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## Ayurvedic medicine for schizophrenia (Review)

Agarwal V, Abhijnhan A, Raviraj P

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Ayurvedic medicine for schizophrenia.

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[Intervention Review]

# Ayurvedic medicine for schizophrenia

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## ABSTRACT

### Background

Ayurvedic medicine has been used to treat mental health problems since 1000 BC.

### Objectives

To review effects of Ayurvedic medicine or treatments for schizophrenia.

### Search methods

We searched the Cochrane Schizophrenia Group Trials Register (March 2007) and AMED (March 2007), inspected references of all identified studies and contacted the first author of each included study.

### Selection criteria

We included all clinical randomised trials comparing Ayurvedic medicine or treatments with placebo, typical or atypical antipsychotic drugs for schizophrenia and schizophrenia-like psychoses.

### Data collection and analysis

We independently extracted data and calculated random effects, relative risk (RR), 95% confidence intervals (CI) and, where appropriate, numbers needed to treat/harm (NNT/H) on an intention-to-treat basis. For continuous data, we calculated weighted mean differences (WMD).

### Main results

From the three small (total n=250) short included studies, we were unable to extract any data on many broad clinically important outcomes such as global state, use of services, and satisfaction with treatment. When Ayurvedic herbs were compared with placebo, about 20% of people left the studies early (n=120, 2 RCTs, RR 0.77 CI 0.37 to 1.62). Mental state ratings were mostly equivocal with the exception of the brahmyadiyoga group using Ayurvedic assessment (n=68, 1 RCT, RR not improved 0.56 CI 0.36 to 0.88, NNT 4 CI 3 to 12). Behaviour seemed unchanged (n=43, 1 RCT, WMD Fergus Falls Behaviour Rating 1.14 CI -1.63 to 3.91). Nausea and vomiting were common in the brahmyadiyoga group (n=43, RR 13.13 CI 0.80 to 216.30). When the Ayurvedic herbs were compared with antipsychotic drugs (chlorpromazine), again, equal numbers left the study early (n=120, 2 RCTs, RR for brahmyadiyoga 0.91 CI 0.42 to 1.97) but people allocated herbs were at greater risk of no improvement in mental state compared to those allocated chlorpromazine (n=45, RR 1.82 CI 1.11 to 2.98). Again, nausea and vomiting were found with use of brahmyadiyoga (n=45, 1 RCT, RR 20.45 CI 1.09 to 383.97, NNH 2 CI 2 to 38). Finally, when Ayurvedic treatment, in this case a complex mixture of many herbs, is compared with chlorpromazine in acutely ill people with schizophrenia, it is equally (~10% attrition, n=36, RR 0.67 CI 0.13 to 3.53), but skewed data does seem to favour the chlorpromazine group.

**Ayurvedic medicine for schizophrenia (Review)**

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## Authors' conclusions

Ayurvedic medication may have some effects for treatment of schizophrenia, but has been evaluated only in a few small pioneering trials.

## PLAIN LANGUAGE SUMMARY

### Ayurvedic medicine for schizophrenia

Ayurvedic medicine was developed in India over 3000 years ago and is the oldest medical system to have survived until the present time. It sees each individual as having a unique mind-body constitution and set of life circumstances. It is similar to traditional Chinese medicine in believing that matter and energy are the same thing. Treatment in an ayurvedic system is holistic, involving natural medicine, massage, diet and the regulation of lifestyle. Ayurveda has been used for the treatment of schizophrenia, a serious long-term mental health condition, since its formulation (c1000 BCE) although nowadays Western-style medication using antipsychotics and hospital treatment are also used.

This review examines randomised controlled trials which compare aspects of ayurvedic medicine with the use of antipsychotics for people with schizophrenia. All trials took place in India and were for 12 weeks or less. When the ayurvedic herbs brahmyadiyoga and tagara were compared to placebo (2 trials) there was no significant difference between the two groups in acceptability of treatment or overall improvement. The brahmyadiyoga group did, however, show some improvement when assessed ayurvedically (a combination of assessing aspects of the mind, decision, orientation, memory and habit, and looking for the absence of symptoms of illness). When these two herbs were compared to groups of people taking the antipsychotic, chlorpromazine, again there was no difference in acceptability of treatment, but in one of the two trials there was an improvement in mental state in those taking chlorpromazine. There was also a trial comparing an ayurvedic package (of herbs and other treatment) to chlorpromazine, and although both treatments were acceptable, the rest of the data were not able to be used. Brahmyadiyoga and tagara tended to have vomiting and nausea as an adverse effect, while chlorpromazine caused people to be sleepy. It may be possible that ayurvedic treatments could be used as adjuncts to antipsychotic medication. A new larger trial comparing ayurvedic herb(s) alone, chlorpromazine alone and both together would answer this question.

(Plain language summary prepared for this review by Janey Antoniou of RETHINK, UK [www.rethink.org](http://www.rethink.org)).

## BACKGROUND

Developed in India more than 3000 years ago ([Subbarayappa 2001](#)), Ayurvedic medicine or Ayurveda is one of the oldest medical systems known. Many other ancient systems of natural medicine are believed to have their roots in Ayurveda.

Ayurveda is a Sanskrit word for the 'Knowledge of Life, defining the trinity of life as body, mind and spiritual awareness. Knowledge arranged systematically with logic becomes science. It is a complete and holistic science of healthy balanced living that views each person as an individual, with a unique mind-body constitution and set of life circumstances. Ayurveda and Traditional Chinese Medicine are very similar, being based on universal natural bi-polar concepts that matter and energy are one. Ayurveda aims to promote health and cure disease through holistic methods involving natural medicine, diet, regulated lifestyle ([Neddermeyer 2006](#), [Lad 1996](#)). The Ayurvedic compendium comprises eight

branches: Kayachikitsa (internal medicine); Salya tantra (surgery); Salakya tantra (ophthalmology and ENT); Kaumarabhrtya (paediatrics, obstetrics and gynaecology); Agadatantra (toxicology); Rasayana (geriatrics and nutrition); Vajikarana (sexology); Bhuta vidya (psychiatry and demonology) as described in Ayurvedic classics. The two Ayurvedic classics are the Charaka samhita and the Susruta samhita ([Subbarayappa 2001](#)).

Ayurveda recognises the fundamental importance of examination by direct perception (pratyaksa) and inference (anumana). In addition, it also accepts verbal or textual knowledge (aptopadesa) and experimentation (yukti). A physician of Ayurveda carries out a physical examination using his five senses (pancendriya pariksa) and elicits patient history (prasna) ([Subbarayappa 2001](#)). Therapy consists of three major categories: divine therapy (daiva vyapasraya), rational therapy (yukti vyapasraya cikitsa) and psychotherapy (sattvavajaya) ([Singh 1994](#)). There are more than 400 drugs

listed in The Ayurvedic Pharmacopoeia of India (API-2006).

Antipsychotic drugs are the mainstay of treatment of schizophrenia today since their development in the 1950s. The role of Ayurveda in treatment of mental illnesses, however, dates back to the Vedic period (c. 1000 BC) (Subbarayappa 2001), and it is still being used as sole treatment or in conjunction with antipsychotic medication in both developing and developed countries (Walter 1999). For example, nearly three quarters of people living in the USA of Asian origin used some kind of Complementary and Alternative medicine in the past 12 months (Hsiao 2006). Also these drugs are socially acceptable, better tolerated and less expensive than conventional modern treatments (Russinova 2002). We know of no systematic review of their effects.

## OBJECTIVES

To review the effects of Ayurvedic medicine compared with antipsychotic, placebo or no treatment for people with schizophrenia.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included all relevant randomised controlled trials. Where a trial was described as 'double-blind' but it was implied that the study was randomised, we included these trials in a sensitivity analysis. If there was no substantive difference within primary outcomes (see 'Types of outcome measures') when these 'implied randomisation' studies were added, then we included these in the final analysis. If there was a substantive difference, we only used clearly randomised trials and the results of the sensitivity analysis were described in the text. We excluded quasi-randomised studies, such as those allocated by using alternate days of the week.

#### Types of participants

We included people with schizophrenia, schizophreniform psychosis and schizophrenia-like illnesses, diagnosed by any criteria.

#### Types of interventions

1. Ayurvedic medicine (plant, animal, mineral or psychological), not used as an adjunct to other treatments: any dose or combination.
2. Ayurvedic medicine (plant, animal, mineral or psychological), used as an adjunct to other treatments: any dose or combination.

3. Placebo or no treatment.
4. Antipsychotic drugs produced by pharmaceutical companies: any compound, dose, pattern or means of administration.

#### Types of outcome measures

1. Leaving the studies early (any reason, adverse events, inefficacy of treatment)
  2. No clinically important response as defined by the individual studies (e.g. global impression less than much improved or less than 50% reduction on a rating scale)\*
  3. Global state
    - 3.1 No clinically important change in global state (as defined by individual studies)\*
    - 3.2 Relapse (as defined by the individual studies)
  4. Mental state (with particular reference to the positive and negative symptoms of schizophrenia)
    - 4.1 No clinically important change in general mental state score
    - 4.2 Average endpoint general mental state score
    - 4.3 Average change in general mental state score
    - 4.4 No clinically important change in specific symptoms (positive symptoms of schizophrenia, negative symptoms of schizophrenia)
    - 4.5 Average endpoint specific symptom score
    - 4.6 Average change in specific symptom score
  5. General functioning
    - 5.1 No clinically important change in general functioning
    - 5.2 Average endpoint general functioning score
    - 5.3 Average change in general functioning score
  6. Quality of life/satisfaction with treatment\*
    - 6.1 No clinically important change in general quality of life
    - 6.2 Average endpoint general quality of life score
    - 6.3 Average change in general quality of life score
  7. Service use
    - 7.1 Number of patients hospitalised\*
  8. Adverse effects\*
    - 8.1 Number of participants with at least one adverse effect
    - 8.2 Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count)
    - 8.3 Average endpoint in specific adverse effects
    - 8.4 Average change in specific adverse effects
- We divided outcomes into primary (\*) and secondary, and into short-term (up to 12 weeks), medium term (13-52 weeks) and long term (more than one year).

#### Search methods for identification of studies

1. Electronic searches
- 1.2 We searched the Cochrane Schizophrenia Group Trials Register (March 2007) using the phrase:  
[(\*ayurved\* or \*brahm\* or \*hindu\* or \*siddha\* or \*unmada\*) in title, abstract and index fields in REFERENCE] OR ((\*ayurved\*

or \*brahm\* or \*hindu\* or \*siddha\*) in interventions field in STUDY]]

This register is compiled by systematic searches of major databases, hand searches and conference proceedings (see Group Module).

1.3 We searched AMED (Allied and Complementary Medicine - 1985 to March 2007) (March 2007) using the phrase:

(((exp clinical trials/ or exp randomized controlled trials/ or exp double-blind method/ or exp random allocation/ or randomized controlled trial.pt. or clinical trial.pt. or controlled clinical trial.pt. or clinic\$ adj4 trial\$).mp. or (random\$ adj5 (assign\$ or allocate\$ or assort\$)).mp. or (randomi\$ adj5 control\$ adj5 trial\$).mp. or (crossover or cross-over).mp. or ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).mp.) and (exp mental disorders/) and (ayurved\$.mp. or ayurved\$.mp. or ayurvedic.mp. or exp ayurvedic medicine/))

## 2. Reference lists

We inspected references of all identified studies (included and excluded) for further relevant trials.

## 3. Personal contact

We contacted the first author of each included study for information regarding unpublished trials and extra data on the published trials.

# Data collection and analysis

## 1. Selection of studies

We (VA and AB) independently inspected all reports. We resolved any disagreement by discussion with (PR). Where there was still doubt, we acquired the full article for further inspection. Once the full articles were obtained, we (VA and AA) decided whether the studies met the review criteria. If disagreement could not be resolved by discussion with PR, we sought further information and added these trials to the list of those awaiting assessment.

## 2. Assessment of methodological quality

We assessed the methodological quality of included studies using the criteria described in the Cochrane Handbook (Higgins 2005), which is based on the degree of allocation concealment. Poor concealment has been associated with overestimation of treatment effect (Schulz 1995). Category A includes studies in which allocation has been randomised and concealment is explicit. Category B studies are those which have randomised allocation but in which concealment is not explicit. Category C studies are those in which allocation has neither been randomised nor concealed. Only trials that are stated to be randomised (categories A or B of the handbook) will be included in this review. The categories are defined below:

A. Low risk of bias (adequate allocation concealment)

B. Moderate risk of bias (some doubt about the results)

C. High risk of bias (inadequate allocation concealment).

When disputes arose as to which category a trial should be allocated, again we attempted resolution by discussion. When this was not possible we did not enter the data and added the trial to the

list of those awaiting assessment until further information could be obtained.

## 3. Data management

### 3.1 Data extraction

We (VA and AA) independently extracted data from selected trials. When disputes arose, we attempted to resolve these by discussion with PR. When disputes could still not be resolved we did not enter the data, but added the outcome of the trial to the list of those awaiting assessment.

### 3.2 Intention to treat analysis

We excluded data from outcomes where more than 50% of participants in any group were lost to follow up (this does not include the outcome of 'leaving the study early'). In studies with less than 50% dropout rate, we considered people leaving the study early to have had the negative outcome, except for the event of adverse effects and death.

We analysed the impact of including studies with high attrition rates (25-50%) in a sensitivity analysis. If inclusion of data from this group did result in a substantive change in the estimate of effect, we did not add this data to trials with less attrition, but presented the data separately.

## 4. Data analysis

### 4.1 Binary data

For binary outcomes we calculated an estimate of the relative risk (RR) (or risk difference (RD) when pooled data included studies with no event scores in both groups) and its 95% (fixed effect) confidence intervals (CI). Where possible, we also calculated the number needed to treat/harm (NNT/NNH) statistic. Where heterogeneity was found (see section 5) we investigated the reasons for this.

### 4.2 Continuous data

#### 4.2.1 Skewed data:

Continuous data on outcomes in trials relevant to mental health issues are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data we applied the following standards to continuous final value endpoint data before inclusion: (a) standard deviations and means were reported in the paper or were obtainable from the authors; (b) when a scale started from zero, the standard deviation, when multiplied by two, should be less than the mean (otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution - Altman 1996); In cases with data that are greater than the mean they were entered into 'Other data' table as skewed data. If a scale starts from a positive value (such as PANSS, which can have values from 30 to 210) the calculation described above in (b) should be modified to take the scale starting point into account. In these cases skewness is present if  $2SD > (S - S_{min})$ , where S is the mean score and  $S_{min}$  is the minimum score. We reported non-normally distributed data (skewed) in the 'other data types' tables.

For change data (mean change from baseline on a rating scale) it is impossible to tell whether data are non-normally distributed (skewed) or not, unless individual patient data are available. Af-

ter consulting the ALLSTAT electronic statistics mailing list, we presented change data in RevMan graphs to summarise available information. In doing this, we assumed either that data were not skewed or that the analysis could cope with the unknown degree of skew.

#### 4.2.2 Final endpoint value versus change data

Where both final endpoint data and change data were available for the same outcome category, we only presented final endpoint data. We acknowledge that by doing this much of the published change data may be excluded, but argue that endpoint data is more clinically relevant and that if change data were to be presented along with endpoint data, it would be given undeserved equal prominence. We are contacting authors of studies reporting only change data for endpoint figures.

4.2.3 Summary statistic: For continuous outcomes we estimated a weighted mean difference (WMD) between groups using a fixed effects model. Again, if heterogeneity was found (see section 5) we investigated reasons for this.

4.2.4 Rating scales: A wide range of instruments are available to measure mental health outcomes. These instruments vary in quality and many are not valid, or are ad hoc. Unpublished instruments are more likely to represent statistically significant findings than those that have been put into print (Marshall 2000). Therefore, we included only continuous data from rating scales if the measuring instrument had been described in a peer-reviewed journal and the instrument was either a self report or completed by an independent rater or relative (not the therapist).

#### 4.2.5 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 was not accounted for in primary studies, we presented the 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 co-efficients of their clustered data and to adjust for this using accepted methods (Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, we will also present 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 intraclass correlation co-efficient (ICC) [Design effect =  $1+(m-1)*ICC$ ] (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999).

#### 5. Test for heterogeneity

Firstly, we considered all the included studies within any comparison to judge for clinical heterogeneity. Then we visually inspected graphs to investigate the possibility of statistical heterogeneity. We supplemented this by using primarily the I-squared statistic. This provides an estimate of the percentage of variability due to heterogeneity rather than chance alone. Where the I-squared estimate was greater than or equal to 50%, we interpreted this as indicating the presence of considerable levels of heterogeneity (Higgins 2003). Where heterogeneity was present, reasons for this were investigated. If it substantially altered the results, data were not summated, but presented separately and reasons for heterogeneity investigated.

#### 6. Addressing publication bias

We entered all data from the included studies into a funnel graph (trial effect against trial size) in an attempt to investigate the likelihood of overt publication bias (Egger 1997).

#### 7. General

Where possible, we entered data in such a way that the area to the left of the line of no effect indicated a favourable outcome for Ayurvedic medicine.

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

For substantive descriptions of the studies please see Included and Excluded Studies tables.

#### 1. Excluded studies

We have excluded four studies in this review. All four were full journal articles (Farg 2003; Fozdar 1962; Hakim 1964; Weiss 1986). Fozdar 1962 and Weiss 1986 were not randomised. Farg 2003 was randomised but recruited people with sleep onset insomnia and not those suffering from schizophrenia. We have not included all the studies included in the chapter on "Review of Previous Studies" from Ramu 1999b as they were all case series.

#### 2. Awaiting assessment

Two studies are currently awaiting assessment. Both reports are minimal and contain no usable data. Interestingly, none of these studies were identified by our standard but comprehensive database search. Ramu 1985 was picked up from our extra search conducted on AMED. Our web search led us to the CCRAS (Central Council for Research in Ayurveda and Siddha) website and correspondence with them gave us the book *Ayurvedic Management of Unmada (Schizophrenia)*. Roy 1964 was obtained from this book. We have contacted the relevant authorities at CCRAS to acquire more information on Roy 1964.

#### 3. Ongoing studies

We are not aware of any ongoing studies.



#### 4. Included studies

We have included three studies in this review. Two, [Mahal 1976](#) and [Ramu 1992](#), were identified through our electronic search of the Cochrane Schizophrenia Group Trials Register. [Ramu 1999](#) was obtained from a book sent to us by the Central Council for Research in Ayurveda and Siddha, in New Delhi, India. Only [Mahal 1976](#) was described as randomised. [Mahal 1976](#) and [Ramu 1999](#) were said to be double blinded.

##### 4.1 Length of trials

Schizophrenia is a lifelong illness that affects young people. All the included studies reported data on short-term follow-up (up to 12 weeks).

##### 4.2 Participants

In [Ramu 1992](#) participants had been diagnosed with schizophrenia using ICD-9 classification. While one study used the diagnostic criteria for schizophrenia in accordance with the NIMHANS collaborative study ([Mahal 1976](#)), another, [Ramu 1999](#), stated that they used the WHO glossary of mental disorders to diagnose schizophrenia. Participants from all the three studies had been diagnosed, using the Ayurvedic classification, as unmade. [Ramu 1992](#) employed the Charaka Ayurvedic definition while another used the Laksana Ayurvedic definition for schizophrenia. [Ramu 1992](#) did not report the sex of participants. Though the male to female ratio was uneven in the other two studies, the total number of participants on pooling both the studies did not vary significantly with respect to sex. The mean age of participants from all three studies was about 28 years. [Ramu 1992](#) and [Ramu 1999](#) recruited people suffering from schizophrenia over a period of two to ten years, while [Mahal 1976](#) only recruited people with less than a two year history of schizophrenia. We could not elicit any exclusion criteria from [Ramu 1999](#) while the other two studies excluded stupor, epilepsy and learning disability. No trial gave information about the severity of illness, although [Ramu 1992](#) mentioned that participants had active psychotic symptoms for a minimum duration of one month.

##### 4.3 Setting

[Ramu 1999](#) was described as taking place in an inpatient department while [Mahal 1976](#) and [Ramu 1992](#) were described as taking place in hospital settings.

##### 4.4 Study size

All three studies are small. [Mahal 1976](#) with 136 participants was the largest of the studies. [Ramu 1999](#) included 78 people while [Ramu 1992](#) recruited only 36.

##### 4.5 Interventions

The main Ayurvedic herb used in all three studies is brahmyadiyoga. When brahmyadiyoga was used on its own ([Mahal 1976](#); [Ramu 1999](#)), it was administered at a mean dose of 12 mg/day at a range of 8-16 mg/day in four times a day schedules. In [Ramu 1992](#), where a complex Ayurvedic treatment was given, brahmayadiyoga was one of the components and was administered at a dose of 500 mg. The other Ayurvedic herb administered was tagara ([Mahal 1976](#)) at a dosage of 8-12 mg/day. All three studies

compared the Ayurvedic medication with chlorpromazine (200-450 mg/day). [Mahal 1976](#) and [Ramu 1999](#) also used placebo as a comparator. All medications were administered orally.

##### 4.6 Outcomes

[Mahal 1976](#) compared brahmyadiyoga and tagara with placebo and reported usable data on mental state and leaving the study early. [Ramu 1999](#) also reported usable data on mental state and leaving the study early for the brahmyadiyoga versus placebo comparison. [Ramu 1992](#) did not compare Ayurvedic treatment to placebo. Some of the data provided by [Mahal 1976](#) and [Ramu 1999](#) were very skewed and we have reported these in other data tables.

[Mahal 1976](#) and [Ramu 1999](#) compared Ayurvedic herbs (brahmyadiyoga) with antipsychotic chlorpromazine. [Mahal 1976](#) also compared tagara (another Ayurvedic herb) with chlorpromazine. Both studies recorded usable data on mental state and number of participants leaving the study early. Some of the data provided by [Mahal 1976](#) and [Ramu 1999](#) were very skewed and we have reported these in other data tables.

Only [Ramu 1992](#) compared Ayurvedic treatment (complex combination of a number of medications) with chlorpromazine and reported data on mental state and leaving the study early. Most of the data reported on mental state were very skewed and we have reported these in other data tables.

4.6.1 Outcome scales: details of the only scales that provided usable data are shown below. Reasons for exclusions of data are given under 'Outcomes' in the 'Included studies' table.

###### 4.6.1.1 Psychotic Symptom Rating Scale - PSRS ([Rockland 1965](#))

This rating scale provides a quantified profile of the reflection of clinical judgement, impressions of degree and nature of psychotic symptomatology. The normality of behaviour, effect or cognition is indicated by the zero score, where as the psychopathology in these areas increases, the score becomes positive or negative. The whole scale total scores are used as quantitative measures of psychosis to compare patient to patient and to compare the patient over time. The sub totals in each category indicate whether the major portion is in the behaviour, affect or cognition. [Mahal 1976](#) and [Ramu 1999](#) used of this rating scale.

###### 4.6.1.2 Brief Psychiatric Rating Scale ([Overall 1962](#))

This is a brief rating scale used to assess the severity of a range of psychiatric symptoms, including psychotic symptoms. The original scale has 16 items (although a revised 18-item scale is commonly used). Each item is defined on a seven-point scale varying from 'not present' to 'extremely severe', scoring from 0-6 or 1-7. Total scores can range from 0-126, with high scores indicating more severe symptoms. Only [Ramu 1992](#) used this scale to assess the changes in mental state.

###### 4.6.1.3 Ayurvedic Assessment

Ayurvedic assessment is comprised of two separate assessments. The first assessment involves the examination of mental aspects: Manas (mind), Buddhi (decision), Sanjnana (orientation and responsiveness), Smrti (memory), Bhakti (desire), Sila (habit), Cesta



(psychomotor activity) and Acara (conduct); in a proforma structured for this purpose. In the second assessment, the presence or absence of Laksana (signs and symptoms) of Dosaga Unmada after the treatment period is noted. The guidelines for completing this proforma can be obtained from [Ramu 1999c](#).

#### 4.6.1.4 Fergus Falls Behaviour rating scale ([Meyer 1953](#))

This is an early ward behaviour scale which has been used with a broad range of hospitalised patients. It provides a single summed score, and is a quick, convenient, fairly objective method of rating behaviour, with which even inexperienced raters obtained greater than 90% agreement. The scale is of the semi-checklist type. Severity judgements are not necessary. Instead, for each statement, the rater has to indicate whether the item does or does not apply to the condition of the patient. Detailed rating instructions are provided which guarantee high inter-rater reliability. One of the 11 categories, 'responds to electroshock or insulin therapy', reflects the scale's age and should be rephrased to 'response to therapy'. This would make the scale more adequate and would probably not affect its reliability or validity. The items cover most of the areas considered to be essential components of ward behaviour scales. In spite of its simplicity for use and good coverage of ward behaviour, this scale seems to have been replaced by those more recently developed. The scale requires seven to ten minutes for completion.

#### 4.6.2 Redundant data

Enormous efforts are usually invested in studies rating and recording data that are then reported in such a way as to render them useless for reviews such as this. For example, in [Ramu 1992](#) the trialists compared Ayurvedic treatment with chlorpromazine. The outcome of change in mental state using Ayurvedic assessment was reported in an obscure manner in that they reported the means without the standard deviations. Such results are of no value to us. We have tried to contact the trialists to obtain the standard deviations. Similarly in [Mahal 1976](#) the data provided on spiral after effect had attrition rates >40%, that the data was considered redundant.

#### 4.6.3 Missing outcomes

No usable outcomes were found for the following categories: death, global state, general functioning, quality of life and service outcomes. It is surprising that none of the included studies have reported on changes in global state.

#### 4.6.4 Primary outcomes

Our primary outcome of adverse effects was reported only by [Ramu 1999](#) (n=78). None of our other primary outcomes were reported.

## Risk of bias in included studies

### 1. Randomisation

Out of the three included studies, one, [Mahal 1976](#), was stated to be randomised. This study, however did not explicitly explain the method of randomisation. None of the studies have categorically

mentioned the method of allocation concealment. This concealment of allocation has repeatedly been shown to be of key importance in excluding selection biases ([Jüni 2001](#)), therefore, all trials have been assigned to category B (moderate risk of bias, see Methods).

### 2. Blindness

Two studies were described as being double-blind ([Mahal 1976](#); [Ramu 1999](#)). One, [Ramu 1992](#), was described as rater-blinded. None of the studies described the process of blinding. Testing of blinding was not reported in any of the three studies.

### 3. Loss to follow up

None of the studies attempted to follow up those who had left the study early. While [Mahal 1976](#) reported "escape and leaving against medical advice" as the reason for 28 people leaving early, [Ramu 1999](#) did not give any specific reason why 13 people discontinued. [Ramu 1992](#) did not give specific reasons for two people leaving early, although this study did account for the remaining three who discontinued. None of the studies had dropout rates greater than 40%.

### 4. Data reporting

Overall most of the data we found could be used. Findings which are presented as graphs, in percentiles or just reported as p-values are often of little use to a reviewer. [Ramu 1992](#) failed to provide standard deviations along with the mean values for the outcomes of a psychological assessment conducted to observe cognitive changes. [Mahal 1976](#) reported on the spiral after effect outcomes of just less than 40% of the trial participants. These particular outcomes from these two trials could not be used for this review. We are seeking further data regarding these outcomes. [Ramu 1999](#) had presented the results of adverse effects experienced by the participants in a slightly awkward and complicated fashion. However we have been able to extract these data.

## Effects of interventions

### 1. The search

The standard search of the Cochrane Schizophrenia Group Trials Register (March 2007) resulted in two citations ([Mahal 1976](#); [Ramu 1992](#)). We included both of these in the review. Inspection of the list of references from these two studies warranted further inspection of one study ([Fozdar 1962](#)). This study was eventually excluded (see Characteristics of excluded studies table). An extra search conducted on AMED (Allied and Complementary Medicine, 1985 - 2007) resulted in 23 citations. Only [Ramu 1985](#) identified in this search was thought to be relevant and is waiting further assessment as we have not been able to get hold of the full text version. We felt that two studies, [Farg 2003](#) and [Weiss 1986](#), should be mentioned in the excluded studies group (see Characteristics of excluded studies table). An additional web search gave links to CCRAS (Central Council for Research in Ayurveda and Siddha). Correspondence with CCRAS resulted in the procurement of a textbook titled "Ayurvedic Management of Unmada

(Schizophrenia)". This book contained the entire text of the two studies which our standard search had identified. In addition, we obtained another study (Ramu 1999) which we felt could be included in this review. We also obtained part of the abstract of another study (Roy 1964) which seems relevant and have contacted CCRAS for the full text. We have included this last study in the category awaiting assessment.

**2. COMPARISON 1: AYURVEDIC HERBS versus PLACEBO**  
Two studies (Mahal 1976 and Ramu 1999, total n=214) compared Ayurvedic herbs with placebo. Mahal 1976 compared two types of herbs, brahmyadiyoga and tagara, with placebo. In the title of the article Ramu 1999 stated that it is a comparison between brahmyadiyoga and tagara versus placebo but they have not mentioned tagara in the text of the report.

**2.1 Leaving the studies early (any reason, adverse events, inefficacy of treatment)**

Overall 17% of people allocated to the brahmyadiyoga left the studies in the short term before the end of the trials and this compares with 22% in the placebo group (n=120, 2 RCTs, RR 0.77 CI 0.37 to 1.62).

**2.2 Global state**

None of the included studies reported usable data on changes in the global state.

**2.3 Mental state (with particular reference to the positive and negative symptoms of schizophrenia)**

Mahal 1976 assessed changes in mental state using PSRS, MPQ and ayurvedic assessment tools. Ramu 1999 employed PSRS and psychological assessment tools to observe changes in mental state.

**2.3.1 Not Improved**

Mahal 1976 recorded usable data in changes in mental state using MPQ and Ayurvedic assessment and Ramu 1999 with a tool that was not clearly described. The only statistically significant result was found in the brahmyadiyoga group using Ayurvedic assessment (n=68, 1 RCT, RR 0.56 CI 0.36 to 0.88, NNT 4 CI 3 to 12). The overall change observed among the two groups is of no statistical significance.

**2.3.2 Uncooperative or did not respond (MPQ assessment)**

This accounts for those participants who were not accounted for during MPQ assessment. Here the trialists found no clear differences (n=68, RR for brahmyadiyoga 2.00 CI 0.39 to 10.20).

**2.3.3 Average improvement - positive or negative symptoms**

The results of these comparisons could not be analysed as they were highly skewed. However, findings, as reported in the trial Mahal 1976 did tend to favour brahmyadiyoga.

**2.4 Behaviour**

The Fergus Falls behaviour rating scale recorded non-skewed data. It showed no difference between groups (n=43, 1 RCT, WMD Fergus Falls Behaviour Rating 1.14 CI -1.63 to 3.91).

**2.5 Psychological assessment**

Only critical flicker fusion threshold recorded data we could analyse and there were no clear differences between groups. Reaction time and vigilance data were much skewed but there was no clear

suggestion of a difference between groups.

**2.6 Adverse effects**

Only Ramu 1999 reported on "clinically relevant" specific adverse effects. Nausea and vomiting were found only in the brahmyadiyoga group as opposed to the placebo group (n=43, RR 13.13 CI 0.80 to 216.30). Drowsiness was absent in either groups. Overall none of the adverse effects were statistically significant, although numbers are small and confidence intervals wide.

**3. COMPARISON 2: AYURVEDIC HERBS versus ANTIPSYCHOTIC**

Mahal 1976 and Ramu 1999 compared Ayurvedic herbs with chlorpromazine (total n=120). Mahal compared two types of herbs, brahmyadiyoga and tagara, with chlorpromazine. The title of Ramu 1999 stated a comparison between brahmyadiyoga and tagara but did not mention tagara again anywhere in the text.

**3.1 Leaving the studies early (any reason, adverse events, inefficacy of treatment)**

Equal numbers of people left the study early from brahmyadiyoga, tagara and chlorpromazine (n=120, 2 RCTs, RR for brahmyadiyoga 0.91 CI 0.42 to 1.97).

**3.2 Mental state (with particular reference to the positive and negative symptoms of schizophrenia)**

**3.2.1 Not Improved**

There were no significant differences in the mental state comparisons between brahmyadiyoga and chlorpromazine in the Mahal 1976 study. Ramu 1999 however reported significantly less improvement in the brahmyadiyoga group (n=45, RR 1.82 CI 1.11 to 2.98). Mahal 1976 showed comparatively less improvement with the use of tagara when assessed using MPQ (n=68, RR 2.00 CI 1.25 to 3.19).

**3.2.2 Uncooperative or did not comprehend**

No significant difference can be found between the usage of brahmyadiyoga or tagara versus chlorpromazine (n=68, 1 RCT, RR for brahmyadiyoga 1.00 CI 0.27 to 3.68).

**3.2.3 Average improvement or endpoint scores - positive symptoms and negative symptoms (PSRS).**

Data recorded on the average improvements or endpoint scores in both positive and negative symptom scores were highly skewed but, if anything, tended to favour the chlorpromazine group.

**3.3 Behaviour**

The Fergus Falls behaviour rating scale provided usable data (Ramu 1999). The results however showed no clear differences between the effects of brahmyadiyoga and chlorpromazine.

**3.4 Psychological assessment**

The Critical flicker fusion threshold provided data that we could analyse (Ramu 1999). None of the results however showed any differences between the effects of brahmyadiyoga and chlorpromazine.

**3.5 Adverse effects**

Specific adverse effects were reported by Ramu 1999. Nausea and vomiting were found only with the use of brahmyadiyoga (n=45, 1 RCT, RR 20.45 CI 1.09 to 383.97, NNH 2 CI 2 to 38) while

drowsiness was present only among those who were administered chlorpromazine. The incidence of giddiness or somnolence in was similar for both groups.

#### 4. COMPARISON 3: AYURVEDIC TREATMENT versus ANTIPSYCHOTIC

Ramu 1992 (n=36) compared the effects of Ayurvedic treatment, in this case a complex mixture of many herbs, with those of chlorpromazine in acutely ill patients with schizophrenia.

##### 4.1 Leaving the studies early (any reason, adverse events, inefficacy of treatment)

There was no difference in the number of participants leaving the study early between those on Ayurvedic treatment and those being administered chlorpromazine (-10%, n=36, RR 0.67 CI 0.13 to 3.53).

##### 4.2 Mental state (with particular reference to the positive and negative symptoms of schizophrenia)

The average endpoint and change scores recorded on BPRS or during Ayurvedic assessment could not be analysed as data were skewed, but most scores do seem to favour the chlorpromazine group. However, inspecting the raw scores does not suggest that there are any great differences between the two treatment groups.

## DISCUSSION

### 1. Applicability of findings

All of the included studies took place in India. We do not know if the findings of this review are transferable to patients in different clinical settings from geographical areas distinct from the Indian subcontinent. Even if there is an element of a placebo effect, this in itself may vary from continent to continent.

All the included trials were of very short term duration. Since schizophrenia has a chronic course, there is the need for trials conducted for longer periods of time to inform practice. People take these treatments for years. It is perfectly feasible that effects may not appear until after a considerable period. Just as conventional antipsychotic drugs have a swift onset of action and little evidence for their longer term effects, the converse may be true for Ayurvedic treatments.

### 2. Limited data

We found it disappointing that, despite considerable investment in clinical trials, no outcome data were available on death, service outcomes, general functioning, behaviour, engagement with services, economic outcomes and cognitive functioning. The primary outcome of this review was change in global state and no data were available on this broad, clinically meaningful, outcome.

### 3. COMPARISON 1: AYURVEDIC HERBS versus PLACEBO

In the short term, about 20% of people left both groups. Ramu 1999 did not cite any specific reasons for the attrition rates while

Mahal 1976 cited reasons such as escape and "left against medical advice". There is no evidence from these studies that Ayurvedic medication is a major cause of unacceptable short term problems. Mental state was measured in numerous ways. When ayurvedic assessment tools were employed, brahmyadigya had advantage over placebo for the outcome of not improved (NNT 4 CI 3 to 12). This is a finding that needs to be replicated and explained for readers of the study. We are unsure if the difference between improved and not improved has clinical meaning. It was a shame that no outcomes relevant to global state were reported. There was no suggestion on the Fergus Falls scale, noted for its real-world pragmatism, of an effect on behaviour. There is a suggestion that brahmyadigya causes nausea and vomiting. These herbal treatments are not innocuous, and their effects are well worth full investigation.

### 4. COMPARISON 2: AYURVEDIC HERBS versus ANTIPSYCHOTIC

Very few people left these short studies early, indicating perhaps that not only are Ayurvedic herbs acceptable, but so too was the trial design. Again, mental state was measured in several different ways and for each of the herbal preparations. Results tended to favour the short term effects of chlorpromazine over the herbs. This does not mean that the herbs could not have a short term effect that has gone unnoticed. However, the findings from these limited studies are not encouraging. It could be that the Ayurvedic treatments do only have a positive effect in the longer term, but we have no evidence for this. If they are being prescribed for short term benefit, evidence is lacking. Ratings on behaviour also tended to favour the chlorpromazine group. Chlorpromazine does cause drowsiness so we were reassured that adverse effects were being well reported. Again, trials in this comparison implicated brahmyadigya to cause nausea and vomiting. This is a herb that is not without problematic effects (NNH 2 CI 2 to 38).

### 5. COMPARISON 3: AYURVEDIC TREATMENT versus ANTIPSYCHOTIC

One very small study (n=36) investigated the effects of Ayurvedic treatment (comprising of a mixture of herbs, psycho-behavioural therapy and occupational therapy), comparing it with chlorpromazine for acutely ill people with schizophrenia. Again, in the context in which it was given, Ayurvedic treatment is acceptable in the short term. All mental state measures have produced skewed results, but do tend to suggest that the overall Ayurvedic package held its own against chlorpromazine. This is much too small and short a trial to produce conclusive evidence upon which to base care. It is hypothesis generating and it may be that for this intervention more trials are justified, at least as an adjunct to modern drugs.

## AUTHORS' CONCLUSIONS

## Implications for practice

### 1. For people with schizophrenia

Most people given Ayurvedic medication or placebo do not show short term mental state improvement, although there is some weak suggestion that brahmyadiyoga may help more than placebo. When compared with a conventional antipsychotic such as chlorpromazine, Ayurvedic treatment does not seem very valuable and it consistently seems to cause nausea and vomiting. There is no evidence to suggest whether or not it is useful as an adjunct to antipsychotic drugs. In some cases Ayurvedic treatment may be more acceptable, and, for very poor people, more affordable than chlorpromazine. It is therefore a therapy option, but not one that has been shown to be clearly effective.

### 2. For clinicians

No convincing differences are evident when comparing Ayurvedic medication with placebo or chlorpromazine and it may produce unwanted gastrointestinal effects. All trials are small and short but nevertheless do not really suggest any convincing clinical effect. It is possible that real effects do exist, or that Ayurvedic treatment may be useful as an adjunct to modern drugs. In any case, concurrent use of this ancient treatment may make taking modern drugs seem more acceptable and therefore be useful for people with psychoses.

### 3. For managers/policy makers

No direct data on hospital and services outcomes, satisfaction with care or economics are available. It is entirely possible, however, that in societies where Ayurvedic medications are more acceptable than modern drugs, they could be used to enhance acceptability of treatments such as chlorpromazine, which has effects on mental state, service use and quality of life.

## Implications for research

### 1. General

If the recommendations of the revised CONSORT statement (Moher 2001) had been anticipated by both authors and editors

it would have helped to clarify methodology and outcomes. None of the included studies specified how participants were allocated to treatment. Allocation concealment is essential for the result of a trial to be considered valid and gives the assurance that selection bias is kept to a minimum. Well described and tested blinding could have encouraged confidence in the control of performance and detection bias. Intention-to-treat analysis should be performed on all outcomes and all trial data should be made easily accessible. A minimal requirement should be that all data should, at least be presented in numeric form. In addition, continuous data should be presented with means, standard deviations (or standard errors) and the number of participants. Data from graphs, 'p' values of differences and statements of significant or non-significant differences are of limited value.

Failure to comply with the revised CONSORT statement, results in both loss of data and confusion in the results, neither of which help clinicians or patients (Tharyan 2007).

### 2. Specific

We realise that data in this review are very few indeed. Studies on any means of use of this widely prescribed acceptable treatment are justified. However, we do feel uncomfortable with recommending a trial of Ayurvedic herbs or treatment versus placebo. Much more justified are trials using Ayurvedic herbs or treatments as an adjunct to treatment such as chlorpromazine. We suggest a design for one such pragmatic, real world, randomised controlled trial in Table 1.

## ACKNOWLEDGEMENTS

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## REFERENCES

### References to studies included in this review

#### Mahal 1976 *[published data only]*

\* Mahal AS, Ramu NG, Chaturvedi DD. Double blind controlled study of brahmyadiyoga and tagara in the management of various types of unmada (schizophrenia). *Indian Journal of Psychiatry* 1976;**18**(4):283–92. [ EMBASE 1978204625]  
Ramu MG, Chaturvedi DD, Venkataram BS, Shankara MR, Leelavathy S, Janakiramiah N, Mukundan H, Thomas KM, Ramachandra M, Mahal AS, Murthy NSN, Devidas KV. A double blind controlled study on the role of Brahmyadiyoga

and Tagara in Navonmada (acute schizophrenia). *Ayurvedic Management of Unmada (Schizophrenia)*. New Delhi: Central Council for Research in Ayurveda & Siddha, 1999: 59–76.

#### Ramu 1992 *[published data only]*

Ramu MG, Chaturvedi DD, Venkataram BS, Shankara MR, Leelavathy S, Janakiramiah N, Mukundan H, Thomas KM, Ramachandra M, Mahal AS, Murthy NSN, Devidas KV. A controlled study on the role of classical Ayurvedic treatment in acutely ill patients with Unmada (schizophrenia). *Ayurvedic Management of Unmada*

(Schizophrenia). New Delhi: Central Council for Research in Ayurveda & Siddha, 1999:89–100.

\* Ramu MG, Venkataram BS, Mukundan H, Shankara MR, Leelavathy S, Janakiramaiah N. A controlled study of ayurvedic treatment in the acutely ill patients with schizophrenia (unmada) - rationale and results. *Nimhans Journal* 1992;**10**(1):1–16.

**Ramu 1999 {published data only}**

Ramu MG, Chaturvedi DD, Venkataram BS, Shankara MR, Leelavathy S, Janakiramaiah N, Mukundan H, Thomas KM, Ramachandra M, Mahal AS, Murthy NSN, Devidas KV. A double blind controlled study on the role of Brahmyadiyoga and Tagara in Jirnomada (chronic schizophrenia). *Ayurvedic Management of Unmada (Schizophrenia)*. New Delhi: Central Council for Research in Ayurveda & Siddha, 1999:77–88.

**References to studies excluded from this review**

**Farag 2003 {published data only}**

Farag NH, Mills PJ. A randomized-controlled trial of the effects of a traditional herbal supplement on sleep onset insomnia. *Complementary Therapies in Medicine* 2003;**Dec**; **11**(4):223–5. [0061115]

**Fozdar 1962 {published data only}**

Fozdar N G, Doongaji, Bagadia V N, Vahia N S. Preliminary Report Of An Indigenous Drug "Acorus Calamus" In Psychiatric Disorders. *Indian Journal of Psychiatry* 1962;**4**(8):12–16.

**Hakim 1964 {published data only}**

\* Hakim RA. A Preliminary report on the use of Malkanguni with other indigenous drugs in the treatment of depression.. *Indian Journal of Psychiatry* 1964;**6**:142.

**Weiss 1986 {published data only}**

Weiss MG, Sharma SD, Sharma JS, Desai A, Doongaji DR. Traditional concepts of mental disorder among Indian psychiatric patients. Preliminary report of work in progress. *Social Science and Medicine* 1986;**23**(4):379–86. [8509322]

**References to studies awaiting assessment**

**Ramu 1985 {published data only}**

Ramu MG, Venkataram BS. Manovikara (mental disorders) in ayurveda. *Ancient Science of Life* 1985;**Jan**; **4**(3):165–73. [8507838]

**Roy 1964 {published data only}**

\* Roy D, Mathur SM, Kaora. A double blind trial of Nuvon- an Ayurvedic Drug on Chronic Schizophrenia. *Indian Journal of Psychiatry* 1964;**6**:26.

**Additional references**

**Altman 1996**

Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**:1200.

**API-2006**

Controller of Publications, Government of India. *The Ayurvedic Pharmacopoeia of India*. Vol. **I, II, III, IV, V**, New Delhi: Controller of Publications, Government of India, 2006.

**Bland 1997**

Bland JM. Statistics notes. Trials randomised in clusters. *BMJ* 1997;**315**:600.

**CCRAS**

Central Council for Research in Ayurveda & Siddha [DEPTT. OF AYUSH, MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA.]. [www.ccras.nic.in](http://www.ccras.nic.in).

**Divine 1992**

Divine GW, Brown JT, Frazier LM. The unit of analysis error in studies about physicians' patient care behaviour. *Journal of General Internal Medicine* 1992;**7**(6):623–9.

**Donner 2002**

Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**:2971–80.

**Egger 1997**

Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**:629–34.

**Gulliford 1999**

Gulliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the Health Survey for England 1994. *American Journal of Epidemiology* 1999;**149**:876–83.

**Higgins 2003**

Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.

**Higgins 2005**

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.5 [updated May 2005]. The Cochrane Library. Chichester: John Wiley & Sons, Ltd, 2005, issue Issue 3.

**Hsiao 2006**

Hsiao A F, Wong M D, Goldstein M S, Becerra L S, Cheng E M, Wenger N S. Complementary and Alternative Medicine Use Among Asian-American Subgroups: Prevalance, Predictors, and Lack of Relationship to Acculturation and Access to Conventional Health Care. *The Journal of Alternative and Complementary Medicine* 2006;**12**, No.10: 1003–10.

**Jüni 2001**

Jüni P, Altman DG, Egger M. Systematic reviews in health care: Assessing the quality of controlled clinical trials. *BMJ* 2001;**323**:42–6.

**Lad 1996**

Lad V. An Introduction to Ayurveda. <http://www.healthy.net/scr/article.asp?Id=373> 1996.

**Marshall 2000**

Marshall M, Lockwood A, Bradley C, Adams C, Joy C, Fenton M. Unpublished rating scales: a major source of bias in randomised controlled trials of treatments for schizophrenia. *British Journal of Psychiatry* 2000;**176**: 249–52.

**Meyer 1953**

Meyer BT, Lucero RJ. A validation study of the L-M Fergus Falls Behavior Rating Scale. *Journal of Clinical Psychology* 1953;**9**(2):192–5.

**Moher 2001**

Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001;**285**:1987–91.

**Neddermeyer 2006**

Neddermeyer D.M. Ayurvedic Medicine - Benefits. <http://ezinearticles.com/?Ayurvedic-Medicine---Benefits&id=359445> 2006.

**Overall 1962**

Overall JE, Gorham DR. The Brief Psychiatric Rating Scale.. *Psychological Reports* 1962;**10**:799–812.

**Ramu 1999b**

Ramu MG. Review of Previous Studies. *Ayurvedic Management of Unmada (Schizophrenia)*. New Delhi: Central Council for Research in Ayurveda & Siddha, Jawahar Lal Nehru Bhartiya Chikitsa Avum Homeopathy Anusandhan Bhawan, 1999:49–56.

**Ramu 1999c**

Ramu MG, Chaturvedi DD, Venkataram BS, Shankara MR, Leelavathy S, Janakiramiah N, Mukundan H, Thomas KM, Ramachandra M, Mahal AS, Murthy NSN, Devidas KV. Appendix 2. General instructions and guidelines for completing the proforma. *Ayurvedic Management of Unmada (Schizophrenia)*. New Delhi: Central Council for Research in Ayurveda & Siddha, Jawahar Lal Nehru Bhartiya Chikitsa Avum Homeopathy Anusandhan Bhawan, 1999:111–20.

**Rockland 1965**

ROCKLAND LH, POLLIN W. Quantification of Psychiatric Mental Status for use with psychotic patients.. *Archives of general psychiatry* 1965;**12**:23–28. [MEDLINE: 14221688]

**Russinova 2002**

Russinova Z, Wewiorski N J, Cash D. Use of Alternative Health Care Practices by Persons With Serious Mental Illness: Perceived Benefits. *American Journal of Public Health* 2002;**92**, No.10:1600–03.

**Schulz 1995**

Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;**273**:408–12.

**Singh 1994**

Singh R H. *Kayachikitsa: 2 volumes*. Chaukhamba Surabharati Prakasana, Varanasi, 1994.

**Subbarayappa 2001**

Subbarayappa B.V. The roots of ancient medicine : an historical outline. *Journal of Biosciences* 2001;**26**:135–44. [MEDLINE: 11426049]

**Tharyan 2007**

Tharyan P, Premkumar TS, Mathew V, Barnabas JP, Manuelraj. Editorial policy and reporting of randomised controlled trials: A systematic survey of instructions for authors and assessment of trial reports in Indian medical journals ( 2004-2005 ). *The National Medical Journal of India* [ in press ];[ **in press** ]:[ in press ].

**Ukoumunne 1999**

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ. Methods for evaluating area-wide and organisation-based intervention in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5): 1–75.

**Walter 1999**

Walter G, Rey JM. The relevance of herbal treatments for psychiatric practice. *Australian and New Zealand Journal of Psychiatry* 1999;**33**(4):482–9.

\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

#### Mahal 1976

Methods	Allocation: randomly allocated - no further details. Blindness: double. Duration: 2 months. Design: parallel groups.
Participants	Diagnosis: both schizophrenia (NIMHANS) and unmada. N=136. Age: mean ~27 years. Sex: M 61, F 47 (completer data only) Setting: hospital. History: duration ill 2-24 months, mean duration 6 months.
Interventions	1. Tagara: dose 8gms/day month-1, 12gms/day month-2. N=27. 2. Brahmyadiyoga: dose 8gms/day month-1, 12gms/day month-2. N=27. 3. Placebo: dose 8gms/day month-1, 12gms/day month-2. N=27. 4. Chlorpromazine: dose 200mg/day month- 1, 300mg/day month-2. N=27. All drugs given orally, four divided doses.
Outcomes	Mental state: Ayurvedic assessment, MPQ, Psychotic Symptom Rating Scale. Leaving the study early. Unable to use - Mental state: Spiral after effect (over 50% attrition).
Notes	* Completer data only - assumed even loss between groups.

#### *Risk of bias*

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

#### Ramu 1992

Methods	Allocation: unclear - 18 participants in each group. Blindness: rater. Duration: 28 days. Design: parallel groups.
Participants	Diagnosis: both schizophrenia (ICD 9) and unmada (Charaka definition). N=36. Age: 16-45 years, mean ~ 26.5. Sex: not reported. Setting: hospital.



	History: duration ill >1month, < 10 years.
Interventions	<p>1. Ayurvedic treatment: combined effect of shodana (cleaning) and shamana (palliative) measures &amp; satwawajayachikitsa (psychobehavioural therapy). N=18.</p> <p>i. Snehapana: Kalyanakaghrita for 3-7 days increasing@10ml daily, daily 15ml.</p> <p>ii. Ayushman 13 (Brahmyadiyoga 500mg) 2-2-2. Ayushman 14 (Nidrakarayoga) 2-0-2.</p> <p>iii. Mridu abhyanga + Dhanwantarataila 2 days after snehana followed by bhaspasweda + hot water.</p> <p>iv. Virechana kashayya: 75ml (with 1-2 Ichabhedi pills whenever required). Item ii stopped for 2 days, on day of Virechana and following day.</p> <p>Where symptoms did not subside by 50% at the end of 2 weeks:</p> <p>i. Kalyanakaghrita in case of Vatapittonmada, Panchagavyaghrita in case of Kaphonmada - 10ml once.</p> <p>ii. Item ii and Unmadagakesarirasa 200mg + Sootasekararasa 200mg b.i.d.</p> <p>iii. Item iii was given weekly 3 times.</p> <p>iv. Saraswatarista 10ml and Aswagandharista 10ml b.i.d. after meals.</p> <p>2. Modern treatment. N=18.</p> <p>i. Chlorpromazine (Tab.300mg/day for 2 weeks and increased to 600mg/day for next 2 weeks if improvement &gt; 50%).</p> <p>ii. Trihexyphenidyl HCl (Tab.2mg/day to reduce the complications of extrapyramidal symptoms).</p> <p>Diazepam (Inj. or Tab. in unmanageable cases in both groups). OCT and leisure hours in both groups</p>
Outcomes	<p>Leaving the study early.</p> <p>Mental state: BPRS, Ayurvedic assessment (Manas score and Symptoms score),</p> <p>Unable to use -</p> <p>Psychological assessment (no usable data).</p>
Notes	Information for one person leaving chlorpromazine group - assumed even loss between groups for other 4 people

### *Risk of bias*

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

### Ramu 1999

Methods	<p>Allocation: unclear.</p> <p>Blindness: double blind (only mentioned in title).</p> <p>Duration: 75 days.</p> <p>Design: parallel groups.</p>
Participants	<p>Diagnosis: both schizophrenia (WHO glossary) and unmada and manah pariksha (according to Laksana present in patients).</p> <p>N=78.</p> <p>Age: 20-50 years, mean ~ 32.</p> <p>Sex:M 30, F 35 (no information re sex of 13 who left early).</p> <p>Setting: hospital (inpatient).</p> <p>History: duration ill 2-6 years.</p>

Interventions	1. Brahmyadiyoga: dose 12gms/day initial 30 days, 16gms/day 31-75th day. N=23. 2. Placebo: dose 12gms/day initial 30 days, 16gms/day 31-75th day. N=20. 3. Chlorpromazine: dose 300mg/day initial 30 days, 450 mg/day 31-75th day. N=22. All medications administered orally in 4 divided doses.	
Outcomes	Leaving the study early. Mental state: Psychotic Symptom Rating Scale, psychological assessment( reaction time, critical flicker fusion threshold and Ferguse fall's behaviour rating scale). Adverse effects	
Notes	We have assumed that the groups were evenly distributed.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

ICD 9 - International Classification of Diseases - 9  
NIMHANS - National Institute of Mental Health And Neuro Sciences  
MPQ - Multiphasic Questionnaire  
BPRS - Brief Psychiatric Rating Scale  
OCT- Occupational Therapy  
b.i.d- twice daily

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

Study	Reason for exclusion
Farag 2003	Allocation: randomised. Participants: people with sleep onset insomnia, not schizophrenia
Fozdar 1962	Allocation: not randomised.
Hakim 1964	Allocation: not randomised, case series.
Weiss 1986	Allocation: not randomised, case series.

## DATA AND ANALYSES

### Comparison 1. AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 brahmyadiyoga	2	120	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.37, 1.62]
1.2 tagara	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.39, 2.54]
2 Mental state: 1. Not improved	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 brahmyadiyoga (Ayurvedic assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.36, 0.88]
2.2 brahmyadiyoga (MPQ assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.60, 1.17]
2.3 brahmyadiyoga (assessment tool not clear)	1	43	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.72, 1.16]
2.4 tagara (Ayurvedic assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.49, 1.05]
2.5 tagara (MPQ assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.79, 1.37]
3 Mental state: 2. Unco-operative or did not comprehend	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 brahmyadiyoga	1	68	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.39, 10.20]
3.2 tagara	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.27, 8.42]
4 Mental state: 3a. Average improvement - positive symptoms (PSRS, high=good, skewed data)			Other data	No numeric data
4.1 brahmyadiyoga			Other data	No numeric data
4.2 tagara			Other data	No numeric data
5 Mental state: 3b. Average improvement - negative symptoms (PSRS, high=good, skewed data)			Other data	No numeric data
5.1 brahmyadiyoga			Other data	No numeric data
5.2 tagara			Other data	No numeric data
6 Behaviour: Average score (Fergus Falls, high score = poor)	1	43	Mean Difference (IV, Fixed, 95% CI)	1.14 [-1.63, 3.91]
7 Psychological assessment: 1. Critical flicker fusion threshold (simple)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
8 Psychological assessment: 2. Reaction and vigilance (skewed data)			Other data	No numeric data
8.1 Reaction time (simple)			Other data	No numeric data
8.2 Vigilance			Other data	No numeric data
9 Adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.1 drowsiness	1	43	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.2 giddiness	1	43	Risk Ratio (M-H, Fixed, 95% CI)	2.63 [0.11, 61.05]
9.3 nausea and vomiting	1	43	Risk Ratio (M-H, Fixed, 95% CI)	13.13 [0.80, 216.30]

9.4 somnolence	1	43	Risk Ratio (M-H, Fixed, 95% CI)	2.63 [0.11, 61.05]
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## Comparison 2. AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 brahmyadiyoga	2	120	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.42, 1.97]
1.2 tagara	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.39, 2.54]
2 Mental state: 1. Not improved	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 brahmyadiyoga (Ayurvedic assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.60, 1.94]
2.2 brahmyadiyoga (MPQ assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [0.98, 2.67]
2.3 brahmyadiyoga (assessment tool not clear)	1	45	Risk Ratio (M-H, Fixed, 95% CI)	1.82 [1.11, 2.98]
2.4 tagara (Ayurvedic assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [0.81, 2.36]
2.5 tagara (MPQ assessment)	1	68	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [1.25, 3.19]
3 Mental state: 2. Unco-operative or did not comprehend	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 brahmyadiyoga	1	68	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.27, 3.68]
3.2 tagara	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.18, 3.10]
4 Mental state: 3a.i. Average improvement - positive symptoms (PSRS, zero =good, skewed data)			Other data	No numeric data
4.1 brahmyadiyoga			Other data	No numeric data
4.2 tagara			Other data	No numeric data
5 Mental state: 3a.ii. Average endpoint score - positive symptoms (PSRS, zero = good, skewed data)			Other data	No numeric data
6 Mental state: 3b.i. Average improvement - negative symptoms (PSRS, zero =good, skewed data)			Other data	No numeric data
6.1 brahmyadiyoga			Other data	No numeric data
6.2 tagara			Other data	No numeric data
7 Mental state: 3b.ii. Average endpoint score - negative symptoms (PSRS, zero =good, skewed data)			Other data	No numeric data
8 Behaviour: Average score (Fergus Falls, high score = poor)	1	45	Mean Difference (IV, Fixed, 95% CI)	3.5 [-0.18, 7.18]
9 Psychological assessment: 1. Critical flicker fusion threshold (simple)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only

10 Psychological assessment: 2. Reaction and vigilance (skewed data)			Other data	No numeric data
10.1 reaction time (simple)			Other data	No numeric data
10.2 vigilance			Other data	No numeric data
11 Adverse effects	2	180	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.48, 2.97]
11.1 drowsiness	1	45	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.01, 1.87]
11.2 giddiness	1	45	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.05, 4.91]
11.3 somnolence	1	45	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.06, 14.37]
11.4 nausea and vomiting	1	45	Risk Ratio (M-H, Fixed, 95% CI)	14.38 [0.87, 237.58]

### Comparison 3. AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term)

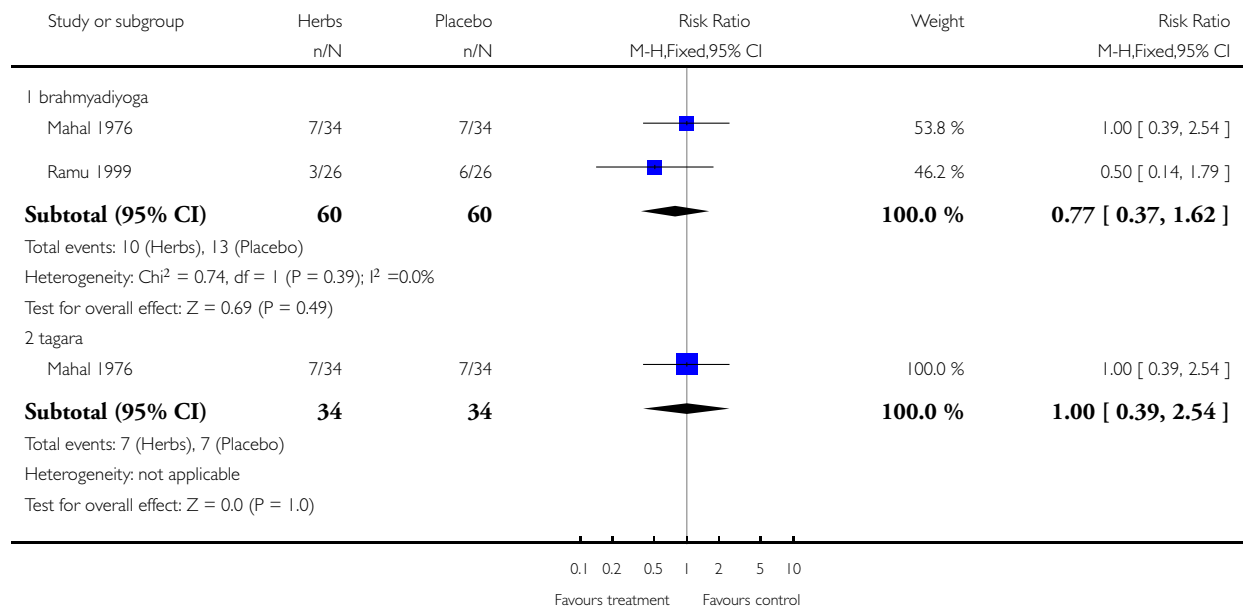
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leaving the study early	1	36	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.13, 3.53]
2 Mental state: 1a.i. Average endpoint score - by 4 weeks (BPRS, high=poor, skewed data)			Other data	No numeric data
3 Mental state: 1a.ii. Average endpoint score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data)			Other data	No numeric data
3.1 manas			Other data	No numeric data
3.2 symptoms			Other data	No numeric data
4 Mental state: 1b.i. Average change score - by 4 weeks (BPRS, high=poor, skewed data)			Other data	No numeric data
5 Mental state: 1b.ii. Average change score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data)			Other data	No numeric data
5.1 manas			Other data	No numeric data
5.2 symptoms			Other data	No numeric data

# **Analysis 1.1. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 1 Leaving the study early.**

Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 1 Leaving the study early

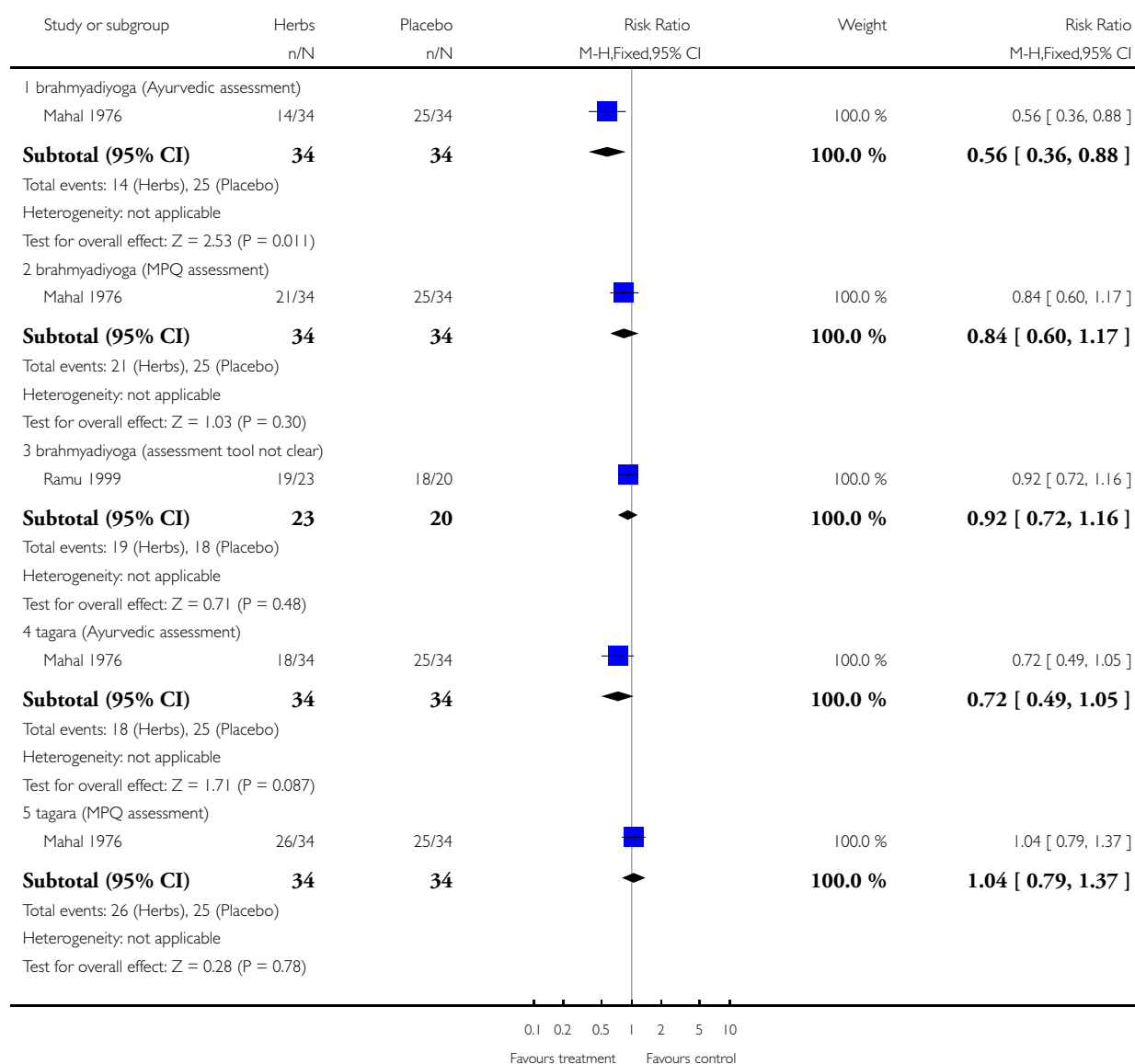


## Analysis 1.2. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 2 Mental state: 1. Not improved.

Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 2 Mental state: 1. Not improved



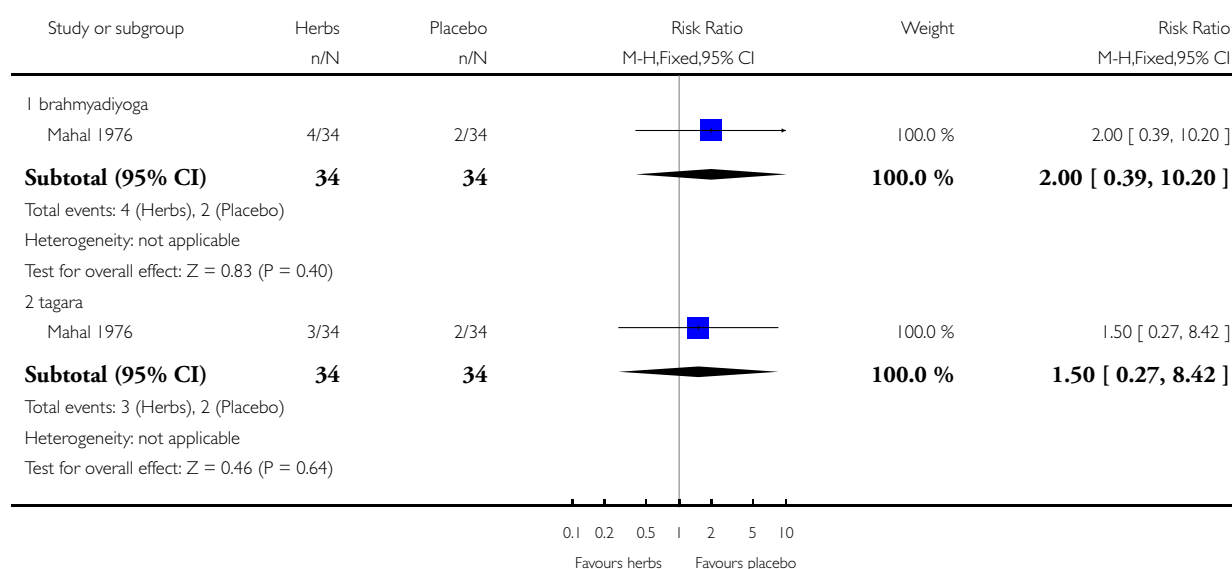


### Analysis 1.3. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 3 Mental state: 2. Unco-operative or did not comprehend.

Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 3 Mental state: 2. Unco-operative or did not comprehend



### Analysis 1.4. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 4 Mental state: 3a. Average improvement - positive symptoms (PSRS, high=good, skewed data).

Mental state: 3a. Average improvement - positive symptoms (PSRS, high=good, skewed data)

Study	Intervention	Mean	SD	N	Notes
<b>brahmyadiyoga</b>					
Mahal 1976	brahmyadiyoga	7.93	9.56	27	F test undertaken. p<0.05 in favour of brahmyadiyoga.
Mahal 1976	placebo	1.48	7.70	27	
Ramu 1999	brahmyadiyoga	17.4	8.97		here high=poor
Ramu 1999	placebo	22.5	15.2		
<b>tagara</b>					

**Mental state: 3a. Average improvement - positive symptoms (PSRS, high=good, skewed data)** (Continued)

Mahal 1976	tagara	2.74	8.09	27	F test undertaken. p<0.05 not significant.
Mahal 1976	placebo	1.48	7.70	27	

**Analysis 1.5. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 5 Mental state: 3b. Average improvement - negative symptoms (PSRS, high=good, skewed data).**

**Mental state: 3b. Average improvement - negative symptoms (PSRS, high=good, skewed data)**

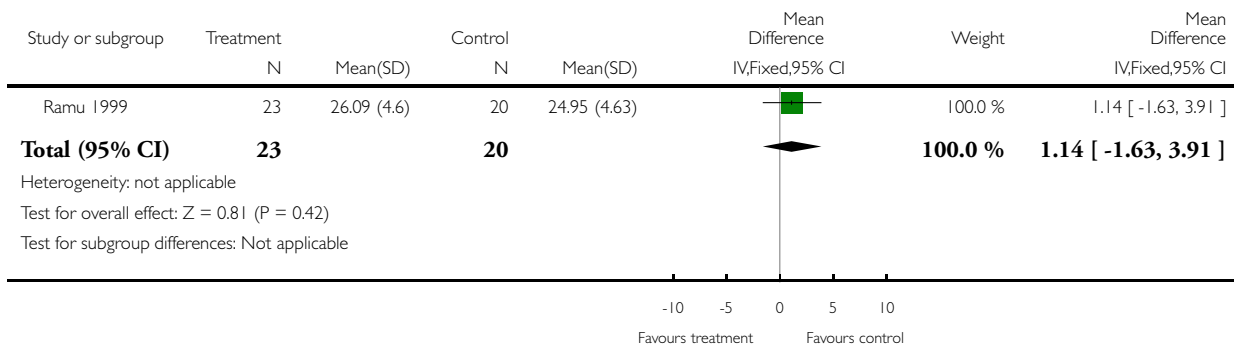
Study	Intervention	Mean	SD	N	Notes
<b>brahmyadiyoga</b>					
Mahal 1976	brahmyadiyoga	3.26	5.69	27	F test undertaken. p<0.05 in favour of brahmyadiyoga.
Mahal 1976	placebo	-0.48	8.54	27	
Ramu 1999	brahmyadiyoga	20.8	11.8		here high=poor
Ramu 1999	brahmyadiyoga	17.6	13.7		
<b>tagara</b>					
Mahal 1976	tagara	-2.81	7.69	27	F test undertaken. p<0.05 not significant.
Mahal 1976	placebo	-0.48	8.54	27	

**Analysis 1.6. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 6 Behaviour: Average score (Fergus Falls, high score = poor).**

Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 6 Behaviour: Average score (Fergus Falls, high score = poor)

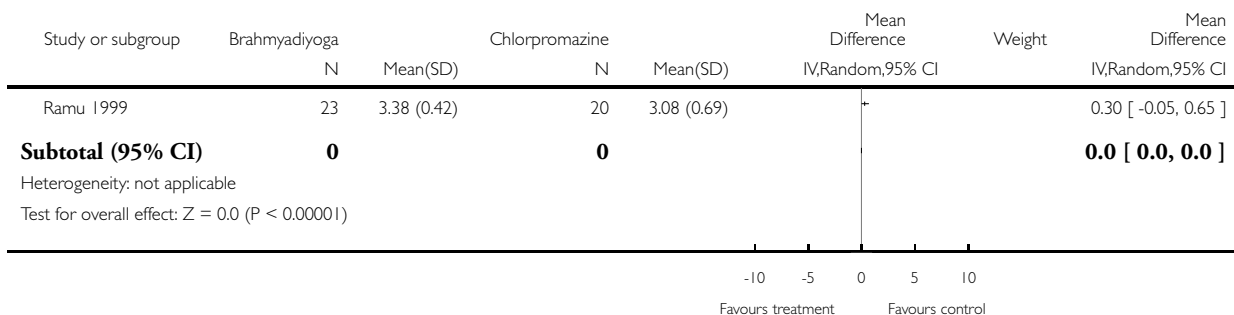


**Analysis 1.7. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 7 Psychological assessment: I. Critical flicker fusion threshold (simple).**

Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 7 Psychological assessment: I. Critical flicker fusion threshold (simple)



**Analysis 1.8. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 8 Psychological assessment: 2. Reaction and vigilance (skewed data).**

**Psychological assessment: 2. Reaction and vigilance (skewed data)**

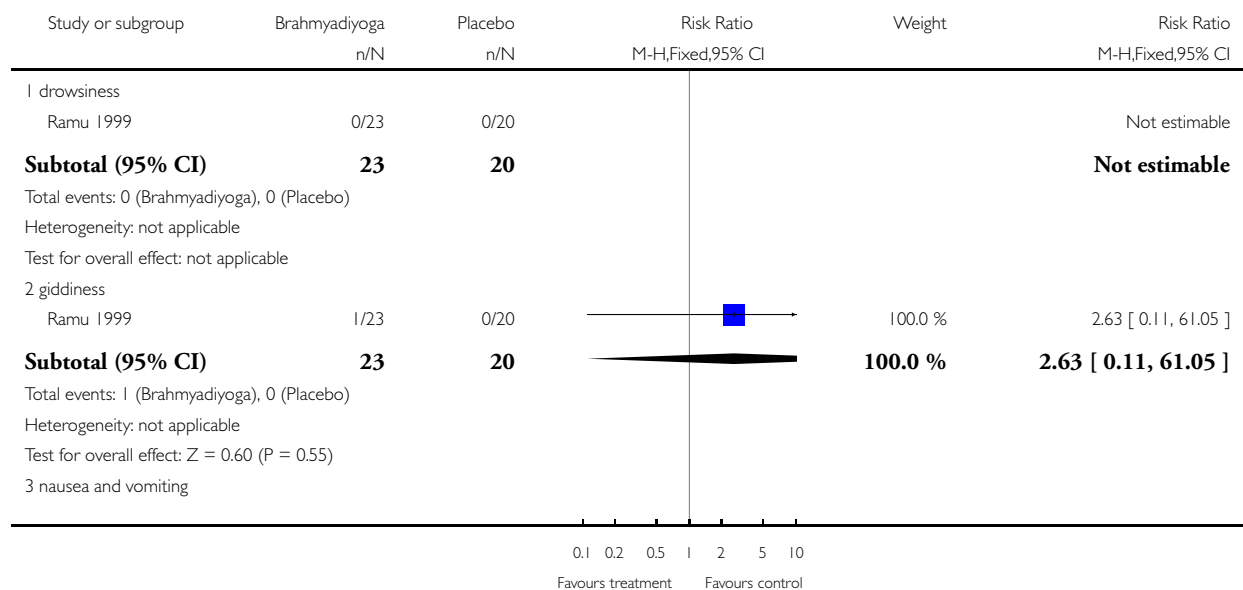
Study	Intervention	Mean	S.D	N	Notes	Order
<b>Reaction time (simple)</b>						
Ramu 1999	Brahmyadiyoga	3.62	3.75	23		
Ramu 1999	Placebo	3.94	3.49	20		
<b>Vigilance</b>						
Ramu 1999	Brahmyadiyoga	28.76	21.37	23		
Ramu 1999	Placebo	24.88	16.01	20		

**Analysis 1.9. Comparison 1 AYURVEDIC HERBS versus PLACEBO (all short term), Outcome 9 Adverse effects.**

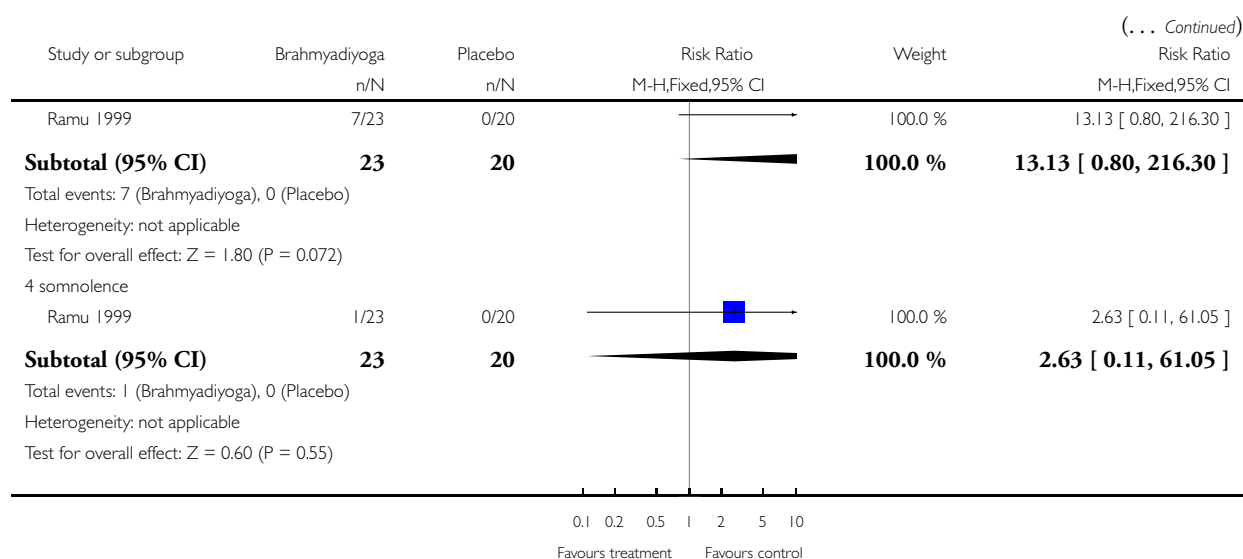
Review: Ayurvedic medicine for schizophrenia

Comparison: 1 AYURVEDIC HERBS versus PLACEBO (all short term)

Outcome: 9 Adverse effects



(Continued ...)

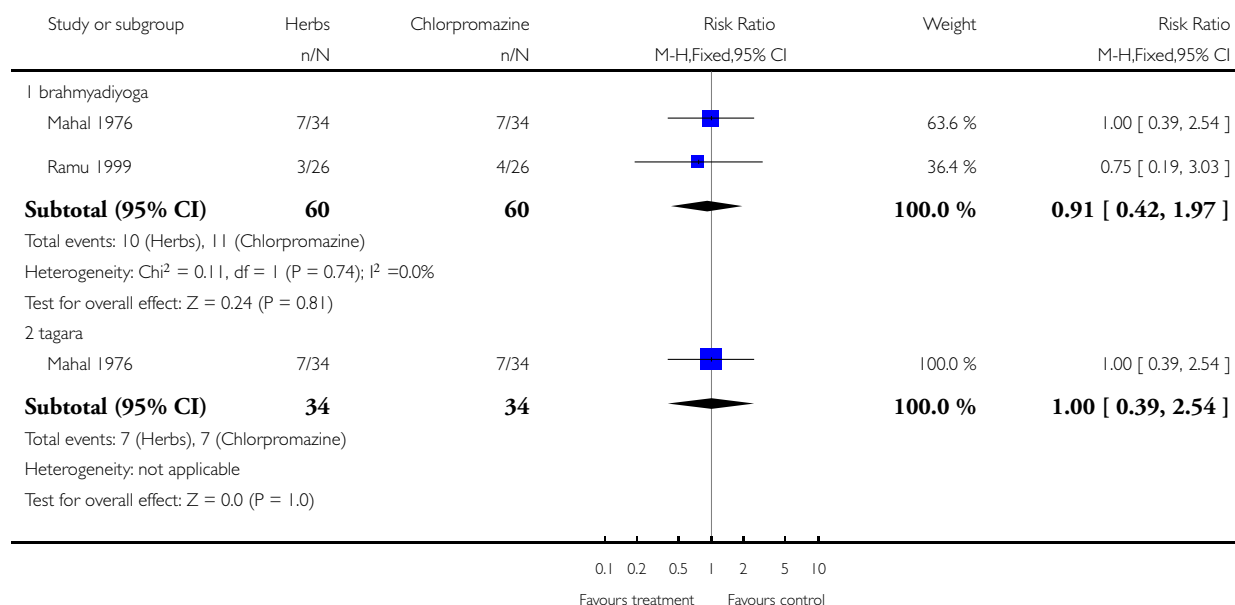


## Analysis 2.1. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 1 Leaving the study early.

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 1 Leaving the study early

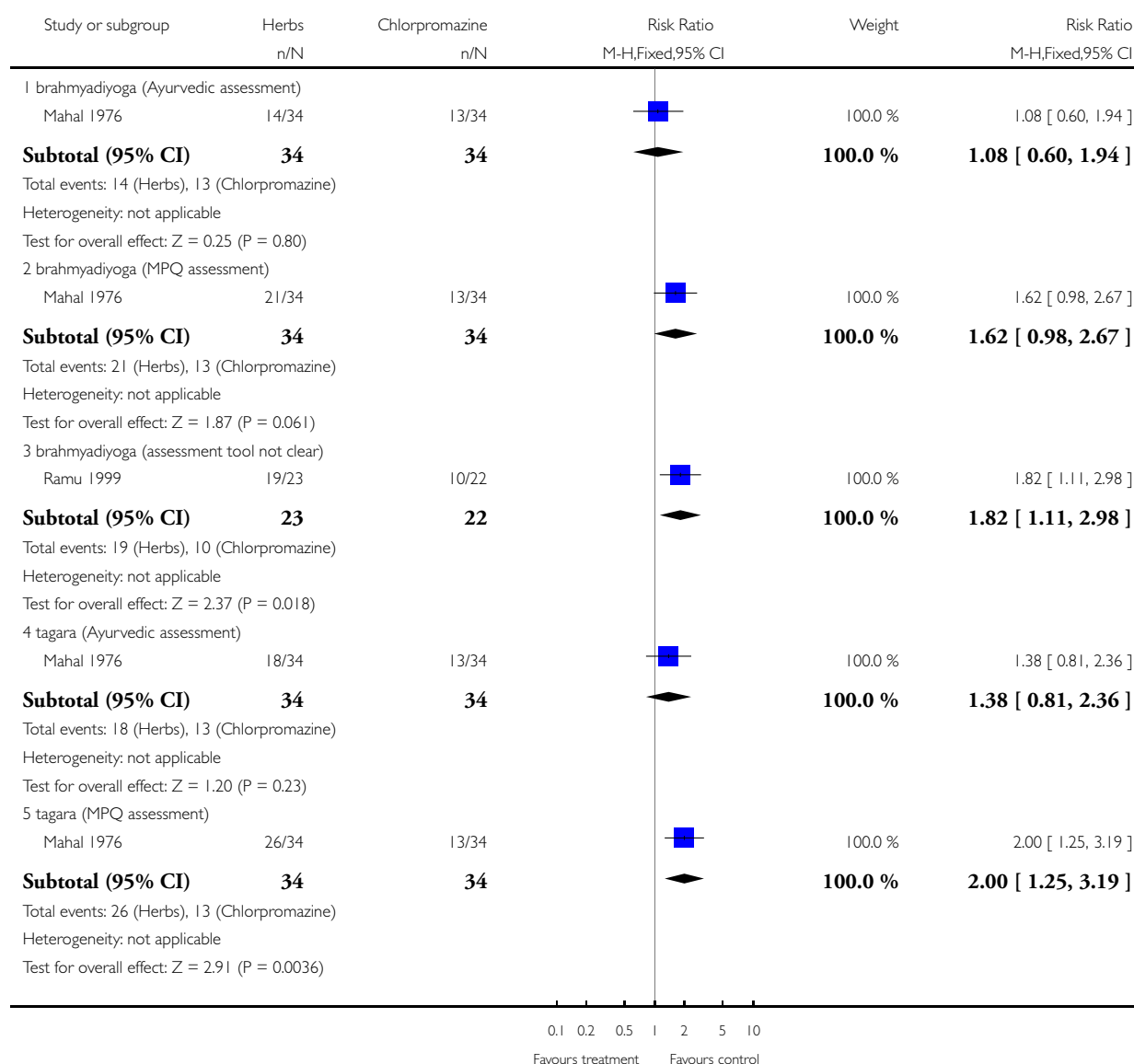


## Analysis 2.2. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 2 Mental state: 1. Not improved.

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 2 Mental state: 1. Not improved

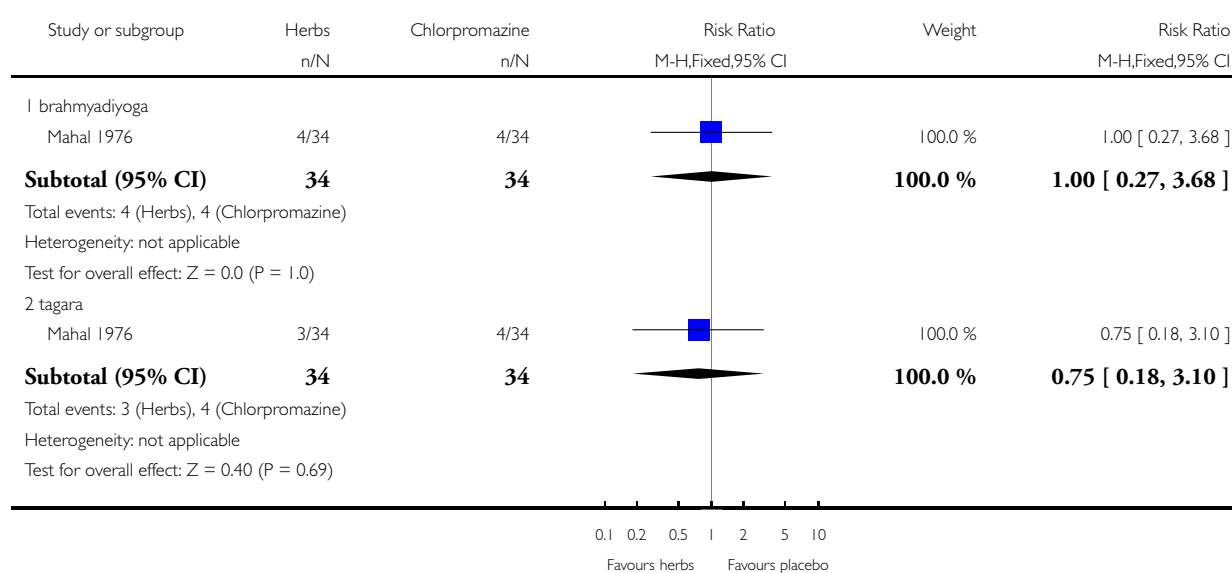


### Analysis 2.3. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 3 Mental state: 2. Unco-operative or did not comprehend.

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 3 Mental state: 2. Unco-operative or did not comprehend



### Analysis 2.4. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 4 Mental state: 3a.i. Average improvement - positive symptoms (PSRS, zero =good, skewed data).

Mental state: 3a.i. Average improvement - positive symptoms (PSRS, zero =good, skewed data)

Study	Intervention	Mean	SD	N	Notes
<b>brahmyadiyoga</b>					
Mahal 1976	brahmyadiyoga	7.93	9.56	27	F test undertaken. p<0.05 in not significant.
Mahal 1976	chlorpromazine	12.33	10.96	27	



**Mental state: 3a.i. Average improvement - positive symptoms (PSRS, zero =good, skewed data)** (Continued)

tagara					
Mahal 1976	tagara	2.74	8.09	27	F test undertaken. p<0.05 in favour of chlorpromazine.
Mahal 1976	chlorpromazine	12.33	10.96	27	

**Analysis 2.5. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 5**  
**Mental state: 3a.ii. Average endpoint score - postive symptoms (PSRS, zero = good, skewed data).**

**Mental state: 3a.ii. Average endpoint score - postive symptoms (PSRS, zero = good, skewed data)**

Study	Intervention	Mean	S.D	N	Notes
Ramu 1999	brahmyadiyoga	17.4	8.97		here high= poor
Ramu 1999	chlorpromazine	8.14	9.56		

**Analysis 2.6. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 6**  
**Mental state: 3b.i. Average improvement - negative symptoms (PSRS, zero =good, skewed data).**

**Mental state: 3b.i. Average improvement - negative symptoms (PSRS, zero =good, skewed data)**

Study	Intervention	Mean	SD	N	Notes
brahmyadiyoga					
Mahal 1976	brahmyadiyoga	3.26	5.69	27	F test undertaken. p<0.05 is not significant.
Mahal 1976	chlorpromazine	5.52	5.37	27	
tagara					
Mahal 1976	tagara	-2.81	7.69	27	F test undertaken. p<0.05 in favour of chlorpromazine.
Mahal 1976	chlorpromazine	5.52	5.37	27	

**Analysis 2.7. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 7 Mental state: 3b.ii. Average endpoint score - negative symptoms (PSRS, zero =good, skewed data).**

**Mental state: 3b.ii. Average endpoint score - negative symptoms (PSRS, zero =good, skewed data)**

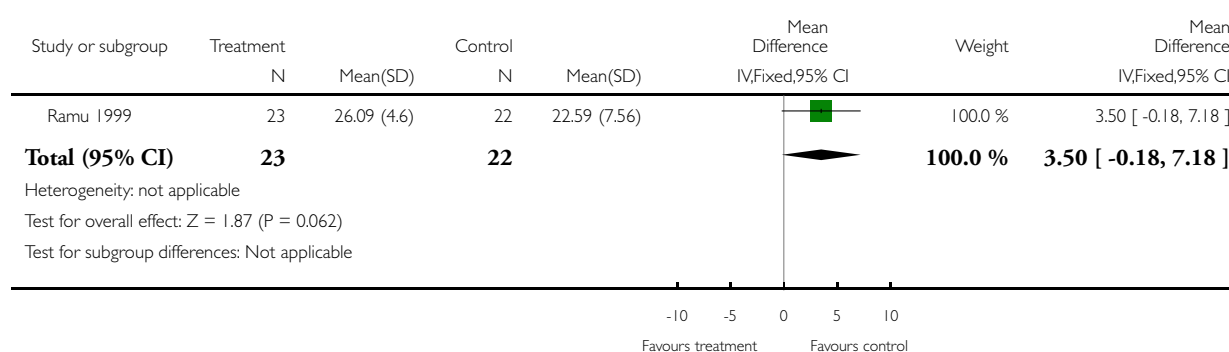
Study	Intervention	Mean	S.D	N	Notes
Ramu 1999	brahmyadiyoga	20.8	11.8		here high=poor
Ramu 1999	chlorpromazine	10.5	8.7		

**Analysis 2.8. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 8 Behavioiur: Average score (Fergus Falls, high score = poor).**

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 8 Behavioiur: Average score (Fergus Falls, high score = poor)



**Analysis 2.9. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 9 Psychological assessment: 1. Critical flicker fusion threshold (simple).**

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 9 Psychological assessment: 1. Critical flicker fusion threshold (simple)



**Analysis 2.10. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 10 Psychological assessment: 2. Reaction and vigilance (skewed data).**

Psychological assessment: 2. Reaction and vigilance (skewed data)

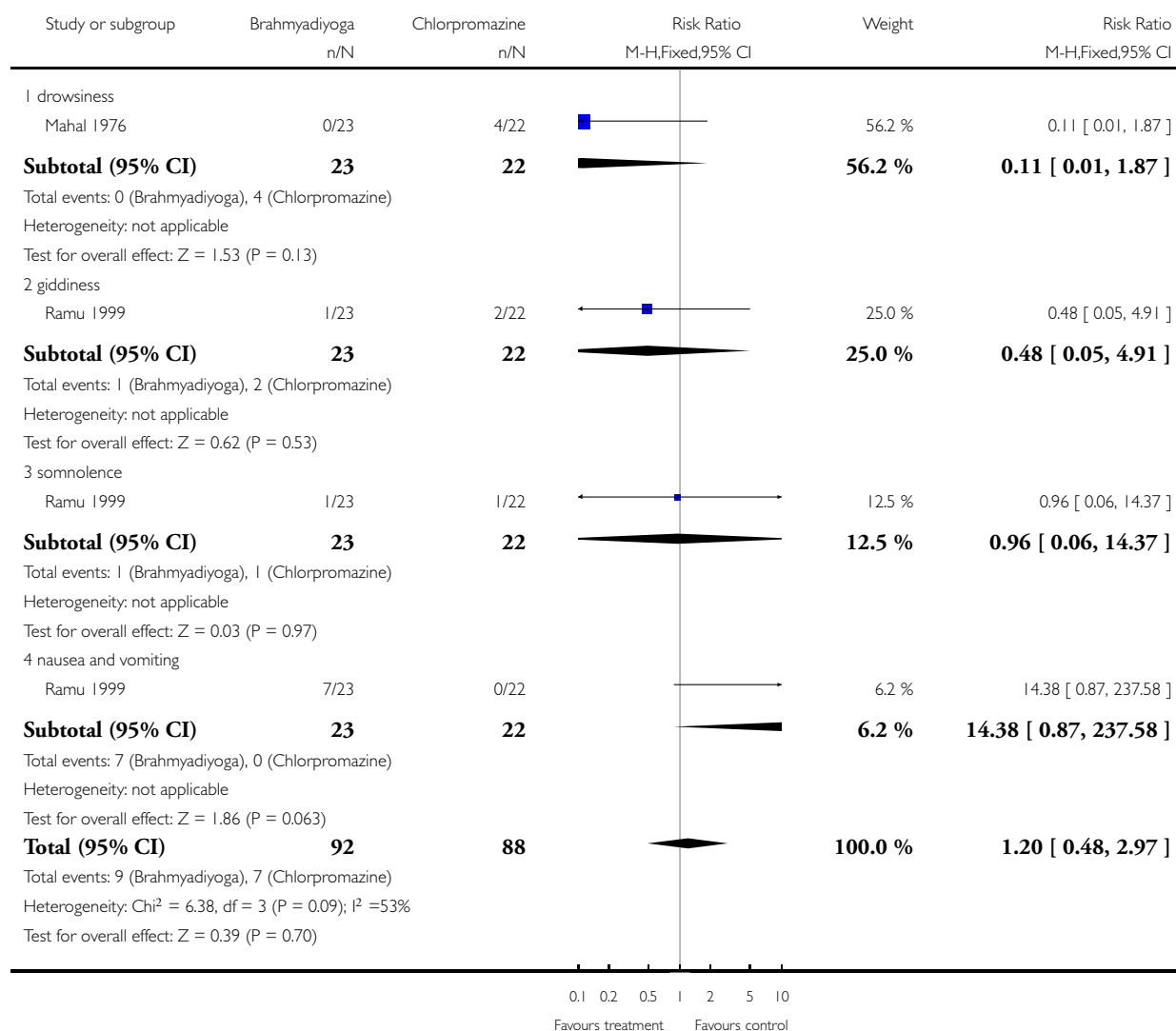
Study	Intervention	Mean	S.D	N	Notes	Order
<b>reaction time (simple)</b>						
Ramu 1999	Brahmyadiyoga	3.62	3.75	23		
Ramu 1999	Chlorpromazine	4.40	4.57	22		
<b>vigilance</b>						
Ramu 1999	Brahmyadiyoga	28.76	21.37	23		
Ramu 1999	Chlorpromazine	24.88	16.01	22		

## Analysis 2.11. Comparison 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term), Outcome 11 Adverse effects.

Review: Ayurvedic medicine for schizophrenia

Comparison: 2 AYURVEDIC HERBS versus ANTIPSYCHOTIC (all short term)

Outcome: 11 Adverse effects

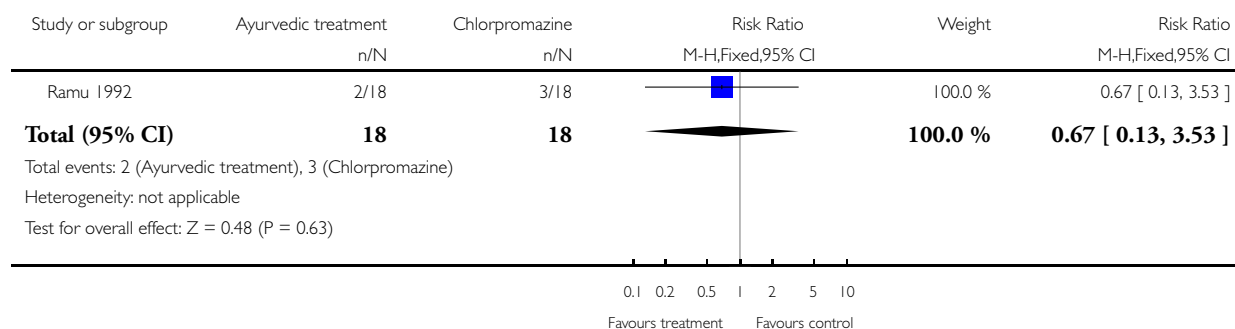


### Analysis 3.1. Comparison 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term), Outcome 1 Leaving the study early.

Review: Ayurvedic medicine for schizophrenia

Comparison: 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term)

Outcome: 1 Leaving the study early



### Analysis 3.2. Comparison 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term), Outcome 2 Mental state: 1a.i. Average endpoint score - by 4 weeks (BPRS, high=poor, skewed data).

Mental state: 1a.i. Average endpoint score - by 4 weeks (BPRS, high=poor, skewed data)

Study	Intervention	Mean	SD	N	Notes
Ramu 1992	Ayurvedic treatment	11.5	7.9	18	
Ramu 1992	Chlorpromazine	12.7	9.9	18	

### Analysis 3.3. Comparison 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term), Outcome 3 Mental state: 1a.ii. Average endpoint score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data).

Mental state: 1a.ii. Average endpoint score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data)

Study	Intervention	Mean	SD	N	Notes
<b>manas</b>					
Ramu 1992	Ayurvedic treatment	4.9	4.2	18	
Ramu 1992	Chlorpromazine	4.8	5.0	18	
<b>symptoms</b>					
Ramu 1992	Ayurvedic treatment	22.5	15.2	18	

**Mental state: 1a.ii. Average endpoint score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data)** (Continued)

Ramu 1992	Chlorpromazine	21.6	20.3	18	
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**Analysis 3.4. Comparison 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term), Outcome 4 Mental state: 1b.i. Average change score - by 4 weeks (BPRS, high=poor, skewed data).**

**Mental state: 1b.i. Average change score - by 4 weeks (BPRS, high=poor, skewed data)**

Study	Intervention	Mean	SD	N	Notes
Ramu 1992	Ayurvedic treatment	-11.9	7.2	18	
Ramu 1992	Chlorpromazine	-17.3	14.2	18	

**Analysis 3.5. Comparison 3 AYURVEDIC TREATMENT versus ANTIPSYCHOTIC (all short term), Outcome 5 Mental state: 1b.ii. Average change score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data).**

**Mental state: 1b.ii. Average change score - by 4 weeks (Ayurvedic Assessment, high=poor, skewed data)**

Study	Intervention	Mean	SD	N	Notes
<b>manas</b>					
Ramu 1992	Ayurvedic treatment	-6.5	2.9	18	
Ramu 1992	Chlorpromazine	-9.4	5.6	18	
<b>symptoms</b>					
Ramu 1992	Ayurvedic treatment	-32	20.4	18	
Ramu 1992	Chlorpromazine	-36.2	26.3	18	

## ADDITIONAL TABLES

**Table 1. Suggested design of study**

Methods	Participants	Interventions	Outcomes	Notes
Allocation: centralised sequence generation with table of random numbers or computer generated code,	Diagnosis: it may be preferred not to use diagnostic categories such as DSM IV and just to include those whose men-	1a. Ayurvedic herbs: dose and choice at clinician's and patient's discretion + chlorpromazine: dose	Quality of life: healthy days. Service outcomes: days in hospital, time attending psychiatric outpa-	* size of study to detect a 10% difference in improvement with 80% certainty.

**Table 1. Suggested design of study** (Continued)

stratified by severity of illness, sequence concealed till interventions assigned. In the context of limited provision, randomisation may be the only equitable way of distributing care. Blindness: double - tested. Duration: 1 year. Design: parallel groups.	tal health problem is designated as schizophrenia or psychosis and un-mada. N=300. Age-any. Sex: either. Setting: any-where (preferably hospital setting ). History: non-acute.	- clinician's and patient's discretion. N=150 OR 1b. Ayurvedic treatment (as a holistic package). + chlorpromazine: dose - clinician's and patient's discretion. N=150. 2. Chlorpromazine: dose - clinician's and patient's discretion. N=150	tient clinic. Satisfaction with care: patients/carers. Global state: CGI.*** Mental state: CGI, relapse.** Functioning: engagement with services, leaving the study early, living independently. Adverse effects: including mortality. Economic outcomes: cost-effectiveness and cost-benefit.	*** Primary outcome. If scales are used to measure outcome then there should be binary cut off points, defined before study start, of clinically important improvement
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## WHAT'S NEW

Last assessed as up-to-date: 18 August 2007.

Date	Event	Description
15 February 2010	Amended	Contact details updated.

## HISTORY

Review first published: Issue 4, 2007

Date	Event	Description
11 November 2009	Amended	Plain language summary updated
5 August 2009	Amended	Contact details updated.
24 April 2008	Amended	Converted to new review format.
19 August 2007	New citation required and conclusions have changed	Substantive amendment



## CONTRIBUTIONS OF AUTHORS

Vishesh Agarwal - protocol development, searching, data extraction, analyses, writing up.

Akhil Abhijnhan - protocol development, searching, data extraction, analyses, writing up.

Prakash Raviraj - protocol development, searching, data extraction, analyses, writing up.

## DECLARATIONS OF INTEREST

Vishesh Agarwal - none known.

Akhil Abhijnhan - none known.

Prakash Raviraj - none known.

## SOURCES OF SUPPORT

### Internal sources

- Cochrane Schizophrenia Group, UK.

### External sources

- No sources of support supplied

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Medicine, Ayurvedic; Antipsychotic Agents [therapeutic use]; Phytotherapy [\*methods]; Randomized Controlled Trials as Topic; Schizophrenia [\*drug therapy]

### MeSH check words

Humans