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Antipsychotic medication for early episode schizophrenia (Review)

Bola JR, Kao D, Soydan H, Adams CE

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[Intervention Review]

Antipsychotic medication for early episode schizophrenia

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ABSTRACT

Background

Long-term treatment with antipsychotic medications in early episode schizophrenia spectrum disorders is common, but both short and long-term effects on the illness are unclear. There have been numerous suggestions that people with early episodes of schizophrenia appear to respond differently than those with multiple prior episodes. The number of episodes may moderate response to drug treatment.

Objectives

To assess the effects of antipsychotic medication treatment on people with early episode schizophrenia spectrum disorders.

Search methods

We searched the Cochrane Schizophrenia Group register (July 2007) as well as references of included studies. We contacted authors of studies for further data.

Selection criteria

Studies with a majority of first and second episode schizophrenia spectrum disorders comparing initial antipsychotic medication treatment with placebo, milieu, or psychosocial treatment.

Data collection and analysis

Working independently, we critically appraised records from 681studies, of which five studies met inclusion criteria. We calculated risk ratios (RR) and their 95% confidence intervals (CI) where possible. For continuous data, we calculated mean difference (MD). We calculated numbers needed to treat/harm (NNT/NNH) where appropriate.

Main results

Five studies (combined total n=998) met inclusion criteria. Four studies (n=724) provided leaving the study early data and results suggested that individuals treated with a typical antipsychotic medication are less likely to leave the study early than those treated with placebo (Chlorpromazine: 3 RCTs n=353, RR 0.4 CI 0.3 to 0.5, NNT 3.2, Fluphenaxine: 1 RCT n=240, RR 0.5 CI 0.3 to 0.8, NNT 5; Thioridazine: 1 RCT n=236, RR 0.44 CI 0.3 to 0.7, NNT 4.3, Trifulperazine: 1 RCT n=94, RR 0.96 CI 0.3 to 3.6). Two studies contributed data to assessment of adverse effects and present a general pattern of more frequent side effects among individuals treated with typical antipsychotic medications compared to placebo. One trial suggested a higher rehospitalisation rate for those receiving chlorpromazine compared to placebo (n=80, RR 2.29 CI 1.3 to 4.0, NNH 2.9). However, a higher attrition in the placebo group is likely to have introduced a survivor bias into this comparison. One study contributes data to a comparison of trifluoperazine to psychotherapy on long-term health in favour of the trifluoperazine group (n=92, MD 5.8 CI 1.6 to 0.0); however, data from this study are also likely to contain biases due to selection and attrition. One other study

contributes data to a comparison of typical antipsychotic medication to psychosocial treatment on six-week outcome measures of global psychopathology (n=89, MD 0.01 CI -0.6 to 0.6) and global improvement (n=89, MD -0.03 CI -0.5 to 0.4), indicating no between-group differences. On the whole, there is very little useable data in the few studies meeting inclusion criteria.

Authors' conclusions

With only a few studies meeting inclusion criteria, and with limited useable data in these studies, it is not possible to arrive at definitive conclusions. The preliminary pattern of evidence suggests that people with early episode schizophrenia treated with typical antipsychotic medications are less likely to leave the study early, but more likely to experience medication-related side effects. Data are too sparse to assess the effects of antipsychotic medication on outcomes in early episode schizophrenia.

PLAIN LANGUAGE SUMMARY

Antipsychotic medication for early episode schizophrenia

There are only a few good quality studies comparing the acute treatment of early episode schizophrenia with an antipsychotic medication compared to placebo or psychosocial treatment. It appears that initial medication treatment reduces the study attrition rates while also increasing the risk for medication-induced side effects. Data are too limited to assess the effects of initial antipsychotic medication treatment on outcomes for individuals with an early episode of schizophrenia.

BACKGROUND

In early-episode schizophrenia spectrum psychosis, clinical practice guidelines recommend intervention with conventional or atypical antipsychotic medication for at least one year (APA 2004; CPA 1998; Frances 1996; Gaebel 2005; National 2002). At the heart of this recommendation is an assumption that early antipsychotic treatment is beneficial. The overall risk-benefit balance is thought, in the short term (Kane 1993; Lehman 1998) as well as long term (Dixon 1995; Kane 1993; Lehman 1998; Wyatt 1991) to be favourable and outweighs risks of drug-induced adverse effects (Popp 1998). This is thought to be particularly true in view of the more benign adverse effect profiles of the atypical or second-generation medications.

The conclusion of a long-term benefit from immediate antipsychotic treatment in early episodes (Wyatt 1991) has several far-reaching implications, including:
a. emphasising the importance of early antipsychotic treatment in psychosis (DeQuardo 1998; Falloon 1998; Lewander 1996; Linszen 1998);
b. discouraging drug-free research on the ethical grounds of withholding a proven treatment (Kirch 1992);
c. contributing to the psychosis may be biologically toxic hypothesis (Norman 2001); and
d. stimulating interest in primary prevention through antipsychotic treatment of high-risk adolescents (Cornblatt 2001; DeGrazia 2001; McGlashan 2001; McGorry 2001; Warner 2001; Yung 1998).

An influential review on this important early treatment question incorporated many uncontrolled studies and used an unspecified analytic method (Wyatt 1991). A recent meta-analysis failed to find a long-term advantage from initial antipsychotic treatment in early episodes (Bola 2006), yet included only published studies. The Cochrane review on chlorpromazine for schizophrenia (Thornley 2006) acknowledged that there may be differences in treatment response for people in their first episode of illness, such as the lower effect observed in the first-episode, multi-site, double-blind NIMH study (Cole 1966; Schooler 1967). Thornley 2006, however, only assesses one medication. The few available early episode studies of chlorpromazine do not permit a sensitivity analysis comparing response across episodes. In evaluating relapse rates in people who have been withdrawn from medication, Gaebel 2002 found different rates of relapse across treatments when comparing people in their first episodes with those later in their illnesses (Pietzcker 1993a). This suggests that episode may moderate treatment response. A related Cochrane review, Rummel 2003, compares second generation antipsychotic medications with conventional (first-generation medications) in people in their first episode of illness. Rummel 2003 identified few relevant studies and, although outcomes such as leaving the study early did favour the newer drugs, other findings on global and mental state were not convincing.

In this review we examine the evidence on the effects of antipsychotic medications in early episode schizophrenia spectrum, which has a broader definition than simply first episode. There is a lack of evidence for any differential responsiveness to treatment when comparing people in their first episode with those in their second (Bola 1998). We therefore decided to include people in their first or second episode of psychotic illness in this review and by doing so hope to thoroughly examine the literature in relation to a pragmatic definition of early episode schizophrenia spectrum disorders.

OBJECTIVES

To assess the effects of antipsychotic medication treatment on people with early episode schizophrenia spectrum disorders.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant randomised controlled trials. (RCTs) If a trial was described as 'double blind' but implied randomisation, we included such trials in a sensitivity analysis. If their inclusion did not result in a substantive difference, they remained in the analyses. If their inclusion resulted in statistically significant differences, we did not add the data from these lower quality studies to the results of the better trials, but presented such data within a subcategory. We excluded quasi-randomised studies, such as those allocating by alternate days of the week.

Types of participants

We included people with first and second episode schizophrenia spectrum disorders. Studies needed to have more than 50% of participants with these disorders. There is no clear evidence that the different diagnostic categories included in the schizophrenia spectrum (e.g. brief reactive psychosis, schizophreniform disorder, schizophrenia, schizoaffective disorder, delusional disorder, etc.) are caused by fundamentally different processes or require different treatment approaches (Carpenter 1994).

Types of interventions

1. Antipsychotic medications

Conventional or first-generation medications or atypical, second-generation medications, any dose range.

2. Placebo

3. No treatment, milieu

4. Psychosocial interventions

Types of outcome measures

We divided outcomes into very short-term (up to twelve weeks), short-term (less than six months), medium-term (7-12 months) and long-term
(more than one year).

Primary outcomes

1. Global state

1.1 Relapse

2. Service outcomes

2.1 Hospitalisation

3. Mental state

3.1 No clinically important change in general mental state

4. Adverse effects

4.1 Clinically important general adverse effects

Secondary outcomes

1. Death - suicide or natural causes

2. Leaving the study early

3. Global state

3.1 Time to relapse

3.2 No clinically important change in global state

3.3 Not any change in global state

3.4 Average endpoint global state score

3.5 Average change in global state scores

4. Service outcomes

4.1 Time to hospitalisation

4.2 Days in hospital

4.3 Change in hospital status

5. Mental state

5.1 Not any change in general mental state

5.2 Average endpoint general mental state score

5.3 Average change in general mental state scores

5.4 No clinically important change in specific symptoms

5.5 Not any change in specific symptoms

5.6 Average endpoint specific symptom score

5.7 Average change in specific symptom scores

6. Leaving the study early

6.1 For specific reasons

6.2 For general reasons

7. General functioning

7.1 No clinically important change in general functioning

7.2 Not any change in general functioning

7.3 Average endpoint general functioning score

7.4 Average change in general functioning scores

7.5 No clinically important change in specific aspects of functioning, such as social or life skills

7.6 Not any change in specific aspects of functioning, such as social or life skills

7.7 Average endpoint specific aspects of functioning, such as social or life skills

7.8 Average change in specific aspects of functioning, such as social or life skills

8.1 No clinically important change in general behaviour

8.2 Not any change in general behaviour

8.3 Average endpoint general behaviour score

8.4 Average change in general behaviour scores

8.5 No clinically important change in specific aspects of behaviour

We searched the Cochrane Schizophrenia Group register with the phrases:

[*early* OR *prodrom* OR *first?episo* OR *second?episo* OR *primary?episo* OR *secondary?episo* in title, abstract and index terms of REFERENCE]

or [Antip* or drug*or tranquil* in interventions of STUDY]

The Schizophrenia Group's trials register is based on regular searches of BIOSIS Inside, CENTRAL, CINAHL, EMBASE, MEDLINE and PsycINFO; the hand searching of relevant journals and conference proceedings, and searches of several key grey literature sources. A full description is given in the Group's module.

1. Reference searching
We inspected references of all identified studies for further relevant studies.

2. Personal contact
We contacted the first author of each included study for information regarding unpublished trials.

Data collection and analysis

Selection of studies

JB and DK independently inspected citations from the searches and identify relevant abstracts. SH independently re-inspected a random 20% sample to ensure reliability. Where disputes arose, we acquired the full report for more detailed scrutiny. JB and DK obtained and inspected full reports of the abstracts meeting the review criteria. Again, SH re-inspected a random 20% of reports in order to ensure reliable selection. When it was not possible to resolve disagreement by discussion, we attempted to contact the authors of the study for clarification.

Data extraction and management

1. Extraction

Reviewers (JB, DK) extracted data from all included studies. In addition, to ensure reliability, HS independently extracted data from a random sample of these studies, comprising 10% of the total. Again, we discussed any disagreements, documented decisions and, if necessary, contacted authors of studies for clarification. We extracted data presented only in graphs and figures whenever possible, but included only if two reviewers independently had the same result. We attempted to contact authors through an open-ended request in order to obtain missing information or for clarification whenever necessary. If studies were multi-centre, where possible, we extracted data relevant to each component centre separately.

2. Management

2.1 Forms

We extracted data onto standard, simple forms.

2.2 Scale-derived data

We included continuous data from rating scales only if a. the psychometric properties of the measuring instrument have been described in a peer-reviewed journal (Marshall 2000); and b. the measuring instrument has not been written or modified by one of the trialists for that particular trial. Ideally the measuring

instrument should either be i. a self-report or ii. completed by an independent rater or relative (not the therapist). We realise that this is not often reported clearly, and we noted in the Description of studies if this was the case or not.

2.3 Endpoint versus change data

There are advantages of both endpoint and change data. Change data can remove a component of between person variability from the analysis. On the other hand calculation of change needs two assessments (baseline and endpoint) which can be difficult in unstable and difficult to measure conditions such as schizophrenia. We decided to primarily use endpoint data, and only use change data if the former were not available. We combined endpoint and change data in the analysis and we used mean differences (MD) rather than standardised mean differences throughout (Higgins 2009, Chapter 9.4.5.2).

2.4 Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aimed to apply the following standards to all data before inclusion: a) standard deviations and means are reported in the paper or obtainable from the authors; b) when a scale starts from the finite number zero, the standard deviation, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution (Altman 1996); c) if a scale started from a positive value (such as PANSS which can have values from 30 to 210) the calculation described above was modified to take the scale starting point into account. In these cases skew is present if 2SD>(S-S min), where S is the mean score and S min is the minimum score. Endpoint scores on scales often have a finite start and end point and these rules can be applied. When continuous data are presented on a scale that includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. Skewed data from studies of less than 200 participants were entered into additional tables rather than into an analysis. Skewed data pose less of a problem when looking at means, if the sample size is large we entered this data into syntheses.

2.5 Common measure

To facilitate comparison between trials, where relevant we converted variables that can be reported in different metrics, such as days in hospital (mean days per year, per week or per month) to a common metric (e.g. mean days per month).

2.6 Conversion of continuous to binary

Where possible, we made efforts to convert outcome measures to dichotomous data. This was done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It is generally assumed that if there is a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, Overall 1962) or the Positive and Negative Syndrome Scale (PANSS, Kay 1986), this could be considered as a clinically significant response (Leucht 2005; Leucht 2005a). If data based on these thresholds were not available, we used the primary cut-off presented by the original authors.

2.7 Direction of graphs

Where possible, we entered data in such a way that the area to the left of the line of no effect indicates a favourable outcome for typical antipsychotic training. Where keeping to this made it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'Not improved') we reported data where the left of the line indicated an unfavourable outcome. This was noted in the relevant graphs.

2.8 Summary of findings table

We used the GRADE approach to interpret findings (Schünemann 2008) and used GRADE profiler (GRADE Profiler) to import data from Review Manager 5 (Review Manager (RevMan)) to create 'Summary of findings' tables. These tables provide outcome-specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes we rated as important to patient-care and decision making. We selected the following main outcomes for inclusion in the summary of findings table:

1. Leaving the study early

2. Clinical response

Clinically significant response in global state - as defined by each of the studies

3. Service utilisation outcomes

Hospital admission, readmission

4. Adverse effects

Any important adverse event

Assessment of risk of bias in included studies

Again JB and DK worked independently to assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009) to assess trial quality. This set of criteria is based on evidence of associations between overestimate of effect and high risk of bias of the article such as sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting. If the raters disagreed, the final rating was made by consensus, with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials were provided, authors of the studies were contacted in order to obtain further information. Non-concurrence in quality assessment was reported, but if disputes arose as to which category a trial should be allocated, again, resolution was made by discussion. The level of risk of bias was noted in both the text of the review and in the Summary of findings tables.

Measures of treatment effect

1. Binary data

For binary outcomes we calculated a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive (Boissel 1999) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). For statistically significant results we had planned to calculate the number needed to treat to provide benefit/to induce harm statistic (NNTB/H), and its 95% confidence interval (CI) using Visual Rx (http://www.nntonline.net/) taking account of the event

rate in the control group. This, however, has been superseded by Summary of findings tables and calculations therein.

2. Continuous data

For continuous outcomes we estimated the mean difference (MD) between groups. We prefer not to calculate effect size measures (standardised mean difference SMD). However, if scales of very considerable similarity are used, we would have presumed there was a small difference in measurement, and we would have calculated effect size and transformed the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems. Firstly, authors often fail to account for intra-class correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992) whereby P values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997; Gulliford 1999). Where clustering is not accounted for in primary studies, we presented such data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. In subsequent versions of this review we will seek to contact first authors of studies to obtain intra-class correlation coefficients for their clustered data and to adjust for this by using accepted methods (Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, we presented these data as if from a non-cluster randomised study, but adjusted for the clustering effect. We have sought statistical advice and have been advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intra-class correlation coefficient (ICC) (Design effect=1+(m-1)*ICC) (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999). If cluster studies had been appropriately analysed taking into account intra-class correlation coefficients and relevant data documented in the report, synthesis with other studies was possible using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. It occurs if an effect (e.g. pharmacological, physiological, or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence on entry to the second phase, the participants can differ systematically from their initial state despite a wash-out phase. For the same reason cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we only used data of the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, if relevant, we presented the additional treatment arms in comparisons. If data were binary, we simply added and combined these data within the two-by-two table. If data were continuous we combined data following the formula in section 7.7.3.8 (Combining groups) of the Cochrane *Handbook*. Where the additional treatment arms were not relevant, we did not reproduce these data.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2009). We chose that, for any particular outcome, should more than 50% of data be unaccounted for, we did not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we marked such data with (*) to indicate that such a result may well be prone to bias.

2. Binary

In the case where attrition for a binary outcome is between 0% and 50% and where these data are not clearly described, we will present data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis). Those leaving the study early are all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death and adverse effects. For these outcomes we will use the rate of those who stayed in the study - in that particular arm of the trial - for those who did not. We will undertake a sensitivity analysis testing how prone the primary outcomes are to change when 'completer' data only are compared to the intention-to-treat analysis using the above assumptions.

3. Continuous

3.1 Attrition

In the case where attrition for a continuous outcome is between 0% and 50%, we reported completer-only data.

3.2 Standard deviations

If standard deviations were not reported, we tried to obtain the missing values from the authors. If not available, where there were missing measures of variance for continuous data, but an exact standard error and confidence intervals available for group means, and either P value or T value available for differences in mean, we calculated them according to the rules described in the Cochrane *Handbook* (Higgins 2009): when only the standard error (SE) is reported, standard deviations (SDs) were calculated by the formula SD=SE * square root (n). Chapters 7.7.3 and 16.1.3 of the Cochrane *Handbook* (Higgins 2009) present detailed formula for estimating SDs from P values, T or F values, confidence intervals, ranges or other statistics. If these formula did not apply, we calculated the SDs according to a validated imputation method which is based on the SDs of the other included studies (Furukawa 2006). Although some of these imputation strategies can introduce error, the alternative would be to exclude a given study's outcome and thus to lose information. We nevertheless examined the validity of the imputations in a sensitivity analysis excluding imputed values.

3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results (Leucht 2007). Therefore, where LOCF data have been used in the trial, if less than 50% of the data have been assumed, we reproduced these data and indicated that they are the product of LOCF assumptions.

Assessment of heterogeneity

1. Clinical heterogeneity

We considered all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We simply inspected all studies for clearly outlying people or situations which we had not predicted would arise. When such situations or participant groups arise, we fully discussed these.

2. Methodological heterogeneity

We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods which we had not predicted would arise. When such methodological outliers arise, we fully discussed these.

3. Statistical heterogeneity

3.1 Visual inspection

We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I^2 statistic

Heterogeneity between studies was investigated by considering the I^2 method alongside the Chi2 'p' value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance Higgins 2003. The importance of the observed value of I^2 depends on i. magnitude and direction of effects and ii. strength of evidence for heterogeneity (e.g. 'p' value from Chi^2 test, or a confidence interval for I^2). I^2 estimate greater than or equal to around 50% accompanied by a statistically significant Chi^2 statistic, was interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2009. When substantial levels of heterogeneity were found in the primary outcome, we explored reasons for heterogeneity (Subgroup analysis and investigation of heterogeneity).

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results (Egger 1997). These are described in Section 10 of the Cochrane Handbook for Systematic Reviews of Interventions Higgins 2009). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We will not use funnel plots for outcomes where there are ten or fewer studies, or where all studies are of similar sizes. In other cases, where funnel plots are possible, we will seek statistical advice in their interpretation.

Data synthesis

We understand that there is no closed argument for preference for use of fixed or random-effects models. The random-effects method incorporates an assumption that the different studies are estimating different, yet related, intervention effects. This often seems to be true to us and the random-effects model takes into account differences between studies even if there is no statistically significant heterogeneity. There is, however, a disadvantage to the random effects model. It puts added weight onto small studies which often are the most biased ones. Depending on the direction of effect these studies can either inflate or deflate the effect size. We chose the fixed effects model for all analyses. The reader is, however, able to choose to inspect the data using the random model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses - only primary outcomes

1.1 Gender

If sufficient data were available we used subgroup analyses to determine if initial antipsychotic treatment had different effects on the primary outcomes for men or women.

2. Investigation of heterogeneity

If inconsistency is high, this was reported. First, we investigated whether data had been entered correctly. Second, if data were correct, we visually inspected the graph and successively removed studies outside of the company of the rest to see if heterogeneity was restored. For this review we decided that should this occur with data contributing to the summary finding of no more than around 10% of the total weighting, we would present data. If not, we have not pooled data and have discussed issues. We know of no supporting research for this 10% cut off but are investigating use of prediction intervals as an alternative to this unsatisfactory state. When unanticipated clinical or methodological heterogeneity were obvious we simply stated hypotheses regarding these for future reviews or versions of this review. We do not anticipate undertaking analyses relating to these.

Sensitivity analysis

1. Implication of randomisation

We aimed to include trials in a sensitivity analysis if they are described in some way as to imply randomisation. For the primary outcomes we included these studies and if there was no substantive difference when the implied randomised studies were added to those with better description of randomisation, then we employed all data from these studies.

2. Assumptions for lost binary data

Where assumptions had to be made regarding people lost to follow-up (see Dealing with missing data), we compared the findings of the primary outcomes when we used our assumption compared with completer data only. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

Where assumptions had to be made regarding missing SDs data (see Dealing with missing data), we compared the findings on primary outcomes when we used our assumption compared with complete data only. We undertook a sensitivity analysis testing how prone results were to change when we compared 'completer' data only to the imputed data using the above assumption. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

3. Risk of bias

We analysed the effects of excluding trials that were judged to be at high risk of bias across one or more of the domains of randomisation (implied as randomised with no further details available): allocation concealment, blinding and outcome reporting for the meta-analysis of the primary outcome. If the

exclusion of trials at high risk of bias did not substantially alter the direction of effect or the precision of the effect estimates, then data from these trials were included in the analysis

4. Imputed values

We also undertook a sensitivity analysis to assess the effects of including data from trials where we used imputed values for ICC in calculating the design effect in cluster randomised trials.

If substantial differences were noted in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we did not pool data from the excluded trials with the other trials contributing to the outcome, but presented them separately.

RESULTS

Description of studies

For substantive descriptions of studies please see: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

We inspected 670 records provided by the Cochrane Schizophrenia Group search (July 2007) and an additional 11 records known to us or suggested by reviewers. Only five studies with a combined sample of n=998, all using typical antipsychotic medications compared to placebo or psychosocial treatment, met inclusion criteria. Data reporting is generally poor, with most studies providing no useable outcome data.

Included studies

We found five studies for inclusion (Cole 1964; May 1976; Mosher 1995; Rappaport 1978; Simon 1965) that randomised a total of 998 participants.

Cole 1964 (n=463) conducted a multi-site double-blind placebo versus chlorpromazine acute treatment trial of six weeks for people (mostly) diagnosed with first-episode acute schizophrenia sponsored by the National Institute of Mental Health in the United States. The acute trial was followed up a year later (Schooler 1967).

May 1976 (n=228) conducted an acute treatment comparison (of unspecified duration) of five treatments (psychotherapy, trifluoperazine, psychotherapy plus trifluoperazine, ECT, and milieu therapy) for people with first episode of schizophrenia deemed in the middle third of the prognostic spectrum (i.e., not remitting within an average 18-day waiting period, and deemed to not be at high risk for long-term schizophrenia). The acute treatment comparison study was followed up in successive studies up to 10 years.

Mosher 1995 (n=100) conducted a six-week randomised comparison of hospital treatment with a typical antipsychotic to milieu treatment in a supervised community residence for people with first-episode schizophrenia type psychosis.

Rappaport 1978 (n=127) conducted an randomised comparison of chlorpromazine versus placebo in the hospital for men diagnosed with first episode of schizophrenia. The length of the initial treatment period is unclear, and there was a post-discharge follow-up three years later.

Simon 1965 (n=80) conducted a 30-day acute treatment comparison of four treatments (chlorpromazine, reserpine, clinical judgement, and hospital routine) in a hospital setting for males diagnosed with schizophrenia that had no prior treatment.

1. Length of studies

Five of the studies were, in the acute treatment phase, "very short-term" with durations of 30 days to eight weeks. Two others (May 1976; Rappaport 1978) were of unclear duration. Follow-up periods ranged widely, from none (Simon 1965) to one year (Cole 1964); one to three years (Rappaport 1978); two years (Mosher 1995); and in successive studies up to 10 years (May 1976).

2. Participants

The majority of participants were adults with a first or second episode of schizophrenia-type psychosis, or (in some cases) experiencing their first hospitalisation for psychosis (e.g. Cole 1964).

3. Setting

Five of the studies were entirely based in the hospital, with one study (Mosher 1995) comparing hospital treatment with treatment in a supervised community facility. All studies were conducted in the USA.

4. Study Size

The numbers of participants were 463 (Cole 1964), 228 (May 1976), 100 (Mosher 1995), 127 (Rappaport 1978), and 80 (Simon 1965).

5. Interventions

5.1 Antipsychotics

5.1.1 Chlorpromazine

In Cole 1964, chlorpromazine dosage ranged 200 to 1600 mg/day or 50 to 400 mg/day (IM); in Rappaport 1978, the dosage was 300 to 900 mg/day; in Simon 1965 the dosage was from 200 mg/day to no maximum dose. May 1976 did not use chlorpromazine, and in Mosher 1995 the typical antipsychotics used were unspecified.

5.1.2 Fluphenazine

Used in Cole 1964, with dosages of 2 to 16 mg/day or 1 to 8 mg/day (IM).

5.1.3 Thioridazine

Used in Cole 1964, with dosages of 200 to 1600 mg/day or 50 to 400 mg/day (IM).

5.1.4 Trifluoperazine

Used in May 1976 at dosages of 10 to 120mg/day.

5.1.5 Resperine

Used in Simon 1965, dosages from 2 mg/day up to no maximum dosage.

5.2 Other therapies

5.2.1 Individual psychotherapy

Used in May 1976 - Psychotherapy for a minimum of two hours per week.

5.2.2 Individual psychotherapy plus trifluoperazine

Used in May 1976. Psychotherapy plus 10 to 40mg/day of trifuloperazine.

5.2.3 Electroconvulsive treatment (ECT)

Used in May 1976.

5.2.4 Milieu therapy

Used in May 1976. In Simon 1965 this is described as "hospital routine" treatment.

5.2.5 Hospital treatment with antipsychotic medications

Used in Mosher 1995, the type of typical antipsychotic medication and the dosages used were unspecified.

5.2.6 Non-hospital milieu treatment

Used in Mosher 1995, one group received a non-hospital milieu treatment combined with a time-limited antipsychotic postponement period of up to six weeks.

5.3 Placebo

Used in Cole 1964 and Rappaport 1978.

6. Outcomes

Data reporting in the studies was generally very poor. The studies compared a total of 13 different treatments, yet we could only analyse data for five comparisons .

6.1 Outcome scales

Scale data reporting, again was poor. The studies used 14 different scales to collect scale data but we could only use data from three scales. These are described below; reasons for excluding data from the other scales are given in the outcome sections of the Characteristics of included studies table.

6.1.1 Global outcomes

6.1.1.1 Global Rating Scale (Cole 1964; Mosher 1995)

A seven-point ordinal global rating of mental illness developed by Cole 1964 and also used by Mosher 1995

6.1.1.2 Global Improvement Scale (Cole 1964; Mosher 1995)

A seven-point ordinal rating of improvement in mental illness developed by Cole 1964 and also used by Mosher 1995.

6.1.1.3 Menninger Health-Sickness Rating Scale (MHSRS; Luborsky 1962)

One hundred point scale; higher score is better.

6.2 Missing outcomes

None of the included studies attempted to quantify death, service use, satisfaction, or quality of life. There is no evidence of any direct economic evaluation of treatments for early episode schizophrenia.

Excluded studies

1. Excluded studies

We excluded 675 of 681 studies. The primary reason for excluding studies was the lack of a non-medication treated group. Many studies compared types of medications, including some that compared conventional and atypical antipsychotic medications. It might be reasonable to address these comparisons in a subsequent version of this review. A second main reason for excluding studies is that they were medication-withdrawal, follow-up or other types of non-acute studies that address questions other than the effectiveness of initial treatment for early episode schizophrenia psychoses.

2. Awaiting Assessment

We are still seeking unpublished data for one study that appears to meet inclusion criteria for this review (Johnstone 1988).

3. Ongoing studies

One study in Melbourne (Francey 2010) is currently recruiting participants into an RCT of psychosocial treatment (Cognitive Behavioural Therapy plus Family Psycho-education) in both groups, and either placebo or low-dose antipsychotic medication for people with an acute first episode of psychosis.

Risk of bias in included studies

We used the tool for assessment of bias described in the Cochrane *Handbook* (Higgins 2009). The quality of randomisation in the studies is generally unclear. Several studies report higher rates of attrition in the non-medicated groups, with the potential for survivor bias. One study (May 1976) intentionally selected a "middle-third" of first-episode patients, but did not report operational selection criteria.

For overall view of risk of bias, see Figure 1 and Figure 2.

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

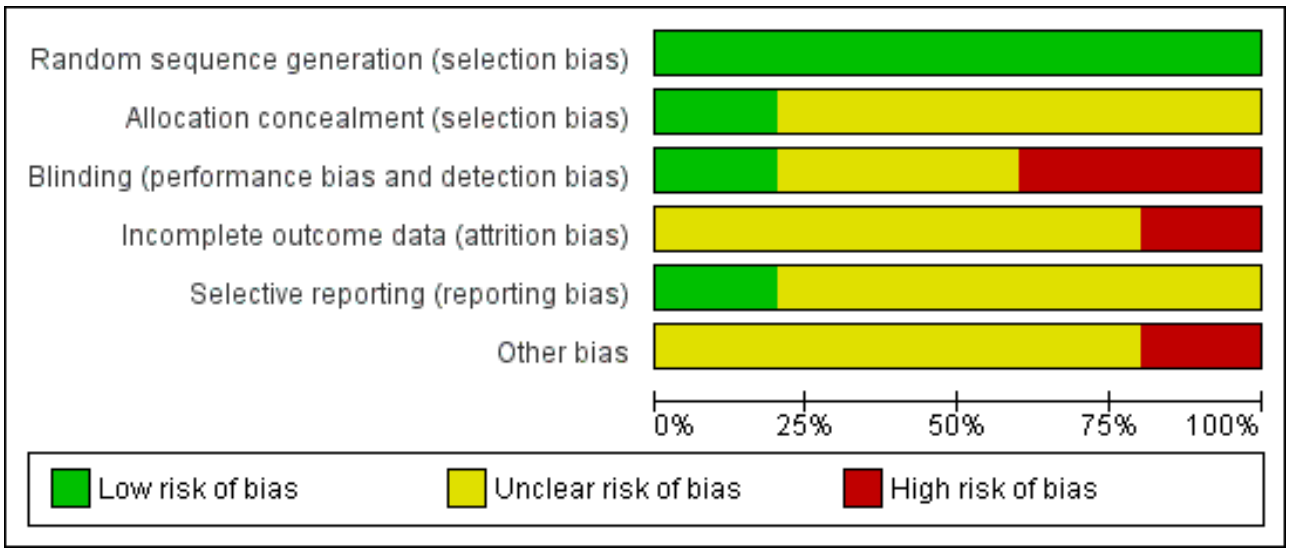
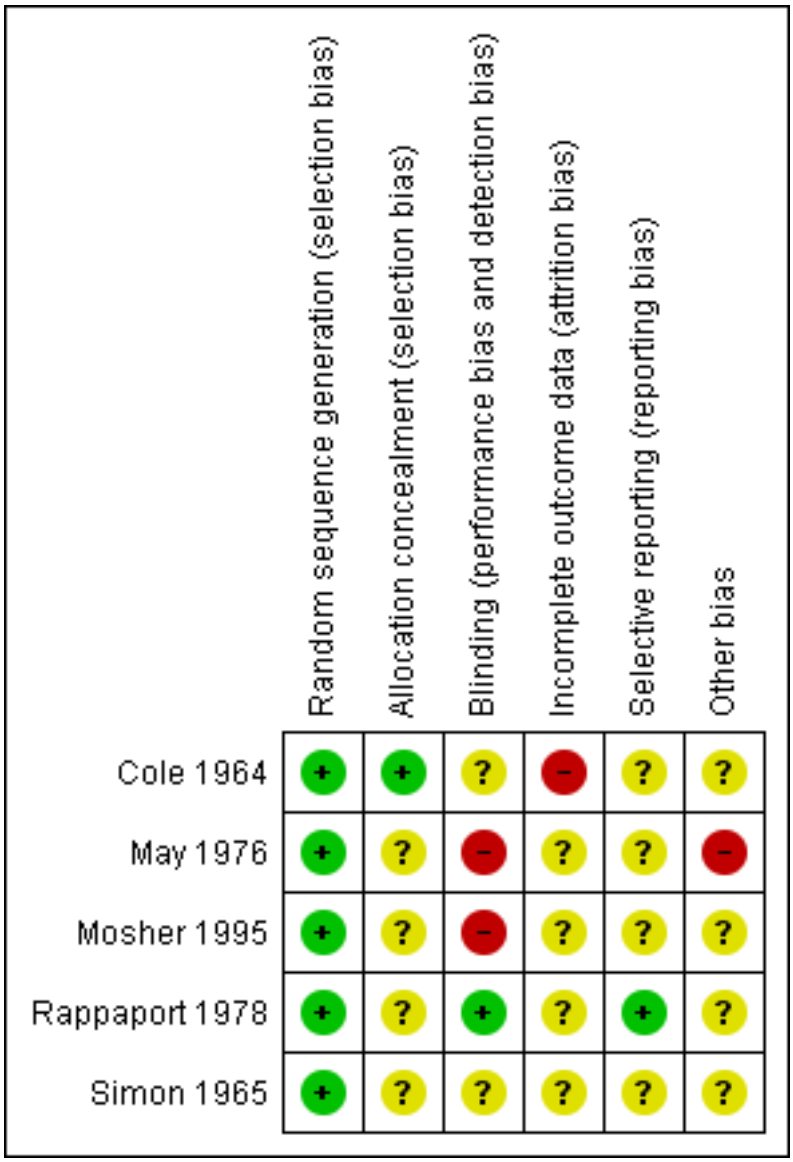


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Each included study indicated that allocation to treatment was made by random assignment.

Blinding

Two studies reported double blinding (Cole 1964), two reported single blinding (May 1976; Rappaport 1978), one was an open study with treatments at different sites (Mosher 1995), and there are no details on blinding reported from one study (Simon 1965).

Incomplete outcome data

May 1976 did not report attrition, but successive follow-up studies have diminishing sample sizes. Mosher 1995 reports six-week outcomes for subjects completing different minimum durations of treatment (seven days in the hospital versus 28 days in the community milieu treatment). Rappaport 1978 reported differential attrition by treatment group and suggested it as a possible bias regarding treatment differences. One study (Simon 1965) did not provide attrition information.

Selective reporting

There are few details on selective reporting, aside from the differential attrition acknowledged in Rappaport 1978.

Other potential sources of bias

The May 1976 study selected first-episode subjects judged to be in the "middle third" of the prognostic spectrum, but did not provide operational criteria for this selection that could be used in a replication. Generalisability of results from this study is therefore limited.

Effects of interventions

We found only five very short-term trials that used a total of 15 different treatments. Several studies had follow-ups of varying

lengths. Data were not available for all outcomes, as reporting was generally poor.

1. Comparison 1: Chlorpromazine versus placebo

1.1 Leaving the study early

Three studies (Cole 1964; Rappaport 1978; Simon 1965) provided data indicating those in the placebo groups were significantly more likely to leave the study early (3 RCTs, n=353, RR 0.40 CI 0.29 to 0.54, NNT 3.2 CI 2.5 to 4.55) (Analysis 1.1).

1.2 Global state: not improved after eight years

One study (Simon 1965) (n=40) contributed data to an assessment of improvement versus non-improvement that does not find a significant between group difference in rates of improvement (1 RCT, n=40, RR 0.76 CI 0.53 to 1.11, NNT 5 CI 2.17 to 16.67) (Analysis 1.2).

1.3 Rehospitalisation within three years - completer

One study (Rappaport 1978) (n=80) indicated a higher rehospitalisation rate for chlorpromazine treated completing patients compared to placebo (1 RCT, n=80, RR 2.29 CI 1.31 to 4.03, NNT 2.9 CI 1.82 to 7.14) (Analysis 1.3).

1.4 Rehospitalisation within three years - intent to treat

Due to higher attrition in the placebo group in Rappaport 1978, we conducted a sensitivity analysis on an intent-to-treat basis, which remains statistically significant (1 RCT, n=127, RR 3.05 CI 1.64 to 5.67, NNT 3.33 CI 2.17 to 6.67), indicating that placebo treated subjects had lower rehospitalisation rates (Analysis 1.4).

1.5 Adverse effects: various outcomes

Only one study (Cole 1964) (n=162) contributed data to an assessment of side effects and presents a pattern of more frequent side effects among individuals treated with chlorpromazine compared to placebo. Five of 13 adverse effect measures were statistically significant, each in the direction indicating more adverse effects associated with chlorpromazine treatment compared to placebo (Summary of findings table 1; Analysis 1.5).

1.5.1 Drowsiness

Individuals treated with chlorpromazine were more likely to experience drowsiness (1 RCT, n=162, RR 5.65 CI 2.72 to 11.73, NNT2.27 CI 1.79 to 3.13).

1.5.2 Restlessness

Data were equivocal for restlessness (1 RCT, n=162, RR 1.19 CI 0.83 to 1.71).

1.5.3 Constipation

Individuals treated with chlorpromazine were more likely to experience constipation (1 RCT, n=162, RR 2.71, CI 1.37 to 5.35, NNT4.76 CI 3.03 to 12.5).

1.5.3 Nausea or upper gastrointestinal distress

Individuals treated with chlorpromazine were more likely to experience nausea or upper gastrointestinal distress (1 RCT, n=162, RR 6.17 CI 1.92 to19.79, NNT 4.76, CI 3.23 to 9.09).

1.5.5 Dryness of mouth or throat

Individuals treated with chlorpromazine were more likely to experience dryness of mouth or throat (1 RCT, n=162, RR 4.63 CI 1.67 to12.82, NNT 5.0 CI 3.3 to 11.11).

1.5.6 Dizziness, faintness, or weakness

Individuals treated with chlorpromazine were more likely to experience dizziness, faintness or weakness (1 RCT, n=162, RR 4.41 CI 1.59 to 12.29, NNT 5.56 CI 3.45 to 12.5).

2. Comparison 2: Fluphenazine versus placebo

Only one study (Cole 1964) compared fluphenazine with placebo

2.1 Leaving the study early

Those treated with placebo were more likely to leave early (1 RCT, n=240, RR 0.51 CI 0.34 to 0.77, NNT 5 CI 3.23 to 11.11) (Analysis 2.1).

2.2 Adverse effects: various outcomes

Data indicated a pattern of fewer side effects in the placebo group (n=74). We present six of 13 adverse effect measures that were statistically significant, each in the direction indicating more adverse effects associated with fluphenazine treatment compared to placebo (Analysis 2.2). The other results were equivocal with no significant differences between treatment groups.

2.2.1 Drowsiness

Individuals treated with fluphenazine were more likely to experience drowsiness (1 RCT, n=165, RR 4.07 CI 1.12 to 4.54, NNT 3.45 CI 2.44 to 5.88).

2.2.3 Constipation

Individuals treated with fluphenazine were more likely to experience constipation (1 RCT, n=165, RR 2.26 CI 1.12 to 4.54, NNT 6.67 CI 3.7 to 33.3).

2.2.5 Dryness of mouth or throat

Individuals treated with fluphenazine were more likely to experience dryness of mouth or throat (1 RCT, n=165, RR 3.46 CI 1.22 to 9.83, NNT 7.69 CI 4.35 to 25.0).

2.2.7 Muscle rigidity

Individuals treated with fluphenazine were more likely to experience muscle rigidity (1 RCT, n=165, RR 2.98 CI 1.28 to 6.97, NNT 6.25 CI 3.7 to 20.0).

2.2.12 Loss of associated movements

Individuals treated with fluphenazine were more likely to experience loss of associated movements (1 RCT, n=165, RR 7.32 CI 1.75 to 30.53, NNT5.88 CI 3.85 to 12.5).

2.2.13 Akathesis - restlessness of feet

Individuals treated with fluphenazine were more likely to experience akathesis (1 RCT, n=165, RR 3.52 CI 1.04 to 11.90, NNT10.0 CI 5.26 to 50.0).

3. Comparison 3: Thioridazine versus placebo

Again, Cole 1964 was the only study to provide data for this comparison

3.1 Leaving the study early

Data suggested that those treated with placebo were more likely to leave early (1 RCT, n=240, RR 0.44 CI 0.28 to 0.69, NNT 4.3 CI 2.94 to 8.33) (Analysis 3.1).

3.2 Adverse effects: various outcomes

One study (Cole 1964) provided data suggesting more frequent side effects among those treated with thioridazine (n=165). Five of 13 adverse effect measures were statistically significant, each in the direction indicating more adverse effects associated with thioridazine treatment compared to placebo (Analysis 3.2). Only the significant results are presented below.

3.2.1 Drowsiness

Individuals treated with thioridazine were more likely to experience drowsiness (1 RCT, n=165, RR 5.46 CI 2.62 to 11.36, NNT 2.38 1.85 to 3.33).

3.2.4 Nausea or upper gastrointestinal distress

Individuals treated with thioridazine were more likely to experience nausea of upper gastrointestinal distress (1 RCT, n=165, RR 8.13 CI 2.58 to 25.59, NNT3.45 CI 2.5 to 5.56).

3.4.5 Dryness of mouth or throat

Individuals treated with thioridazine were more likely to experience dryness of mouth or throat (1 RCT, n=165, RR 5.69 CI 2.09 to 15.5, NNT4.0 CI 2.78 to 6.67).

3.4.6 Dizziness, faintness, or weakness

Individuals treated with thioridazine were more likely to experience dizziness, faintness, or weakness (1 RCT, n=165, RR 4.47 CI 1.61 to 12.41, NNT5.26 CI 3.45 to 11.11).

3.4.8 Nasal congestion

Individuals treated with thioridazine were more likely to experience nasal congestion (1 RCT, n=165, RR 3.25 CI 1.14 to 9.31, NNT 8.33 CI 4.55 to 33.3).

4. Comparison 4: Trifluoperazine versus psychotherapy

May 1976 was the only study to provide useable data for this comparison.

4.1 Leaving the study early

The data indicate no difference in the rates of leaving the study early (1 RCT, n=94, RR 0.96 CI 0.25 to 3.61) (Analysis 4.1).

4.2 Global State: overall health score - mean endpoint score Meninger Health Sickness Scale

Significantly higher endpoint scores on the Meninger Health sickness scale were found among those treated with trifluoperazine (RCT, n=92, MD 5.8 CI 1.61 to 9.99) (Analysis 4.2).

4.3 Adverse effects

More frequent side effects were found among those treated with trifluoperazine compared to psychotherapy (1 RCT, n=162, RR 5.65 CI 2.72 to 11.73, NNT 2.3 CI 1.79 to 3.13) (Analysis 4.3).

5. Comparison 5: Typical antipsychotic versus psychosocial treatment (milieu therapy)

5.1 Global state - global psychopathology scale

One study (Mosher 1995) contributed data to an assessment of global psychopathology suggesting no between group differences at six weeks (1 RCT, n=89, MD 0.01 CI -0.55 to 0.57) (Analysis 5.1).

5.2 Global state - global improvement scale

Mosher 1995 contributed data to an assessment of global improvement in psychopathology suggesting no between group differences at six weeks (1 RCT, n=89, MD -0.03 CI -0.49 to0.43) (Analysis 5.2).

DISCUSSION

The searches

The Cochrane Schizophrenia Group provided search results that included records from 670 studies. An additional 11 studies were either known to us or suggested by reviewers. Although antipsychotic treatment of acute early episode schizophrenia psychoses is uniformly recommended around the world in published clinical practice guidelines (Gaebel 2005b), we found only five studies meeting inclusion criteria for this review. It is possible that we have failed to identify all relevant studies. We have as yet been unsuccessful in gaining access to unpublished data from one study (Johnstone 1988), thus we have not included these data in the review.

Summary of main results

We found only five very short-term trials that used a total of 15 different treatments. Data reporting was generally very poor. Data were not available for all outcomes, and we could only analyse four outcomes, global state, rehospitalisation, adverse effects and leaving the study early.

With only a few studies meeting inclusion criteria and with limited useable data in these studies, it is not possible to arrive at definitive conclusions. The data suggest that early episode patients treated with typical antipsychotic medications are less likely to leave the study early and more likely to experience medication-related side effects. Data are too sparse to assess the effects of antipsychotic medication on outcomes in early episode schizophrenia.

1. Global outcomes

1.1 Global state

One study Mosher 1995 contributed data to a comparison of typical antipsychotic medication to psychosocial treatment on six-week outcome measures of global psychopathology (1 RCT, n=89, MD 0.01 CI -0.6, 0.6) and global improvement (1 RCT, n=89, MD -0.03 CI -0.5, 0.4), indicating no between-group differences (Analysis 5.1). This same study did not find between-group differences on the six-week measurement of improvement in psychopathology (1 RCT, n=89, MD -0.03 CI -0.49 to 0.43) (Analysis 5.2). One study (May 1976) contributed data to a two-year post-discharge comparison of global state using the Menninger Health-Sickness Scale Luborsky 1962 finding that trifluoperazine-treated individuals had higher mean scores than psychotherapy treated individuals (1 RCT, n=92, MD 5.8 CI 1.61 to 9.99) (Analysis 4.2). However, data from this study contain both selection and attrition biases.

One study (Simon 1965) contributed data to an eight-year post-discharge comparison of chlorpromazine versus placebo on a dichotomised rating scale (improved or not improved) that did not find a significant between group difference (1 RCT, n=40, RR 0.76 CI 0.53 to 1.11, NNT 5 CI 2.17 to 16.67) (Analysis 1.2).

1.2. Rehospitalisation

One study (Rappaport 1978) (n=80) suggested a higher rehospitalisation rate after two years for chlorpromazine treated completing participants compared to placebo (1 RCT, n=80, RR 2.29 CI 1.31 to 4.03, NNT 2.9 CI: 1.82 to 7.14) (Analysis 1.3). Due to higher attrition in the placebo group in Rappaport 1978, we conducted a sensitivity analysis on an intent-to-treat basis, which remains statistically significant (1 RCT, n=127, RR 2.30 CI 1.50 to 3.54, NNT 3.33 CI 2.17 to 6.67) (Analysis 1.4). This is similar to the finding of lower rehospitalisation in the placebo treated group at the one-year follow-up to Cole 1964 reported in Schooler 1967. However the Schooler 1967 paper does not quantify the differences in rehospitalisation and the original data appear to have been lost.

1.3. Adverse effects

Two studies (Cole 1964; May 1976; n=506) contributed data to an assessment of adverse effects and present a general pattern of more frequent adverse effects among individuals treated with typical antipsychotic medications compared to placebo.

2.4. Leaving the study early

Four studies (Cole 1964; May 1976; Rappaport 1978; Simon 1965; n=724) contributed data to an assessment of the likelihood of leaving the study early, suggesting that individuals treated with a typical antipsychotic medication are less likely to leave the study early than those treated with placebo (Analysis 1.1; Analysis 2.1; Analysis 3.1 Analysis 4.1).

The preliminary pattern from the limited quantity of available evidence suggests that early episode participants treated with typical antipsychotic medications are less likely to leave the study early and more likely to experience medication-related adverse effects. Data are too sparse to assess the effects of antipsychotic medication on outcomes in early episode schizophrenia.

Overall completeness and applicability of evidence

A majority of participants (n=998) in the five included studies had an early (first or second) episode of schizophrenia-type psychosis or a first hospitalisation for psychosis. The acute treatment phase in each study was very short-term (30 days to eight weeks) and follow-up periods ranged from no follow-up to 10 years. Available data were severely limited by the limited number of studies and by poor data reporting.

Quality of the evidence

We included five trials (n=998). The methodological quality of these studies was judged to be poor to fair and data reporting was generally poor.

Potential biases in the review process

We endeavoured to avoid publication bias; however, it is possible that all relevant studies have not yet been discovered. This review found five studies, each with methodological problems, and most with inadequate data reporting. Selection bias was apparent in one study (May 1976) and attrition was significant in at least two studies (May 1976; Rappaport 1978). This review found very few studies, and available evidence does not support a conclusion that antipsychotic treatment in an acute early episode of schizophrenia is effective. This does not mean that antipsychotic treatment is not effective, only that evidence is not available to adequately evaluate its effectiveness. This is of particular concern given the widespread use of antipsychotic medications around the world in the acute treatment of early episode schizophrenia-type psychoses (Gaebel 2005b).

Agreements and disagreements with other studies or reviews

Many reviews examine the effectiveness of first-generation antipsychotic medications (FGAs; e.g., chlorpromazine, Adams 2007; fluphenazine, Matar 2007, 2007; haloperidol, Irving 2006a; perphenazine, Hartung 2005; trifluoperazine, Marques 2004) or second-generation antipsychotics (SGAs; e.g., amisulpride, Silveira da Mota Neto 2002; aripiprazole, El-Sayeh 2006; olanzapine, Duggan 2005; risperidone, Rattehalli 2010) for schizophrenia. One review compares the two FGAs haloperidol and chlorpromazine (Leucht 2008). Two reviews compare the SGAs ziprasidone (Komossa 2009) or zotepine (Komossa 2010) to other SGAs. There are reviews of ayurvedic medicine (Agarwal 2007), Chinese herbal medicine (Rathbone 2005), and Omega-3 fatty acid supplementation (Irving 2006b) for schizophrenia.

In each of these reviews, individuals at different stages of illness are grouped together, allowing an overall estimate of effectiveness (data permitting) that is not specific to stage of illness. To the best of our knowledge, the present review is the only effort to estimate the effectiveness of antipsychotic medications in early episode schizophrenia-spectrum disorder, in which a majority of treated individuals are experiencing a first or second acute episode.

AUTHORS' CONCLUSIONS

Implications for practice

Clinical practice guidelines for treating early episodes of schizophrenia psychoses uniformly advise treatment with antipsychotic medications for six to 24 months (Gaebel 2005b). Evidence supporting this guideline is very limited. A more cautious approach to medication use in early episodes might be advisable while additional research is conducted.

Implications for research

1. General

Trials in this review preceded the international review of schizophrenia practice guidelines (Gaebel 2005b) uniformly recommending treatment with an antipsychotic medication in early episodes. Clear reporting of outcomes would certainly have resulted in this review being more informative.

2. Specific

The effectiveness of antipsychotic medications in early episode schizophrenia is under-researched and current evidence is inadequate to support international practice guideline recommendations. Even though antipsychotic medications have been used for decades, there are only a small number of randomised, placebo-controlled trials measuring the efficacy

of these medications for people with an early episode of schizophrenia. The use of antipsychotic medications for millions of people with an early episode appears based on the evidence for those with multiple previous episodes (e.g. Thornley 2006). It is possible that early episode schizophrenia includes a higher proportion of people with a relatively better prognosis and potentially different response to treatment. Undertaking placebo-controlled trials for people with schizophrenia is problematic and many would disagree as to whether such a study was ethical (Fleischhacker 2003). There is however, some evidence that carefully conducted short-term placebo controlled trials can be conducted safely and without long-term harm to those later found to need medications (Bola 2006; Johnstone 1999). We feel that one or more large, well-planned, conducted and reported randomised, placebo-controlled trials is indicated. Preliminary evidence also suggests a possible benefit from an active therapeutic milieu or other psychosocial intervention (Bola 2006) that might be considered in a three- or four-arm study. Concrete and simple outcomes are of interest such as clearly reporting improvement, 'hospital admission' 'days in hospital' or even 'healthy days'. In addition, future trials need to report not only those clinically useful data but also information relating to cost effectiveness, employment, family burden, and satisfaction with care which are currently lacking. Any data on adverse effects, including those of medium- or long-term, would be most welcome. Most of these outcomes do not necessitate the use of scales as outcome measures.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cole 1964

Methods	Allocation: randomised (individually numbered containers of medicines). Blindness: double-blind. Duration: 6 weeks. Setting: multi-centre.
Participants	Diagnosis:DSM schizophrenia (50% first episode). N=463. Age: 16-45 years, mean ˜ 28 years. Sex: male and female (proportions not given). History: acute, 60% first hospitalisation, no significant hospitalisation 12 months prior to current admission.
Interventions	1. Chlorpromazine: dose range 200-1200 mg/day. N=112. 2. Fluphenazine: dose range 2-16 mg/day. N=115. 3. Thioridazine: dose range 200-1600 mg/day. n=111. 4. Placebo. 2-16 doses. N=125.

Cole 1964 *(Continued)*

	Plus antiparkinsonian medication as needed for extrapyramidal side effects.
Outcomes	Leaving the study early. Adverse effects. Unable to use. Global state: Global rating of severity of illness, improved/not improved -no usable data. Inpatient Multidimensional Psychiatric Scale (IMPS) - no usable data. Ward Behaviour Rating Scale (WBRS) - no usable data.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised - no further details.
Allocation concealment (selection bias)	Low risk	Individually numbered containers of medicines.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Double blind, untested.
Incomplete outcome data (attrition bias) All outcomes	High risk	Study attrition reported (not addressed in analysis).
Selective reporting (reporting bias)	Unclear risk	No details.
Other bias	Unclear risk	No details.

May 1976

Methods	Allocation: random, no further details. Blinding: single. Duration: until discharge or 6-12 months. Post-discharge follow up to 5 years.
Participants	Diagnosis: schizophrenia (clinical consensus); selected 'middle third of prognostic spectrum' (selection criteria unspecified). N=228. Age: range 16-45 years. Sex: male and female. History: first admission, 'middle prognostic range', not remitted with average 14 day observation period. Excluded: people who were assessed as unlikely to be discharged within 2 years, and those whose illness went into remission during 14 day average assessment period.
Interventions	1. Individual psychotherapy. N=46. 2. Ataraxic drugs (trifluoperazine). N=48.

May 1976 *(Continued)*

	3. Individual psychotherapy and ataraxic drugs. N=44. 4. ECT. N=47. 5. Milieu therapy and ataraxic drugs. N=43.
Outcomes	Leaving the study early Menninger Health-Sickness Rating Scale (HSRS).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised, no further details.
Allocation concealment (selection bias)	Unclear risk	No further details.
Blinding (performance bias and detection bias) All outcomes	High risk	Open study.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study attrition not reported. Successive follow-up studies have diminishing sample size.
Selective reporting (reporting bias)	Unclear risk	No details.
Other bias	High risk	Participants not representative of the whole range of “early episode psychosis”. Two-thirds of first-episode patients were excluded by trialists with the criteria used to select the "middle third of prognostic spectrum" not specified. Quote: “patients were excluded if there seemed little chance of their leaving the hospital within two years or if the illness was already remitting during the initial evaluation period (average, 18 days)” (p. 474).

Mosher 1995

Methods	Allocation: random. Blinding: single (evaluators presumed to be blind, however groups were treated at different facilities). Duration: 6 weeks, with follow-up to two years.
Participants	Diagnosis: DSM-II schizophrenia, "in need of hospitalisation". N=100. History: No more than one prior hospitalisation (51% first-episode). Sex: 80 M, 20 F. Age: range 18-30 yrs.
Interventions	1. Hospital treatment with antipsychotic medications (100% received antipsychotic medications, 98% continuously), n=55.

Mosher 1995 *(Continued)*

	2. Non-hospital milieu treatment + postponement of antipsychotic medications for a maximum of 6 weeks (67% received no antipsychotics, 31% > 7 days of antipsychotic treatment, 12% continuous antipsychotic treatment), n=45.
Outcomes	Global Rating: Severity of Mental Illness (7-point scale). Global Rating of Improvement (7-point scale).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Reported as "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	High risk	Treated at different sites.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data reported for patients receiving minimum duration of treatments (7+ days of hospital treatment or 28+ days of therapeutic milieu).
Selective reporting (reporting bias)	Unclear risk	No details.
Other bias	Unclear risk	No details.

Rappaport 1978

Methods	Allocation: randomly assigned (no further description). Blinding: single, staff 'remained blind as to whether the patient was receiving medication or placebo'. Duration: unclear; mean hospitalisation=43 days, follow-up at 1-36 months after discharge.
Participants	Diagnosis: schizophrenia (criteria not specified). N=127. Sex: all male. Age: range 16-40 yrs. History: 'acute' illness.
Interventions	1. Chlorpromazine: dose variable 300-900 mg/day. N=53. 2. Placebo. N=74.
Outcomes	Leaving study early. Rehospitalisation. Unable to use. Clinical Change Index and Global Assessment Scores (data skewed).
Notes	

Rappaport 1978 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned (no further description).
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	Low risk	Reported that "staff remain blind to whether the patient was receiving medication or placebo".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details.
Selective reporting (reporting bias)	Low risk	Differential attrition reported by authors.
Other bias	Unclear risk	No further details.

Simon 1965

Methods	Allocation: random. Blinding: unclear. Duration: 30 days. Setting: hospital.
Participants	Diagnosis: DSM-I schizophrenia (no further details), no prior treatment for schizophrenia, an average of 32.7 days treatment prior to evaluation for this study. N=80. Age: average ~ 31 years. Sex: all male.
Interventions	1. Chlorpromazine: dose minimum 200 mg/day, maximum 1200 mg/day, average 400mg/day. n=20. 2. Hospital routine care (occupational and manual arts therapy, special services activities). N=20 3. Reserpine: dose minimum 2 mg/day, maximum 16 mg/da, average 6 mg/day. N=20. 4. Clinical judgement. N=20.
Outcomes	Leaving the study early. Not improved (Psychiatric improvement rating scale). Unable to use. Behaviour rating scale - no usable data. Minnesota Multiphasic Personality Iinventory (MMPI) - no usable data.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Simon 1965 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomised - no further details.
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No details.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details.
Selective reporting (reporting bias)	Unclear risk	No details.
Other bias	Unclear risk	No details.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
ACE 2003	Allocation: randomised Participants: people with first episode schizophrenia Interventions: CBT + medications vs befriending + medications (no un-medicated group)
Adson 2003	Allocation: randomised Participants: people with schizophrenia (unknown proportion of first and second episode participants)
Aguilar 1994	Allocation: randomised Participants: people with first episode psychosis Interventions: haloperidol + biperiden vs. haloperidol + placebo (no un-medicated group)
Ahmed 1997	Allocation: unknown method of assignment to treatment Participants: people with first episode psychosis Interventions: haloperidol vs. risperidone (no un-medicated group)
Alaghband-rad 2006a	Allocation: randomised Participants: people with first episode psychosis Interventions: treatment as usual + standard telephone follow-up vs. treatment as usual + home visit groups (both groups received standard or low dose medications)
Allison 2001	Allocation: randomised Participants: people with psychosis Interventions: Clozapine, Haloperidol, Olanzapine, Risperidone or Placebos (unknown proportion of first and second episodes)

Study	Reason for exclusion
Altamura 1985	Allocation: randomised Participants: people with schizophrenia (n=7) Interventions: fluphenazine (unknown proportion of early episodes; no un-medicated group)
Altamura 1999b	Allocation: random assignment to adjunctive antidepressant medication Participants: people (n=76) with diagnosis of schizophrenia or schizoaffective disorder and with a concomitant major depressive disorder Interventions: atypical antipsychotic drugs (AAD) vs. haloperidol decanoate (HL-D) (not an acute schizophrenia treatment study; unknown proportion of early episodes; no un-medicated group)
Alvarez 2005	Allocation: randomised Participants: people with first episode schizophrenia Intervention: an early behavioural intervention (n=35) vs. routine care (n=27). All had been received antipsychotic treatments (risperidone n=23), olanzapine (n=18) and haloperidol (n=21) before the randomisation (no un-medicated group)
Amminger 2006	Allocation: randomised Participants: people assessed at ultra high risk for psychosis (UHR), a prodromal phase intervention study Intervention: omega-3 fatty acids + standard care vs. placebo + standard care (not acute schizophrenia treatment study)
An 2006b	Allocation: randomised Participants: people with first episode schizophrenia Intervention: olanzapine vs. quetiapine (no un-medicated group)
Anonymous 1972	Allocation: randomised Participants: people with chronic schizophrenia (n=20) Interventions: Piperacetazine vs. Thioridazine (not treatment for people in acute schizophrenia; no un-medicated group)
Apicella 2001	Allocation: unknown method of assignment to treatment Participants: people with schizophreniform disorder, between the ages of 16 and 40 years of age and who have been recently diagnoses (within the last five years) with schizophrenia, schizophreniform disorder or schizoaffective disorder. Interventions: haloperidol vs. olanzapine (unknown method of assignment to treatment; unknown proportion of first and second episodes; no un-medicated group)
Apiquian 2003	Allocation: unknown method of assignment to treatment Participants: people with first episode psychosis Interventions: haloperidol (the minimum dose) vs. olanzapine vs. risperidone (unknown method of assignment to treatment; no un-medicated group)
Appelberg 2004a	Allocation: randomised Participants: people in the clinically stable status of psychosis

Study	Reason for exclusion
	Interventions: conventional neuroleptic(s), (with a mean dose of 312 chlorpromazine equivalents) vs. olanzapine (unknown proportion of first and second episodes; no un-medicated group)
Archie 2006	Allocation: randomised Participants: people with first episode psychosis (n=547) Interventions: Integrated care (based on the Assertive Community Treatment model and delivered by a multidisciplinary team and people received social skill training or general psychoeducation as required) vs. standard care (the usual mental health services). Both integrated and standard care could include standard antipsychotic medication (no un-medicated group)
Ascher-Svanum 2006a	Allocation: randomised Participants: people with schizophrenia (n=664) Interventions: olanzapine vs. risperidone vs. typical antipsychotics (unknown proportion of first and second episodes; no un-medicated group)
Auby 2002	Allocation: randomised Participants: people with stable schizophrenia or schizoaffective disorder (mean baseline PANSS 43-64) Interventions: aripiprazole 30 mg/day (n=12) vs. 45 mg/day (n=7) vs. 60 mg/day (n=7) vs. 75 mg/day (n=7) vs. 90 mg/day (n=7) Outcomes: positive and negative symptoms, akathisia and tachycardia, adverse and side effects (not treatment for acute schizophrenia; no un-medicated group)
Awad 2006	Allocation: randomised Participants: people with first-episode schizophrenia (ICD-10) Interventions: olanzapine vs. haloperidol Outcome: psychosocial functioning and QOL (quality of life) (no un-medicated group)
Bai 2005d	Allocation: randomised Participants: people with schizophrenia Interventions: quetapine and chlorpromazine (unclear proportion of first and second episodes; no un-medicated group)
Bandelow 1992	Allocation: randomised Participants: people with schizophrenia (ICD-9). Interventions: 3 groups: continuous medication, intermittent medication with crisis intervention, intermittent medication with early intervention (unclear proportion of first and second episodes; not an acute treatment study, but a follow-up maintenance treatment study)
Barrowclough 2001b	Allocation: randomised Participants: people with recent onset of schizophrenia (within 2 years) Interventions: CBT + usual treatment vs usual treatment only (no un-medicated group; usual treatment is unspecified and group assignment is unspecified; this is not an acute treatment study)
Beasley 1996a	xxAllocation: randomised

Study	Reason for exclusion
	Participants: people with psychosis Interventions: Olanzapine vs Risperidone or Olanzapine vs. placebo (no un-medicated group; unknown proportion of early episodes)
Beasley 1997	Allocation: randomised Participants: people with schizophrenia Interventions: olanzapine and haloperidol (Unclear proportion of first and second episodes; no un-medicated group)
Bechdolf 2004a	Allocation: randomised Participants: people in the pre-psychotic prodromal period Interventions: CBT vs. antipsychotic amisulpride + clinical management vs. clinical management only (not treatment for acute episode schizophrenia)
Bechdolf 2004c	Allocation: randomised Participants: people in the pre-psychotic prodromal period Interventions: CBT vs. antipsychotic amisulpride + clinical management vs. clinical management only (not treatment for acute episode schizophrenia)
Bechdolf 2005a	Allocation: randomised Participants: people in pre-psychotic prodromal period Interventions: CBT vs. antipsychotic amisulpride + clinical management vs. clinical management only (not treatment for acute episode schizophrenia)
Bechdolf 2006	Allocation: randomised Participants: people with “subthreshhold psychosis” (5.5% in CBT gruop vs 18.3% in supportive therapy) Interventions: cognitive behavioral therapy vs supportive therapy (Not psychotic; No contrast of medication vs not medication treatment)
Bendall 2004	Allocation: randomised Participants: people with first episode psychosis. Interventions: Befriending vs CBT (No contrast of medication vs not medication treatment)
Bentall 2000	Allocation: randomised Participants: people with first and second episode schizophrenia. Interventions: Usual treatment, usual treatment + CBT, or medication + supportive counseling (No un-medicated group)
Berger 2004a	Allocation: randomised Participants: people with episode psychosis Interventions:Ethyl-eicosapentaenoic Acid (E-EPA) vs. placebo (i.e. as a supplement to antipsychotic treatment) (No un-medicated group)
Berger 2004b	Allocation: randomised

Study	Reason for exclusion
	Participants: people with episode psychosis Interventions: Ethyl-eicosapentaenoic Acid (E-EPA) vs placebo (i.e. as a supplement to antipsychotic treatment) (no un-medicated group)
Berger 2005	Allocation: randomised Participants: people with first episode psychosis Interventions: antipsychotic medications + Ethyl-eicosapentaenoic Acid vs antipsychotic medications + placebo (No un-medicated group)
Berger 2006	Allocation: randomised Participants: people assessed as having high risk for psychosis Interventions:lithium vs placebo (Persons not psychotic; No antipsychotic medication use)
Bertelsen 2004	Allocation: randomised Participants: people with first episode psychosis Interventions: Integrated treatment (standard treatment + ACT) vs standard treatment (No un-medicated group)
Bertelsen 2005	Allocation: randomised Participants: people with first episode psychosis Interventions:Integrated treatment (standard treatment + ACT) vs standard treatment (No un-medicated group)
Bertelsen 2006	Allocation: randomised Participants: people with first episode psychosis Interventions: Integrated treatment (ACT + family involvement + social skills training) vs standard treatment (No un-medicated group)
Binder 2006	Allocation: randomised Participants: people with recent onset schizophrenia (3 or less years from onset) Interventions: risperidol vs. oral olanzapine vs. oral quetiapine (Unclear proportion of first and second episodes; No un-medicated group)
Birchwood 2000a	Allocation: unclear Participants: people with multiple episodes of severe relapses. Interventions: early intervention vs psychoeducation (Not early episodes; no clear specification of medicated vs un-medicated groups)
Birchwood 2000b	Allocation: randomised Participants: people with “relapsing psychosis”. Interventions: medication vs placebo (Not first and second episodes)
Birchwood 2000c	Allocation: randomised Participants: people with schizophrenia (n=60)

Study	Reason for exclusion
	Interventions: targeted medication for 4 weeks (placebo) vs. active medication (Unclear proportion of first and second episodes; no un-medicated group; not an acute treatment study)
Blaha 1980	Allocation: Unclear Participants: People with schizophrenia (n=32) Interventions: Haloperidol at differing dosages (Unclear proportion of early episodes; No un-medicated group)
Bola 2003	Allocation: Combination of 2 cohorts, one cohort assigned to treatment with a quasi-random procedure (consecutive space available), and the second cohort randomly assigned. Participants: People with first and second episode schizophrenia (n=179) Interventions: Immediate antipsychotic medication in the hospital vs. psychosocial therapeutic milieu with up to 6 week postponement of antipsychotic treatment (Combines randomly assigned and quasi-randomly assigned cohorts)
Borison 1991b	Allocation: randomised Participants: people with chronic schizophrenia. Interventions: Risperidone vs Haloperidol vs placebo (Not first and second episodes)
Brecher 1998	Allocation: randomised Participants: people with schizophrenia, schizophrenic disorder or psychotic disorder. Interventions: Risperidone vs Olanzapine (Unclear proportion of first and second episodes; No un-medicated group)
Bredkjar 1999	Allocation: randomised Participants: people with first episode psychosis Interventions: integrated care vs standard care (No un-medicated group)
Bredkjar 2000	Allocation: randomised Participants: people with first episode psychosis Interventions: integrated care vs.standard care (No un-medicated group)
Breier 2002b	Allocation: randomised Participants: people at high-risk for psychosis, symptomatic, prodromal states. Interventions: 1 year medication (PBO or Olanzapine) followed by 1 year of no medication (persons not psychotic)
Brewer 2002	Allocation: randomised Participants: neuroleptics-naïve people with first episode psychosis Interventions: Haloperidol vs. Risperidone (No un-medicated group)
Brooker 1992	Allocation: quasi-experimental design Participants: people with recent diagnosis of schizophrenia.

Study	Reason for exclusion
	Interventions: psychosocial interventions delivered by community psychiatric nurses plus usual treatment vs usual treatment (unclear proportion of first and second episodes; No contrast of medicated vs un-medicated group)
Burns 2002b	Allocation: no treatment assignment Participants: people with first episode psychosis Interventions: Not an intervention study (looks for neuroimaging correlates of social functioning) (not an intervention study; no contrast of medicated vs. un-medicated group; unclear proportion of early episodes)
Burrell 1960	Allocation: randomised Participants: people with acute, multi-episode schizophrenia and bipolar disorder clinically assessed as “tense” Interventions: Chlorpromazine vs Hydroxyzine vs Placebos (mix of schizophrenia and bipolar cases; not early episodes)
Caffey 1968	Allocation: randomised Participants: people with "all types of acute emotional disturbances" Interventions: brief hospitalization, crisis therapy, and family involvement (mix of diagnoses; Unclear proportion of first and second episodes; Unclear contrast of medication use vs. non-medication use)
Cao 2000	Allocation: not an intervention study Participants: people with first episode schizophrenia (<=2 years) (coded for types of traditional Chinese medicine syndromes) Interventions: Risperidone (not an intervention study; No un-medicated group)
Carpenter 1977	Allocation: historical two-group comparison (NIH acute treatment vs. IPSS Washington, DC cohort), one and two year follow-ups. Participants: people with acute schizophrenia, adequate prior work and social functioning, >50% not first-episode, n=122. Interventions: (after a 3-week medication washout period) 1. TAU (hospitalization and antipsychotic medications) n=73; and 2. Milieu treatment (therapeutic community) with minimal antipsychotic medications, n=49 (Historical comparison group study (subjects not randomly allocated to treatment), unclear proportion of first and second episodes)
Carpenter 1982	Allocation: randomised Participants: people with schizophrenia Interventions: targeted and time limited drug use vs continuous drug use (Not an acute treatment study; Unclear proportion of first and second episodes)
Carpenter 1983b	Allocation: randomised Participants: people with schizophrenia or schizoaffective disorder. Interventions: targeted drug use vs continuous drug use (not an acute treatment study; Unclear proportion of first and second episodes)
Carpenter 1999a	Allocation: randomised

Study	Reason for exclusion
	Participants: people with schizophrenia or schizoaffective disorder (DSM-III-R). Interventions: Diazepam vs. fluphenazine vs. placebo (Not an acute treatment study; Unclear proportion of first and second episodes)
Carson 2000	Allocation: randomised Participants: people with acute relapse of schizophrenia or schizoaffective disorder Interventions: aripiprazole, haloperidol and placebo (Not first and second episodes)
Carson 2000b	Allocation: randomised Participants: people with chronic schizophrenia. Interventions: aripiprazole and placebo (Not first and second episodes)
Casey 2002	Allocation: randomised Participants: people with chronic and stable schizophrenia or schizoaffective disorder. Interventions: aripiprazole (Not first and second episodes; No un-medicated group)
Castilla 2002	Allocation: randomised Participants: children with onset of psychotic symptoms, hallucinations and delusions within 7 days Interventions: Olanzapine and Haloperidol (Not first and second episodes; not adults; No un-medicated group)
Cavozzoni 2002a	Allocation: randomised Participants: people with schizophrenia during the acute phase(<= 8 weeks) Interventions: haloperidol, risperidone or Clozapine and placebo (Unclear proportion of early episodes)
Centorrino 2003	Allocation: randomised Participants: people with schizophrenia or schizoaffective disorder. Interventions: haloperidol and Olanzapine (Unclear proportion of first and second episodes; no un-medicated group; not an acute treatment study)
Chaudhry 2004	Allocation: randomised Participants: people with first-episode schizophrenia Interventions: Randomised trial of the addition of Lamotrigine and Minocycline to standard medication treatment (inadequate detail to determine types of medications used) (No un-medicated group)
Chen 2000a	Allocation: randomised Participants: people with first-episode schizophrenia Interventions: Risperidone (fixed vs. curative effect dosage groups) (No un-medicated group)
Chen 2000c	Allocation: unclear method of assignment to treatment Participants: males with first-episodes schizophrenia

Study	Reason for exclusion
	Interventions: Risperidone (unclear method of assignment to treatment; No un-medicated group)
Chen 2004a	Allocation: unclear method of assignment to treatment Participants: people with first-episodes schizophrenia Interventions: Risperidone (unclear method of assignment to treatment; controls were not people with schizophrenia; no un-medicated group)
Chen 2004c	Allocation: unclear method of assignment to treatment Participants: people in a difficult situation and people with stress-induced schizophrenia Interventions: Neither group receives medication (unclear method of assignment to treatment; Unclear proportion of first and second episodes; No contrast of medicated vs un-medicated group)
Chen 2006d	Allocation: randomised Participants: people with first episode schizophrenia Interventions: Chlorpromazine and Clozapine (No un-medicated group)
Cheng 2006b	Allocation: unclear method of assignment to treatment Participants: children with schizophrenia. Interventions: Perphenazine and Risperidone (unclear method of assignment to treatment; Unclear proportion of first and second episodes; No un-medicated group)
Chiu 2006b	Allocation: randomised Participants: people with atypical schizophrenic Interventions: Olanzapine and Risperidone (Unclear proportion of first and second episode; No un-medicated group)
Chouinard 1992	Allocation: randomised Participants: people with chronic schizophrenia Interventions: Risperidone, Haloperidol or placebo (Not first and second episodes)
Ciompi 1993	Allocation: case-control Participants: People with DSM-IIIR Schizophrenia or Schizophreniform disorder, onset within one-year, ages 17-35, ≥2 of 6 cardinal symptoms of schizophrenia (hallucinations, delusions, thought disorders, catatonia, schizophrenic disorders of affect, severely deviant social behavior), n=44. Interventions: TAU Hospitalization and antipsychotic medications, n=22; therapeutic milieu with time-limited postponement (up to 4 weeks) of antipsychotic medications, n=22 (Not randomly assigned to treatment)
Claus 1992	Allocation: randomised Participants: people with chronic schizophrenia. Interventions: Risperidone, Haloperidol (Not first and second episodes; No un-medicated group)
Conley 1999	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia.

Study	Reason for exclusion
	Interventions: Risperidone, Clozapine, Olanzapine and typical antipsychotic (unclear method of assignment to treatment; No un-medicated group)
Craig 2004b	Allocation: randomised Participants: people with first or second episode schizophrenia Interventions: assertive outreach with evidence based biopsychosocial interventions (CBT, medication, family support) vs. standard care (control group) delivered by community mental health teams (not an acute treatment study; no un-medicated group)
Crespo-Facorro 2006a	Allocation: randomised Participants: people with first episode schizophrenia Interventions: Olanzapine vs Risperidone vs Haloperidol (No un-medicated group)
Csernansky 2003	Allocation: randomised Participants: people in acute relapse and requiring hospitalization Interventions: Aripiprazole vs. placebo (Not first or second episodes)
Cullberg 2002	Allocation: Quasi-random (assigned to treatment available in catchment area) plus one historical (past) comparison group. Participants: people with first-episode acute schizophrenia, n=388 Interventions: Milieu treatment with time-limited (up to 3 week) postponement of antipsychotic medications, n=253; hospital treatment with time-limited (duration unspecified) antipsychotic medication postponement, n=71; hospital treatment with antipsychotic medications (at a previous time), n=64 (Non-random assignment to treatments; both contemporary treatments postponed use of antipsychotic medications(i.e., no initial antipsychotic use vs non-use comparison); unable to assure equality of selection in the historical group)
Dahl 2000	Allocation: not randomised (consecutive) Participants: people with first episode psychosis Interventions: a special program including education, medical/social detection network, early detection team of clinicians (not randomised; not a treatment comparison study; no un-medicated group)
Daniel 2000b	Allocation: randomised Participants: people in acute schizophrenic relapse and hospitalized. Interventions: aripiprazole vs. haloperidol vs. placebo (Not first and second episodes)
David 1999a	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia Interventions: Olanzapine vs Risperidone (unclear method of assignment to treatment; Unclear proportion of first and second episodes; No un-medicated group)
David 1999b	Allocation: unclear method of assignment to treatment Participants: people in early phase schizophrenia or schizophrenic disorder.

Study	Reason for exclusion
	Interventions: Olanzapine vs. Risperidone vs. Haloperidol (unclear method of assignment to treatment; Unclear proportion of first and second episodes; No un-medicated group)
David 2000a	Allocation: randomised Participants: people with schizophrenia, schizophriform disorder, or schizoaffective disorder. Interventions: Olanzapine vs. Risperidone vs. Haloperidol (Unclear proportion of first and second episodes; No un-medicated group)
Davidson 2003	Allocation: randomised Participants: people with first episode schizophrenia Interventions: low-dose Risperidone vs. low-dose Haloperidol (No un-medicated group)
Davidson 2004	Allocation: randomised Participants: people with early psychosis Interventions: Risperidone vs. Haloperidol (No un-medicated group)
Davis 1977	Allocation: randomised Participants: people with schizophrenia and affective disorders (n=19) Interventions: naloxone vs placebo (Unclear proportion of first and second episodes; mixture of people with schizophrenia and affective disorder)
De Smedt 1999	Allocation: randomised Participants: people with first episode psychosis (DSM-IV diagnosis of schizophreniform, schizophrenia, or schizoaffective disorder) Interventions: Risperidone vs. Haloperidol (No un-medicated group)
Deng 2006b	Allocation: randomised Participants: people with first episode psychosis Interventions: early treatment vs. routine treatment (No un-medicated group)
Ding 2001	Allocation: case-control group selection Participants: people with first episode psychosis and normals Interventions: Clozapine, unspecified additional antipsychotic, no treatment (not randomly assigned to treatment; not a treatment comparison study)
Dollfus 2006	Allocation: randomised Participants: people with a post-psychotic depression (DSMIV). Interventions: Olanzapine vs. Risperidone (Not first and second episodes; No un-medicated group)
Dossenbach 1997	Allocation: randomised Participants: people with schizophrenia Interventions: Olanzapine vs. Fluphenazine (Unknown proportion of first and second episodes; No un-medicated group)

Study	Reason for exclusion
Dubitsky 2002a	Allocation: randomised Participants: people with stable schizophrenia or schizoaffective disorders. Interventions: aripiprazole vs. olanzapine (Not first and second episode schizophrenia; no un-medicated group; not an acute treatment study)
Dursun 2002	Allocation: randomised Participants: people with first episode psychosis Interventions: lamotrigine, minocycline and placebo added to treatment as usual (No un-medicated group)
Eack 2007	Allocation: randomised Participants: people with schizophrenia. Interventions: Cognitive Enhancement Therapy (CET) vs. Enriched Supportive Therapy (Unclear proportion of first and second episodes; Both groups received medications (no contrast of medicated to un-medicated subjects))
Edwards 1999	Allocation: randomised Participants: people with first episode psychosis Interventions: Clozapine vs. Clozapine plus CBT vs. thioridazine vs. thioridazine plus CBT (No un-medicated group)
Edwards 2003	Allocation: randomised Participants: people with first episode psychosis not meeting remission criteria within 12 weeks Interventions: Clozapine vs. Clozapine plus CBT vs. thioridazine vs. thioridazine plus CBT (No un-medicated group)
Edwards 2004	Allocation: randomised Participants: young people with first-episode psychosis; Interventions: Cannabis + Psychosis (CAP) therapy versus psycho-education (PE) (Not a study of treatment of schizophrenia but of interventions to reduce cannabis use among people with schizophrenia)
Edwards 2006	Allocation: randomised; Participants: people with first-episode psychosis; Interventions: Cannabis + Psychosis (CAP) therapy versus psycho-education (PE) (Not a study of treatment of schizophrenia but of interventions to reduce cannabis use among people with schizophrenia)
Eguiluz 1998	Allocation: randomised Participants: people with first-episode psychosis (n=79) Interventions: Psychoeducation plus medications compared to standard treatment (no un-medicated group, unclear proportion of early episodes, not an acute treatment study)
Eli Lilly 2006d	Allocation: randomised

Study	Reason for exclusion
	Participants: people experiencing exacerbation of psychotic symptoms within the previous 2 weeks. Interventions: Risperidone vs. Olanzapine (No un-medicated group, unclear proportion of first and second episodes)
Emsley 1999	Allocation: randomised Participants: people with first episode psychosis (n=183) Interventions: Risperidone vs. Haloperidol (No un-medicated group)
Emsley 2004b	Allocation: randomised Participants: people with recent onset schizophrenia Interventions: Risperidone (n=278) vs. Haloperidol (n=277) (No un-medicated group, unclear proportion of first and second episodes)
Emsley 2006b	Allocation: randomised Participants: people with first episode psychosis (n=522) Interventions: Risperidone vs. Haloperidol (No un-medicated group)
Emsley 2007	Allocation: randomised Participants: people with first episode psychosis Interventions: Risperidone vs. Haloperidol (No un-medicated group)
Engelhardt 1994	Allocation: Randomised Participants: people with schizophrenia with at least one year of illness (Studies 1 and 2); children with schizophrenia (Study 3) Inverventions: Butaperazine and fluphenazine (Study 2) (Unclear proportion of first and second episodes; No un-medicated group)
Faber 2005	Allocation: randomised Participants: people with first episode psychosis (n=54) Interventions: Risperidone vs. Olanzapine. One group discontinued their medication after 6 months of stable remission, the other group continued medication and served as the control group (Not an acute treatment study (medication withdrawal post-stabilization))
Fabre 1995	Allocation: randomised Participants: 12 males with chronic and sub-chronic schizophrenia Interventions: Quetiapine vs. placebo (Not first and second episodes)
Fan 2006	Allocation: randomised Participants: people with first episode psychosis Interventions: Risperidone vs. Chlorpromazine (No un-medicated group)
Fang 2003	Allocation: randomised Participants: people with first episode psychosis (n=126)

Study	Reason for exclusion
	Interventions: Risperidone plus psychosocial treatment vs. Risperidone (No un-medicated group)
Ferenc 2000	Allocation: unclear method of allocation to treatment Participants: people with schizophrenia. Interventions: Olanzapine vs. Fluphenazine (unclear method of allocation to treatment; Unclear proportion of first and second episodes; No un-medicated group)
Ferrari 1997	Allocation: randomised Participants: young people with chronic schizophrenia Interventions: Risperidone vs. conventional neuroleptics (Not first and second episodes; No un-medicated group)
Filatre 1998	Allocation: randomised Participants: people with first episode psychosis Interventions: antipsychotic medications vs. antidepressant medications (No un-medicated group)
Fleischhacker 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=500) Interventions: second-generation antipsychotic medications (amisulpride, quetiapine, olanzapine and ziprasidone) vs. low dose of haloperidol (No un-medicated group)
Fowler 2004	Allocation: randomised Participants: young people with duration less than five years and relative remission of psychotic symptoms (less than moderate severity on the PANSS). Interventions: SRCBT (Social Recovery oriented CBT) vs. standardized treatment as usual. (standard use of medication in both group) (Not an acutetreatment study;Unclear proportion of first and second episodes; no un-medicated group)
Gaebel 1993	Allocation: unclear Participants: People with stabilized schizophrenia with an average duration of 7.2 years since onset and an average of 3.0 prior hospitalizaitons. Interventions: Maintenance treatment vs. early intervention vs. crisis intervention (Not an acute treatment study, predominantly multi-episodes)
Gaebel 1995	Allocation: randomised Participants: people with schizophrenia (n=364) Interventions: maintenance does vs. early intervention vs. crisis intervention (Unclear proportion of first and second episodes; No un-medicated group; a study of maintenance treatments not acute treatment)
Gaebel 2001	Allocation: randomised Participants: people with schizophrenia (n=115 first-episodes; n=248 multi-episodes) Interventions: maintenance does vs. early intervention vs. crisis intervention (the proportion of first episodes is less than 50% (115/363=32%); No un-medicated group, a study of maintenance treatments not acute treatment)

Study	Reason for exclusion
Gaebel 2002a	Allocation: randomised Participants: people with first-episode schizophrenia Interventions: Risperidone vs Haloperidol (8 weeks acute, n=360; 1 year maintenance, n=280; 1 year randomised open withdrawal plus early intervention with either neuroleptic or lorazepam, n=136) (No un-medicated group during acute treatment)
Gaebel 2004	Allocation: randomised Participants: people with first episode schizophrenia (n=142) Interventions: Risperidone vs. low-dose haloperidol (No un-medicated group)
Gaebel 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=159) Interventions: Risperidone vs. low-dose haloperidol (No un-medicated group)
Gaebel 2006	Allocation: randomised Participants: people with first-episode schizophrenia Interventions: Risperidone vs Haloperidol (8 weeks acute, n=302; 1 year maintenance, n=176; 1 year randomised open withdrawal plus early intervention with either neuroleptic or lorazepam, n=57) (No un-medicated group during acute treatment phase)
Gafoor 2005a	Allocation: randomised Participants: people with first episode schizophreniform psychosis (n=60) Interventions: Risperidone vs. Quetiapine Outcomes: depressive and anxiety symptoms (No un-medicated group, treatment for depression within schizophrenia)
Gafoor 2006	Allocation: randomised Participants: people with first episode schizophreniform psychosis (n=72) Interventions: Risperidone vs. Quetiapine (No un-medicated group)
Gallo 2006	Allocation: Randomised (n=180) Participants: Persons with first-episode schizophrenia Interventions: trimethoprim sulfamethoxazole plus anpipsychotics compared to antipsychotic treatment only (no un-medicated group)
Gan 1999	Allocation: randomised Participants: people with first episode schizophrenia (n=60, BPRS>=40, CCMD-2-R) Interventions: Clozapine vs Risperidone (No un-medicated group)
Gan 2000	Allocation: unclear method of allocation to treatment Participants: people with first episode schizophrenia (n=46) Interventions: Risperidone (unclear method of allocation to treatment; No un-medicated group)

Study	Reason for exclusion
Garcia 2006	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia Interventions: atypical vs typical antipsychotics (no definition of medicines) (unclear method of assignment to treatment; Unclear proportion of first and second episodes; No un-medicated group)
Garety 2000a	Allocation: randomised Participants: people with early schizophrenia (first or second episode) Interventions: Cognitive Behavioral Therapy (No contrast of medicated vs. un-medicated group)
Garety 2006	Allocation: randomised; Participants: people with first or second episode schizophrenia (n=144) Interventions: care by the early onset team (a mix of medication, cognitive behavioral therapy, vocational input and family interventions, which provided based on individual need) vs. standard care (No un-medicated group)
Garver 2005	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia Interventions: Risperidone vs. Ziprasidone vs. Haloperidol (Unclear proportion of first or second episodes; unclear method of assignment to treatment)
Gary 1990	Allocation: randomised Participants: people with schizophrenia Interventions: experimental group (n=11) vs. control group (n=12): both group received medication and experimental group was given instructions regarding self-assessment of extrapyramidal side effects (unclear proportion of first and second episodes; No un-medicated group)
Gattaz 1989	Allocation: randomised Participants: people with schizophrenia (n=30; 8 first episodes) Interventions: haloperidol plus bromocriptine (n= 15) vs. haloperidol plus placebo (n= 15) (proportion of first episodes is less than 50% (8/30=27%); No un-medicated group)
Genduso 1996	Allocation: randomised Participants: people with schizophrenia, schizophreniform disorder, or schizoaffective disorder (n=1996) Interventions: Olanzapine (n=1,336) vs. Haloperidol (n=660) (Unclear proportion of first and second episodes; No un-medicated group)
Gharabawi 2006d	Allocation: unclear method of assignment to treatment Participants: people with first-episode psychosis Interventions: haloperidol vs. Risperidone (unclear method of assignment to treatment; No un-medicated group)
Gillin 1978	Allocation: unclear method of assignment to treatment Participants: People with schizophrenia

Study	Reason for exclusion
	Interventions: pretreatment with pimozide (unclear method of assignment to treatment; Unknown proportion of first and second episodes; No un-medicated group)
Glenthoj 2000	Allocation: randomised Participants: people with first-episode and drug-naïve schizophrenia Interventions: Risperidone vs. zuclopenthixol (No un-medicated group)
Glenthoj 2005	Allocation: randomised Participants: people with first-episode and drug-naïve schizophrenia (n=19) Interventions: low doses of the typical drug zuclopenthixol vs. the atypical compound risperidone (No un-medicated group)
Godemann 1999	Allocation: randomised Participants: people with psychosis Interventions: long-term vs. interval medication (Unknown proportion of first and second episodes; No un-medicated group)
Good 2004	Allocation: randomised Participants: people with schizophrenia-like illnesses and neuroleptics-naive Interventions: haloperidol vs. risperidone (No un-medicated group)
Grasso 1974	Not related to medication treatment
Grawe 1998	Allocation: randomised Participants: people with recent onset schizophrenia Interventions: optimal multimodal treatment (neuroleptics, family psycho-education, family communicational problem-solving and stress management training, individualized psychotherapy) VS. treatment-as-usual (No un-medicated group)
Grawe 2006	Allocation: randomised Participants: people with less than 2-year duration of schizophrenia Interventions: integrated (pharmacotherapy, case management, cognitive-behavioural family treatment) vs. standard treatment (optimal pharmacotherapy and case management) (No un-medicated group)
Green 2001b	Allocation: randomised; Participants: people with first episode schizophrenia, schizoaffective disorder or schizophreniform disorder Interventions: olanzapine vs. haloperidol (No un-medicated group)
Gumley 2001b	Allocation: randomised Participants: people with schizophrenia-spectrum disorder Interventions: two methods of early signs monitoring : standardized vs. individualized early signs monitoring systems (Unknown proportion of first and second episodes; Unknown medication)
Gumley 2003a	Allocation: randomised

Study	Reason for exclusion
	Participants: people with schizophrenia or a related disorder and receiving antipsychotic medication and considered relapse prone Interventions: treatment as usual (n=72) vs. treatment as usual +CBT(n=72) (not an acute treatment study; No un-medicated group)
Gumley 2003b	Allocation: randomised Participants: people with a diagnosis of schizophrenia spectrum disorder and admitted to an acute psychiatric ward with a first or subsequent episode of psychosis Interventions: CBT plus antipsychotic medications vs. medications alone (No un-medicated group, unclear proportion of first and second episodes)
Gumley 2006	Allocation: randomised Participants: people with schizophrenia or a related disorder and receiving antipsychotic medication, and considered relapse-prone Interventions: treatment as usual (n=72) vs. CBT (n=72) (not treatment for acute schizophrenia, no un-medicated group, unclear proportion of early episodes)
Guo 1995	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia Interventions: Clozapine vs. Risperidone (unclear method of assignment to treatment; No un-medicated group)
Guo 2001a	Allocation: unclear method of assignment to treatment Participants: People with schizophrenia Interventions: Risperidone (unclear method of assignment to treatment; the proportion of first episodes does not exceed 50%; No un-medicated group)
Guo 2004	Allocation: randomised Participants: people with schizophrenia Interventions: treatment group (modified-ECT) plus medications vs. control group (without modified-ECT) plus medications (risperide and clozapine) (unclear proportion of first and second episodes; not a study of medication effectiveness)
Haddock 1999	Allocation: randomised Participants: people with acute schizophrenia within 5 years of first onset Interventions: short-term individual CBT vs. supportive counseling/Psychoeducation + standard inpatient hospital care and medication (no un-medicated group)
Haddock 2000a	Allocation: randomised Participants: people dually diagnosed with recent onset schizophrenia and substance abuse Interventions: combination of cognitive behavior therapy for individuals and cognitive behavioral interventions for family and carergivers, compared to usual treatment (no contrast of medicated versus un-medicated groups)
Haddock 2000b	Allocation: unclear method of assignment to treatment

Study	Reason for exclusion
	Participants: people with an ICD10 diagnosis of schizophrenia, schizo-affective disorder or delusional disorder and have less than five years since onset and with alcohol or drug abuse. Intervention: a family support and cognitive behavioural treatment service (unclear method of assignment to treatment; no contrast of medicated versus un-medicated groups)
Haddock 2006	Allocation: randomised Participants: people with first or second admission (within 2 years of a first admission) Interventions: cognitive behavioral therapy (CBT) + treatment as usual, vs. supportive counseling + treatment as usual, vs. treatment as usual (no un-medicated group (not a medication effectiveness study))
Haldun 2002	Allocation: randomised Participants: people with a history of schizophrenia less than 10 years Interventions: optimal clinical management vs. routine case management (not acute schizophrenia treatment comparison; No un-medicated group)
Hawkins 2004a	Allocation: randomised Participants: people in the prodromal phase of schizophrenia Interventions: placebo (n= 29) vs. Olanzapine (n=31) (not acute schizophrenia treatment comparison)
Hawkins 2004b	Allocation: randomised Participants: people in the prodromal phase of schizophrenia Interventions: placebo vs. Olanzapine (not treatment for acute schizophrenia)
Herrmann 1991	Allocation: randomised Participant: young healthy males (n=15) Interventions: Maroxepin vs. Chlorpromazine vs. Imipramine vs. Methanesulfonate salt vs. Savoxepine vs. Placebos (not treatment for people with first and second episode schizophrenia)
Herz 1982	Allocation: consecutive Participants: People with schizophrenia Interventions: intermittent vs. continuious antipsychotic medication (not randomised; not an acute schizophrenia treatment comparison; no un-medicated group)
Herz 1989a	Allocation: randomised Participants: people with schizophrenia Interventions: Stage 1: drug washout for 8 weeks; Stage 2: active medication vs. placebo (no definition of the medications used) (not acute schizophrenia treatment comparison; unclear proportion of first and second episodes)
Herz 1998	Allocation: randomised Participants: people with schizophrenia maintained on antipsychotic medication

Study	Reason for exclusion
	Interventions: early intervention treatment vs. treatment as usual (not treatment for acute schizophrenia; no un-medicated group; unclear proportion of early episodes)
Heydebrand 2004	Allocation: randomised Participants: people with first episode schizophrenia Interventions: haloperidol and risperidone (no un-medicated group)
Himei 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=14) or not receiving drug treatment within the previous 6 months (n=6) or receiving therapy with haloperidol only for more than 5 years (treated group, n=100). Interventions: Risperidone (group A: increasing the dose; group B: decreasing the dose; group C: abruptly to a new regimen) (proportion of early episodes less than 50%; no unmedicatd group)
Hirsch 1986	Allocation: Randomised (n=45) Participants: people with schizophrenia Interventions: Depot Preparations/fluphenazine and placebo (Not an acute treatment study; unclear proportion of early episodes)
Hodgekins 2006a	Allocation: Randomised Participants: People with early psychosis Interventions: Usual treatment plus cognitive treatment versus usual treatment (Combined consecutive referral allocation with random assignment; no un-medicated group)
Hoffman 2006	Allocation: randomised Participants: people in prodromal status of psychosis Interventions: Olanzapine vs. Placebo (not treatment for acute schizophrenia)
Hogarty 1991	Allocation: randomised Participants: people with schizophrenia (n=103) Interventions: family psychoeducation/management (FT) vs. individual social skills training (SST) vs. the combination of FT and SST vs. medication controls (unclear proportion of first and second episodes; no un-medicated group; not an acute treatment study)
Honer 2005b	Allocation: randomised Participants: people with first episode psychosis (n=533) Interventions: Haloperidol vs. Risperidone (no un-medicated group)
Hornung 1995	Allocation: randomised Participants: people with schizophrenia, having at least two acute psychotic episode within 5 years Interventions: psychoeducational medication training (PMT) vs. Cognitive psychotherapy (CP) vs. Key-person counselling (KC) vs. non-specific treatment in the control group (consisted of regular leisure-time group activities: games, excursions, visits to organized functions, etc.) (not early episodes; not acute treatment; no un-medicated group)
Hu 2003b	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode schizophrenia (n=62) Interventions: Chlorpromazine vs. Risperidone vs. Quetiapine (no un-medicated group)
Huang 2004c	Allocation: randomised Participants: senile people with first episode schizophrenia Interventions: trilafon+ nimodipine vs. trilafon (only include senile people; no un-medicated group)
Huang 2006d	Allocation: randomised Participants: adolescents with first episode schizophrenia Interventions: Olanzapine vs. Risperidone (no un-medicated group)
Ishigooka 2001	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia Interventions: Olanzapine vs. Haloperidol (unclear method of assignment to treatment; unclear proportion of first and second episodes; no un-medicated group)
Ivarson 1998	Allocation: randomised Participants: people with recent onset of schizophrenic disorders Interventions: integrated treatment (medication + psychosocial interventions) vs. standard treatment (no un-medicated group)
Jackson 2001a	Allocation: nonrandomised Participants: people with first episode psychosis (n=80) Interventions: Cognitively oriented psychotherapy for early psychosis (COPE). There are three group of comparison: those who were offered and accepted COPE; (2) those who were offered COPE but refused it, and continued to receive other services; and (3) those who were offered neither COPE nor any other continuing treatment (control subjects) (treatment assignment by choice; unclear use of medications)
Jackson 2001b	Allocation: randomised Participants: people with first episode schizophrenia Interventions: recovery intervention (cognitive therapy) vs. treatment-as-usual (Not an acute treatment study; no un-medicated group)
Jackson 2004a	Allocation: randomised Participants: people with first episode schizophrenia (n=66) Interventions: cognitive therapy vs. treatment-as-usual (no un-medicated group; not an acute treatment study)
Jackson 2004b	Allocation: randomised Participants: people with first episode schizophrenia (n=79) Interventions: Cognitively oriented psychotherapy for early psychosis (COPE) vs. no COPE (not an acute treatment study; no un-medicated group)
Jackson 2005	Allocation: randomised

Study	Reason for exclusion
	Participants: people in the early phase of schizophrenia (n=62) Interventions: Active Cognitive Therapy for Early Psychosis (ACE) plus medications vs. Befriending plus medications (no un-medicated group)
Jackson 2006	Allocation: randomised Participants: people with first episode psychosis (n=66) Interventions: cognitive therapy vs. treatment as usual (Not an acute treatment study; no contrast of medicated versus un-medicated group)
Janicak 1998	Allocation: randomised Participants: People with acute mania (n=33) Interventions: Verapamil versus placebo (Not people with schizophrenia)
Jarboe 2001	Allocation: unclear method of allocation to treatment Participants: people with first episode schizophrenia or schizoaffective disorder Interventions: Haloperidol vs. Olanzapine (unclear method of allocation to treatment; no un-medicated group)
Jasovic 1995	Allocation: randomised Participants: people with schizophrenia and depression Intervention: active drug (moclobemide) vs. placebo (moclobemide free). Both groups also receive antipsychotic medications (dually diagnosed persons (schizophrenia and depression); unclear proportion of first and second episodes; no un-medicated group)
Jasovic 1998	Allocation: randomised Participants: people with schizophrenia and depression Intervention: Mianserin, Moclobemide, or placebo, as an adjunctive therapy with classical neuroleptic medication (dually diagnosed persons (schizophrenia and depression); unclear proportion of first and second episodes; no un-medicated group)
Jenner 2004b	Allocation: randomised Participants: people with treatment refractory schizophrenia (n=76) Interventions: Hallucination-focused Integrative Treatment (HIT) vs. routine treatment (Not an acute treatment study; Unclear proportion of first and second episodes; No un-medicated group)
Ji 2006	Allocation: randomised Participants: people with first episode schizophrenia (n=82) Interventions: antipsychotic medication + general nursing + system health education intervention vs. antipsychotic medication + general nursing (no un-medicated group)
Jiang 2006	Allocation: randomised Participants: people with first episode schizophrenia (n=120) Interventions: antipsychotic medications + CBT vs. antipsychotic medications (no un-medicated group)

Study	Reason for exclusion
Jiang Xinyan 2004	Allocation: randomised Participants: Older adults (over 60 years of age) with first episode schizophrenia (n=62) Interventions: Olanzapine vs. Risperidone (only older adults with schizophrenia; no un-medicated group)
Johnson 2004b	Allocation: unclear method of allocation to treatment Participants: people in early psychosis Intervention: unclear (Not enough information)
Johnston-Cronk 1993	Allocation: randomised Participants: people with schizophrenia Interventions: antipsychotic medication plus placebo supplement vs antipsychotic medication and active medication supplement (not an acute treatment study; unclear proportion of early episodes; no un-medicated group)
Johnstone 1998b	Allocation: randomised Participants: people with schizophrenia (n=814) Interventions: olanzapine (OLZ) vs. haloperidol (HAL) (Unclear proportion of first and second episodes; No un-medicated group)
Jolley 1989	Allocation: randomised Participants: people with chronic schizophrenia (n=54) Interventions: intermittent treatment group (n=27, placebo injection) vs. control group (n=27, Fluphenazine injections) (maintenance treatment study (not acute schizophrenia); unclear proportion of early episodes)
Jolley 2003	Allocation: randomised Participants: people with first or second episode schizophrenia spectrum disorder and diagnosed within five years (n=21) Interventions: cognitive therapy + treatment as usual vs. treatment as usual (no un-medicated group)
Jones 1998	Allocation: randomised Participants: people with schizophrenia (n=65) Interventions: Haloperidol vs. Olanzapine vs. Risperidone (not treatment for acute schizophrenia; No un-medicated group)
Jones 2005b	Allocation: randomised Participants: young people with early psychosis and severe mood disorder (n=100) Interventions: Social Recovery oriented CBT (SRCBT) vs. standard case management (Not a medication treatment study)
Jones 2006	Allocation: randomised Participants: people with schizophrenia and related disorders (n=227)

Study	Reason for exclusion
	Interventions: first generation antipsychotics vs. second generation antipsychotics (No un-medicated group, Less than 50% first and second episodes, not an acute treatment study)
Kahn 2003	Allocation: randomised Participants: people with schizophrenia or schizoaffective disorders Interventions: Haloperidol; Olanzapine (Unclear proportion of first and second episodes; No un-medicated group)
Kahn 2006	Allocation: randomised Participants: people with first episode schizophrenia, schizoaffective disorders or schizophreniform disorders (n=500) Interventions: Amisulpride or Olanzapine or Quetiapine or Ziprasidone vs. low-dose Haloperidol (No un-medicated group)
Kane 1982a	Allocation: randomised Participants: people with remitted, first-episode schizophrenia (n=28) Interventions: Fluphenazine vs. Placebo (not treatment for acute schizophrenia)
Kane 2001b	Allocation: randomised Participants: people with schizophrenia (n=370) Interventions: 25mg, or 50mg or 75mg Risperidone microspheres vs. Placebo (Unclear proportion of first and second episodes)
Kapur 2000b	Allocation: randomised Participants: people with first-episode schizophrenia (n=22) Interventions: 1.0 mg/day haloperidol vs. 2.5 mg/day haloperidol (No un-medicated group)
Kavanagh 2004	Allocation: randomised Participants: people with early psychosis and current misuse of non-opioid drugs (n=25) Interventions: Start Over and Survive (SOS) + standard care vs. standard care (No un-medicated group)
Keefe 2005	Allocation: randomised Participants: people with first episode psychosis Interventions: Olanzapine vs. Quetiapine vs. Risperidone (no un-medicated group)
Keefe 2006b	Allocation: randomised Participants: people with first episode psychosis Interventions: Olanzapine vs. low dose haloperidol (no un-medicated group)
Kenny 1992	Allocation: Randomised Participants: people with treatment resistant schizophrenia Interventions: Clozapine (n=24) vs. standard neuroleptics (n=13) (unclear proportion of first and second episodes; no un-medicated group)

Study	Reason for exclusion
Keri 2006	Allocation: Not a treatment comparison study (one group study) Participants: People meeting ACE criteria for ultra-high risk of psychsis Interventions: Risperidone plus psychoeducation an supportive psychotherapy (Not a treatment comparison study (one group study), not acute schizophrenia, no un-medicated group)
Kern 2001	Allocation: randomised Participants: people with clinically stable schizophrenia or schizoaffective disorder Interventions: Aripiprazole versus. Olanzapine (unclear proportion of first and second episodes; no un-medicated group)
Keshavan 1998	Allocation: Not a treatment comparison study; studies brain morphology over time in first-episodes treated with conventional antipsychotics or risperidone Participants: people with first episode schizophrenia Interventions: Haloperidol (n=19) or Risperidone (n=16) (not a treatment comparison study, no un-medicated group)
Keshavan 2003	Allocation: unclear method of assignment to treatment Participants: people with recent onset of psychosis (n=60) Interventions: Psycho Education and Collaboration Enhancement (PEACE) (unclear method of assignment to treatment; not a medication treatment comparison study)
Killackey 2006	Allocation: randomised Participants: young people with early psychosis (n=40) Interventions: treatment as usual + Individual Placement and Support Model versus treatment as usual (not a medication treatment comparison study)
Kingdon 2000	Allocation: randomised Participants: people with first or second episode (unclear number) Interventions: CBT + treatment as usual versus treatment as usual (drug only) (no un-medicated group)
Kistrup 1991	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia and a duration of illness of 2 or more years Interventions: cis(z)- flupenthixol decanoate (n=24) versus Perphenazine decanoate (n=24) (unclear method of assignment to treatment; not treatment for recent onset schizophrenia but maintenance treatment, no un-medicated group)
Klier 2005	Allocation: randomised Participants: adolescents with “At-Risk-Mental-State” Interventions: fish oil (EPA/DHA) (Omega-3 fatty acids) + standard care versus standard care (not treatment for recent onset of schizophrenia; no un-medicated group)
Knapp 2004	Allocation: randomised Participants: people with first or second episode schizophrenia

Study	Reason for exclusion
	Interventions: Early psychosis service versus. Standard service (unclear definition of these two services) (inadequate information on the types of treatments provided)
Kolivakis 2001	Allocation: randomised Participants: people with schizophreniform disorder and early paranoid schizophrenia (n=20) Interventions: Risperidone versus haloperidol, with or without anticonvulsant medications (no un-medicated group)
Kopala 2003	Allocation: randomised Participants: people with recent onset schizophrenia Interventions: Haloperidol (n=277) versus Risperidone (n=278) (no un-medicated group)
Kuipers 2004	Allocation: randomised Participants: people with a diagnosis of any functional psychosis Interventions: Croydon Outreach and Assertive Support Team or COAST (optimum atypical medication, and psychological interventions, e.g. individual CBT and family intervention, and a range of vocational and welfare support) vs. treatment as usual (n=27) (unclear proportion of first and second episodes; no un-medicated group, not an acute treatment study)
Kujawa 2002	Allocation: randomised Participants: people with acute relapse of chronic schizophrenia Interventions: aripiprazole 30 mg (n=861) or haloperidol 10 mg (n=433) (not treatment for recent onset of schizophrenia; no un-medicated group)
Lambert 1995	Allocation: unknown method of assignment to treatment Participants: people with schizophrenia (n=144) but only 28 first episodes Interventions: Remoxipride versus. Thioridazine (unknown method of assignment to treatment; no un-medicated group, majority are not early episodes)
Lambert 2006	Allocation: randomised Participants: people with schizophrenia, schizophreniform disorder, or schizoaffective disorder (n=263) Interventions: Olanzapine versus haloperidol (unclear proportion of first and second episodes; no un-medicated group)
Lane 2001	Allocation: randomised Participants: people with first episode schizophrenia (n=24) Interventions: risperidone 3mg/day versus. risperidone 6mg/day (no un-medicated group)
Lauriello 2005	Allocation: randomised Participants: people with schizophrenia (n=34) Interventions: Haloperidol versus Quetiapine (unclear proportion of first and second episodes; no un-medicated group)
Lavalaye 1999	Allocation: randomised

Study	Reason for exclusion
	Participants: young people with first episode schizophrenia (n=36) Interventions: Olanzapine versus. Risperidone (no un-medicated group, not a treatment outcome comparison study (but a study of dopamine occupancy))
Leavey 2004	Not an acute early-episode medication treatment comparison study, but a study of the response and satisfaction to adjunctive psychosocial treatment among relatives of persons with schizophrenia
Leblanc 2006	Allocation: randomised Participants: people with schizophrenia or related psychosis and in a stable status (no score >=5 at PANSS positive symptom subscale) Interventions: Modafinil versus placebo (not treatment for acute schizophrenia)
Leclerc 2006	Allocation: randomised Participants: people with first episode psychosis (n=19) Interventions: group CBT versus control group (not a medication treatment study, not acute treatment study, unclear use of medications)
Lecomte 2006	Allocation: randomised Participants: people with first episode psychosis (n=129) Interventions: group CBT versus. group skills training focusing on symptom management versus a wait-list control group (not an acute treatment study, not a medications treatment comparison study, unclear use of medications)
Lecrubier 2003	Allocation: randomised Participants: people with acute or sub-acute episode of schizophrenia (with a paranoid, disorganized or undifferentiated subtype), excluding first-episode Interventions: BP4897 (n=52) versus placebos (n=25) (not treatment for early episode schizophrenia (recent onsets excluded))
Lehtinen 1990	Allocation: Quasi-random (assigned to treatment available in the catchment area) Participants: People with first-episode functional non-affective psychosis, n=135, 80M, 55W. Interventions: 'Finnish need-specific treatment' plus usual use of antipsychotic medications, n=51, vs 'Finnish need-specific treatment' plus 'minimal neuroleptic regimen', n=84 (Not randomly allocated to treatments)
Lehtinen 2000	Allocation: Subjects were consecutively recruited in three experimental centers and other three control centers separately, but not randomly assigned to treatement Participants: people with first-episode functional non-affective psychosis (n=106) Interventions: integrated treatment versus standard treatment (in the former, a minimal neuroleptic regime was applied while in the latter neuroleptics were used according to the usual practice) (No random assignment)
Lei 2006	Allocation: Randomised Participants: Relatives of children with first-episode schizophrenia (n=60)

Study	Reason for exclusion
	Interventions: Health education and psychotherapy (focused on relatives of people with schizophrenia)
Lemmer 2001	Allocation: unclear method of assignment to treatment Participants: people with acute paranoid halluzinatory schizophrenia (n=46) Interventions: Zotepine versus Haloperidol (unclear method of assignment to treatment ; unclear proportion of early episodes; no un-medicated group)
Lencz 2006	Allocation: randomised Participants: people with first episode schizophrenia (n=61) Interventions: Risperidone versus olanzapine (no un-medicated group)
Lenior 2001	Allocation: randomised Participants: people with early-onset schizophrenia (n=72) Interventions: standard intervention versus family intervention + standard intervention (no un-medicated group)
Lenior 2002	Allocation: randomised Participants: young people with early onset schizophrenia and related disorders Interventions: standard intervention versus family intervention + standard intervention (no un-medicated group)
Lester 2004a	Allocation: unknown method of assignment to treatment Participants: General practitioners (GPs) Interventions: video-based educational programme for GPs about first episode psychosis (FEP) (Not an early episode acute treatment medication comparison study)
Lester 2004b	Allocation: unknown method of assignment to treatment Participants: People with a developing first episode psychosis and their caregivers and family members Interventions: Primary care training programme for General Practitioners (GPs) regarding the early recognition of psychosis and adherence to guidelines (Not an early episode acute treatment medication comparison study; no people with acute schizophrenia)
Lewis 2000a	Allocation: randomised Participants: people with early schizophrenia with 82% first episode (total n=360) Interventions: routine care + CBT versus routine care + supportive counseling versus routine care only (no un-medicated group)
Lewis 2000d	Allocation: randomised Participants: people with recent onset schizophrenia and substance use Intervention: psychosocial intervention versus routine treatments (unclear use of medications)
Lewis 2000f	Allocation: randomised Participants: people with first or second episode schizophrenia

Study	Reason for exclusion
	Interventions: CBT (unclear use of medications)
Lewis 2001e	Allocation: randomised Participants: people with psychosis Interventions: monitoring only + routine care versus CBT + routine care (unclear proportion of first and second episodes)
Lewis 2002a	Allocation: randomised Participants: people with first or second episode psychosis (n=315) Interventions: CBT + routine care versus 1st control group (supportive counseling + routine care) versus 2nd control group (routine care only) (no un-medicated group)
Lewis 2006b	Allocation: randomised Participants: people with schizophrenia Interventions: one of the second-generation antipsychotics (risperidone, olanzapine, quetiapine, amisulpride) versus. Clozapine (n=136) (unclear proportion of first and second episodes; no un-medicated group)
Lewis 2006c	Allocation: randomised (2 RCTs in this study) Participants: people with schizophrenia Interventions: first RCT: atypical drugs (risperidone, olanzapine, quetiapine and amisulpride) versus conventional drugs (n=227); second RCT: new (non-clozapine) atypical drugs versus. Clozapine (n=136) (unclear proportion of first and second episodes; no un-medicated group)
Li 2003f	Allocation: only one treatment group Participants: people with first episode schizophrenia (n=36) Interventions: Quetiapine (no contrast of medicated versus un-medicated group)
Li 2004a	Allocation: not randomised Participants: people with first episode schizophrenia Interventions: psychological and social intervention + treated with medication (n=50) versus treatment with medication only (n=50) (no random assignment; no un-medicated group)
Li 2004f	Allocation: randomised Participants: people with first episode schizophrenia (n=86) Interventions: family mental intervention + medicine treatment versus medicine treatment only (no un-medicated group)
Li 2004h	Allocation: randomised Participants: people with early schizophrenia (n=80) Interventions: Clozapine + nursing care + self care versus Clozapine only (no un-medicated group)
Li 2005d	Allocation: randomised Participants: people with first episode schizophrenia (n=46)

Study	Reason for exclusion
	Interventions: Quetiapine versus Risperidone (no un-medicated group)
Liang 2003a	Allocation: only one treatment group Participants: children with age <14 years and with first episode schizophrenia Intervention: Risperidone (not treatment for adults; no contrast of medicated versus un-medicated)
Liao Chunping 2004	Allocation: randomised Participants: people with first episode schizophrenia (n=60) Interventions: Risperidone (n= 30) and Clozapine (n= 30) (no un-medicated group)
Liberman 1988	Allocation: randomised Participants: people with schizophrenia Interventions: low-dose neuroleptic therapy + highly structured skills training versus. low-dose neuroleptic therapy + unstructured, goup discussion (unclear proportion of first and second episodes; no un-medicated group)
Lieberman 2001b	Allocation: randomised Participants: people with first episode schizophrenia and drug naïve (n=164) Interventions: Clozapine versus chlorpromazine (no un-medicated group)
Lieberman 2003a	Allocation: randomised Participants: people with schizophrenia and schizoaffective disorders Interventions: Haloperidol versus Olanzapine (unclear proportion of first and second episodes; no un-medicated group)
Lieberman 2003c	Allocation: randomised Participants: people with first episode schizophrenia and drug naïve (n=160) Interventions: Clozapine versus chlorpromazine (no un-medicated group)
Lieberman 2005b	Allocation: randomised Participants: people with first episode schizophrenia (n=263) Interventions: haloperidol versus olanzapine (no un-medicated group)
Lieberman 2005c	Allocation: randomised Participants: people with first episode schizophrenia (n=263) Interventions: haloperidol versus olanzapine (no un-medicated group)
Lin 2006b	Allocation: randomised Participants: people with first episode schizophrenia (n=84) Interventions: Aripiprazole (n=42) versus Chlorpromazine(n=42) (no un-medicated group)
Lin 2006c	Allocation: consecutively according to admission time

Study	Reason for exclusion
	Participants: females with first episode schizophrenia (n=60) Interventions: Aripiprazole versus Chlorpromazine (no random assignment; no un-medicated group)
Linszen 1994	Allocation: randomised Participants: people with recent onset schizophrenia or related disorders post-hospitaliztion Interventions: individually oriented early (psychosocial) intervention program + family intervention and medications versus individually oriented early (psychosocial) intervention program and medications (not an acute treatment comparison study, no un-medicated group)
Linszen 2004a	Allocation: randomised Participants: young people with first episode schizophrenia (n=200) Interventions: outpatient intervention program versus standard outpatient facilities (not an acute treatment comparison study, no un-medicated group)
Linszen 2006	Allocation: randomised Participants: young people with first episode psychosis (n=183) Interventions: early and sustained intervention (not an acute treatment comparison, no un-medicated group)
Lis 2003	Allocation: randomised Participants: people with schizophrenia (n=34, a majority with first episodes) Interventions: Haloperidol versus Sertindole (no un-medicated group)
Liu 2006c	Allocation: randomised Participants: people with first episode schizophrenia (n=60) Interventions: Aripiprazole versus Clozapine (no un-medicated group)
Liu Lin 2004b	Allocation: randomised Participants: people with first episode schizophrenia (n=112) Interventions: chlorpromazine therapy group (n= 56) + health education versus chlorpromazine therapy group only (n= 56) (no un-medicated group)
Loza 1999	Allocation: randomised Participants: people with acute schizophrenia Interventions: Olanzapine (n=27) versus Chlorpromazine (n=14) (no un-medicated group; unspecified proportion of first-episodes)
Loza 2001	Allocation: randomised Participants: people with first-episode paranoid schizophrenia (n=32) Interventions: typical antipsychotics (zuclopenthixol, perphenazine, haloperidol, perazine) versus atypical antipsychotics (risperidone, olanzapine, quetiapine) (no un-medicated group)
Loza 2002	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first-episode paranoidschizophrenia (n=39) Interventions: Clozapine versus Olanzapine versus Risperidone (no un-medicated group)
Lu 2002b	Allocation: not random (case-control) Participants: people with first episode schizophrenia (n=19) and healthy controls (n=22) Interventions: Clozapine (no random assignment; no contrast of medicated versus un-medicated groups with acute psychosis; not a treatment comparison study)
Ma 2000a	Allocation: randomised Participants: people with first episode schizophrenia (n=56) Interventions: Chlorpromazine and Clozapine (no un-medicated group; not a treatment comparison study)
Ma 2002	Allocation: randomised Participants: people with first episode schizophrenia (n=38) and healthy controls (n=20) Interventions: Chlorpromazine and Clozapine (no contrast of medicated versus un-medicated group; not a treatment comparison study)
Ma 2004b	Allocation: randomised Participants: people with first episode schizophrenia (n=118) Interventions: Risperidone (n=59) + nursing intervention versus Risperidone (n=59) (no un-medicated group)
Ma Xiaozhi 2004	Allocation: randomised Participants: people with first episode schizophrenia (n=106) Interventions: medications + individualized quantitative healthy education versus. medications + random healthy education (no un-medicated group; not an acute treatment study)
Mackeprang 2001	Allocation: randomised Participants: people with drug-naïve first episode schizophrenia Interventions: Risperidone versus zuclopenthixol (no un-medicated group; not a treatment outcome study)
Malla 2000	Allocation: unclear method of assignment to treatment Participants: people with first episode of psychosis Interventions: a community focused early intervention (antipsychotics and adjunct medications, youth education and support, cognitively oriented skills training, case management and group intervention, and family intervention) versus standard treatment (unclear method of assignment to treatment; no un-medicated group)
Malla 2001	Allocation: not random (matched case-control study: matched on age, gender, length of illness and length of treatment) Participants: people with first episode schizophrenia (n=38)

Study	Reason for exclusion
	Interventions: Risperidone versus typical antipsychotics (not randomly assigned to treatment; no un-medicated group)
Mandelson 2000	Allocation: randomised Participants: people with first or second episode schizophrenia Interventions: CBT + medications versus psychoeducational and supportive counseling + medication versus Treatment as usual (no un-medicated group; unclear proportion of first-episodes)
Marder 1991	Allocation: randomised Participants: people with stabilized schizophrenia (n=50) Interventions: in the beginning, all subjects randomly received either behavioural skills training or supportive group therapy; then in the prodromal period, subjects were randomly treated with Fluphenazine or placebo (not an acute treatment study; unclear proportion of first-episodes)
Marder 1994	Allocation: randomised Participants: people with schizophrenia Interventions: 2mg or 6mg or 10mg or 16mg risperidone versus 20mg haloperidol versus placebo (unclear proportion of first and second episodes)
Marder 1996	Allocation: Randomised Participants: males with schizophrenia undergoing treatment at West Los Angeles Veterans Affair Medical Center (n=80) Interventions: behaviorally oriented social skills training or supportive group therapy (not an acute treatment comparison study, no un-medicated group, and unclear proportion of first-epsiodes)
Marques 2001b	Allocation: randomised Participants: women with acute schizophrenia (n=40) Interventions: haloperidol + conjugated estrogens versus haloperidol + placebo (no un-medicated group; unclear proportion of first-episodes)
Marquez 2004a	Allocation: randomised Participants: people with first episode, early phase and stabilized chronic schizophrenia Interventions: Olanzapine versus Haloperidol (unclear proportion of first and second episodes; no un-medicated group)
Martényi 2000	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia Interventions: Olanzapine versus. Fluphenazine (unclear method of assignment to treatment; unclear proportion of first episodes; no un-medicated group)
McConchie 2004	Allocation: randomised Participants: people with first episode psychosis Interventions: essential fatty acid (EAC) versus placebo (no antipsychotics were included)
McEvoy 2003	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode of schizophrenia and schizoaffective disorders (n=262) Interventions: Olanzapine versus haloperidol (no un-medicated group)
McEvoy 2006b	Allocation: randomised Participants: people with first episode of schizophrenia and schizophreniform or schizoaffective disorders (n=400) Interventions: Olanzapine (n=133) versus Quetiapine (n=134) versus Risperidone (n=133) (no un-medicated group)
McEvoy 2006d	Allocation: randomised Participants: people with first episode of schizophrenia and schizophreniform or schizoaffective disorders (n=400) Interventions: Olanzapine versus Quetiapine versus Risperidone (no un-medicated group)
McEvoy 2006f	Allocation: randomised Participants: people with first episode psychosis (n=251) Interventions: olanzapine versus haloperidol (no un-medicated group)
McGlashan 1999	Allocation: randomised Participants: people in the prodromal period of psychosis Interventions: Olanzapine versus placebo (not treatment for acute schizophrenia)
McGlashan 2006	Allocation: randomised Participants: people in the pre-onset phase of the prodromal to schizophrenia (n=60) Interventions: Olanzapine (n=31) versus placebo (n=29) (not treatment for acute schizophrenia)
McGorry 1997a	Allocation: Randomised Participants: Young people aged 16 to 30 years, experiencing a first (non-affective) psychotic episode, non-responders (slow) Inteverntions: 2 mg or 4 mg of risperidone or 2 mg of risperidone + Lithium therapy (No un-medicated group)
McGorry 1997b	Allocation: not random (matched cohorts) Participants: people with first episode schizophrenia Interventions: standard inpatient care versus. intensive community based early intervention (not randomised; no un-medicated group)
McGorry 2002b	Allocation: randomised Participants: people at incipient risk of progression to first episode schizophrenia (n=59) Interventions: needs based intervention (no antipsychotics but could receive antidepressants if necessary) versus low dose risperidone + cognitive behavioral therapy (not treatment for acute schizophrenia)
McGorry 2002c	Allocation: not random

Study	Reason for exclusion
	Participants: people with first episode schizophrenia (n=95) Interventions: in Phase I, all subjects received 2mg Risperidone for 4 weeks; in Phase II, fast responders continue 2mg Risperidone while slow responders were randomised to the following 3 groups: 2mg Risperidone; 4mg Risperidone; lithium + 2gm risperidone (not randomly assigned to treatment; no un-medicated group)
McQuade 2003	Allocation: randomised Participants: people in acute relapse of schizophrenia and requiring hospitalization (n=317) Interventions: Aripiprazole (n=156) versus Olanzapine (n=161) (Unclear proportion of first episodes; no un-medicated group)
Melle 2006	Not a study of the treatment of early onset schizophrenia but of the early detection of susicde attempts among peole with first episode schizophrenia in areas with and without early detection programs.
Melnyk 1966	Allocation: randomised Participants: people with schizophrenia (n=40) after stabilization Interventions: Chlorpromazine or Thioridazine versus Placebos (unclear proportion of first and second episodes; study of medication withdrawal study not of acute treatment)
Merlo 2000	Allocation: randomised Participants: people with first episode psychosis (n=52) Interventions: Risperidone (2 mg or 4 mg) (no un-medicated group)
Merlo 2002b	Allocation: randomised Participants: people with acute psychosis and drug naïve (n=49) Interventions: 2mg Risperidone versus 4mg Risperidone (no un-medicated group)
Merson 1992	Allocation: randomised Participants: people with psychosis (n=100) Interventions: multidiscipline community based intervention (n=48) versus. conventional hospital based psychiatric intervention (n=52) (unclear proportion of first episodes; no un-medicated group)
Michael 2005	Allocation: randomised Participants: people with affective or nonaffective functional psychosis Interventions: SRCBT (Social Recovery Cognitive Behaviour Therapy) versus. standard case management (not an acute treatment study; unclear proportion of first episodes; no un-medicated group)
Miller 2004	Not a study of the treatment for acute schizophrenia but a validation study of Structured Interview for Prodromal Syndromes (the SIPS), which is used to identify people in prodromal phase to schizophrenia
Min 2001	Allocation: randomised Participants: people with first episode schizophrenia (n=81) Interventions: systematic early intervention + risperidone versus risperidone alone (no un-medicated group)

Study	Reason for exclusion
Montero 2005	Allocation: randomised Participants: people with schizophrenia Interventions: Behavioral Family Intervention Group (n=46) versus Relatives Group (n=41) (unclear proportion of first episodes; no contrast of medicated versus. un-medicated group)
Morken 2005	Allocation: randomised Participants: people with recent onset of schizophrenia (within 2 years) (n=50) Interventions: standard treatment + a multidiscipline team with a low case-load (patient-staff ratio about 1:10) versus. standard treatment (no un-medicated group; not an acute treatment study)
Morrison 2004d	Allocation: randomised Participants: people at high risk to develop a first episode psychosis (n=58) Interventions: cognitive therapy versus treatment as usual (not treatment for acute schizophrenia)
Morrison 2006b	Allocation: randomised Participants: young people at high risk of developing psychosis Interventions: cognitive therapy + monitoring versus monitoring only (not treatment for acute schizophrenia)
Mortimer 2003c	Allocation: randomised Participants: people with recent onset schizophrenia, schizoaffective and schizophreniform disorder Interventions: haloperidol, olanzapine, quetiapine, amisulpride, and ziprasidone (no un-medicated group)
Mosher 1978	Allocation: Not randomised Participants: people with DSM-II Schizophrenia, nor more than one prior hospitalization, ages 16-35, unmarried, n=79. Interventions: TAU Hospitalization and antipsychotic medications, n=42; and therapeutic milieu with time-limited postponement (up to 6 weeks) of antipsychotic medications, n=37 (Not randomly assigned to treatment)
Mottaghipour 2000	Allocation: not a treatment comparison study (no assignment to comparative treatments) Participants: families with early onset psychosis (n=34) and families with chronic psychosis (n=39) Interventions: family education (no assignment to comparative treatments; not an acute treatment comparison study)
Mottaghipour 2006	Allocation: randomised Participants: families with first episode psychosis (n=22) Interventions: two models of family education: home based family education versus. family groups at hospital (not an acute treatment comparison study)
Mozes 2006	Allocation: randomised Participants: children with childhood onset schizophrenia (n=25)

Study	Reason for exclusion
	Interventions: Olanzapine versus risperidone (no un-medicated group)
Mueller 2005b	Allocation: randomised Participants: people with schizophrenia or major depression Interventions: risperidone + celecoxib vs. riperidone + placebo (no un-medicated group, unclear proportion of first and second episodes)
Muller 2004	Allocation: randomised Participants: people with recent onset of schizophrenia (n=50) Interventions: Celecoxibplus + Amisulpride versus Amisulpride alone (no un-medicated group)
Murasaki 1999a	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia (n=53) (13 first episodes and 9 second episodes) Interventions: Unclear (needs translation) (unclear method of assignment to treatment; less than 50% first and second episodes (22/54=41%))
Newton 2005	Allocation: unclear (wait list control) Participants: young people with recent onset of auditory hallucinations (n=22) Interventions: group CBT plus medications vs. medications alone (no un-medicated group, not an acute treatment comparison study; unclear proportion of early episodes)
Newton 2006	Allocation: randomised (unclear number of subjects) Participants: young people with recent onset schizophrenia Interventions: Cognitive Remediation Therapy plus standard care versus standard care alone (unclear use of medications; no outcome data reported)
Nienhuis 2006	Allocation: randomised Participants: people with a first onset of non-affective psychosis (n=131) Interventions: after a stable remission phase of 6 months, individuals were randomly assigned to either maintenance treatment group or targeted treatment group (not an acute treatment comparison (medication withdrawal post-stabilization))
Nordentoft 2002	Allocation: randomised Participants: people with first episode psychosis (n=547) Interventions: integrated treatment (assertive community treatment, psychoeducational, multi-family groups, social skills training and antipsychotic, medication) versus treatment as usual (no un-medicated group)
Nuechterlein 1992	Allocation: randomised Participants: people indicating stable remission of psychosis after 1 year of maintenance psychotics Interventions: fluphenazine versus placebo (not an acute treatment comparison study)
Nuechterlein 2005	Allocation: randomised Participants: people with recent onset of schizophrenia (n=51)

Study	Reason for exclusion
	Interventions: Individual Placement and Support (IPS) + a Workplace Fundamental Module (WFM) versus traditional vocational rehabilitation (not an acute treatment comparision study; unclear use of medications)
Nugter 1997	Allocation: randomised Participants: people with recent onset of psychosis and their parents Interventions: individual out-patient treatment versus. a combination of individual out-patient and family treatment (not an acute treatment comparions study, no un-medicated group)
O'Donnell 2003b	Allocation: randomised Participants: people with early psychosis Interventions: Vitamin B (Folic acid and Pyridoxine and Hydroxycobalamin) versus placebo (no antipsychotics were used (no contrast of antipsychotic treated versus un-medicated subjects))
O'Regan 2005	Allocation: randomised Participants: young people with early psychosis (n=40) Interventions: B-complex Vitamin B + antipsychotics versus placebo + antipsychotics (no un-medicated group)
O'Sullivan 2001	Allocation: randomised Participants: people with acute psychosis (n=92) Interventions: Olanzapine (n=46) versus. Ziprasidone (n=46) (unclear proportion of first and second episodes; no un-medicated group)
Offord 1998	Allocation: randomised Participants: people with schizophrenia (n=47) Interventions: M100907 versus placebo (unclear proportion of first and second episode)
Ohlenschlaeger 2002	Allocation: randomised Participants: People with first episode Schizophrenia Interventions: Standard treatment, integrated OPUSteam ACT or inpatient rehabilitation (no un-medicated group)
Oosthuizen 2002a	Allocation: subjects were recruited from 2 trials (one is RCT and the other is an open trial) Participants: people with first-episode schizophrenia or schizophreniform disorder (n=80) Interventions: low-dose Risperidone versus low-dose haloperidol (no un-medicated group)
Oosthuizen 2004	Allocation: randomised Participants: people with first episode schizophreniform disorder, schizophrenia or schizoaffective disorder Interventions: 2 mg/d haloperidol versus. 8 mg/d haloperidol (no un-medicated group)
Opjordsmoen 2000	Allocation: not randomly assigned to treatment (consecutively) Participants: people with early psychosis (n=134)

Study	Reason for exclusion
	Interventions: Olanzapine, risperidone, perphenazine, clozapine (not randomly assigned to treatment; no un-medicated group)
Pagsberg 2004	Allocation: randomised Participants: people with first-episode schizophrenia (n=20) Interventions: Zyclopenthixol (n= 8) versus risperidone (n= 12) (no un-medicated group)
Pai 1982	Allocation: not randomised Participants: people with first episode of psychosis and no previous treatment Interventions: hospital group versus home group (not randomly assigned; no un-medicated group)
Painter 2001	Allocation: unclear method of assignment to treatment Participants: people with schizophrenia (n=50) Interventions: a relapse prevention program versus standard outpatient treatment (unclear method of assignment to treatment; unclear proportion of first and second episodes; unclear use of medications, not a comparison of acute treatments)
Pan Miao 2004b	Allocation: randomised Participants: people with first episode schizophrenia (n=120) Interventions: Quetiapine (n=60) versus Risperidone (n=60) (no un-medicated group)
Papas 2005	Allocation: randomised Participants: young people with first episode psychosis Interventions: B-complex Vitamin versus. placebo (unclear use of antipsychotics)
Parellada 2006	Allocation: randomised Participants: people with first episode psychosis (n=50) Interventions: olanzapine (n= 26) or quetiapine (n= 24) (no un-medicated group)
Parent 1983	Allocation: unclear method of assignment to treatment Participants: people with acute psychosis (n=40) Interventions: Flupenthixol versus haloperidol (unclear method of assignment to treatment; unclear proportion of first and second episodes; no un-medicated group)
Paulman 1980	Not a treatment study for early onset of schizophrenia, but rather a comparison of two theoretical models used to explain schizophrenia
Perez 2003	Allocation: randomised Participants: people with first episode psychosis (n=44) Interventions: Olanzapine, haloperidol or risperidone (no un-medicated group)
Perkins 2000	CBT to improve medication adherence in first-episode psychosis (unclear assignment to treatment, unclear use of medications)
Perkins 2006	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode schizophrenia, schizophreniform, or schizoaffective disorder (n=254) Interventions: Olanzapine versus haloperidol (no un-medicated group)
Petersen 2005a	Allocation: randomised Participants: people with first episode of schizophrenia spectrum disorder (n=547) Interventions: integrated treatment (assertive community treatment + programmes for family involvement + social skills training) versus. treatment as usual (no un-medicated group)
Peuskens 1992	Allocation: randomised Participants: people with chronic schizophrenia Interventions: Risperidone (1, 4, 8, 12, 16mg/day) versus haloperidol (10 mg/day) (not treatment for recent onset schizophrenia; no un-medicated group)
Philips 1999	Allocation: randomised Participants: young people describing state and trait risk factors of psychosis (n=64) Interventions: a combined medical and psychological (specific) approach versus supportive (non-specific) case management (not acute-phase schizophrenia subjects; unclear use of medications)
Pietzcker 1993	Allocation: randomised Participants: people with schizophrenia and in stabilized phase (n=79 for the randomization) Interventions: prophylactic early intervention treatment versus. prophylactic maintenance treatment versus neuroleptics crisis intervention (unclear proportion of first and second episodes; not an acute treatment comparison study; no un-medicated group)
Potkin 2003b	Allocation: randomised Participants: people with acute relapse of schizophrenia (n=404) Interventions: Aripiprazole 20 mg/d (n=101) versus Aripiprazole 30 mg/d (n=101) versus Risperidone 6mg/d (n=99) versus placebo (n=103) (unclear proportion of first and second episode schizophrenia (acute treatment comparision with multi-episodes))
Power 2002	Allocation: randomised Participants: people with non-affective early psychosis Interventions: an assertive outreach multidisciplinary team versus local community mental health team (unclear use of medications; not an acute treatment comparison (follow-up after acute initial treatment))
Power 2003	Allocation: randomised Participants: young people with first episode psychosis (n=56) Interventions: LifeSPAN Therapy (a brief individual cognitively, oriented therapy) + standard clinical care (n=31) versus standard clinical care (n= 25) (no un-medicated group; not an acute medication treatment study)
Power 2006	Allocation: randomised Participants: young people with first episode psychosis

Study	Reason for exclusion
	Interventions: Early Detection and Crisis Assessment team (LEOCAT) versus standard community mental health (unclear use of medications; not an acute medication treatment study)
Poyurovsky 2002b	Allocation: randomised Participants: people with first episode schizophrenia (n=30) Interventions: Olanzapine + Fluoxetine (n= 15) versus Olanzapine + placebo (n=15) (no un-medicated group)
Poyurovsky 2003b	Allocation: randomised Participants: people with first episode schizophrenia (n=26) Interventions: Olanzapine + reboxetine (n= 13) versus Olanzapine + placebo (n=13) (no un-medicated group)
Poyurovsky 2004	Allocation: randomised Participants: people with first episode psychosis (n=13) Interventions: Olanzapine + famotidine (n=7) versus Olanzapine + placebo (n=6) (no un-medicated group)
Proffitt 2004	Allocation: randomised Participants: people with first episode psychosis (n=80) Interventions: Ethyl-Eicosapentenoic Acid (essential fatty acid supplements) versus placebo (not an acute medication treatment study)
Qian 2002b	Allocation: only one treatment group Participants: people with first episode schizophrenia (n=88) Interventions: Risperidone (not randomly assigned; no un-medicated group)
Qiu 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=92) Interventions: Clozapine + family circumstance group versus control group (Clozapine + close circumstance in hospital) (no un-medicated group)
Qu 2005	Allocation: randomised Participants: people with schizophrenia Interventions: chlorpromazine versus risperidal (unclear proportion of first and second episodes; no un-medicated group)
Rabinowitz 2004	Allocation: Post-hoc analysis of clinical dosage of risperidone (not randomly assigned) Participants: people with early episode psychosis (n=276) Interventions: risperidone <= 4mg/d versus risperidone <=5 mg/d versus risperidone >5mg/d (not randomly assigned to treatment; no un-medicated group)
Rabinowitz 2006	Allocation: randomised Participants: people with recent onset psychosis

Study	Reason for exclusion
	Interventions: Haloperidol (n=278) versus Risperidone (n=281) (no un-medicated group)
Rasmussen 1998	Allocation: randomised Participants: people with first episode psychosis (n=500) Interventions: Haloperidol versus risperidone (no un-medicated group)
Reeder 2004	Allocation: Unclear Participants: people with schizophrenia Interventions: individual cognitive remediation therapy (n=18) versus occupational therapy activities (n=14) versus treatment as usual (n=19) (majority multiple-episodes; unclear allocation of treatment; not an acute treatment comparison study)
Reilly 2006	Allocation: randomised Participants: people with early psychosis Interventions: CBT (unclear control group treatment) (unclear use of medications; unclear whether this is an acute or post-acute treatment comparison)
Ren 2005c	Allocation: randomised Participants: people with first episode schizophrenia (n=104) Interventions: antipsychotic drug treatment + CBT (n=54) versus antipsychotic drug treatment (n=50) (no un-medicated group)
Renshaw 2003	Allocation: randomised Participants: people with first episode psychosis (n=263) Interventions: Olanzapine versus haloperidol (no un-medicated group)
Renton 2004	Allocation: unclear method of assignment to treatment Participants: people with psychosis Interventions: cognitive therapy versus treatment as usual (unclear method of assignment to treatment ; unclear proportion of first and second episodes; no un-medicated group)
Reveley 2000a	Allocation: randomised Participants: people with early psychosis (n=26) Interventions: Risperidone versus haloperidol (no un-medicated group)
Rimon 2004	Allocation: randomised Participants: people with acute schizophrenia or chronic schizophrenia with acute symptoms (n=46) Interventions: Olanzapine versus Perphenazine (unclear proportion of first and second episodes; no un-medicated group)
Robles 2006	Allocation: randomised Participants: young people with first episode psychosis (n=50) Interventions: quetiapine (n=24) or olanzapine (n=26) (no un-medicated group)

Study	Reason for exclusion
Ropert 1973	Allocation: unclear method of assignment to treatment Participants: people with acute onset of psychosis (n=17) Interventions: fluphenazine versus pipothiazine (unclear method of assignment to treatment ; unclear proportion of first and second episodes; no un-medicated group)
Rosebush 2000	Allocation: randomised Participants: people with first episode schizophrenia Interventions: olanzapine versus haloperidol (no un-medicated group)
Rosen 2002	Allocation: randomised Participants: people in late prodromal phase of psychosis (n=8) Interventions: medication versus placebo (not an acute schizophrenia treatment comparison study)
Ruhrmann 2006a	Allocation: randomised Participants: people in imminent prodromal state of psychosis (n=124) Interventions: Amisulpride + a needs focused intervention versus a needs focused intervention (not an acute schizophrenia treatment comparison study; no un-medicated group)
Ryu 2006	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia or people with chronic schizophrenia in acute exacerbation (n=71) Interventions: risperidone, olanzapine, quetiatpine, amisulpride, haloperidol and trifluoperazine (unclear method of assignment to treatment; unclear proportion of first and second episodes; no un-medicated group)
Sanger 1999	Allocation: randomised Participants: people with first episode psychosis (with duration <=5 years and age<=45) Interventions: Olanzapine versus haloperidol (no un-medicated group)
Sarkar 1994	Allocation: randomised Participants: people with first episode schizophrenia (n=30) Interventions: electroconvulsive therapy + haloperidol versus placebo electroconvulsive therapy plus haloperidol (no un-medicated group)
Schlogelhofer 2006	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia (n=30) Interventions: Clozapine, Olanzapine, Quetiapine, or Risperidone (unclear method of assignment to treatment; no un-medicated group)
Schooler 1989	No unmedicatred group (in the acute treatment portion of the study), and not an acute treatment study (in the medication withdrawal phase)
Schooler 2005	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode psychosis (n=555) Interventions: Risperidone versus Haloperidol (no un-medicated group)
Schulz 1997	Allocation: unclear method of assignment to treatment Participants: young people with early onset schizophrenia (n=40) Interventions: Clozapine versus standard neuroleptics medications (unclear method of assignment to treatment; no un-medicated group)
Schwannauer 2002	Allocation: randomised Participants: people with first episode of bipolar disorder Interventions: psychosocial intervention versus waiting list control (not treatment for first and second episode schizophrenia; unclear use of medications)
Scottish 1992	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia (n=44) Interventions: Flupenthixol versus Pimozide (unclear method of assignment to treatment; no un-medicated group)
Sharifi 2006	Allocation: randomised Participants: people with first episode psychosis Interventions: routine practice versus telephone follow-up aftercare versus home visits by a team of the general trained practitioners, nurses and social workers (unclear use of medications; not an acute treatment comparison study)
Sharma 2000a	Allocation: randomised Participants: people with first episode psychosis (n=35) Interventions: Haloperidol versus Risperidone (no un-medicated group)
Sharma 2003	Allocation: randomised Participants: people with first episode schizophrenia and schizoaffective disorders (n=263) Interventions: Haloperidol versus Olanzapine (no un-medicated group)
Sheng 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=62) Interventions: Clozapine (n=31) versus risperidone (n=31) (no un-medicated group)
Shi Tianyuan 2004	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia (n=60) Interventions: Clozapine versus Risperidone (unclear method of assignment to treatment; no un-medicated group)
Silverstone 1984b	Allocation: randomised Participants: people with first episode schizophrenia or acute relapse of schizophrenia (n=56)

Study	Reason for exclusion
	Interventions: Haloperidol versus Zetidoline (unclear proportion of first and second episodes; no un-medicated group)
Simonsen 2000	Allocation: randomised Participants: people with non-affective psychosis (n=281) Interventions: an early detection program versus treatment as usual (unclear proportion of first and second episodes; no un-medicated group)
Spencer 1992	Allocation: randomised Participants: children with schizophrenia (n=12) Interventions: Haloperidol versus placebo (unclear proportion of first and second episodes)
Srihari 2006	Allocation: randomised Participants: people with first episode psychosis Interventions: STEP program (antipsychotics, multi-family psycho-education, group CBT, case management and cognitive remediation) versus usual community care (no un-medicated group)
SSRG 1987	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia (n=49) Interventions: In the first year : Flupenthixol versus Pimozide; In the second year: active medications versus placebos (unclear method of assignment to treatment; no initial un-medicated group)
Stain 2006	Allocation: randomised Participants: young people at risk of developing psychotic disorders Interventions: an early intervention (CBT + motivational interviewing) for rural and remote communities (not an acute treatment comparison study (prodromal phase))
Stotsky 1977	Allocation: randomised Participants: people with acute excitement and agitation (n=30) Interventions: Haloperidol versus Thiothixene (not an acute psychosis treatment comparison study; no un-medicated group)
Strakowski 1997	Allocation: randomised Participants: people with first episode manic or schizophrenic psychosis (n=13) Interventions: amphetamine, placebos (not an acute treatment comparison of antipsychotic medications (amphetamine challenge study))
Strakowski 2005	Allocation: randomised Participants: people with first episode schizophrenia (n=195) Interventions: olanzapine versus haloperidol (no un-medicated group)
Stuart 2004	Allocation: unclear method of assignment to treatment Participants: people with first episode psychosis Interventions: amisulpride (unclear method of assignment to treatment; no un-medicated group)

Study	Reason for exclusion
Su 2002b	Allocation: randomised Participants: people with first episode schizophrenia (n=94) Interventions: Chlorpromazine versus Risperidone (no un-medicated group)
Sun 2000a	Allocation: randomised Participants: people with first episode schizophrenia (n=117) Interventions: Clozapine versus Risperidone (no un-medicated group)
Sun 2006a	Allocation: randomised Participants: people with first episode schizophrenia (n=117) Interventions: Clozapine versus Risperidone (no un-medicated group)
Sun 2006e	Allocation: randomised Participants: people with first episode schizophrenia (n=71) Interventions: Chlorpromazine versus Quetiapine (no un-medicated group)
Suri 2001	Allocation: randomised Participants: people with early schizophrenia Interventions: CBT plus medications versus medications alone (no un-medicated group)
Svestka 2003a	Allocation: randomised Participants: people with first episode schizophrenia and schizophreniform disorders (n=42 females) Interventions: Olanzapine versus Risperidone (no un-medicated group)
Tait 2002	Allocation: randomised Participants: people with schizophrenia spectrum disorders (n=20) Interventions: cognitively oriented intervention (3 stages: initial engagement and formulation; early sings monitoring; targeted cognitive therapy if required) versus treatment as usual (unclear proportion of first and second episodes; unclear use of medications; not an acute treatment comparison study (relapse prevention))
Tait 2005	Allocation: randomised Participants: young people with first episode psychosis Interventions: educational intervention versus alternative educational session on cognitive behavior therapy for depression (control practices) (not an acute treatment comparison study (reduction of DUP))
Tan 2005b	Allocation: randomised Participants: older adults with first episode schizophrenia (n=51) Interventions: Haloperidol versus Risperidone (no un-medicated group)
Tao 2005a	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode schizophrenia (n=177) Interventions: medications plus CBT versus medications alone (no un-medicated group)
Tao Yuan Li 2004	Allocation: randomised Participants: people with first episode schizophrenia (n=97) Interventions: antipsychotic medications plus psychological and social interventions versus antipsychotic medications alone (no un-medicated group)
Tarrier 2000d	Allocation: randomised Participants: people with recent onset schizophrenia and substance abuse (dual diagnosis) Interventions: psychological intervention (dual diagnosed persons; unclear use of medications)
Thompson 2005	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia (n=39) Interventions: Haloperidol (n=18) versus Olanzapine (n=21) (unclear method of assignment to treatment; no un-medicated group)
Tian 2005	Allocation: randomised Participants: children with first episode schizophrenia (n=60) Interventions: family nursing intervention plus Risperidone versus routine treatment plus Risperidone (no un-medicated group)
Toben 1998	Allocation: randomised Participants: people with an acute episode of bipolar disorder (manic or mixed) Interventions: Olanzapine (n=70) versus Placebos (n=69) (unclear proportion of first and second episodes)
Tohen 1997a	Allocation: randomised Participants: people with first episode psychosis (n=82) Interventions: Haloperidol versus Olanzapine (no un-medicated group)
Tohen 2000b	Allocation: randomised Participants: people with bipolar I disorder and manic or mixed, with or without psychotic features Interventions: Olazanpine versus placebo (unclear proportion of first and second episodes)
Tollefson 1997 HGAJ	Allocation: randomised Participants: people with schizophrenia, schizophreniform, or schizoaffective disorder Interventions: Olanzapine or haloperidol (unclear proportion of first and second episodes; no un-medicated group)
Tollefson 1997b	Allocation: controlled longitudinal study Participants: people with chronic schizophrenia, schizophreniform disorder, or schizoaffective disorder

Study	Reason for exclusion
	Interventions: olanzapine (n=707) or haloperidol (n=197) (not randomly assigned to treatment; not an acute treatment comparison study (tardive dyskinesia in long-term treatment); not first and second episodes; no un-medicated group)
Tollefson 1997c	Allocation: randomised Participants: people with schizophrenia or related diagnosis (n=1996) Interventions: Olanzapine or haloperidol (unclear proportion of first and second episodes; no un-medicated group)
Tong 2003	Allocation: only one treatment group Participants: people with first episode schizophrenia (n=30) and recurrent schizophrenia (n=36) Interventions: Risperidone (not randomly assigned to treatment; the proportion of first episodes does not exceed 50%; no un-medicated group)
Tran 1997a	Allocation: randomised Participants: people with schizophrenia, schizophreniform or schizoaffective disorders Interventions: Olanzapine versus Risperidone (unclear proportion of first and second episodes; no un-medicated group)
Ueland 2004	Allocation: randomised Participants: adolescents with early onset psychosis Interventions: cognitive remediation (four modules: four modules: cognitive differentiation, attention, memory and social perception) (n=14) versus control group (n=12) (not an acute treatment comparison study; unclear use of medications)
Vaglum 2002	Allocation: unclear method of assignment to treatment Participants: people with first episode schizophrenia Interventions: an early detection program (unclear method of assignment to treatment; unclear use of medications; not an acute treatment comparison study)
Van Bruggen 1999	Allocation: randomised Participants: young people with a relatively short duration of untreated first or second psychosis Interventions: Olanzapine versus Risperidone (no un-medicated group)
Van Bruggen 2003	Allocation: randomised Participants: young people with recent onset schizophrenia (n=44) Interventions: Olanzapine versus Risperidone (no un-medicated group)
Van Meijel 2006a	Allocation: randomised Participants: people with stable schizophrenia or related psychosis Interventions: experimental group (Relapse Prevention plans) or control condition (care as usual) (not an acute treatment comparison study; not first and second episodes; unclear use of medications)
Van Meijel 2006b	Allocation: randomised

Study	Reason for exclusion
	Participants: people with first episode non-affective psychosis (n=144) Interventions: adapted interventions (cognitive behavioural therapy plus medication management plus vocational support plus family interventions) versus standard generic community services (no un-medicated group)
Van Nimwegen 2006a	Allocation: randomised Participants: people with first episode psychosis (n=131) Interventions: Olanzapine versus Risperidone (no un-medicated group)
Van Nimwegen 2006b	Allocation: randomised Participants: young people with recent onset schizophrenia or related disorders (n=131) Interventions: Olanzapine versus Risperidone (no un-medicated group)
Van Nimwegen 2006c	Allocation: randomised Participants: adolescents with first episode psychosis (n=78) Interventions: Olanzapine versus Risperidone (no un-medicated group)
Verhaegh 2006	Allocation: not randomly assigned to treatment Participants: young people with first episode psychosis Interventions: assertive community treatment versus care as usual (unclear use of medications; not an acute treatment comparison study; not randomly assigned to treatment)
Vollenweider 2003	Allocation: matched case-control study Participants: males with first episode schizophrenia (n=15) and controls Interventions: scanned brain activity (not randomly assigned to treatment; not an acute treatment comparison study)
Volterra 1996	Allocation: randomised Participants: people with recent onset schizophrenia (n=40) Interventions: a group or individual one-year treatment with insight-oriented therapy plus haloperidol (n= 22) versus drug therapy alone (n=18) (unclear proportion of first and second episodes; no un-medicated group)
Wang 2000a	Allocation: randomised Participants: people with first episode psychosis (n=100) Interventions: Clozapine versus Risperidone (no un-medicated group)
Wang 2003a	Allocation: randomised Participants: people with first episode schizophrenia (n=251) Interventions: CBT + regular antipsychotics (Risperidone and Clozapine) versus antipsychotics alone (Risperidone and Clozapine) (no un-medicated group)
Wang 2003i	Allocation: randomised Participants: people with first episode schizophrenia (n=200)

Study	Reason for exclusion
	Interventions: Risperidone plus Valproic Acid versus Risperidone alone (no un-medicated group)
Wang 2004d	Allocation: randomised Participants: people with first episode schizophrenia (n=80) Interventions: Hyberzine plus Quetiapine versus Quetiapine alone (control group) (no un-medicated group)
Wang 2004k	Allocation: randomised Participants: people with first-episode schizophrenia (n=64) Interventions: Olazepine or risperdal (No un-medicated group)
Wang 2005c	Allocation: randomised Participants: people with first-episode schizophrenia (n=72) Interventions: Aripiprazole or chlorpromazine (No un-medicated group)
Wang 2005d	Allocation: randomised Participants: people with first episode schizophrenia (n=96) Interventions: Risperidone or perphenazine (No un-medicated group)
Wang 2005e	Allocation: randomised Participants: people with first episode schizophrenia (n= 67) Interventions: Quetiapine or risperidone (No un-medicated group)
Wang 2005g	Allocation: randomised Participants: people with first episode schizophrenia (n=64) Interventions: Risperidone and clozapine (No un-medicated group)
Wang 2005h	Allocation: randomised Participants: people with first episode schizophrenia (n= 55) Interventions: Risperidone and chlorpromazine (No un-medicated group)
Wang 2005j	Allocation: randomised Participants: people with first episode schizophrenia (n=60) Interventions: Aripiprazloe and clozapine (No un-medicated group)
Wang 2005m	Allocation: randomised Participants: people with first episode schizophrenia (n=100) Interventions: Chlorpromazine and risperidone (No un-medicated group)
Wang 2006b	Allocation: randomised Participants: people with first episode schizophrenia (n=86) Interventions: Chlorpromazine, clozapine, and risperidone (No un-medicated group)

Study	Reason for exclusion
Wang 2006c	Allocation: randomised Participants: people with first episode schizophrenia (n=117) Interventions: Risperidone, clozapine, and chlorpromazine (No un-medicated group)
Wang 2006e	Allocation: randomised Participants: people with first episode schizophrenia (n=64) Interventions: Aripiprazole and clozapine (No un-medicated group)
Wang 2006i	Allocation: randomised Participants: people with first episode schizophrenia (n=60) Interventions: Quetiapine and clozapine (No un-medicated group)
Wang 2006k	Allocation: randomised Participants: people with first episode schizophrenia (n=61) Interventions: Clozapine and risperidone (No un-medicated group)
Warrington 2006	Allocation: randomised Participants: Unknown Interventions: 2 mg vs. 20 mg of ziprasidone (No un-medicated group)
Wei 2006a	Allocation: randomised Participants: people with first-episode schizophrenia (n=58) Interventions: Quetiapine and risperidone (No un-medicated group)
Wei 2006b	Allocation: randomised Participants: people with first episode schizophrenia (n=101 females) Interventions: Aripiprazole and quetiapine (No un-medicated group)
Wei 2006c	Allocation: randomised Participants: people with first episode schizophrenia (n=101 females) Interventions: Aripiprazole and quetiapine (No un-medicated group)
WHO 1979	Allocation: Multi-site study (no allocation to treatment)
Williams 2005b	Allocation: randomised Participants: Persons aged 14-35 with early psychosis Interventions: Systematic psychosocial interventions + treatment as usual VS. treatment as usual alone (No un-medicated group; not an acute treatment comparison study)
Wilson 1982b	Allocation: Randomised Participants: People with schizophrenia (n=39)

Study	Reason for exclusion
	Interventions: Flutroline (4 dosage groups: 1, 5, 10, and 20 mg) (unclear proportion of first and second episodes; no un-medicated group)
Wirshing 1992b	Allocation: Randomised Participants: People with schizophrenia (n=81) Interventions: Oral neuroleptic supplementation vs. Placebo supplementation to active medication in both groups (Unclear proportion of first and second episodes; not an acute treatment study (dosage reduction study); no un-medicated group)
Woggon 1978	Allocation: Randomised Participants: people with schizophrenia (n=40) Interventions: Bromperidol vs. perphenazine (no un-medicated group; unclear proportion of first and second episodes)
Woods 2002a	Allocation: Randomised Participants: People with schizophrenia, diagnosed as prodromal Interventions: Olanzapine vs. placebo (Pre-acute treatment comparison study)
Woods 2002b	Allocation: Unknown Participants: people with schizophrenia patients (n=25) Interventions: Glycine (not sure of whether there is a comparison or control group) (unclear method of treatment assignment; pre-acute treatment comparison study)
Woods 2003	Allocation: Randomised Participants: people with schizophrenia (n=60) Interventions: Olanzapine vs. placebo (Pre-acute treatment comparison study)
Woods 2004	Allocation: Non random Participants: people with first-episode schizophrenia with zero duration of untreated psychosis (vs. two historical first episode samples treated after usual DUP) Interventions: Olanzapine (Not randomly assigned to treatment; no un-medicated group; not an acute treatment study)
Wu 2001a	Allocation: Unknown Participants: people with first episode schizophrenia (n=97) Interventions: Three groups: clozapine and 2 risperdione groups (middle dosage and very low dosage) (unknown method of assignment to treatment; no un-medicated group)
Wu 2002c	Allocation: Unknown Participants: people with schizophrenia (negative vs. positive subtypes) Interventions: Clozapine (unknown method of assignment to treatment; no un-medicated group)
Wu 2006	Allocation: Unknown Participants: People with first-episode schizophrenia

Study	Reason for exclusion
	Interventions: Aripiprazole vs. haldol (unknown method of assignment to treatment; no un-medicated group)
Wu 2006a	Allocation: Randomised Participants: people with first episode schizophrenia (n=112) Interventions: Clozapine, olanzapine, risperidone, and sulpiride (no un-medicated group)
Wunderink 2003	Allocation: Randomised Participants: People with first episode schizophrenia Interventions: short (6 months) vs. sustained (2 years) antipsychotic drug treatment (not an acute treatment study, no un-medicated group)
Wunderink 2006	Allocation: Randomised Participants: people with remitted first episode schizophrenia (n=131) Interventions: Discontinuation strategy vs. maintenance treatment (not an acute treatment study)
Xie 1998	Allocation: Randomised Participants: people with first episode schizophrenia (n=122) Interventions: Clozapine vs. chlorpromazine (no un-medicated group)
Xu 2003d	Allocation: Randomised Participants: people with first episode schizophrenia (n=287) Interventions: Recovery psychotherapy vs. control (not an acute treatment study; not a medication treatment comparison study)
Xu 2005b	Allocation: Randomised Participants: people with first episode schizophrenia (n=110) Interventions: Insight education + risperidone vs. risperidone (no un-medicated group)
Yang 1999c	Allocation: Unknown Participants: people with first episode schizophrenia (n=78) Interventions: Chlorpromazine vs. clozapine (unknown method of assignment to treatment; no un-medicated group)
Yang 2000b	Allocation: Randomised Participants: people with first episode schizophrenia (n=164) Interventions: chlorpromazine or clozapine Outcomes: Brief Psychiatric Rating Scale (BPRS), Scale for Assessment of Negative Symptoms (SANS; Chinese version), Global Assessment of Functioning Scale (GAF) (No un-medicated group)
Yang 2001	Allocation: Unknown Participants: people with first episode schizophrenia (n=124)

Study	Reason for exclusion
	Interventions: Chlorpromazine or clozapine (unknown method of assignment to treatment; no un-medicated group)
Yang 2003a	Allocation: Randomised Participants: people with first episode schizophrenia (n=70) Interventions: Olanzapine or risperidone (no un-medicated group)
Yang 2004b	Allocation: Randomised Participants: people with first episode schizophrenia (n=160) Interventions: Chlorpromazine or clozapine (no un-medicated group)
Yang 2005c	Allocation: Randomised Participants: people with first episode schizophrenia (n=60) Interventions: quetiapine or risperidone (no un-medicated group)
Yang 2006b	Allocation: Randomised Participants: people with first episode schizophrenia (n=100) Interventions: Aripirazole or haloperidol (no un-medicated group)
Yang 2006g	Allocation: Randomised Participants: people with first episode schizophrenia (n=75) Interventions: Ximin or Zyprexa (no un-medicated group)
Yang Bin 2004	Allocation: Randomised Participants: people with first episode schizophrenia (n=95) Interventions: Clozapine, risperidone, and haloperidol (no un-medicated group)
Yanos 2004	Allocation: Nonrandomised Participants: homeless participants with severe mental illness (38.8% with schizophrenia or related) Interventions: Referral to Pathways to Housing (not randomly assigned to treatment; unclear proportion of first and second episodes; not an acute treatment study; no medicated group)
Ye 2005a	Allocation: Randomised Participants: people with first episode schizophrenia (n=34) Interventions: Aripiprazole or risperidone (no un-medicated group)
Ye 2005b	Allocation: Randomised Participants: people with first episode schizophrenia (n=54) Interventions: Clozapine or risperidone (no un-medicated group)
Yu 2001b	Allocation: Randomised Participants: people with first episode schizophrenia (n=62)

Study	Reason for exclusion
	Interventions: Risperidone or chlorpromazine (no un-medicated group)
Yu E Li 2004	Allocation: Randomised Participants: people with first-episode schizophrenia (n=66) Interventions: Clozapine vs. clozapine + psychological/social intervention (no un-medicated group)
Zeng 2003	Allocation: Randomised Participants: people with first episode schizophrenia (n=136) Interventions: Clozapine vs. clozapine plus psychological education (no un-medicated group)
Zeng 2006	Allocation: Randomised Participants: people with first episode schizophrenia (n=116) Interventions: anti-psychotics vs. anti-psychotics plus comprehensive intervention (no un-medicated group)
Zhang 1994a	Allocation: Randomised Participants: males with first episode schizophrenia (n=78) Interventions: Family intervention vs. control group (both medicated) (no un-medicated group)
Zhang 1998c	Allocation: Randomised, Cross-sectional 4-group design Participants: Children with autism and first-episode schizophrenia Interventions: This is not an intervention study (not an acute treatment study (4 group comparison of lymphocyte levels))
Zhang 1998d	Allocation: Unknown Participants: relatives of people with schizophrenia (682 experimental; 366 control) Interventions: Group psychotherapy + conventional services vs. conventional services for the family members of persons with schizophrenia (not an acute treatment study of people with schizophrenia-type psychoses)
Zhang 2000f	Allocation: Nonrandomised Participants: women with first episode psychosis (119 pregnancy/parturition; 55 non-pregnancy/parturition) Interventions: None (not an acute treatment comparison study; no un-medicated group)
Zhang 2002j	Allocation: Nonrandomised Participants: people with first episode schizophrenia or schizophrenic form psychosis (n=24) Interventions: Clozapine (not randomly assigned to treatments (a single treatment group study); no un-medicated group)
Zhang 2003l	Allocation: Randomised Participants: people with first episode schizophrenia (n=250) Interventions: Celexib plus risperidone vs. risperidone (no un-medicated group)

Study	Reason for exclusion
Zhang 2004a	Allocation: Randomised Participants: people with first episode schizophrenia (n=126) Interventions: Varying doses of risperidone (2, 3, 4, or 5 mg) (no un-medicated group)
Zhang 2005k	Allocation: Randomised Participants: people with first episode schizophrenia (n=111) Interventions: Parents health education vs. routine services (not an acute treatment study; no contrast of medicated vs. un-medicated subject groups)
Zhang 2005l	Allocation: Randomised Participants: people with first episode schizophrenia (n=200) Interventions: Artemisinin (an anti-malarial medication) vs. placebo (adjunctive treatment comparison) (no contrast of a treatment group receiving antipsychotic medication treatment and another group not receiving antipsychotics)
Zhang Fuying 2005	Allocation: Randomised Participants: people with first episode schizophrenia (n=93) Interventions: Nurse home visits vs. none (not an acute treatment study; no contrast of medicated vs. un-medicated subject groups)
Zhao 2006	Allocation: Randomised Participants: people with first-episode schizophrenia (n=68) Interventions: Aripiprazole vs. quetiapine (no un-medicated group)
Zheng 2003c	Allocation: Randomised Participants: people with first episode schizophrenia (n=68) Interventions: Clozapine vs. risperidone (no un-medicated group)
Zhi 2006	Allocation: Randomised Participants: females with first episode schizophrenia (n=124) Interventions: risperidone vs. self-efficacy plus risperidone (no un-medicated group)
Zhou 2005c	Allocation: Randomised Participants: people with first episode schizophrenia (n=118) Interventions: Risperidone vs. clozapine (no un-medicated group)
Zhu 2001a	Allocation: Nonrandomised Participants: people with first episode schizophrenia or schizophreniform psychosis (n=28) Interventions: Clozapine (varying dosages) (not randomly assigned to treatment; not a treatment comparison study (one-group design); no un-medicated group)
Zhu 2001b	Allocation: Randomised Participants: people with first episode schizophrenia (n=23)

Study	Reason for exclusion
	Interventions: Risperidone: full vs. half dosage (no un-medicated group)
Zhu 2002g	Allocation: Randomised Participants: people with first episode schizophrenia (n=90) Interventions: He-Ne laser intravascular irradiation vs. none (both groups received risperidone) (no un-medicated group)
Zhu 2002i	Allocation: Randomised Participants: 68 people with first episode schizophrenia (n=68) Interventions: Haloperidol, clozapine, and risperidone (no un-medicated group)
Zipursky 2004	Allocation: Randomised Participants: people with first episode psychosis (n=25; 80.4% diagnosed with schizophrenia) Interventions: Home intervention for psychosis (HIP) vs. specialized first-episode psychosis clinic (FEPC) (no un-medicated group)
Zipursky 2005a	Allocation: Randomised Participants: People with first episode schizophrenia (n=239) Interventions: Olanzapine or haloperidol (no un-medicated group)
Zipursky 2005b	Allocation: Randomised Participants: people with first episode schizophrenia, schizophreniform disorder, or schizoaffective disorder (n=263) Interventions: Olanzapine or haloperidol (no un-medicated group)
Zuo 2000	Allocation: Unknown Participants: people with first episode schizophrenia (n=35) Interventions: Risperidone (dosage ranging from 2 to 8 mg a day) (no un-medicated group)
Zuo 2002	Allocation: Unknown Participants: People with first episode schizophrenia Interventions: Clozapine or risperidone (no un-medicated group)

Characteristics of studies awaiting assessment *[ordered by study ID]*

Johnstone 1988

Methods	Randomised.
Participants	People with definite or possible psychosis. Stage/state: admitted under care of participating clinicians. Age: 16-69 years of age. N=120.

Johnstone 1988 *(Continued)*

Interventions	1. Lithium and pimizode. 2. Lithium. 3. Pimizode. 4. Placebo.
Outcomes	No useable data published, seeking unpublished data from authors.
Notes	

Characteristics of ongoing studies *[ordered by study ID]*

Francey 2010

Trial name or title	
Methods	Randomised.
Participants	People with first-episode psychosis.
Interventions	1. Cognitive Behavioural Treatment plus Family Treatment and placebo 2. Cognitive Behavioural Treatment plus Family Treatment and low dose antipsychotic medication.
Outcomes	Social functioning: SOFAS. Clinical symptoms: remission and recovery.
Starting date	July 2009.
Contact information	Patrick McGorry, pmcgorry@unimelb.edu.au
Notes	

DATA AND ANALYSES

Comparison 1. CHLORPROMAZINE vs PLACEBO

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	3	353	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.29, 0.54]
2 Global state: not improved after 8 years (Psychiatric rating scale, not improved=1,2; improved=4,5)	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.53, 1.11]
3 Rehospitalisation within 3 years - completer	1	80	Risk Ratio (M-H, Fixed, 95% CI)	2.29 [1.31, 4.03]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Rehospitalisation within 3 years - intent to treat	1	127	Risk Ratio (M-H, Fixed, 95% CI)	2.30 [1.50, 3.54]
5 Adverse effects: various outcomes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 drowsiness	1	162	Risk Ratio (M-H, Fixed, 95% CI)	5.65 [2.72, 11.73]
5.2 restlessness	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.83, 1.71]
5.3 constipation	1	162	Risk Ratio (M-H, Fixed, 95% CI)	2.71 [1.37, 5.35]
5.4 nausea or upper gastrointestinal distress	1	162	Risk Ratio (M-H, Fixed, 95% CI)	6.17 [1.92, 19.79]
5.5 dryness of mouth or throat	1	162	Risk Ratio (M-H, Fixed, 95% CI)	4.63 [1.67, 12.82]
5.6 dizziness, faintness or weakness	1	162	Risk Ratio (M-H, Fixed, 95% CI)	4.41 [1.59, 12.29]
5.7 muscle rigidity	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.60, 3.97]
5.8 nasal congestion	1	162	Risk Ratio (M-H, Fixed, 95% CI)	2.10 [0.69, 6.43]
5.9 facial rigidity	1	162	Risk Ratio (M-H, Fixed, 95% CI)	2.31 [0.77, 6.96]
5.10 tremor of hands, arms or face	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.29, 3.77]
5.11 headache	1	162	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.33, 2.13]
5.12 loss of associated movements	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.22, 7.35]
5.13 akathesis-restlessness of feet	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.40 [0.35, 5.67]

Analysis 1.1. Comparison 1 CHLORPROMAZINE vs PLACEBO, Outcome 1 Leaving the study early.

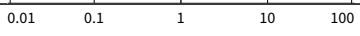
Study or subgroup	CPZ n/N	PLACEBO n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Simon 1965	0/20	0/20			Not estimable
Cole 1964	24/112	51/74		69.04%	0.31[0.21,0.46]
Rappaport 1978	14/53	33/74		30.96%	0.59[0.35,0.99]
Total (95% CI)	**185**	**168**		**100%**	**0.4[0.29,0.54]**
Total events: 38 (CPZ), 84 (PLACEBO)					
Heterogeneity: Tau^2=0; Chi^2=3.85, df=1(P=0.05); I^2=74.02%					
Test for overall effect: Z=5.9(P<0.0001)					

Favours experimental

Favours control

Analysis 1.2. Comparison 1 CHLORPROMAZINE vs PLACEBO, Outcome 2 Global state: not improved after 8 years (Psychiatric rating scale, not improved=1,2; improved=4,5).

Study or subgroup	CPZ n/N	PLACEBO n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Simon 1965	13/20	17/20		100%	0.76[0.53,1.11]
Total (95% CI)	**20**	**20**		**100%**	**0.76[0.53,1.11]**
Total events: 13 (CPZ), 17 (PLACEBO)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.42(P=0.16)					



Analysis 1.3. Comparison 1 CHLORPROMAZINE vs PLACEBO, Outcome 3 Rehospitalisation within 3 years - completer.

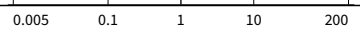
Study or subgroup	CPZ n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Rappaport 1978	24/39	11/41		100%	2.29[1.31,4.03]
Total (95% CI)	**39**	**41**		**100%**	**2.29[1.31,4.03]**
Total events: 24 (CPZ), 11 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.89(P=0)					

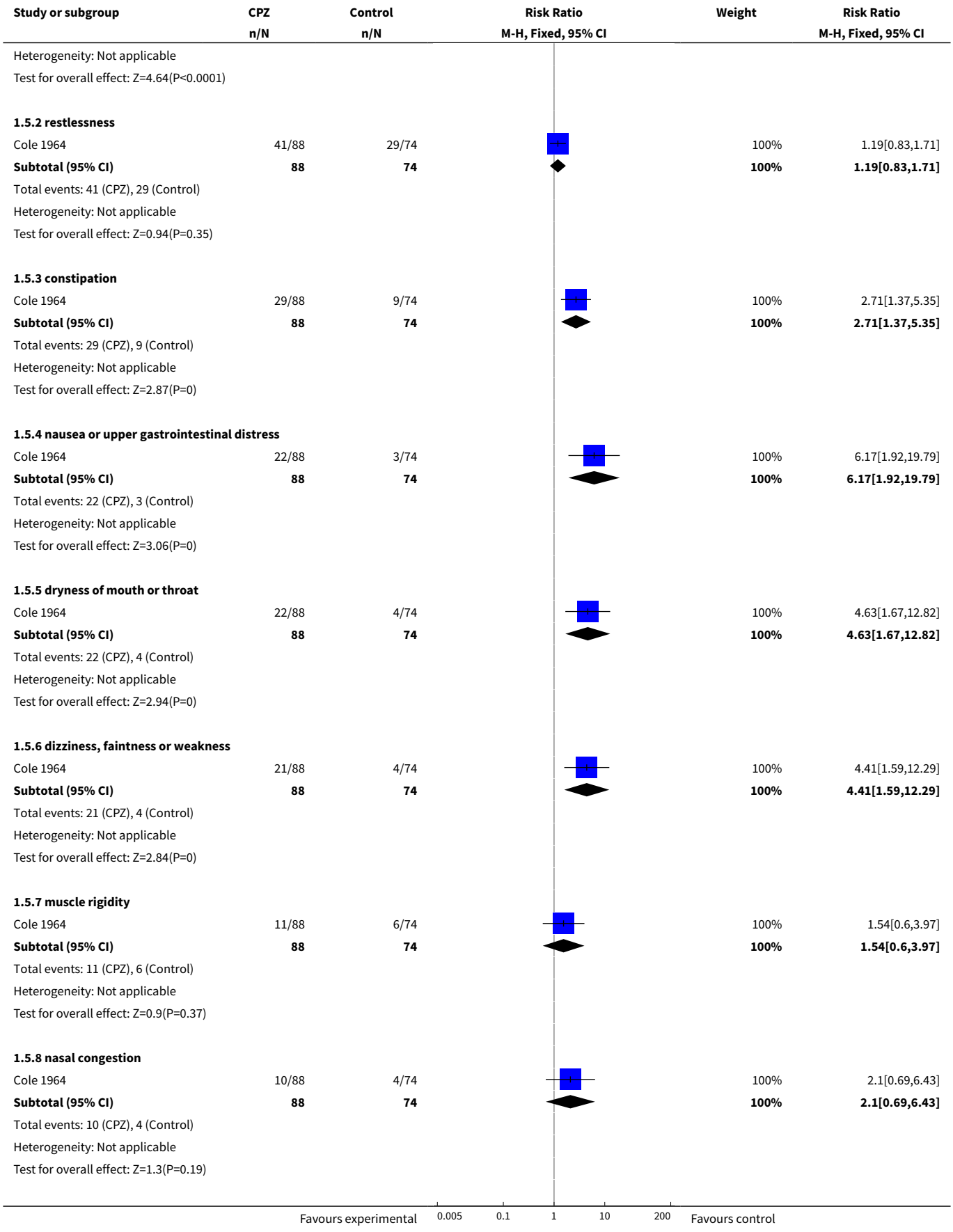
Analysis 1.4. Comparison 1 CHLORPROMAZINE vs PLACEBO, Outcome 4 Rehospitalisation within 3 years - intent to treat.

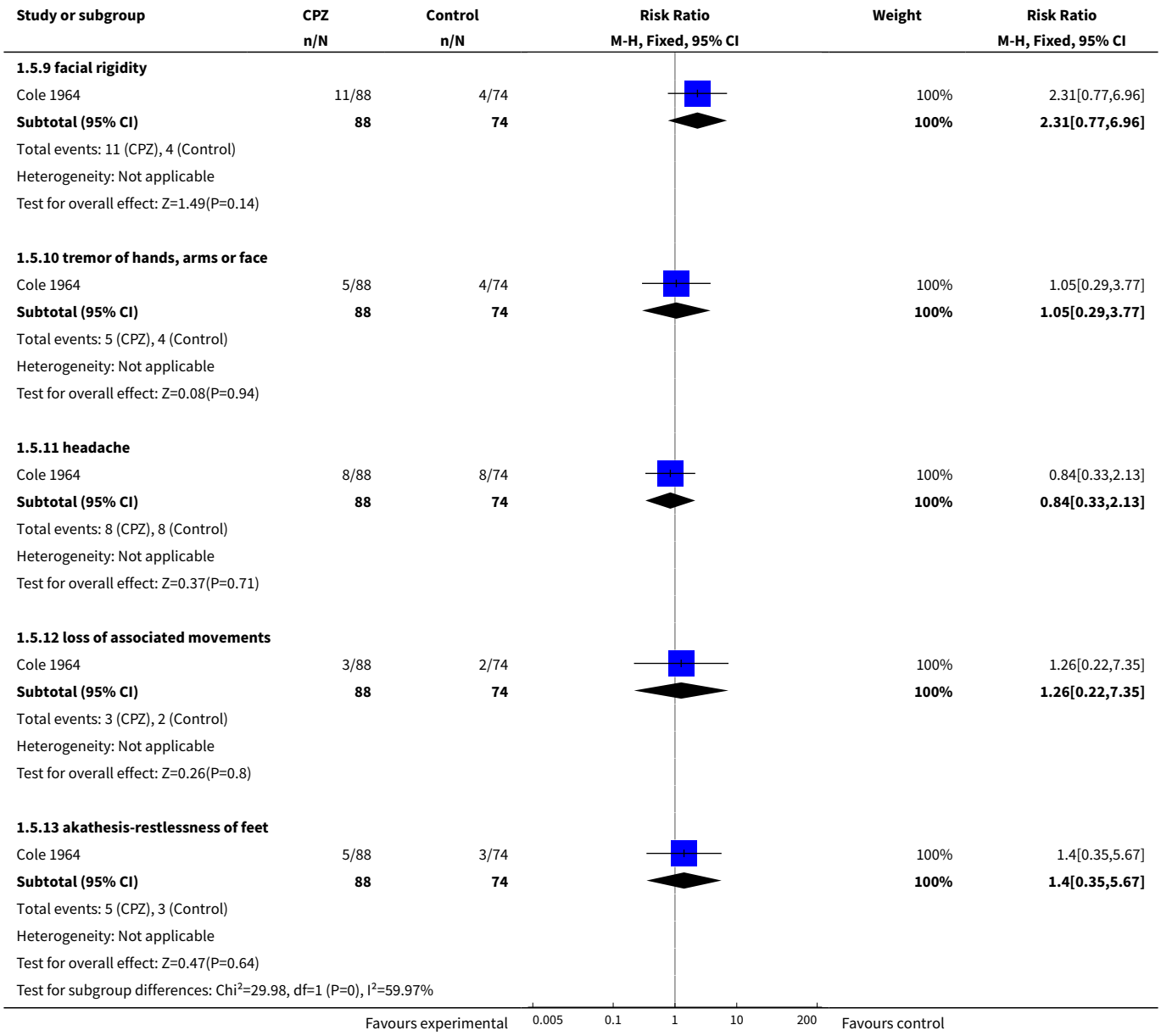
Study or subgroup	CPZ n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Rappaport 1978	33/53	20/74		100%	2.3[1.5,3.54]
Total (95% CI)	**53**	**74**		**100%**	**2.3[1.5,3.54]**
Total events: 33 (CPZ), 20 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=3.81(P=0)					

Analysis 1.5. Comparison 1 CHLORPROMAZINE vs PLACEBO, Outcome 5 Adverse effects: various outcomes.

Study or subgroup	CPZ n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.5.1 drowsiness					
Cole 1964	47/88	7/74		100%	5.65[2.72,11.73]
Subtotal (95% CI)	**88**	**74**		**100%**	**5.65[2.72,11.73]**
Total events: 47 (CPZ), 7 (Control)					





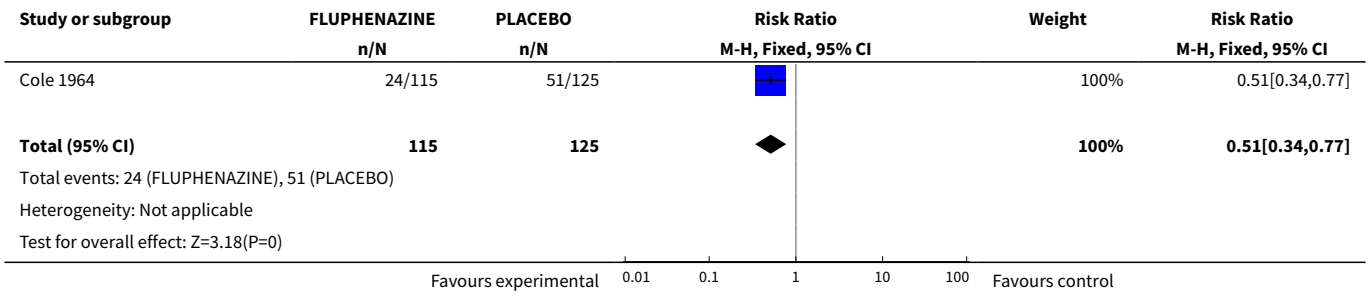


Comparison 2. FLUPHENAZINE vs PLACEBO

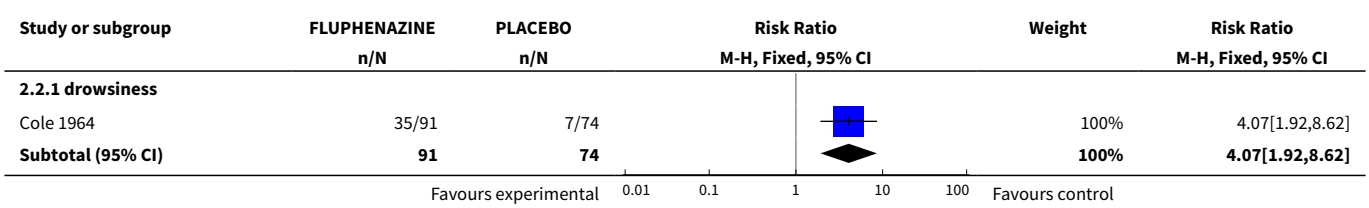
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	1	240	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.34, 0.77]
2 Adverse effects: various outcomes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 drowsiness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	4.07 [1.92, 8.62]
2.2 restlessness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.60, 1.34]

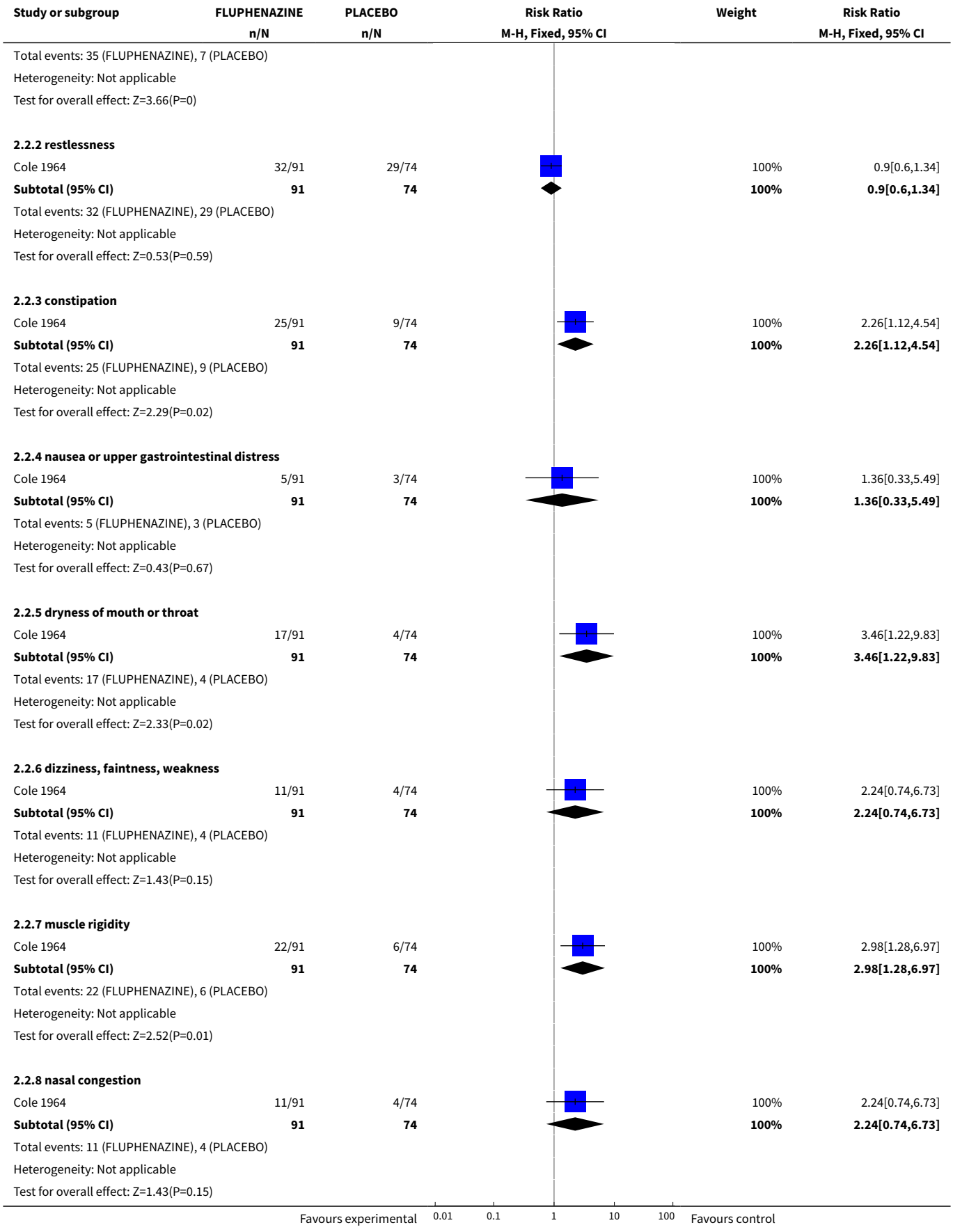
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 constipation	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.26 [1.12, 4.54]
2.4 nausea or upper gastrointestinal distress	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.36 [0.33, 5.49]
2.5 dryness of mouth or throat	1	165	Risk Ratio (M-H, Fixed, 95% CI)	3.46 [1.22, 9.83]
2.6 dizziness, faintness, weakness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.24 [0.74, 6.73]
2.7 muscle rigidity	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.98 [1.28, 6.97]
2.8 nasal congestion	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.24 [0.74, 6.73]
2.9 facial rigidity	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.64 [0.90, 7.77]
2.10 tremor of hands, arms, face	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.24 [0.74, 6.73]
2.11 headache	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.47, 2.64]
2.12 loss of associated movements	1	165	Risk Ratio (M-H, Fixed, 95% CI)	7.32 [1.75, 30.53]
2.13 akathesis-restlessness of feet	1	165	Risk Ratio (M-H, Fixed, 95% CI)	3.52 [1.04, 11.90]

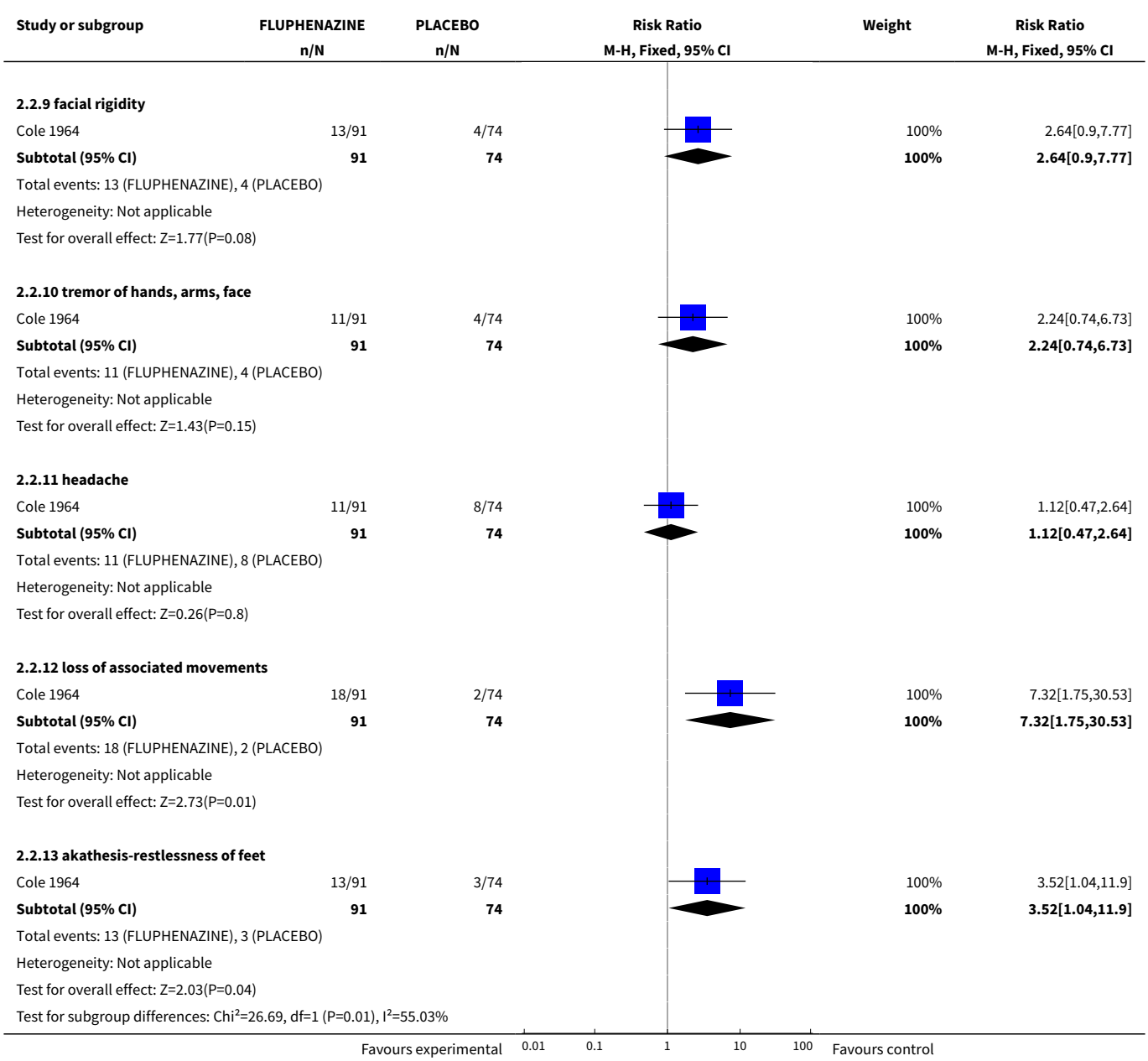
Analysis 2.1. Comparison 2 FLUPHENAZINE vs PLACEBO, Outcome 1 Leaving the study early.



Analysis 2.2. Comparison 2 FLUPHENAZINE vs PLACEBO, Outcome 2 Adverse effects: various outcomes.





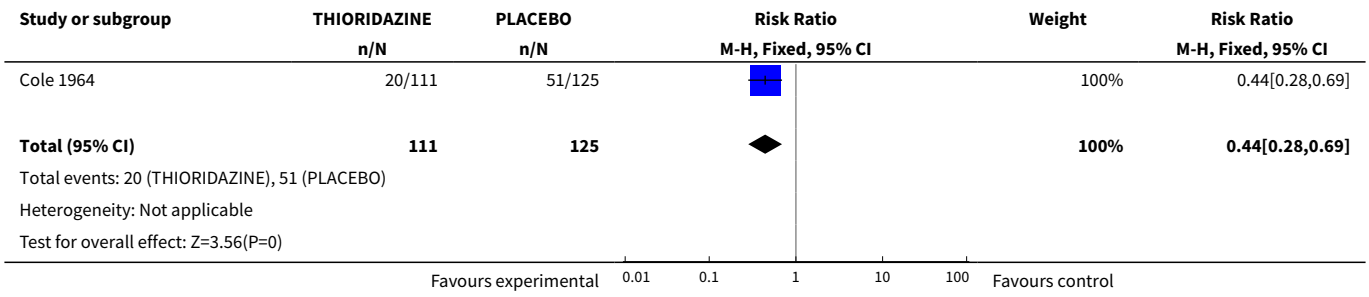


Comparison 3. THIORIDAZINE vs PLACEBO

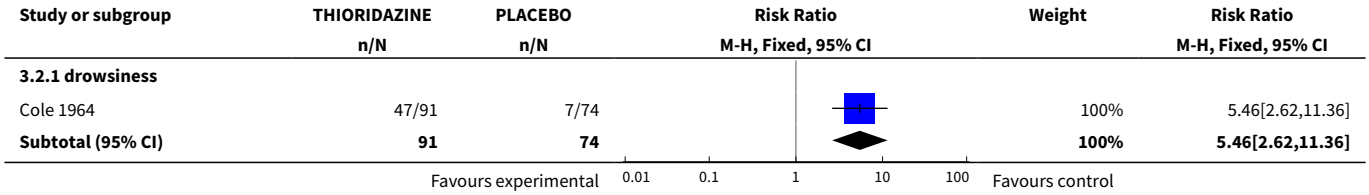
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	1	236	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.28, 0.69]
2 Adverse effects: various outcomes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 drowsiness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	5.46 [2.62, 11.36]
2.2 restlessness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.69, 1.48]

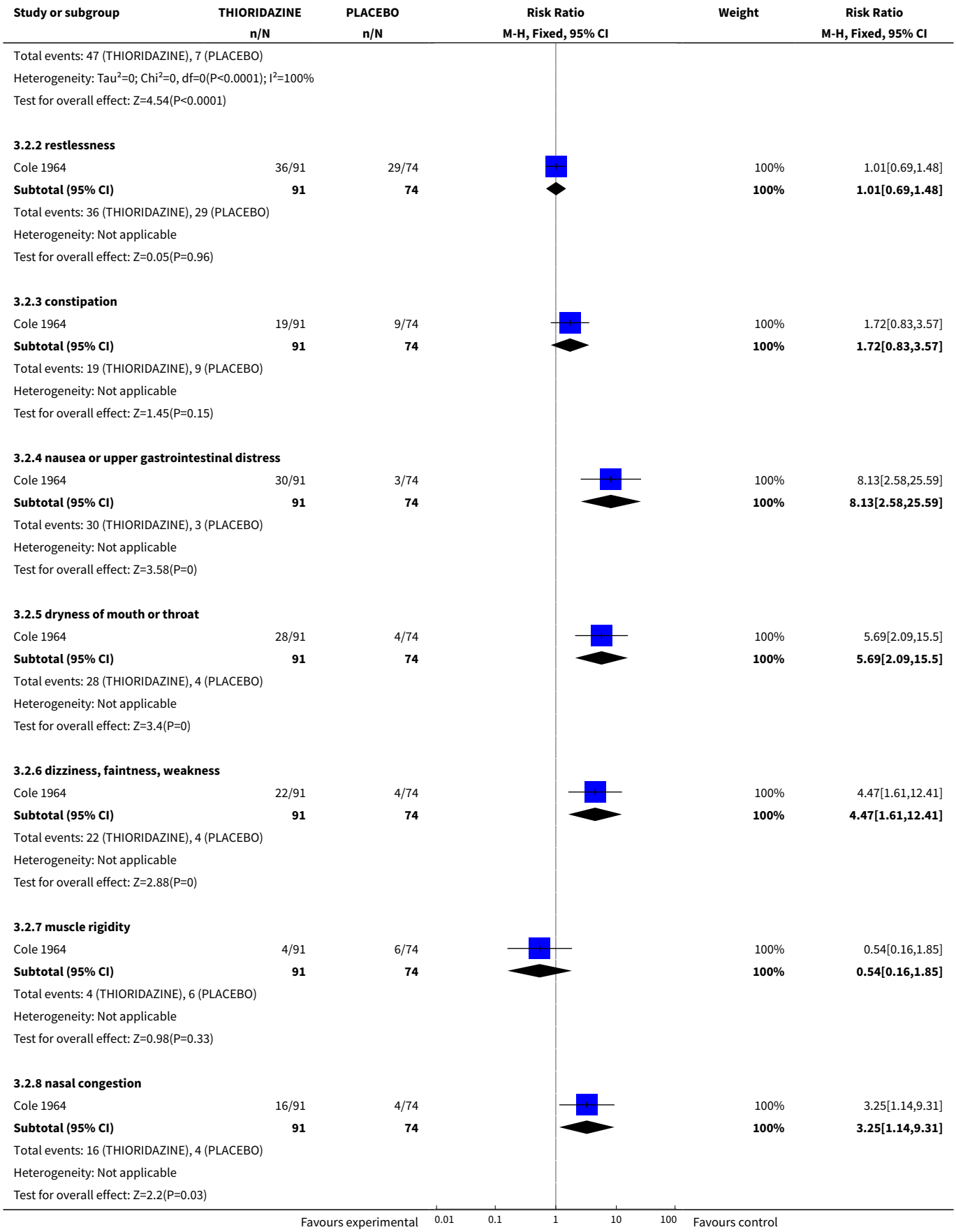
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 constipation	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [0.83, 3.57]
2.4 nausea or upper gastrointestinal distress	1	165	Risk Ratio (M-H, Fixed, 95% CI)	8.13 [2.58, 25.59]
2.5 dryness of mouth or throat	1	165	Risk Ratio (M-H, Fixed, 95% CI)	5.69 [2.09, 15.50]
2.6 dizziness, faintness, weakness	1	165	Risk Ratio (M-H, Fixed, 95% CI)	4.47 [1.61, 12.41]
2.7 muscle rigidity	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.16, 1.85]
2.8 nasal congestion	1	165	Risk Ratio (M-H, Fixed, 95% CI)	3.25 [1.14, 9.31]
2.9 facial rigidity	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.63 [0.51, 5.19]
2.10 tremor of hands, arms, face	1	165	Risk Ratio (M-H, Fixed, 95% CI)	2.44 [0.82, 7.25]
2.11 headache	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.32, 2.06]
2.12 loss of associated movements	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.16 [0.01, 3.34]
2.13 akathesis-restlessness of feet	1	165	Risk Ratio (M-H, Fixed, 95% CI)	1.36 [0.33, 5.49]

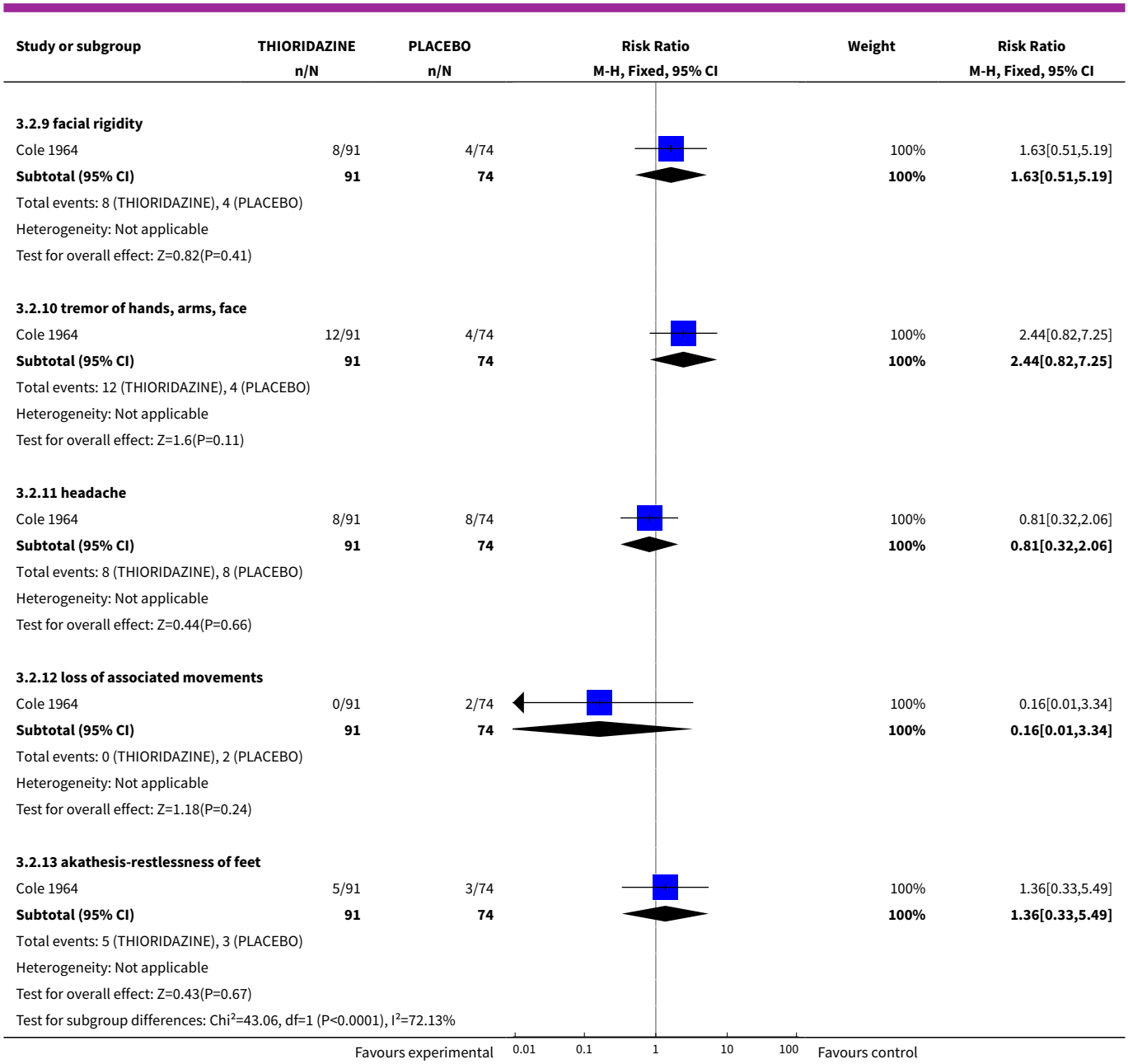
Analysis 3.1. Comparison 3 THIORIDAZINE vs PLACEBO, Outcome 1 Leaving the study early.



Analysis 3.2. Comparison 3 THIORIDAZINE vs PLACEBO, Outcome 2 Adverse effects: various outcomes.





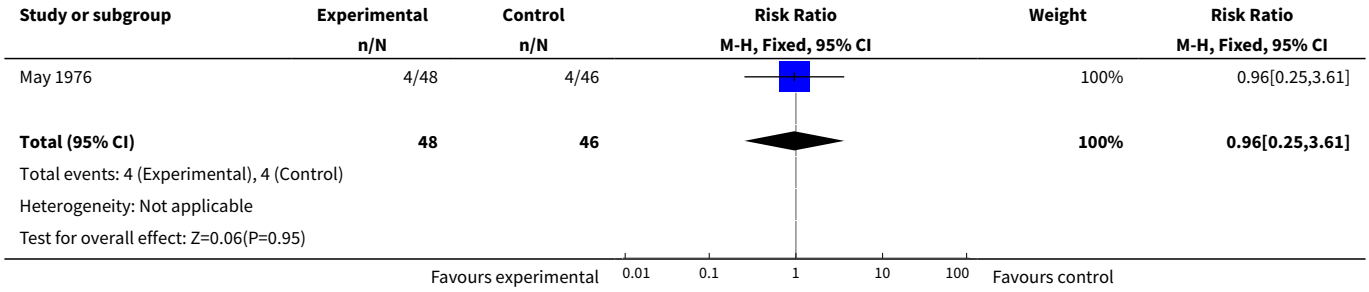


Comparison 4. TRIFLUOPERAZINE vs PSYCHOTHERAPY

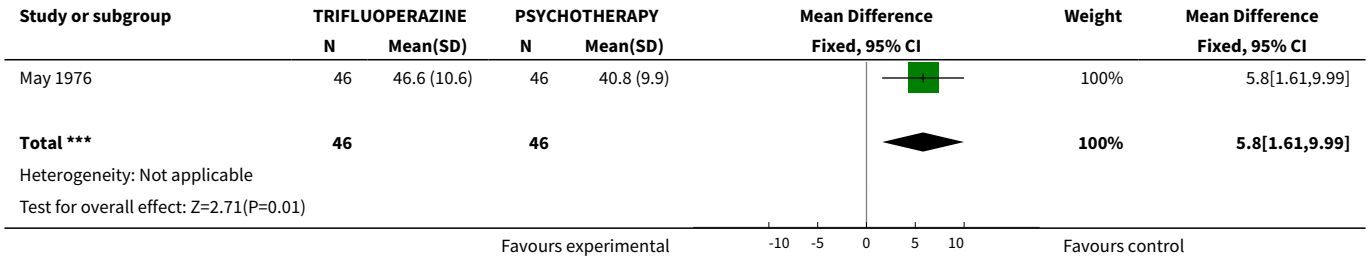
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	1	94	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.25, 3.61]
2 Global state: Overall Health Score - Meninger Health Sickness Scale (higher score=better) 2-years post-discharge	1	92	Mean Difference (IV, Fixed, 95% CI)	5.80 [1.61, 9.99]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Adverse effects: number of adverse events	1	162	Risk Ratio (M-H, Fixed, 95% CI)	5.65 [2.72, 11.73]

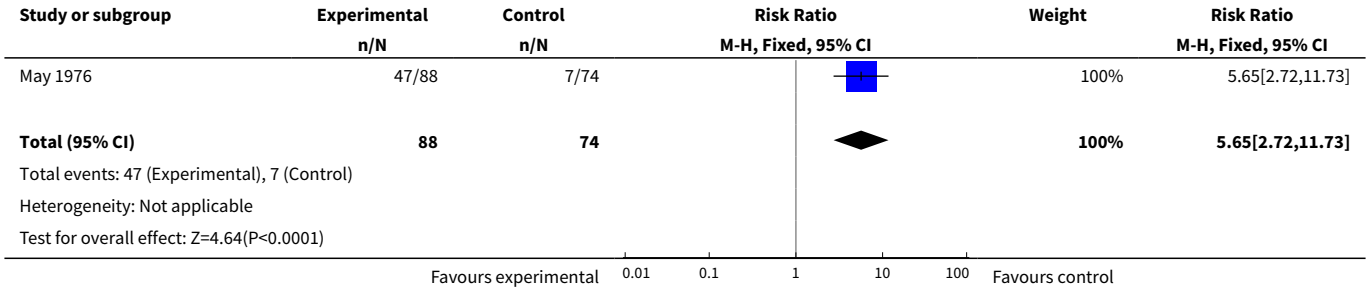
Analysis 4.1. Comparison 4 TRIFLUOPERAZINE vs PSYCHOTHERAPY, Outcome 1 Leaving the study early.



Analysis 4.2. Comparison 4 TRIFLUOPERAZINE vs PSYCHOTHERAPY, Outcome 2 Global state: Overall Health Score - Meninger Health Sickness Scale (higher score=better) 2-years post-discharge.



Analysis 4.3. Comparison 4 TRIFLUOPERAZINE vs PSYCHOTHERAPY, Outcome 3 Adverse effects: number of adverse events.

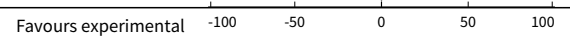


Comparison 5. TYPICAL ANTIPSYCHOTIC vs PSYCHOSOCIAL TREATMENT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global state: 1.Global Psychopathology Scale	1	89	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.55, 0.57]
2 Global state: 2. Global Improvement Scale	1	89	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.49, 0.43]

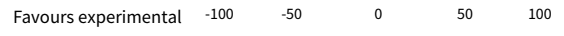
Analysis 5.1. Comparison 5 TYPICAL ANTIPSYCHOTIC vs PSYCHOSOCIAL TREATMENT, Outcome 1 Global state: 1.Global Psychopathology Scale.

Study or subgroup	TYPICAL ANTIPSYCHOTICS N	TYPICAL ANTIPSYCHOTICS Mean(SD)	PSYCHOSOCIAL TREATMENT N	PSYCHOSOCIAL TREATMENT Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Mosher 1995	50	3.5 (1.3)	39	3.5 (1.4)		100%	0.01[-0.55,0.57]
Total ***	**50**		**39**			**100%**	**0.01[-0.55,0.57]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.03(P=0.97)							



Analysis 5.2. Comparison 5 TYPICAL ANTIPSYCHOTIC vs PSYCHOSOCIAL TREATMENT, Outcome 2 Global state: 2. Global Improvement Scale.

Study or subgroup	TYPICAL ANTIPSYCHOTIC N	TYPICAL ANTIPSYCHOTIC Mean(SD)	PSYCHOSOCIAL TREATMENT N	PSYCHOSOCIAL TREATMENT Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Mosher 1995	50	2.5 (0.9)	39	2.5 (1.2)		100%	-0.03[-0.49,0.43]
Total ***	**50**		**39**			**100%**	**-0.03[-0.49,0.43]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.13(P=0.9)							



WHAT'S NEW

Date	Event	Description
8 February 2017	Amended	We have corrected an error in data entry for comparison 1.4 (Re-hospitalisation within 3 years - intent to treat) and we have removed from the abstract a RR value for this outcome that was calculated by authors outside of Revman 5.3. Further detail for May 1976 'other risk of bias' added. These changes do not alter the conclusions of this review.

HISTORY

Protocol first published: Issue 1, 2007
Review first published: Issue 6, 2011

Date	Event	Description
5 October 2011	Amended	Format updated, search undertaken, data extracted and conclusions revised

CONTRIBUTIONS OF AUTHORS

John Bola - wrote the protocol, reviewed studies for inclusion, guided and took a lead role in writing the review.

Dennis Kao - reviewed studies for inclusion, entered data into RevMan, edited the review.

Haluk Soydan - helped write the protocol, reviewed studies for inclusion, edited the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- School of Social Work, University of Southern California, USA.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In reviewing studies for inclusion in this review, we realised that additional focusing of our review question was needed. The initial intent of this review was to assess the evidence supporting the clinical practice guideline to treat early episodes of schizophrenia psychosis in the acute phase with antipsychotic medications. We have therefore excluded (and left for a subsequent edition of this review) studies addressing the question about medication maintenance in the post-acute phase. For example, the Schooler 1989a study treated all first-episode patients in the acute phase with antipsychotic medications and, after stabilisation, randomised to two medication dosages and placebo that was followed up for two years. This, and similar studies, can address the effectiveness of maintenance medications in the post-acute phase of early episodes, but not the effectiveness of antipsychotics in the acute episode, since in that phase there was no un-medicated group. In addition, we have preliminarily excluded RCTS that compare two or more antipsychotic medications in the acute treatment of individuals with early episode schizophrenia. Subsequent editions of this review might include the medication to medication comparisons to address questions of differential medication effectiveness. Pseudo-random studies have not yet been included in this version of the review, but might be incorporated in a subsequent version of the review, along with a sensitivity analysis to assess the influence of their inclusion. We have also updated the protocol method's section with the Cochrane schizophrenia group's current guidelines.

INDEX TERMS

Medical Subject Headings (MeSH)

Antipsychotic Agents [adverse effects] [*therapeutic use]; Chlorpromazine [therapeutic use]; Fluphenazine [therapeutic use]; Patient Dropouts; Randomized Controlled Trials as Topic; Schizophrenia [*drug therapy]; Thioridazine [therapeutic use]; Trifluoperazine [therapeutic use]

MeSH check words

Humans