lorazepram (0.5 to 2 mg/day) was provided to treat insomnia or to decrease agitation and anxiety. • Psychoeducation and dietary counselling was provided. • Inpatients received routine group, recreational and family therapies.
Extractable outcomes	Symptoms: PANSS (Total, General, Positive, Negative). Psychosocial functioning: CGAS. Global state: CGI. Leaving the study early: Leaving the study early for any reason. Side effects: Akathisia, extrapyramidal side effects (AIMS, SAS), weight (kg), BMI (m^2/kg).
Quality	Sequence generation: Low.

	Allocation concealment: Unclear. Participants blinded: High. Providers blinded: High. Outcome assessors blinded: High. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	None.

Study ID	**KRYZHANOVSKAYA2009B**
Bibliographic reference	Kryzhanovskaya, L., Schulz, S. C., McDougle, C., *et al.* (2009) Olanzapine versus placebo in adolescents with schizophrenia: a 6-week, randomized, double-blind, placebo-controlled trial. *Journal of the American Academy of Child and Adolescent Psychiatry*, *48*, 60-70.
General information	Funding source: Eli Lilly and Company. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case for side effect outcomes, LOCF for efficacy outcomes. Blindness: Participants blind, providers not blind, unclear blinding of raters. Duration: Number of weeks of treatment – 6 weeks; length of follow-up 6 weeks. Raters: Unclear. Design: Multicentre (20 sites in US and Russia).RCT. Number of people screened, excluded and reasons: 115 screened, eight excluded (reasons not reported). Notes about study methods: • It is not clear if baseline measures were administered before or after randomisation. • Patients were excluded if they had a previous non-response to an adequate dose/duration of olanzapine treatment. • Variance associated with mean scores on primary outcomes is not reported.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • 13 to 17 years • met DSM-IV-TR diagnosis of schizophrenia • total score of >35 on the anchored version of the BPRS-C with a score of >3 or higher on at least one of the following BPRS-C items at enrolment and randomisation: hallucinations, delusions, or peculiar fantasies. Exclusion criteria: • previous participation in a clinical trial of oral olanzapine

	• treatment within 30 days of the trial with a drug without regulatory approval for any indication • documented olanzapine allergic reaction • previous non-response to an adequate dose/duration of olanzapine treatment • potential safety concerns • for females: pregnancy, nursing or refusal to practice acceptable contraception • acute/unstable medical conditions • current/expected use of any concomitant psychotropic medication (except for certain benzodiazepines and anticholinergics) • >200ng/ml of baseline prolactin • clinically significant laboratory abnormalities • DSM-IV-TR substance dependence within 30 days (except nicotine and caffeine) • current DSM-IV-TR diagnosis of a comorbid psychiatric or developmental disorder. Total sample size: Number randomised = 107. Gender: 70.1% male. Age: Mean 16.7 years (range not reported). Ethnicity: 72% white. Setting: Inpatients and outpatients. Mean duration of disorder: 3.2 years. Mean age of onset: 13 years. Prior antipsychotic use: 56.5% participants antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: olanzapine, mean (range) 11.1 (2.5 to 20) mg/day, over 6 weeks, N = 72; Group 2: placebo (mean N/A), over 6 weeks, N = 35. Notes about the interventions: • Starting dose of olanzapine was 2.5 or 5 mg/day at the investigator's discretion and could be increased (to a maximum of 20 mg/day) or decreased by an increment of 2.5 or 5 mg/day at the investigator's discretion. The dose was titrated to least 10 mg/day by the third week (providing there were no tolerability concerns). Doses were increased to the highest tolerated dose if there were no concerns. Dose adjustments were allowed at any time in any number of increments/decrements. • Patients who were unable to tolerate the minimum dose (2.5 mg/day) were discontinued from the study. • Patients who did not respond to therapy (<20% decrease in BPRS-C and CGI-S score >3 after at least 3 weeks of treatment) were able to receive open-label olanzapine without completing the double-blind period. • Benzodiazepines and anticholinergics allowed.
Extractable outcomes	Symptoms: BPRS-C, PANSS (Total, General, Positive, Negative). Global state: CGI. Leaving the study early: Leaving the study early for any reason.

	Side effects: Weight (kg), BMI (m^2/kg), fasting triglycerides (mg/dl), fasting glucose (mg/dl), fasting total cholesterol (mg/dl), fasting high-density lipoprotein cholesterol level (mg/dl), fasting low-density lipoprotein cholesterol level (mg/dl), QT interval (ms), prolactin level (µg/l).
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Low. Providers blinded: High. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: Low. Other bias: Low.
Related publications	None.

Study ID	**MOZES2006**
Bibliographic reference	Mozes, T., Ebert, T., Michal, S. E., *et al.* (2006) An open-label randomized comparison of olanzapine versus risperidone in the treatment of childhood-onset schizophrenia. *Journal of Child and Adolescent Psychopharmacology*, *16*, 393-403.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Open-label trial, unclear if raters were blinded. Duration: Number of weeks of treatment – 12 weeks; length of follow-up – 12 weeks. Raters: Unclear. Design: Single-centre (Ness Ziona Mental Health Center, Israel) open-label RCT. Number of people screened, excluded and reasons: Not reported. Notes about study methods: Population included comorbid OCD (n = 3); attention deficit hyperactivity disorder (ADHD) (n = 3); grand mal epilepsy (n = 2); neurofibromatosis (n = 1); familial Mediterranean fever (n = 1); chronic motor tic disorder (n = 1).
Participants	Diagnosis: Schizophrenic disorder. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: Not reported. Exclusion criteria: • learning disability. Total sample size: Number randomised = 25. Gender: 40% male. Age: Mean 11.1 (range 9 to 14) years.

	Ethnicity: Not reported. Setting: Inpatient unit. Mean duration of disorder: 2.1 years. Mean age of onset: 9 years. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: risperidone, mean (range) 1.62 (0.25 to 4.5) mg/day, over 12 weeks, N = 13; Group 2: olanzapine, mean (range) 8.18 (2.5 to 20) mg/day, over 12 weeks, N = 12. Notes about the interventions: Dosing of either intervention was determined according to clinical response and side effects.
Extractable outcomes	Symptoms: PANSS (Total, General, Positive, Negative), BPRS. Psychosocial functioning: CGAS. Leaving the study early: Leaving the study early for any reason. Side effects: Extrapyramidal side effects (SAS, BARS), tremor, weight (kg).
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: High. Providers blinded: High. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: Unclear. Other bias: Low.
Related publications	None.

Study ID	**PAILLIERE-MARTINOT1995**
Bibliographic reference	Paillère-Martinot, M. L., Lecrubier, Y., Martinot, J. L., *et al.* (1995) Improvement of some schizophrenic deficit symptoms with low doses of amisulpride. *The American Journal of Psychiatry*, *152*, 130-133.
General information	Funding source: Laboratories Synthèlabo (now Sanofi-Aventis). Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Available case. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Unclear. Design: Single-centre (Hôpital de la Salpêtrière, Paris, France) RCT. Number of people screened, excluded and reasons: Not reported. Notes about study methods:

	• Baseline ratings were performed after a pre-treatment period of 8 days. • Side effect outcome data were not reported in sufficient detail for extraction. • Significant sex difference between groups existed, with only one female in the amisulpride group and six in the placebo group (p=0.03).
Participants	Diagnosis: Schizophrenic disorder. Diagnostic tool: DSM-III-R (interview schedule not reported). Inclusion criteria: • male and female • important negative schizophrenic symptoms defined as mean items rating of 3 on at least two subscales of the SANS • short disease course, assessed as time since onset of DSM-III-R prodromal symptoms and neuroleptic–naïve condition or lifetime neuroleptic treatment shorter than 1 month. Exclusion criteria: • organic brain disorder • somatic disease • alcohol or drug misuse • prominent positive symptoms or depression. Total sample size: Number randomised = 27. Gender: 74% male. Age: Mean 20 years (range not reported). Ethnicity: Not reported. Setting: Inpatient and outpatient clinics. Mean duration of disorder: 34 months. Mean age of onset: 17 years. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: Amisulpride, mean (range) dose: not reported (50 to 100) mg/day, over 6 weeks, N = 14; Group 2: placebo (mean dose N/A), over 6 weeks, N = 13. Notes about the interventions: During the first 3 weeks each patient received one 50 mg tablet a day. On day 21, if the patient was not improved, the dose was increased to two tablets per day for 3 more weeks.
Extractable outcomes	Symptoms: PANSS (Positive, Negative) Depression: Depressive Retardation Rating Scale, MADRS Leaving the study early: Leaving due to any reason.
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear.

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

Study ID	**POOL1976**
Bibliographic reference	Pool, D., Bloom, W., Mielke, D. H., *et al.* (1976) A controlled evaluation of loxitane in seventy-five adolescent schizophrenic patients. *Current Therapeutic Research: Clinical and Experimental, 19*, 99-104.
General information	Funding source: Public Health Service Grant MH-03701-16 (*Psychopharmacology* Research Branch, NIMH). Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: Available case. Blindness: Participants and raters blind, provider blinding not reported. Duration: Number of weeks of treatment 4 weeks; length of follow-up 4 weeks. Raters: Independent of study. Design: Single-centre (US) RCT. Number of people screened, excluded and reasons: Not reported. Notes about study methods: Patients who failed to complete 4 weeks of daily medication because of voluntary withdrawal or for administrative reasons were not included in the analyses of efficacy ratings and were replaced by new patients. Withdrawal of patients by the investigator because of side effects or inadequate response to study medication were included in the analysis of efficacy ratings.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: Not reported. Inclusion criteria: • 13 to 18 years • undisputed diagnosis of schizophrenia associated with a gross disorder of thought associations and/or hallucinations at the time of admission. Exclusion criteria: • not a danger to self or others • DSM-IV diagnosis other than schizophrenia; substance dependence (DSM-IV criteria) in 3 months preceding screening • history of seizure, neuroleptic malignant syndrome, encephalopathic syndrome, tardive dyskinesia, insulin-dependent diabetes mellitus; and any significant or unstable systemic disease • increased risk for *torsade de pointes* or sudden death (investigator's assessment) • had received clozapine in the 2 months before baseline visit, depot antipsychotic therapy within two treatment cycles

	before, or ECT in the 3 months before • (for females) pregnant, planning to become pregnant, or breastfeeding. Total sample size: Number randomised = 75. Gender: 94.7% male. Age: Mean 15.5 years (range not reported). Ethnicity: Not reported. Setting: Inpatient (adolescent hospital). Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: haloperidol mean dose 9.8 mg/day, over 4 weeks, N = 25; Group 2: loxapine mean dose 87.5 mg/day, over 4 weeks, N = 26; Group 3: placebo (mean dose N/A), over 4 weeks, N = 24. Notes about the interventions: • The capsule unit for haloperidol was 2 mg: dose schedule was: one capsule h.s. for days 1 and 2; one capsule b.i.d. for day 3; two capsules daily through days 4 to 7; five capsules daily through days 8 to 10. On days 11 to 14 the patient received six capsules daily and eight capsules if necessary on days 15 to 28. • Dosage could be adjusted in the event of troublesome side effects or if the patient showed a good response and it was felt advisable to continue at that level. After the patient reached a dosage of three capsules b.i.d. by day 15, the dosage regimen was then made flexible and could be regulated according to individual patient response.
Extractable outcomes	Side effects: Number of people experiencing an extrapyramidal side effect.
Quality	Sequence generation: Unclear. Allocation concealment: Unclear. Participants blinded: Low. Providers blinded: Unclear. Outcome assessors blinded: Low. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	None.

Study ID	**SIKICH2004**
Bibliographic reference	Sikich, L., Hamer, R. M., Bashford, R. A., *et al.* (2004) A pilot study of risperidone, olanzapine, and haloperidol in psychotic youth: a double-blind, randomized, 8-week trial. *Neuropsychopharmacology*, *29*, 133-145.
General information	Funding source: Eli Lilly, Janssen and non-industry sponsors. Published or unpublished data: Published.

Method	Type of study: Individual randomised trial. Type of analysis: Available case (study reports LOCF). Blindness: Participants blind. Provider and rater blinding unclear. Duration: Number of weeks of treatment – 8 weeks; length of follow-up – 8 weeks. Raters: Unclear. Design: Multicentre (UNC Health Care System, Dorothea Dix Hospital and other psychiatric practices, North Carolina, US) RCT. Number of people screened, excluded and reasons: 160 screened, 109 excluded (ineligible: n = 20; lived too far away: n = 15; refused to participate: n = 74). Notes about study methods: None.
Participants	Diagnosis: Psychosis, including schizophrenia spectrum disorders (52%) and affective disorders (48%). Diagnostic tool: SCID. Inclusion criteria: • at least one positive psychotic symptom of moderate or greater severity on the BPRS-C which had been present • throughout the past 2 weeks • full scale IQ >69 • permitted primary diagnoses were psychosis NOS, schizophreniform disorder, schizophrenia, schizoaffective disorder, delusional disorder, major depression with psychotic features, and bipolar affective disorder with psychotic features Exclusion criteria: • psychotic symptoms that appeared to result from acute substance intoxication or withdrawal • history of serious adverse reactions or non-response to an adequate trial of any of the study medications during this psychotic episode • prior diagnosis of a pervasive developmental disorder • serious medical or neurological disorder • (for females) pregnancy or refusal to practice contraception • imminent risk in current setting to harm self or others • individuals with comorbid diagnoses of PTSD were permitted only if the majority of psychotic symptoms appeared unrelated to the PTSD • individuals with a current or recent diagnosis of ADHD, Tourette's syndrome or OCD, or with a past history of substance misuse or dependence were allowed to participate only if their psychotic symptoms were not better accounted for by the comorbid disorder. Total sample size: Number Randomised = 51. Gender: 60% male. Age: Mean 14.8 years (range not reported). Ethnicity: 60% white. Setting: Inpatient and outpatient services.

	Mean duration of disorder: 2.4 years. Mean age of onset: 12.4 years. Prior antipsychotic use: 24% antipsychotic naïve at baseline.
Interventions	Intervention: Group 1: risperidone, mean (range) 4 (0.5 to 6) mg/day, over 8 weeks, N = 20; Group 2: olanzapine, mean (range) 12.3 (2.5 to 20) mg/day, over 8 weeks, N = 16; group 3: haloperidol, mean (range) 5 (1 to 8) mg/day, over 8 weeks, N = 15. Notes about the interventions: • Doses were titrated to a moderate dose (risperidone 0.5 to 3 mg/day in 0.5 mg increments; olanzapine 2.5 to 12.5 mg/day in 2.5 mg increments; and haloperidol 1 to 5 mg/day in 1 mg increments) over 1 to 2 weeks. • Titration was determined by participant response. Slower titration was used if participants had significant side effects. Participants with intolerable side effects were withdrawn. • Doses were maintained below target if participants demonstrated marked improvement at a lower dose; or if participants continued to show significant psychotic symptoms after 2 weeks, the dose could be titrated upwards to a maximum of 6 mg/day (risperidone); 20 mg/day (olanzapine); 8 mg/day (haloperidol). • Psychoeducation and supportive psychotherapy were provided to all participants and their families during the course of the study. • Inpatients also received routine group, recreational and occupational therapies.
Extractable outcomes	Symptoms: BPRS-C, Children's Psychiatric Rating Scale (Total, Positive, Negative). Global state: CGI. Leaving the study early: Leaving the study early for any reason. Side effects: Weight (kg), BMI (kg/m^2), SAS, prolactin level (ng/ml), QT interval (msec).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Low. Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: High. Selective outcome reporting: Unclear. Other bias: Low.
Related publications	None.

Study ID	**SINGH2011**
Bibliographic reference	Singh, J., Robb, A., Vijapurkar, U., *et al.* (2011) A randomized, double-blind study of paliperidone extended-release in treatment of acute schizophrenia in adolescents. *Biological Psychiatry*, *70*, 1179-1187.
General information	Funding source: Johnson and Johnson. Published or unpublished data: Published.

Method	Type of study: Individual randomised trial. Type of analysis: Available case for side effect outcomes, LOCF for efficacy outcomes. Blindness: Participants, providers and raters blind. Duration: Number of weeks of treatment – 6 weeks; length of follow-up – 6 weeks. Raters: Independent of study. Design: Multicentre (35 centres in Russia, India, Ukraine, US, Romania) RCT. Number of people screened, excluded and reasons: 228 screened, 27 excluded (adverse event: n = 1; 'other': n = 25; withdrew for unknown reasons: n = 1). Notes about study methods: Duration of exposure (days) was higher in the paliperidone extended-release medium-treatment and high-treatment groups than in placebo and paliperidone extended-release low-treatment groups.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • 12 to 17 years (inclusive). • weighing at least 29 kg • diagnosed with schizophrenia (DSM-IV criteria) for at least 1 year before screening • PANSS total score between 60 and 120 (inclusive) at screening and baseline (indicative of an acute, symptomatic episode of schizophrenia) • history of at least one adequate antipsychotic trial. Exclusion criteria: • not a danger to self or others • DSM-IV diagnosis other than schizophrenia; substance dependence (DSM-IV criteria) in 3 months preceding screening • history of seizure, neuroleptic malignant syndrome, encephalopathic syndrome, tardive dyskinesia, insulin-dependent diabetes mellitus and any significant or unstable systemic disease • increased risk for *torsade de pointes* or sudden death (investigator's assessment) • had received either clozapine in the 2 months before baseline visit, depot antipsychotic therapy within two treatment cycles before, or ECT in the 3 months before • (for females) pregnant, planning to become pregnant, or breastfeeding Total sample size: Number randomised = 201. Gender: 59% male. Age: Mean 15.4 years (range not reported). Ethnicity: 68% white. Setting: Inpatient and outpatient clinics. Mean duration of disorder: 2.5 years. Mean age of onset: 12.9 years.

	Prior antipsychotic use: 36% and 60% atypical and typical antipsychotic naïve at baseline, respectively.
Interventions	Intervention: Group 1: paliperidone 1.5 mg/day, over 6 weeks, N = 54; Group 2: for patients <51 kg: paliperidone 3 mg/day; or for patients >51 kg: paliperidone 6 mg/day); over 6 weeks, N = 48; Group 3: for patients <51 kg: paliperidone 6 mg/day; or for patients >51 kg: paliperidone 12 mg/day); over 6 weeks, N = 47; Group 4: placebo (mean dose N/A), over 6 weeks, N = 51. Notes about the interventions: • Participants who did not respond to treatment or whose symptoms worsened (defined as >20% increase in PANSS total score from baseline) were discontinued on the basis of the clinical judgment of the investigator. • Patients could also be withdrawn for safety reasons. • Benzodiazepines were allowed as rescue medication when clinically indicated (except for 8 hours before any behavioural assessment), during the screening and washout phase and up to day 21 of the double-blind treatment phase. • Beta-adrenergic blockers were allowed throughout the double-blind phase for the relief of treatment-emergent akathisia and extrapyramidal side effects.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative). Depression: PANSS – anxiety and depression symptoms. Global state: CGI. Psychosocial functioning: CGAS. Leaving the study early: Leaving the study early for any reasons. Side effects: Extrapyramidal side effects (AIMS, SAS, BARS), weight (kg), prolactin level (µg/l), tachycardia (BPM), QT interval (msec).
Quality	Sequence generation: Low. Allocation concealment: Low. Participants blinded: Low. Providers blinded: Low. Outcome assessors blinded: Low. Missing outcome data: High. Selective outcome reporting: High. Other bias: Low.
Related publications	None.

Study ID	**XIONG2004/KENNEDY2012[1]**
Bibliographic reference	Kennedy, E., Kumar, A.& Datta, S. S. (2007; updated 2012) Antipsychotic medication for childhood-onset schizophrenia (review). *Cochrane Database of Systematic Reviews, Issue 3*, Art. No.: CD004027.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Randomised trial.

	Type of analysis: Not reported by KENNEDY2012. Blindness: Unclear. Duration: 8 weeks. Length of follow-up: 8 weeks Raters: Unclear. Design: Single-centre (China) RCT. Number of people screened, excluded and reasons: Not reported by KENNEDY2012. Notes about study methods: Unclear reporting of methods of blinding and no explicit description of randomisation methods.
Participants	Diagnosis: Childhood-onset schizophrenia. Diagnostic tool: Chinese Classification of Mental Disorders (2nd edition)(CCMD-II-R) Inclusion criteria: • children with a diagnosis of schizophrenia according to the CCMD-II-R • 7 to 16 years. Exclusion criteria: • physical problems or any organic neurological disease. Total number randomised: 60. Gender: 57% male. Age: Mean 13 years (range not reported). Ethnicity: Not reported by KENNEDY2012. Setting: Inpatient. Mean duration of disorder: 9 to 9.5 years. Mean age of onset: Not reported by KENNEDY2012.
Interventions	Intervention: Group 1: risperidone, mean (range) dose: not reported (0.5 to 5) mg/day, over 8 weeks, N = 30; Group 2: chlorpromazine, mean (range) dose: not reported (50 to 400) mg/day, over 8 weeks, N = 30. Notes about the interventions: No additional information provided by KENNEDY2012.
Extractable outcomes	Symptoms: BPRS. Side effects: Tremor (Treatment Emergent Symptoms Scale [TESS]).
Quality	Sequence generation: Unclear (not reported by KENNEDY2012). Allocation concealment: Unclear. Participants blinded: Unclear. Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: Unclear (not reported by KENNEDY2012). Selective outcome reporting: Unclear (not reported by KENNEDY2012). Other bias: Low.

Related publications	None.
[1] Study characteristics and quality assessment has been derived from KENNEDY2012 (Cochrane Collaboration Review: 'Antipsychotic medication for childhood-onset schizophrenia').	

Study ID	**YAO2003/KENNEDY2012[1]**
Bibliographic reference	Kennedy, E., Kumar, A. & Datta, S. S. (2007; updated 2012) Antipsychotic medication for childhood-onset schizophrenia (review). *Cochrane Database of Systematic Reviews, Issue 3*, Art. No.: CD004027.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Randomised trial. Type of analysis: Not reported by KENNEDY2012. Blindness: Unclear. Duration: 6 weeks. Length of follow-up: 6 weeks. Raters: Unclear. Design: Single-centre (China) RCT. Number of people screened, excluded and reasons: Not reported by KENNEDY2012. Notes about study methods: Unclear reporting of methods of blinding and no explicit description of randomisation methods.
Participants	Diagnosis: Childhood-onset schizophrenia. Diagnostic tool: Not reported by KENNEDY2012. Inclusion criteria: Not reported by KENNEDY2012. Exclusion criteria: Not reported by KENNEDY2012. Total number randomised: 60. Gender: 56% male. Age: Mean 11 years (range not reported). Ethnicity: Not reported by KENNEDY2012. Setting: Inpatient and outpatient. Mean duration of disorder: Not reported by KENNEDY2012. Mean age of onset: Not reported by KENNEDY2012.
Interventions	Intervention: Group 1: risperidone, mean (range) dose: not reported (0.25 to 3) mg/day, over 6 weeks, N = 30; Group 2: haloperidol, mean (range) dose: not reported (0.5 to 12) mg/day, over 6 weeks, N = 30. Notes about the interventions: No additional information provided by KENNEDY2012.
Extractable outcomes	Symptoms: BPRS. Side effects: Extrapyramidal side effects (TESS).
Quality	Sequence generation: Not reported by KENNEDY2012.

	Allocation concealment: Not reported by KENNEDY2012. Participants blinded: Unclear. Providers blinded: Unclear. Outcome assessors blinded: Unclear. Missing outcome data: Not reported by KENNEDY2012. Selective outcome reporting: Not reported by KENNEDY2012. Other bias: Not reported by KENNEDY2012.
Related publications	None.
[1] Study characteristics and quality assessment has been derived from KENNEDY2012.	

APPENDIX 13C (III): INCLUDED STUDIES FOR ANTIPSYCHOTICS FOR CHILDREN AND YOUNG PEOPLE WHOSE ILLNESS HAS NOT RESPONDED ADEQUATELY TO TREATMENT

Study ID	**KUMRA1996**
Bibliographic reference	Kumra, S., Frazier, J. A., Jacobsen, L. K., *et al.* (1996) Childhood-onset schizophrenia: a double-blind clozapine-haloperidol comparison. *Archives of General Psychiatry*, *53*, 1090-1097.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial. Type of analysis: LOCF. Blindness: Participants and providers blind, raters unblinded. Duration: Number of weeks of treatment - 6 weeks; length of follow-up – 104 weeks. Raters: Publication authors. Design: Single-centre (Clinical Center of the National Institute of Health, Bethesda, US) RCT. Number of people screened, excluded and reasons: Not reported. Notes about study methods: None.
Participants	Diagnosis: Schizophrenia. Diagnostic tool: K-SADS-PL, DSM-III. Inclusion criteria: • male and female, 6 to 18 years • diagnosis of schizophrenia (DSM-III) (documented psychotic symptoms by age 12 years, intolerance, non-response or both to at least 2 different neuroleptic drugs and full scale IQ>70). Exclusion criteria: • neurologic or medical disease. Total sample size: Number randomised = 21.

	Gender: 52.4% male. Age: Mean 14.1 (range not reported). Ethnicity: Not reported. Setting: Participants were identified though national recruitment via professional and patient advocacy organisations. Mean duration of disorder: 4.1 years. Mean age of onset: 10 years. Definition of inadequate response: Not reported.
Interventions	Intervention: Group 1: clozapine, mean (range) dose: 176 (25 to 125) mg/day, over 6 weeks, N = 10; Group 2: haloperidol, mean (range) dose: 16 (7-27) mg/day, over 6 weeks, N = 11. Notes about the interventions: • Starting dose of clozapine was 6.25 to 25 mg/day. And for haloperidol 0.25 to 1 mg/day depending on the weight of the participant. Doses could be increased and three to four days by one to two times the starting dose, on an individual basis. • In addition to the study antipsychotic medication, participants prophylactically received benzotropin mesylate tablets up to 6 mg/day (haloperidol group) or identical placebo tablets (clozapine group).
Extractable outcomes	Symptoms: PANSS (Positive, Negative), BPRS. Global state: CGI. Psychosocial functioning: CGAS. Leaving the study early: Leaving the study early for any reason. Side effects: AIMS, SAS, sinus tachycardia (BPM).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Yes. Providers blinded: Yes. Outcome assessors blinded: Unclear. Missing outcome data: Low. Selective outcome reporting: High. Other bias: Low.
Related publications	None.

Study ID	**KUMRA2008A**
Bibliographic reference	Kumra, S., Kranzler, H., Gerbino-Rosen, G., *et al.* (2008) Clozapine and 'high-dose' olanzapine in refractory early-onset schizophrenia: a 12-week randomized and double-blind comparison. *Biological Psychiatry*, *63*, 524-529.
General information	Funding source: Not reported, Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.

	Type of analysis: ITT (method of analysis unclear). Blindness: Participants and providers blind, rater blinding unclear. Duration: Number of weeks of treatment – 12 weeks; length of follow-up – 12 weeks. Raters: Unclear. Design: Multicentre (Bronx Children's Psychiatric Center; Sagamore Children's Psychiatric Center; Zucker-Hillside Hospital, US) RCT. Number of people screened, excluded and reasons: 248 screened, 208 excluded (ineligible: n = 191, refused to participate: n = 10; 'other': n = 7). Notes about study methods: The included population was not treatment-refractory to study medications (see eligibility criteria).
Participants	Diagnosis: Schizophrenic disorder. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • aged between 10 and 18 years • diagnosis of schizophrenia or schizoaffective disorder based on a structured interview (K-SADS-PL) • meet study criteria for treatment-refractoriness that was defined as a documented treatment failure of at least two prior adequate antipsychotic trials and a baseline BPRS total score of at least 35 and a score of at least 'moderate' on one or more psychotic item(s) on the BPRS (for example, conceptual disorganisation, suspiciousness, hallucinatory behaviour and unusual thought content). Exclusion criteria: • premorbid diagnosis of learning disabilities (IQ<70) • history of serious adverse reactions to the proposed treatments • (for females) pregnancy • serious and unstable medical condition • failed an adequate trial of clozapine (at least 12 weeks) at adequate doses (300 mg/day or higher) and/or had failed an adequate trial of olanzapine (at least 8 weeks) at high doses (20 mg/day or higher) • total sample size: Number randomised = 40. • total sample size: ITT 39 (one participant was excluded owing to withdrawal of parental consent after randomisation but before administration of first dose of study medication) Total sample size: Number randomised = 39. Gender: 53.8% male. Age: Mean 15.6 years (range not reported). Ethnicity: 20.5% white. Setting: Inpatient and outpatient (35 of 39 began treatment as inpatients). Mean duration of disorder: 3.4 years. Mean age of onset: 12.2 years.

	Definition of inadequate response: Documented treatment failure of at least two prior adequate antipsychotic trials (not including clozapine or olanzapine) and a baseline BPRS total score of at least 35 and a score of at least 'moderate' on one or more psychotic item(s) on the BPRS.
Interventions	Intervention: Group 1: clozapine, mean (range) dose: 403.1 (25 to 900) mg/day, over 12 weeks, N = 18; Group 2: olanzapine, mean (range) dose: 26.2 (5 to 30) mg/day, over 12 weeks, N = 21. Notes about the interventions: • Clozapine therapy started at a dose of 25 mg/day and could be increased in 25-mg or 50-mg increments every 3 days to a maximum dose of 900 mg/day. • Olanzapine therapy was started at a dose of 5 mg/day up and could be increased in 5-mg increments every 3 days to a maximum of 30 mg/day. • As study medications were being titrated, current medication therapies were tapered as tolerated over the first 4 weeks of the trial to allow patients to achieve a therapeutic dosage of study medications. • Patients never received less than the same dosage of antipsychotic medication (in terms of chlorpromazine equivalents) than they had at study entry.
Extractable outcomes	Symptoms: BPRS (Total, Psychotic); PANSS (Negative). Global state: CGI. Psychosocial functioning: CGAS. Leaving the study early: Leaving the study early for any reason. Side effects: BMI (kg/m^2), fasting serum glucose level (mg/dl), fasting triglycerides (mg/dl), fasting total cholesterol (mg/dl).
Quality	Sequence generation: Low. Allocation concealment: Unclear. Participants blinded: Low. Providers blinded: Low. Outcome assessors blinded: Unclear. Missing outcome data: Unclear. Selective outcome reporting: Low. Other bias: High.
Related publications	None.

Study ID	**SHAW2006**
Bibliographic reference	Shaw, P., Sporn, A., Gogtay, N., *et al.* (2006) Childhood-onset schizophrenia: a double-blind, randomized clozapine-olanzapine comparison. *Archives of General Psychiatry*, *63*, 721-730.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Individual randomised trial.

	Type of analysis: Available case (study reports LOCF). Blindness: Participants, providers and raters blind. Duration: Number of weeks of treatment - 8 weeks' double-blind plus 104 weeks' open-label following medication switch; length of follow-up - 8 weeks (plus 104 weeks following medication switch). Raters: Blind. Design: Single-centre (Bethesda, US) RCT. Number of people screened, excluded and reasons: 96 screened, 71 excluded (ineligible: n = 71; refused to participate: n = 4). Notes about study methods:None.
Participants	Diagnosis: Schizophrenia, resistant to antipsychotic medication. Diagnostic tool: K-SADS-PL, DSM-IV. Inclusion criteria: • diagnosis of schizophrenia with a definite onset of symptoms before 13 years of age • IQ > 70 • no history of progressive neurological or medical disorders such as epilepsy • failure to respond to two antipsychotic medications (typical or atypical) used at adequate doses (>100-mg chlorpromazine equivalents) and for adequate duration (>4 weeks unless terminated owing to intolerable adverse effects). Exclusion criteria: • non-response to an adequate trial of clozapine or olanzapine (an adequate trial for these medications was defined as 8 weeks of olanzapine at a dosage of 20 mg/day or of clozapine at a dosage of 200 mg/day). Total sample size: Number randomised = 25. Gender: 60% male. Age: Mean 12.3 (range 7 to 16) years. Ethnicity: 56% white. Setting: Inpatient. Mean duration of disorder: 3.2 years. Mean age of onset: 9.1 years. Definition of inadequate response: Failure to respond to two antipsychotic medications (typical or atypical, not including clozapine or olanzapine) used at adequate doses (>100-mg chlorpromazine equivalents) and for adequate duration (>4 weeks unless terminated owing to intolerable adverse effects). 'Failure' was defined as insufficient response with persistence of symptoms significantly impairing the child's functioning according to child, parental, medical and school reports or intolerable adverse effects.
Interventions	Intervention: Group 1: clozapine, mean (range) dose: 327 (12.5 to 900) mg/day, over 8 weeks, N = 12; Group 2: olanzapine, mean (range) dose: 18.1 (5 to 20) mg/day, over 8 weeks, N = 12. Notes about the interventions: • Doses were titrated from starting doses of 12.5 mg/day (clozapine) and 5 mg/day (olanzapine). Clozapine was increased

	every other day with the first increase of 12.5 mg/day and thereafter increments of 25 mg/day. When the clozapine dose reached 150 mg/day (typically day 12), olanzapine was increased to 10 mg/day. When the clozapine dose reached 300 mg/day (typically week 3) olanzapine was increased to 15 mg/day. Further increases were guided by clinical judgment to maximum doses. • After double-blind treatment, participants were offered an open trial of the second medication if non-response to the trial medication was evident.
Extractable outcomes	Symptoms: PANSS (Total, Positive, Negative); BPRS; Bunney Hamburg Psychosis Rating Scale. Global state: CGI. Leaving the study early: Leaving the study early for any reason. Side effects: Weight (kg), BMI (kg/m^2), tachycardia (BPM).
Quality	Sequence generation: Low. Allocation concealment: Low. Participants blinded: Low. Providers blinded: Low. Outcome assessors blinded: Low. Missing outcome data: Low. Selective outcome reporting: High. Other bias: High.
Related publications	None.

APPENDIX 13C (IV): INCLUDED OBSERVATIONAL STUDIES

Study ID	**AZD1441C00150**
Bibliographic reference	AstraZeneca D1441C00150 (unpublished) A 26-week, international, multicenter, open-label phase IIIb study of the safety and tolerability of quetiapine fumarate (SEROQUEL™) immediate-release tablets in daily doses of 400 mg to 800 mg in children and adolescents with bipolar I disorder and adolescents with schizophrenia. Available from: www.astrazenecaclinicaltrials.com/_mshost800325/content/clinical-trials/resources/pdf/8579486 [accessed 6 November 2012].
General information	Funding source: AstraZeneca. Published or unpublished data: Unpublished.
Method	Type of study: Open-label phase IIIb study. Type of analysis: LOCF. Blindness: None. Duration: Number of weeks of treatment - 26 weeks; length of follow-up 26 weeks Raters: N/A. Design: Multicentre (59 centres in the US and other countries) prospective cohort. Number of people screened, excluded and reasons: Of the 383 patients screened in this study, 207 patients with bipolar I disorder were previously enrolled in acute feeder Study 149, and 176 patients with schizophrenia were previously enrolled in acute feeder Study 112. Two patients with bipolar I disorder were screen 'failures' in Study 150 (one patient did not fulfil eligibility criteria [willingness to adhere to schedule of assessments] and one was not willing to continue) and one patient with schizophrenia discontinued before receiving the study drug. Thus, of 381 enrolled patients, 380 were included in the safety population (205 patients with bipolar I disorder and 175 patients with schizophrenia). Notes about study methods: Data only extracted for patients with schizophrenia.
Participants	Diagnosis: Schizophrenia: 46.1%, bipolar: 53.9%. Diagnostic tool: DSM-IV. Inclusion criteria: • provision of written informed consent by one or both parents or by legal guardian prior to any study procedure • provision of written assent by the patient prior to any study procedure • prior participation in Study 149 or Study 112 for ≥14 days • male or female, aged 13 to 17 years at randomisation of Study 112 or aged 10 to 17 years at baseline of Study 149; patients who became 18 years of age after entering Study 112 or Study 149 were permitted to enter this open-label study • if female and of childbearing potential, must have used a reliable method of contraception; reliable methods included abstinence, hormonal contraceptives (for example, oral contraceptive or long-term injectable or implantable hormonal contraceptive), double-barrier methods (for example, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices and tubal ligation

	• all female patients needed to have the absence of pregnancy confirmed by a negative serum β-human chorionic gonadotropin (β-hCG) before open-label baseline • DSM-IV criteria for schizophrenia or bipolar I disorder, confirmed by the K-SADS-PL at entry into the preceding double-blind Study 149 or Study 112 • willingness to agree not to harm self • had a parent or legal guardian accompany the patient at each scheduled study visit, who provided reliable information and was responsible for receiving and dispensing study medication • willingness to adhere to the schedule of assessments. Exclusion criteria: • DSM-IV Axis I diagnoses of schizophreniform disorder, schizoaffective disorder, psychotic disorder NOS, bipolar II disorder, bipolar disorder NOS • an interval greater than 7 days between the last double-blind study visit (open-label baseline) and Day 1 • premorbid IQ <70 or diagnosis of mental retardation. • psychosis judged to be the direct physiological consequence of a medical condition or treatment; these conditions included degenerative neurological conditions (for example, Parkinson's disease, Huntington's disease), cerebrovascular disease (for example, stroke), metabolic conditions (for example, vitamin B12 deficiency), autoimmune conditions (for example, systemic lupus erythematosus), viral or other infections (for example, hepatitis, mononucleosis, human immunodeficiency) and cancers • psychosis judged to be the direct physiological effect (for example, intoxication, withdrawal) of a misused medication or substance • history of any serious suicide attempt that required medical intervention, or current suicidal risk that could not be safely managed as determined by the clinical judgment of the investigator • serious homicidal risk or homicidal behaviour within the past 3 months that resulted in adjudication • known intolerance for or lack of response to quetiapine, as judged by the investigator • contraindications as detailed in country-specific prescribing information for quetiapine • for female patients, pregnancy or lactation • substance abuse or dependence including alcohol (except for caffeine or nicotine dependence) as defined in DSM-IV within 1 month prior to screening • use of depot antipsychotics (for example, haloperidol decanoate, fluphenazine decanoate or risperidone microspheres), within one dosing interval of the start of open-label treatment • ECT within 30 days before enrolment • use of potent cytochrome P450 (children and young people) 3A4 inhibitors (for example, ketoconazole, itraconazole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir and saquinavir) in the 14 days preceding enrolment • use of potent children and young people 3A4 inducers (for example, phenytoin, carbamazepine, barbiturates, rifampin,

	glucocorticoids, St John's wort) in the 14 days preceding enrolment • TSH concentration more than 10% above the upper limit of the normal range at open-label baseline • laboratory test results outside the reference range at open-label baseline and considered by the investigator to be clinically significant • baseline QTc interval (Fridericia formula) ≥450 milliseconds at open-label baseline • renal, cardiovascular, hepatic, hematologic, endocrinologic, ophthalmologic or other disease or clinical finding that is unstable or that in the opinion of the investigator would be negatively affected by study medication or that would affect study medication • unstable diabetes mellitus with an open-label baseline HbA1c ≥8.5 • patients admitted to a hospital for treatment of diabetes or diabetes-related illness in past 12 weeks • not under the care of a physician responsible for the patient's diabetes care • diabetes mellitus clinically unstable in the opinion of the physician responsible for the patient's diabetes management at the time of open-label baseline • the physician responsible for the patient's diabetes care had not approved the patient's participation in the study • the patient had not been on the same dose of oral hypoglycaemic drug(s) and/or diet for the 4 weeks prior to open-label baseline; for thiazolidinediones (glitazones) this period should not have been less than 8 weeks • a patient taking insulin whose daily dose on one occasion in the past 4 weeks was more than 10% above or below their mean dose in the preceding 4 weeks • if the patient's complete blood count with white blood cell count differential showed an absolute neutrophil count <1.0 x 109/L, the test was to be repeated within 24 hours; if it remained <1.0 x 109/L, the patient was to be excluded • medical condition that would affect absorption, distribution, metabolism or excretion of study medication • history of seizure disorder, except febrile convulsions • use of experimental drug outside of a quetiapine study within 30 days of enrolment • significant medical illness that could prevent patient from completing open-label treatment • previous participation in this study. Total sample size: Number randomised = 381. Gender: 60% male. Age: Mean: 14.4 (range: not reported) years. Ethnicity: 71% white. Setting: Not reported. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: Not reported.
Interventions	Intervention: Group 1: Quetiapine (mean dose 400 to 800 mg/day), over 26 weeks, N = 381 Notes about the interventions: No additional information provided by AZD1441C00150.

Extractable Outcomes	Metabolic symptoms: Weight, BMI, fasting serum glucose, total cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides. Neurological symptoms: AIMS, SAS, BARS, UKU. Hormonal symptoms: Prolactin, TSH. Cardiac symptoms: Blood pressure, QTc interval. Leaving the study early: Leaving due to any reason.
Related publications	AstraZeneca D1441C00112 (unpublished) A 6-week, international, multicenter, randomized, double-blind, parallel-group, placebo-controlled, phase IIIb study of the efficacy and safety of quetiapine fumarate (SEROQUEL™) immediate-release tablets in daily doses of 400 mg and 800 mg compared with placebo in the treatment of adolescents with schizophrenia. Available from: www.astrazenecaclinicaltrials.com/_mshost800325/content/clinical-trials/resources/pdf/8579471 [accessed 6 November 2012]).

Study ID	**CASTRO-FORNIELES2008**
Bibliographic reference	Castro-Fornieles, J., Parellada, M., Soutullo, C. A., *et al.* (2008) Antipsychotic treatment in child and adolescent first-episode psychosis: a longitudinal naturalistic approach. *Journal of Child and Adolescent Psychopharmacology*, *18*, 327-336.
General information	Funding source: Carlos III Institute of Health, Spanish Department of Health, Cooperative Research Thematic Network and from the Spanish Ministry of Health, Instituto de Salud Carlos III, CIBERSAM Network. Published or unpublished data: Published.
Method	Type of study: Naturalistic, longitudinal. Type of analysis: Available case. Blindness: None. Duration: Number of weeks of treatment - 52 weeks; length of follow-up 26 weeks. Raters: N/A. Design: Multicentre (six university hospitals, Spain) prospective cohort. Number of people screened, excluded and reasons: 116 individuals met the inclusion criteria; six were excluded, three due to 'mental retardation' and three due to parents' refusal to participate; the final sample comprised 110 children and adolescents. Notes about study methods: None.
Participants	Diagnosis: Schizophrenia type disorder: 39.1%, psychotic disorder NOS: 38.2%; depressive disorder with psychotic symptoms: 11.8%; bipolar disorder, manic episode with psychotic symptoms: 10.9%. Diagnostic tool: DSM-IV. Inclusion criteria: • age between 7 and 17 years at the time of first evaluation • presence of positive psychotic symptoms (within a psychotic episode) such as delusions or hallucinations of less than 6 months' duration. Exclusion criteria: • presence of a concomitant Axis I disorder at the time of evaluation that might account for the psychotic symptoms (such as

	substance misuse, autism, PTSD or acute stress disorder) • 'mental retardation' according to DSM-IV criteria including not only an IQ below 70 but also impaired functioning • pervasive developmental disorder • neurological disorders • history of head trauma with loss of consciousness • pregnancy • occasional substance use was not an exclusion criterion if positive symptoms persisted for more than 2 weeks after a negative urine drug test. Total sample size: Number randomised = 110. Gender: 67% male. Age: Mean 15.5 (range: 9 to 17) years. Ethnicity: 86% white. Setting: Inpatient and outpatient psychiatric units. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 51% antipsychotic naïve.
Interventions	Intervention: Group 1: olanzapine (mean dose 11.6 mg/day), over 26 weeks, N = 14; Group 2: quetiapine (mean dose 405.1 mg/day), over 26 weeks, N = 15; Group 3: risperidone (mean dose 3.3 mg/day), over 26 weeks, N = 31. Notes about the interventions: No additional information provided by CASTRO-FORNIELES2008.
Extractable Outcomes	Metabolic symptoms: Weight. Neurological symptoms: AIMS, SAS, BARS, UKU. Leaving the study early: Leaving due to any reason.
Related publications	None.

Study ID	**CROCQ2007**
Bibliographic reference	Crocq, M. A., Guillon, M. S., Bailey, P. E., *et al.* (2007) Orally disintegrating olanzapine induces less weight gain in adolescents than standard oral tablets. *European Psychiatry*, *22*, 453-454.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Open-label, non-randomised, observational. Type of analysis: Available case. Blindness: None. Duration: Number of weeks of treatment - 12 weeks; length of follow-up - 12 weeks. Raters: N/A.

	Design: Single-site (France) prospective cohort. Number of people screened, excluded and reasons: Screening information not reported; data available for 52 hospitalised adolescents. Notes about study methods: No additional information provided by CROCQ2007.
Participants	Diagnosis: Schizophreniform disorder. Diagnostic tool: DSM-IV. Inclusion criteria: Not reported. Exclusion criteria: Not reported. Total sample size: Number Randomised = 52. Gender: Not reported. Age: Mean 15.2 years (range not reported). Ethnicity: 100% white. Setting: Inpatient unit. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 75% antipsychotic naïve.
Interventions	Intervention: Group 1: olanzapine standard tablet (mean dose 18 mg/day), over 12 weeks, N = 10; Group 2: olanzapine orally disintegrating tablet (mean dose 16.6 mg/day), over 12 weeks, N = 16; Group 3: risperidone (mean dose 2.8 mg/day), over 12 weeks, N = 26. Notes about the interventions: Subjects were hospitalised during the study period. Consequently, medication compliance was verified; also, all participants took part in the same sports activities and they were served the same meals. However, the quantity of food that was eaten was not kept constant and depended on individual appetites.
Extractable outcomes	Metabolic symptoms: Weight. Leaving the study early: Leaving due to any reason.
Related publications	None.

Study ID	**DITTMANN2008**
Bibliographic reference	Dittmann, R. W., Meyer, E., Freisleder, F. J., *et al.* (2008) Effectiveness and tolerability of olanzapine in the treatment of adolescents with schizophrenia and related psychotic disorders: results from a large, prospective, open-label study. *Journal of Child and Adolescent Psychopharmacology*, *18*, 54-69.
General information	Funding source: Lilly Deutschland. Published or unpublished data: Published.
Method	Type of study: Open-label, prospective. Type of analysis: LOCF. Blindness: None.

	Duration: Number of weeks of treatment - 24 weeks; length of follow-up - 24 weeks. Raters: N/A. Design: Multicentre (ten inpatient units, Germany) prospective open-label study. Number of people screened, excluded and reasons: 100 participants signed consent forms. Of these four dropped out prior to starting olanzapine because they did not meet all inclusion and exclusion criteria after baseline examination. Notes about study methods: After a 6-week treatment period participants were assessed using the BPRS. Responders (absolute BPRS improvement >30%) continued treatment as outpatients in an open-label extension period lasting 18 weeks.
Participants	Diagnosis: Schizophrenia (84.3%), schizophreniform (9.4%), schizoaffective (6.3%). For the majority of participants (85.4%) this was their first episode. Diagnostic tool: DSM-IV. Inclusion criteria: • aged 12 to 21 years • initial BPRS total score of at least 18. Exclusion criteria: • previous participation in a study investigating olanzapine • serious unstable illnesses • uncorrected hypo- or hyperthyroidism • narrow-angle glycoma • history of seizures • agranulocytosis • jaundice • allergic reaction to study medication • substance misuse • recent pre-treatment with depot neuroleptics • taking monoamine oxidase inhibitors • taking other medications with primarily central nervous system activity • pregnant or breastfeeding. Total sample size: Number randomised = 100. Gender: 71% male. Age: Mean 15.5 (range 12 to 19) years. Ethnicity: 95% white. Setting: Inpatients during phase I (6 weeks); outpatients during phase II (18 weeks). Mean duration of disorder: Not reported. Mean age of onset: 15.5 years. Prior antipsychotic use: 38 % antipsychotic naïve.

Interventions	Intervention: Group 1: olanzapine (mean dose 14 mg/day), over 24 weeks, N = 96. Notes about the intervention: 80 participants completed the 6-week acute period; 62.5% of enrolled patients were responders at week 6 and continued treatment into the 18-week extension period.
Extractable outcomes	Metabolic symptoms: Weight. Hormonal symptoms: Prolactin. Leaving the study early: Leaving due to any reason.
Related publications	None.

Study ID	**KUMRA1998**
Bibliographic reference	Kumra, S., Jacobsen, L. K., Lenane, M., *et al.* (1998) Case series: spectrum of neuroleptic-induced movement disorders and extrapyramidal side effects in childhood-onset schizophrenia. *Journal of the American Academy of Child and Adolescent Psychiatry*, *37*, 221-227.
General information	Funding source: Not reported. Published or unpublished data: Published.
Method	Type of study: Open, controlled continuation of a 6-week double-blind RCT. Type of analysis: Available case. Blindness: None. Duration: Number weeks of treatment - unclear; length of follow-up - 104 to 208 weeks. Raters: N/A. Design: Prospective open-label. Number of people screened, excluded and reasons: Not reported. Notes about study methods: Participants recruited via professional and patient advocacy organisations.
Participants	Diagnosis: Schizophrenia – treatment resistant. Diagnostic tool: DSM-III. Inclusion criteria: • aged 6 to 18 years • psychotic symptoms documented by age 12 years • non-response to two prior typical neuroleptic treatments • IQ >70. Exclusion criteria: • significant unstable neurological or medical disorder • current serious risk of suicide • active alcohol/drug misuse. Total sample size: Number randomised = 34 Gender: 56% male.

	Age: Mean 14.15 (range not reported) years. Ethnicity: 32% white. Setting: Not reported. Mean duration of disorder: Not reported. Mean age of onset: 10.31 years. Prior antipsychotic use: 0% antipsychotic naïve – on average 22.35 months of neuroleptic exposure.
Interventions	Intervention: Group 1: clozapine (mean dose 176 mg/day), over 24 weeks, N = 10; Group 2: haloperidol (mean dose 16 mg/day), over 24 weeks, N = 11; Group 3: olanzapine (mean dose 17.5 mg/day), over 24 weeks, N = 8. Notes about the interventions: N/A
Extractable outcomes	Extrapyramidal symptoms: Tardive dyskinesia
Related publications	Kumra, S., Jacobsen, L. K. & Rapoport, J. L. (1996) Childhood-onset schizophrenia – a double-blind clozapine trial. 149th Annual Meeting of the American Psychiatric Association. New York, NY. 4 to 9 May, 1996.

Study ID	**ROSS2003**
Bibliographic reference	Ross, R. G., Novins, D., Farley, G. K., *et al.* (2003) A 1-year open-label trial of olanzapine in school-age children with schizophrenia. *Journal of Child and Adolescent Psychopharmacology*, *13*, 301–309.
General information	Funding source: Veterans' Administration Research Services; Public Health Service; Eli Lilly. Published or unpublished data: Published.
Method	Type of study: Prospective, open-label, naturalistic trial. Type of analysis: LOCF. Blindness: None. Duration: Number of weeks of treatment - 52 weeks; length of follow-up - 52 weeks. Raters: N/A. Design: Single-site (Colorado, US) prospective open-label study. Number of people screened, excluded and reasons: Not reported. Notes about study methods: No additional information provided by ROSS2003.
Participants	Diagnosis: Schizophrenia or schizoaffective disorder. Inclusion criteria: • diagnostic tool: DSM-IV • no recent exposure and preferably naïve to olanzapine treatment • chronological age 6 to 15 years, with recruitment focused on children ages 6 to 12 years • agreement by the current treating clinician that the child had either childhood-onset schizophrenia or schizoaffective disorder and that treatment with olanzapine was one of the treatment options currently being considered • lack of concurrent neurological disease (for example, seizures or tumour)

	• lack of concurrent substance misuse • lack of medical disease with which antipsychotic use might be contraindicated (for example, hepatitis). Exclusion criteria: Not reported. Total sample size: Number randomised = 20. Gender: 74% male. Age: Mean: 10.5 (range: 6 to 15) years. Ethnicity: 84% white. Setting: Not reported. Mean duration of disorder: Not reported. Mean age of onset: <13 years old. Prior antipsychotic use: 58% antipsychotic naïve.
Interventions	Intervention: Group 1: olanzapine (mean dose 7.7 mg/day), over 52 weeks, N = 20. Notes about the interventions: No additional information provided by ROSS2003.
Extractable outcomes	Metabolic symptoms: Weight, BMI. Extra pyramidal symptoms: AIMS, SAS, BARS, UKU. Leaving the study early: Leaving due to any reason.
Related publications	None.

Study ID	**SCHIMMELMANN2007**
Bibliographic reference	Schimmelmann, B. G., Mehler-Wex, C., Lambert, M., *et al.* (2007) A prospective 12-week study of quetiapine in adolescents with schizophrenia spectrum disorders. *Journal of Child and Adolescent Psychopharmacology*, *17*, 768–778.
General information	Funding source: AstraZeneca. Published or unpublished data: Published.
Method	Type of study: Prospective, longitudinal. Type of analysis: LOCF. Blindness: None. Duration: Number of weeks of treatment - 12 weeks; length of follow-up - 12 weeks. Raters: N/A. Design: Multicentre (six university and two non-university affiliated departments, Germany) open-label study. 2002–2004. Number of people screened, excluded and reasons: 61 individuals screened, five were excluded (four did not meet inclusion criteria and one refused to participate); 56 participants entered the study. Four participants discontinued in the first week, one withdrew consent and three needed impermissible medication. Therefore, 52 participants were included in the ITT analysis. Notes about study methods: No additional information provided by SCHIMMELMANN2007.
Participants	Diagnosis: 76.8% schizophrenia, 12.5% schizophreniform, 10.7% schizoaffective disorder Diagnostic tool: DSM-IV.

	Inclusion criteria: • medically healthy subjects • ages 12 to 17 years • meeting DSM-IV criteria for schizophrenia, schizoaffective or schizophreniform disorder • PANSS total score of 60 points Exclusion criteria: • Alcohol or drug dependency within 2 months before study • Clinically significant electrocardiogram, electroencephalogram or laboratory abnormalities. • Pregnant or lactating women as assessed prior to study entry • Women of childbearing potential not using an acceptable method of contraception • Concomitant medication not allowed by the protocol. Total sample size: Number randomised = 56. Gender: 68% male. Age: Mean: 15.9 years (range 12 to 17.9). Ethnicity: 84% white. Setting: 98% hospitalised. Mean duration of disorder: Not reported. Mean age of onset: Not reported. Prior antipsychotic use: 77% antipsychotic naïve.
Interventions	Intervention: Group 1: quetiapine (mean dose 594.9 mg/day), over 52 weeks, N = 56. Notes about the interventions: No additional information provided by SCHIMMELMANN2007.
Extractable outcomes	Metabolic symptoms: Weight, BMI, total cholesterol. Extra pyramidal symptoms: AIMS, SAS, BARS, UKU. Hormonal symptoms: Prolactin, TSH. Cardiac symptoms: Blood pressure. Leaving the study early: Leaving due to any reason.
Related publications	None.

EXCLUDED STUDIES

Excluded study IDs and reasons for exclusion

Study	Reason for exclusion
ABUZZAHAB1973	Adult population.
ADDINGTON2002	Adult population.
ADDINGTON2003	Design: non-RCT.
ADDINGTON2011	Adult population.
AGID2007	Adult population.
AGID2011	Design: non-RCT.
AHLFORS1990	Adult population.
AITCHISON2011	Adult population.
AKKAYA2007	Design: non-RCT.
AKHONDZADEH2002	Adult population.
AKHONDZADEH2009	Adult population.
ALACQUA2008	Design: non-RCT.
ALAPIN1967	Adult population.
ALBERT1970	Adult population.
ALFARO2002	Design: non-RCT.
ALFREDSSON1984A	Adult population.
ALFREDSSON1985	Adult population.
ALPHS2004	Design: protocol only.
ALHAMAD2005	Adult population.
ALMANDIL2011	Design: review.
ALPTEKIN2008	Design: review.
ALVAREZ-JIMENÉZ2006	Adult population.
ALVAREZ-JIMENÉZ2010	Adult population.
ANAND2010	Intervention not included in the review protocol.
ANANTH1972	Not in English.
ANDERSEN1990	Adult population.
ANDERSEN2008	Design: non-RCT.
ANDRADE2011	Design: non-RCT.
ANDREZINA2006	Adult population.
ANGELOPOULOS2002	Design: non-RCT.
ANGUS1969	Adult population.
ANTROPOV1981	Not in English.
APIQUIAN2003	Adult population.
APIQUIAN2005	Adult population.
ARANGO2003	Adult population.
ARANGO2004	Design: review.
ARATO2002	Adult population.
ARDIZZONE2010	Design: non-RCT.
ARMENTEROS1997	Design: non-RCT.
ARMENTEROS2006	Design: non-RCT.
ARRANZ2007	Design: non-RCT.
ARVANITIS1997	Adult population.
ASCHER-SVANUM2008	Design: non-RCT.
ASCHER-SVANUM2011	Intervention not included in the review protocol.
ASSION2008	Adult population.
AVNON1995	Design: non-RCT.
AWAD1997	Adult population.

AYD1972	Design: non-RCT.
AZORIN2006A	Adult population.
BACHMAN2009	Design: non-RCT.
BACHMANN2012	Design: non-RCT.
BAGADIA1980	Intervention not included in the review protocol.
BAGADIA1983	Adult population.
BAI2006	Adult population.
BALDWIN1995	Design: non-RCT.
BAN1975A	Intervention not included in the review protocol.
BAO1988	Not in English.
BARBUI1996	Adult population.
BARBUI2006	Design: non-RCT.
BARNETT2009	Design: non-RCT.
BASSON2001	Design: non-RCT.
BASU2006	Design: non-RCT.
BASU2000	Design: non-RCT.
BATPITAULT2009	Design: case study.
BATTAGLIA1997	Adult population.
BAUER1996	Design: non-RCT.
BEASLEY1996	Adult population.
BEASLEY2003	Adult population.
BEASLEY2006	Adult population.
BECKER2003	Design: non-RCT.
BEER2007	Design: non-RCT.
BEG1979	Adult population.
BEHERE2009	Outcomes not included in the review protocol.
BELLOMO1988	Not in English.
BEN AMOR2012	Design: review.
BIRKENAES2008	Design: non-RCT.
BISHOP2008	Design: non-RCT.
BISWASL2001	Design: non-RCT.
BJÖRKHEM-BERGMAN2011	Intervention not included in the review protocol.
BITTER2004	Adult population.
BOBES2003	Design: non-RCT.
BOBO2011	Adult population.
BONDOLFI1998	Adult population.
BONDOLFI2002	Adult population.
BONNOT2011	Design: non-RCT.
BONNOT2012	Adult population.
BOONSTRA2011	Adult population.
BORISON1989	Adult population.
BORISON1994	Adult population.
BORISON1996	Adult population.
BORKOWSKA2002	Adult population.
BOTER2009	Adult population.
BOULTON2008	Adult population.
BOURIN2001	Design: non-RCT.
BREIER2002	Adult population.
BREIER1994	Adult population.
BRIZER1985	Adult population.
BROERSE2002	Adult population.
BRUNNAUER2004	Design: non-RCT.
BRYDEN2001	Design: literature review.

BUCHAN1977	Intervention not included in the review protocol.
BUCHANAN2007	Adult population.
BUCHANAN1992	Design: non-RCT.
BUCKLEY1991	Design: non-RCT.
BUCKLEY2004	Design: combined analysis of three trials.
BUHAGIAR2008	Design: non-RCT.
BUSTILLO2003	Adult population.
BURKE1995	Design: non-RCT.
BURNS2001	Design: review.
BYERLY2009	Adult population.
BYRNE2010	Design: non-RCT.
CALARGE2009	Design: non-RCT.
CALARGE2010	Design: non-RCT.
CAMM2012	Design: non-RCT.
CAMPBELL1972A	Design: non-RCT.
CAMPBELL1972B	Design: non-RCT.
CAMPBELL1973	Design: non-RCT.
CAMPBELL1976	Design: non-RCT.
CAMPBELL1995	Design: non-RCT.
CAMPBELL1999	Design: non-RCT.
CANUSO2009	Adult population.
CARADOCDAVIES1987	Not relevant to review.
CARLISLE2011	Design: review.
CARLSON1999	Design: non-RCT.
CARMAN1981	Adult population.
CARPENTER1983	Adult population.
CARRIERE2000	Adult population.
CASE1971	Adult population.
CASEY2003	Adult population.
CASTILLA2002	Conference abstract.
CATTS2008	Design: non-RCT.
CAVAZZONI2004	Design: non-RCT.
CESKOVA2004	Design: non-RCT.
CHAKOS1992	Design: non-RCT.
CHANPATTANA1999	Adult population.
CHARALAMPOUS1974	Not available.
CHATTERJEE1995	Design: non-RCT.
CHEN2008	Adult population.
CHEN2010	Design: non-RCT.
CHEN2011	Design: non-RCT.
CHEN2012	Adult population.
CHENGAPPA2003A	Adult population.
CHENGSHANNON2004	Design: review.
CHIU1976	Adult population.
CHIU2006	Adult population.
CHOUINARD1988	Design: non-RCT.
CHOUINARD1989	Adult population.
CHOUINARD1990	Adult population.
CHOUINARD1994	Adult population.
CHOUINARD1998	Adult population.
CHOUINARD2007	Adult population.
CHOWDURY1999	Adult population.
CHRISTODOULIDIS1975	Adult population.

CHRZANOWSKI2006	Adult population.
CHUE2005	Adult population.
CIANCHETTI2011	Design: non-RCT.
CIESLIK1969	Not in English.
CITROME2003	Design: non-RCT.
CITROME2006	Adult population.
CIUDAD2006	Adult population.
CIUREZU1976	Not in English.
CLAGHORN1972	Not population of interest.
CLARK1971	Adult population.
CLARK1977	Adult population.
CLARK1998	Design: review.
CLARK2001	Design: non-RCT
COHEN2011	Design: non-RCT
COLDHAM2002	Design: non-RCT
COLEMAN1974	Design: non-RCT
COLEY1999	Design: non-RCT
COLONNA2000	Adult population
CONLEY2005	Adult population
CONLEY2009	Adult population
CONLON2002	Design: non-RCT
CONNOR2001	Design: non-RCT
COOPER2000	Adult population
COOPER2005	Design: non-RCT
CORDES2009	Intervention not included in the review protocol
CORNBLATT2007	Design: non-RCT
CORRELL2001	Design: non-RCT
CORRELL2007	Systematic review where no included studies are RCTs
CORRELL2008A	Design: non-RCT
CORRELL2008B	Design: review
CORRELL2009A	Conference abstract.
CORRELL2009B	Design: non-RCT.
CORRELL2010	Conference abstract.
CORRELL2011	Conference abstract.
CORRIGAN2004	Adult population.
CORSINI1981	Intervention not included in the review protocol.
CORTESE2004	Design: non-RCT.
CRESPOFACORRO2006	Adult population.
CRESPOFACORRO2007	Adult population.
CRESPOFACORRO2011A	Adult population.
CRESPOFACORRO2011B	Adult population.
CRESPOFACORRO2012	Adult population.
CROARKIN2008	Systematic review where no included studies are RCTs.
CROCQ2010	Design: non-RCT.
CUESTA2009A	Outcomes not included in the review protocol.
CURTIS2011	Design: non-RCT.
CUTLER2008	Adult population.
CZEKALLA2005	Design: non-RCT.
CZOBOR1995	Adult population.
DANIEL1998	Adult population.
DANIEL1999	Adult population.
DANIEL2007	Adult population.
DANION1999	Adult population.

DARADKEH1996	Design: non-RCT.
DASSA2010	Design: non-RCT.
DAVIDSON2009	Adult population.
DAVIS1977	Intervention not included in the review protocol.
DELUCENA2009	Adult population.
DEGIACOMO2008	Design: non-RCT.
DEHURT2006	Design: non-RCT.
DEHURT2008	Design: non-RCT.
DEHURT2010	Design: non-RCT.
DEJESUSMARI2004	Adult population.
DELASCUEVAS2004	Design: non-RCT.
DELBELLO2008	Population: 71% bipolar disorder.
DENAYER2003	Adult population.
DENBOER1990A	Adult population.
DENBOER1990B	Adult population.
DENZEL1966	Adult population.
DEO1990	Adult population.
DERISIO2011	Design: non-RCT.
DERKS2010	Adult population.
DESTA2002	Adult population.
DEURELL2008	Mixed populations and relevant data cannot be disaggregated.
DICKERSON2009	Adult population.
DITTMANN2010	Design: non-RCT.
DOCHERTY2010	Adult population.
DODD2010	Design: non-RCT.
DOEY2012	Mixed populations and relevant data cannot be disaggregated.
DOLLFUS2005	Adult population.
DONLON1980	Adult population.
DOSE1987	Adult population.
DOSSENBACH2004	Adult population.
DOSSENBACH2007	Adult population.
DOUCET2011	Population not of interest.
DUTT2010	Design: non-RCT.
DUVAL2008	Design: non-RCT.
EASTONCARTER2003	Mixed populations.
ECCLESTON1985	Adult population.
EDLINGER2009	Design: non-RCT.
EDWARDS2006	Intervention not included in the review protocol.
EERDEKENS2004	Design: non-RCT.
ELIZUR1979	Design: non-RCT.
EMSLEY1999	Adult population.
EMSLEY2000	Adult population.
EMSLEY2002	Adult population.
EMSLEY2007	Outcomes not included in the review protocol.
EMSLEY2008A	Design: non-RCT.
EMSLEY2008B	Design: non-RCT.
EMSLEY2008C	Intervention not included in the review protocol.
ENDICOTT2009	Conference abstract.
ENGELHARDT1978	Intervention not included in the review protocol.
ERANTI1998	Adult population.
ESCANDE1983	Not in English.
ESENDANACI2008	Design: non-RCT.
ESSOCK2006	Adult population.

FABRE1995	Adult population.
FAKRA2008	Adult population.
FAKRA2009	Adult population.
FALLON2011	Design: non-RCT.
FALLOON1978	Adult population.
FARETRA1970	Intervention not included in the review protocol.
FARIES2008	Adult population.
FENGJU2006	Not in English.
FERNANDEZEGEA2011	Design: non-RCT.
FERREIRA2010	Adult population.
FINDLING1996	Conference abstract.
FINDLING1998	Design: review.
FINDLING2000	Design: review.
FINDLING2002	Design: review.
FINDLING2003	Design: non-RCT.
FINDLING2005	Design: review.
FINDLING2007	Design: non-RCT.
FINDLING2008B	Design: non-RCT.
FINDLING2010A	Conference abstract.
FISH1966	Design: non-RCT.
FISH1969	Design: non-RCT.
FLANDERS2007	Design: non-RCT.
FLEISCHHACKER2003	Design: non-RCT.
FLEISCHHACKER2006	Design: non-RCT.
FLEISCHHACKER2007	Design: non-RCT.
FLEISCHHACKER2008	Design: non-RCT.
FLEISCHHACKER2009	Adult population.
FLYNN1998	Design: non-RCT.
FOLEY2011	Systematic review where RCT data cannot be disaggregated.
FOSTER1997	Adult population.
FRAGUAS2008	Design: non-RCT.
FRAGUAS2010	Design: review.
FRAGUAS2011	Design: review.
FRAZIER1994	Design: non-RCT.
FRAZIER2003	Design: non-RCT.
FRAZIER2012	Design: review.
FREEDMAN1982	Design: non-RCT.
FREEMAN1968	Not available.
FREUDENREICH2009	Adult population.
FRIBERG2009	Adult population.
FRUENSGAARD1978	Adult population.
GALLEGO2011	Outcomes not of interest.
GALLHOFER2007	Adult population.
GANGULI2008	Adult population.
GAO2007	Not in English.
GARCIA2009	Adult population.
GARZATREVINO1989	Adult population.
GASZNER2004	Design: non-RCT.
GEARING2009	Design: non-RCT.
GEBHARDT2006	Design: non-RCT.
GEBHARDT2008	Design: non-RCT.
GEBHARDT2009	Design: non-RCT.
GEORGOTAS1981	Adult population.

GERBINOROSEN2005	Design: non-RCT.
GERLACH1974	Adult population.
GERLACH1975	Adult population.
GERLACK2007	Design: non-RCT.
GERSTENZANG1977	Adult population.
GHARABAWI2006	Adult population.
GIBSON2007	Design: non-RCT.
GILBERT2000	Design: non-RCT.
GILBERT2008	Design: review.
GILCHRIST2002	Design: non-RCT.
GILLBERG2000	Design: review.
GIRGIS2011	Adult population.
GITLIN2001	Adult population.
GLAZER1994	Design: non-RCT.
GLICK2001	Design: non-RCT.
GODLESKI2003	Adult population.
GOEB2008	Design: non-RCT.
GOFF2008	Adult population.
GOGTAY2008	Design: review.
GOLDBERG1972	Adult population.
GOLDBERG1987	Adult population.
GOLDBERG2009	Outcomes not included in the review protocol.
GOLDEN2008	Adult population.
GOMEZ2000	Design: non-RCT.
GOODE1983	Adult population.
GOTHELF2003	Design: non-RCT.
GOTTFRIES1974	Adult population.
GRAHAM2008	Design: non-RCT.
GRAM1972	Intervention not included in the review protocol.
GRCEVICH1996	Design: non-RCT.
GREBB1986	Adult population.
GREENAWAY2009	Design: review.
GREENBAUM1970	Intervention not included in the review protocol.
GROOTENS2011	Adult population.
GROTHE2000	Design: non-RCT.
GROVER2011	Design: non-RCT.
GU1992	Not in English.
GUEST2010	Design: non-RCT.
GUILERA2009	Outcomes not of interest.
GUNBY1968	Adult population.
GUNDLACH1966	Intervention not included in the review protocol.
GUO2011	Design: non-RCT.
GUTTGEMANNS2011	Not in English.
HABIL2007	Design: non-RCT.
HAGG2009	Design: review.
HAIDER1985	Adult population.
HAKOLA1973	Adult population.
HALSTEAD1994	Design: non-RCT.
HAMID1973	Adult population.
HAMILL1975	Adult population.
HAMILTON1998	Adult population.
HAMMERMAN2008	Design: non-RCT.
HANDOO2010	Design: non-RCT.

HARDY2011	Adult population.
HARNRYD1984	Adult population.
HARRIGAN2004	Adult population.
HARRIS1975	Adult population.
HARRISONWOOLRYCH2007	Design: non-RCT.
HARVEY2003A	Adult population.
HARVEY2006	Adult population.
HASNAIN2008	Design: non-RCT.
HAUPT2007	Design: non-RCT.
HAW2010	Design: non-RCT.
HEBENSTREIT1991	Adult population.
HELLEWELL2007	Design: non-RCT.
HERESCOLEVY1993	Design: non-RCT.
HERTLING2003	Adult population.
HEYDEBRAND2004	Design: non-RCT
HINZESELCH2000	Adult population.
HIROSE2000	Design: non-RCT.
HIRSCH1973	Adult population.
HIRSCH2002	Adult population.
HOFER2006	Design: non-RCT.
HOGAN1992	Adult population.
HOGARTY1973	Adult population.
HOGARTY1974A	Adult population.
HOGARTY1974B	Adult population.
HOGARTY1995	Adult population.
HOLZER2011A	Design: non-RCT.
HOMEL2002	Design: non-RCT.
HOMMER1984	Adult population.
HONER1995	Adult population.
HORI2009	Design: non-RCT.
HOUGH2011	Adult population.
HRDLICKA2007	Design: non-RCT.
HRDLICKA2009	Design: non-RCT.
HRDLICKA2010	Conference abstract.
HUANG2012	Adult population.
HUFFMAN1997	Design: non-RCT.
HUGENHOLTZ2005	Design: non-RCT.
HUO2007	Not in English.
HUQ2004	Design: non-RCT.
HUTTUEN1995	Adult population.
IAGER1986	Design: non-RCT.
INGOLE2009	Design: non-RCT.
IONESCU1983	Design: non-RCT.
IBISTER2005	Systematic reviews that includes no RCTs.
ISHIGOOKA2000	Adult population.
ITIL1971A	Adult population.
JACOBSEN1994	Design: non-RCT.
JACOBSSON1974	Adult population.
JAINER2009	Design: non-RCT.
JAMES2008A	Design: review.
JAMES2008B	Design: review.
JAMES2010	Design: review.
JANICAK2009	Design: non-RCT.

JANOWSKY1973	Intervention not included in the review protocol.
JANSSEN1972	Adult population.
JEFFERSON1998	Design: non-RCT.
JENSEN2007	Design: review.
JERRELL2002	Adult population.
JERRELL2008	Design: non-RCT.
JERRELL2009	Design: non-RCT.
JERRELL2009	Design: non-RCT.
JERRELL2010A	Design: non-RCT.
JERRELL2010B	Design: non-RCT.
JIBIKI1994	Adult population.
JOHNSEN2008A	Adult population.
JOHNSEN2008B	Design: non-RCT.
JOHNSON1973	Adult population.
JOHNSON1994	Design: non-RCT.
JOHNSTONE1978	Adult population.
JOHNSTONE1988	Adult population.
JONES2006	Adult population.
JOSEPH2011	Adult population.
JUULPOVLSEN1985	Design: non-RCT.
KALEDA2000	Conference abstract.
KALYANASUNDARAM1981	Adult population.
KAMPMAN2002	Design: non-RCT.
KANE1994	Design: non-RCT.
KANE2003	Adult population.
KANE2010	Adult population.
KAPETANOVIC2006	Design: review.
KAPUR2005	Adult population.
KARIYA1983	Intervention not included in the review protocol.
KECK1998	Adult population.
KECK2001B	Adult population.
KEEFE2003	Adult population.
KEEFE2006	Adult population.
KEEFE2007	Outcomes not included in the review protocol.
KEKS1994	Adult population.
KELLY1998	Design: non-RCT.
KELLY2004	Design: non-RCT.
KELLY2010	Design: non-RCT.
KEMPERMAN2006	Design: non-RCT.
KERWIN2007	Adult population.
KHAN2009	Design: non-RCT.
KIM2002	Design: non-RCT.
KIM2008A	Adult population.
KIM2008B	Design: non-RCT.
KIM2009A	Design: non-RCT.
KIM2009B	Design: non-RCT.
KINON1993A	Adult population.
KINON2005	Design: non-RCT.
KINON2008A	Adult population.
KINON2008B	Adult population.
KIROV1997	Design: non-RCT.
KLEIN1973	Adult population.
KLEMP2011	Adult population.

KLUGE2005	Design: non-RCT.
KLUGE2007	Adult population.
KNEGTERING2008	Design: non-RCT.
KOBAYASHI2009	Design: non-RCT.
KOLIVAKIS1974	Adult population.
KONGSAKON2006	Adult population.
KOPALA2006	Design: non-RCT.
KOPONEN1991	Design: non-RCT.
KORNEGAY	Design: non-RCT.
KOWATCH1995	Design: review.
KOZLOVA2001	Not in English.
KRABBENDAM2000	Design: non-RCT.
KRAKOWSKI2011	Adult population.
KRAMER2010	Design: non-RCT.
KRANZLER2006	Design: review.
KRATOCHVIL2010	Design: review.
KREISMAN1988	Design: non-RCT.
KRYZHANOVSKAYA2009A	Design: review.
KRYZHANOVSKAYA2012	Design: non-RCT.
KUDO1972	Adult population.
KUMAR2012	Design: protocol only.
KUMRA1999	Design: non-RCT.
KUMRA2000	Design: review.
KUMRA2008A	Design: review.
KUMRA2008B	Design: non-RCT.
KUMRA2010	Conference abstract.
KUNIYOSHI1994	Design: non-RCT.
KURUVILLA1992	Adult population.
KUWILSKY2010	Intervention not included in the review protocol.
KWON2009	Design: non-RCT.
LAITA2007	Design: non-RCT.
LAMBERT1995	Adult population.
LAMBERT2005	Design: non-RCT.
LAMBERT2005	Design: non-RCT.
LAMBERT2006	Design: non-RCT.
LANE2000	Design: non-RCT.
LANE2001	Design: non-RCT.
LANE2003	Design: non-RCT.
LANE2006	Design: non-RCT.
LANE2008	Adult population.
LANG2004	Design: non-RCT.
LAPIERRE1975	Adult population.
LAPIERRE1990	Adult population.
LARMO2005	Adult population.
LASSER2004	Adult population.
LAURIELLO2005	Adult population.
LAURIELLO2008	Adult population.
LAUX1990	Adult population.
LEE1968	Adult population.
LEE2002A	Adult population.
LEE2011	Design: non-RCT.
LEFF1971	Adult population.
LEJEUNE2004	Design: non-RCT.

LEONARD2002	Design: non-RCT.
LEONG1989	Adult population.
LEPOLA1989	Adult population.
LERNER1988	Adult population.
LERNER2007	Design: non-RCT.
LEVENSON1976	Intervention not included in the review protocol.
LEVINE1997A	Adult population.
LIAO2011	Design: non-RCT.
LIEBERMAN2003B	Adult population.
LIEW2010	Design: non-RCT.
LIM2010	Adult population.
LINDENMAYER2007	Adult population.
LINDENMAYER2011	Adult population.
LINDSTROM1990	Adult population.
LINGJAERDE1987	Design: non-RCT.
LIPKOVICH2009	Design: non-RCT.
LITTRELL2001	Design: non-RCT.
LIU2010A	Conference abstract.
LIU2010B	Design: non-RCT.
LOZE2010	Conference abstract.
LUND2001	Design: non-RCT.
MAAGENSEN1999	Design: non-RCT.
MAAYAN2011	Systematic review: not all included studies RCTs (relevant studies included).
MACFADDEN2011	Design: non-RCT.
MACKAY1998	Design: non-RCT.
MADAAN2008	Design: review.
MADAAN2009	Design: review.
MALHOTRA2000	Design: non-RCT.
MALIK1980	Intervention not included in the review protocol.
MALONE1999	Design: review.
MANCHANDA1986	Adult population.
MANDOKI1995	Design: non-RCT.
MANN1987	Adult population.
MARCELLI2002	Not in English.
MARDER1994	Adult population.
MARDER1997	Adult population.
MARDER2003	Adult population.
MARJERRISON1971	Adult population.
MARSHALL2006	Systematic review: relevant studies included.
MARTIN2002	Adult population.
MARTIN2002	Adult population.
MASI2006	Design: review.
MASI2011	Design: review.
MATTAI2010	Design: review.
MAURI1994	Adult population.
MAYOR2011	Conference abstract.
MCCLELLAN2007	Protocol (TEOSS study).
MCCLELLAND1976	Adult population.
MCCLURE2009	Design: non-RCT.
MCCONVILLE2000	Design: non-RCT.
MCCONVILLE2003	Design: non-RCT.
MCCORMACK2010	Design: review.

MCEVOY1991	Adult population.
MCGLASHAN2003	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
MCGLASHAN2006	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
MCGORRY2002	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
MCINTYRE2003	Design: non-RCT.
MEGNA1999	Design: non-RCT.
MEHLERWEX2010	Design: review.
MELNIK2010	Systematic review: relevant studies included.
MELTZER2003	Adult population.
MELTZER2004	Adult population.
MELTZER2011	Adult population.
METZ1982	Design: non-RCT.
MIKKELSEN1982	Design: review.
MILLER2007	Adult population.
MIN1993	Adult population.
MIR2008	Design: non-RCT.
MOLDAVSKY1998	Design: non-RCT.
MOLLER2001	Design: review.
MOLLER2004	Adult population.
MOLLER2008A	Adult population.
MOLLER2008B	Adult population.
MONTEJO2008	Design: non-RCT.
MORRATO2008	Design: non-RCT.
MORTIMER2004	Adult population.
MOYANO1975	Adult population.
MOZES2003	Design: non-RCT.
MULE2008	Design: non-RCT.
MULHOLLAND2003	Adult population.
MULLEN2001	Adult population.
MULLER2002A	Adult population.
NABER2005	Adult population.
NAHUNEK1970A	Conference abstract.
NAHUNEK1970B	Not in English.
NAHUNEK1979	Adult population.
NAIR1988	Adult population.
NAKAZAWA1983	Intervention not included in the review protocol.
NEWCOMER2008	Adult population.
NISHIZONO1984	Not in English.
NOORBALA1999	Adult population.
NOURY1967	Design: non-RCT.
NUECHTERLEIN2008	Design: non-RCT.
NYILAS2010	Adult population.
OKEANE2005	Design: non-RCT.
OKUMA1989	Design: non-RCT.
OLESEN1995	Design: non-RCT.
OLLENDORF2004	Design: non-RCT.
OOSTHUIZEN2003	Design: non-RCT.
OYEWUMI1983	Adult population.

PAE2007	Adult population.
PAE2009	Adult population.
PALOSCIA2007	Design: review.
PANAGIOTOPOULOS2009	Design: non-RCT.
PANAGIOTOPOULOS2010	Design: review.
PAPROCKI1977	Adult population.
PARELLADA2010	Design: non-RCT.
PARENT1982	Not in English.
PARENT1983	Adult population.
PARSONS2009	Design: non-RCT.
PATEL2009	Design: non-RCT.
PENN2009	Adult population.
PEREZIGLESIAS2007	Adult population.
PEREZIGLESIAS2008A	Adult population.
PEREZIGLESIAS2008B	Adult population.
PEREZIGLESIAS2009	Adult population.
PERICLEOUS2010	Outcomes not included in the review protocol.
PERKINS2004A	Design: review.
PERKINS2004B	Outcomes not included in the review protocol.
PEUSKENS2004	Design: non-RCT.
PEUSKENS2010A	Adult population.
PEUSKENS2010B	Design: non-RCT.
PFLUG1990	Adult population.
PHILIPPE2005	Design: non-RCT.
PHILLIPS2007	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
PHILLIPS2009	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
POTKIN2002A	Adult population.
POTKIN2006	Adult population.
POTKIN2008	Adult population.
POTKIN2009B	Adult population.
POURCHER1995	Design: non-RCT.
POYRAZ2008	Design: non-RCT.
PRINGSHEIM2011a	Design: non-RCT.
PRINGSHEIM2011b	Systematic review: relevant studies included.
PROSELKOVA1991	Not in English.
PURDON2000	Adult population.
QUINTANA2007	Adult population.
QUITKIN1975	Adult population.
RAEDLER2004	Design: non-RCT.
RATZONI2002	Design: non-RCT.
REALMUTO1984	Intervention not included in the review protocol.
REMSCHMIDT1994	Design: non-RCT.
REN2006	Adult population.
RETTENBACHER2006	Design: non-RCT.
RETTENBACHER2007	Design: non-RCT.
REVELEY2004	Design: non-RCT.
RIEDEL2005	Adult population.
RIEDEL2007A	Adult population.
RIEDEL2007B	Adult population.
RIFKIN1976	Adult population.

ROKE2009	Design: non-RCT.
ROUILLON2005	Design: non-RCT.
RUAN2010	Design: non-RCT.
RUBIO2006	Adult population.
RUGINO2005	Design: non-RCT.
RUHRMANN2007	Adult population.
RUMMELKLUGE2012	Adult population.
SAARI2005	Design: non-RCT.
SACHDEV1995	Design: non-RCT.
SACRISTAN2001	Design: non-RCT.
SAFA2008	Adult population.
SALOKANGAS1996	Adult population.
SALVENSEN1973	Adult population.
SALYERS2001	Design: non-RCT.
SANGER1999	Design: non-RCT.
SANFORD2007	Design: review.
SANFORD2008	Design: non-RCT.
SAWAMURA2006	Design: non-RCT.
SCHENNACHWOLFF2011	Adult population.
SCHIELE1969	Intervention not included in the review protocol.
SCHIMMELMANN2005	Design: non-RCT.
SCHOEMAKER2010	Intervention not included in the review protocol.
SCHOOLER1971	Adult population.
SCHOOLER1976	Intervention not included in the review protocol.
SCHOOLER1994	Not obtainable.
SCHOOLER1997A	Adult population.
SCHOPF1994	Design: non-RCT.
SECHTER2002	Adult population.
SEIDA2012	Design: non-RCT.
SELMAN1976	Intervention not included in the review protocol.
SEVY2011	Secondary analysis.
SHAW2001	Design: non-RCT.
SHAW2004	Design: review.
SHIN2009	Intervention not included in the review protocol.
SHOLEVAR2000	Design: non-RCT.
SIKICH2001	Conference abstract.
SIKICH2008B	Design: review.
SIMEON2002	Design: non-RCT.
SIMPSON1976	Adult population.
SIMPSON2004	Adult population.
SIMPSON2008	Design: pooled analysis.
SIRIS1992	Adult population.
SIVRIOGLU2007	Design: non-RCT.
SMITH2005A	Adult population.
SPENCER1992	Fewer than 10 participants in each trial arm.
SPENCER1994	Design: review.
SPIVAK2003	Adult population.
SPOHN1977	Adult population.
SPORN2005	Design: non-RCT.
SPORN2007	Design: non-RCT.
STALLER2006	Design: non-RCT.
STAUFFER2011A	Secondary analysis.
STERLIN1970	Intervention not included in the review protocol.

STEVENS1973	Adult population.
STEVENS2005	Design: non-RCT.
STEWART2009	Design: non-RCT.
STRASSNIG2007	Design: non-RCT.
STROUP2003	Adult population.
STROUP2009	Adult population.
STROUS2006	Design: non-RCT.
STROUS2007	Adult population.
SUZUKI2011	Adult population.
SVESTKA1970	Not in English.
SVESTKA1972	Adult population.
SVESTKA1973	Adult population.
SVESTKA1974	Adult population.
SVESTKA2007	Design: non-RCT.
SWANSON1967	Intervention not included in the review protocol.
SWARTZ2008	Design: review.
SZEGEDI1999	Design: non-RCT.
TAKAHASHI1982	Intervention not included in the review protocol.
TANIGUCHI2006	Design: non-RCT.
TARRICONE2008	Design: non-RCT.
TAUSCHER-WISNIEWSKI2002	Design: non-RCT.
TAYLOR2005	Design: non-RCT.
TAYLOR2007	Design: non-RCT.
TAYLOR2008A	Adult population.
TAYLOR2009	Design: non-RCT.
THANGAVELU2006	Design: non-RCT.
THEISEN2001	Design: non-RCT.
THOMAS2006	Design: review.
TIMDAHL2007	Adult population.
TOLLEFSON1997A	Adult population.
TOREN2004	Design: review.
TOWBIN1994	Design: non-RCT.
TSCHOENER2009A	Design: non-RCT.
TSCHOENER2009B	Design: non-RCT.
UCHIDA2009	Design: non-RCT.
TURETZ1997	Design: non-RCT.
VALENCIA2004	Not in English.
VANNIMWEGEN2006	Design: non-RCT.
VAN OS2000	Design: non-RCT.
VARTIAINEN1995	Adult population.
VERMA2009	Design: non-RCT.
VERSAVEL2005	Intervention not included in the review protocol.
VERSIANI1978	Intervention not included in the review protocol.
VESER2006	Adult population.
VIANNAFILHO1975	Intervention not included in the review protocol.
VIEWEG2005	Design: review.
VILLARI2008	Adult population.
VINAR1968	Adult population.
VINAR1971	Intervention not included in the review protocol.
VORUGANTI2000	Design: non-RCT.
VUKSAN-CUSA2011	Design: non-RCT.
WADZISZ1969	Adult population.
WAHBA1981	Adult population.

WAHLBECK1999	Adult population.
WAIZER1972	Design: non-RCT.
WALTER2001	Design: review.
WANG2010	Adult population.
WEIDEN2003A	Adult population.
WEIDEN2003B	Adult population.
WEIDEN2009	Adult population.
WEISER1978	Intervention not included in the review protocol.
WEISER2000	Adult population.
WETTERLING1999	Design: non-RCT.
WIESEL1985	Not in English.
WIGMAN2010	Design: non-RCT.
WILSON1993	Adult population.
WOGGON1984	Intervention not included in the review protocol.
WOODS2002	Design: non-RCT.
WOODS2003	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
WOJCIK1991	Design: non-RCT.
WONODI2007	Design: non-RCT.
WRIGHT2001	Adult population.
WUDARSKY1999	Design: non-RCT.
XU2011	Adult population.
YASSA1986	Design: non-RCT.
YUSUFI2007	Design: non-RCT.
YILMAZ1971	Intervention not included in the review protocol.
YOUNG2004	Design: review.
YOUNIS2012	Conference abstract.
YUNG2011	Not relevant to this section. Included in 'At risk mental states for psychosis and schizophrenia in children and young people: recognition and management', Chapter 5.
ZALSMAN2003	Design: non-RCT.
ZHANG2006A	Adult population.
ZHANG2007	Adult population.
ZHONG2006	Intervention not included in the review protocol.
ZIEGENBEIN2006	Adult population.
ZIMBROFF1997	Adult population.
ZINK2009	Adult population.

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