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Broderick J, Vancampfort D

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[Intervention Review]

Yoga as part of a package of care versus non-standard care for schizophrenia

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ABSTRACT

Background

Yoga is an ancient body-mind practice which originated in India and is popular in the Western world as a form of relaxation and exercise. It has been of interest for people with schizophrenia to determine the efficacy of yoga delivered as a package of care versus non-standard care.

Objectives

To examine the effects of yoga as part of a package of care versus non-standard care for schizophrenia.

Search methods

We searched the Cochrane Schizophrenia Group Trials Register (latest 15 May 2018) which is based on regular searches of MEDLINE, PubMed, Embase, CINAHL, BIOSS, AMED, PsychINFO, and registries of clinical trials. We searched the references of all included studies. There are no language, date, document type, or publication status limitations for inclusion of records in the register.

Selection criteria

All randomised controlled trials (RCTs) including people with schizophrenia comparing yoga as part of a package of care with non-standard care.

Data collection and analysis

There were no data to analyse as no studies met the inclusion criteria.

Main results

The searches identified 30 studies that could be relevant to this review. After careful inspection, 29 were excluded and one is ongoing. No data were available for analyses.

Authors' conclusions

In view of the lack of evidence from RCTs, it is currently not possible for us to comment on the use of yoga as part of a package of care versus non-standard care.

PLAIN LANGUAGE SUMMARY

Yoga as part of a package of care versus non-standard care

Review question

Is yoga, delivered as part of a larger package of care, effective for people with schizophrenia compared with non-standard care?

Background

Yoga involves physical postures and breathing exercises to promote balance between mind and body. Yoga has now been widely adopted as a method of relaxation and exercise for reduction of stress and promotion of health and feelings of well-being. Schizophrenia is a serious mental illness where people experience symptoms such as hearing voices that are not there, poor emotional response and social withdrawal. Schizophrenia often affects people for long periods of their life and is treated primarily by antipsychotic medications. However, these medications are not always fully effective and some research suggests that yoga as an add-on treatment could be beneficial and help improve the quality of life of people with schizophrenia. Yoga can be combined with other therapies such as counselling or other forms of exercise into a 'package of care'. Non-standard care can consist of talking therapies, expressive therapies (art, dance, drama, music and writing) and other forms of exercise.

Searching for evidence

In May 2018, the Information Specialist for Cochrane Schizophrenia searched Cochrane Schizophrenia's specialised register of randomised controlled trials for trials of people with schizophrenia. Thirty studies were found that could be relevant. The review authors carefully inspected full-text versions of these studies, checking that they were randomised controlled trials that randomised people with schizophrenia to receive, in addition to their ongoing care, either yoga as part of a package of care or another type of non-standard care intervention. Twenty-nine of these studies did not meet the above inclusion criteria and are excluded from the review. One study is 'ongoing' as data are not available at the moment.

Key results

Currently, there are no data available from randomised controlled trials regarding the effects of yoga as part of a package of care compared with non-standard care for people with schizophrenia.

Quality of the evidence

Currenlty, there is no high-quality evidence to support or discourage the use of yoga as part of a package of care versus non-standard care. Schizophrenia is often a long-term illness and studies which compare yoga packages to other types of therapies are necessary.

BACKGROUND

Description of the condition

Schizophrenia is a relatively common mental disorder with an incidence of 10.2 to 22.0 per 100,000 people (McGrath 2008). Typical presentation is in early adulthood or late adolescence (McGrath 2008). Schizophrenia is characterised by a constellation of symptoms that can present in a wide variety of ways depending on the individual. Core features or symptoms can broadly be divided into positive symptoms and negative symptoms. Positive symptoms include delusions, hallucinations, disorganised speech, and disorganised behaviour. Negative symptoms include anhedonia (lack of pleasure), alogia (reduced speech), affective flattening (lack of emotional responsiveness), amotivation and social withdrawal (Owen 2016). Additionally, while they are not included in the current *International Statistical Classification of Diseases and Health Related Problems* (ICD-10) or the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) diagnostic systems as diagnostic criteria, characteristic cognitive deficits are widely recognised in schizophrenia and are the target of considerable clinical and research attention (Carbon 2014).

Schizophrenia has been identified as a serious public health concern, ranking eleventh in the causes of years lived with disability worldwide (Global Burden of Disease Study 2013). It is worldwide associated with a weighted average of 14.5 years of potential life lost (95% confidence interval 11.2 to 17.8) (Hjorthoj 2017). The mainstay of treatment is antipsychotic medication (Owen 2016). Previous research has demonstrated that changes in hippocampal volume and cortical thickening (or less thinning) following aerobic exercise were correlated with improvements in aerobic fitness (Firth 2018). Although antipsychotic medication is effective in reducing positive symptoms, usually within the early stages of treatment (Leucht 2013), it is of less benefit for negative symptoms and cognitive deficits (Fusar-Poli 2015 and Nielsen 2015 respectively). Unfortunately, it is the negative and cognitive symptoms that cause most long-term disability (Vancampfort 2011a; Vancampfort 2012). The side-effect profile and inherent limitations of antipsychotics, as well as patient preference to avoid this route where possible, have resulted in additional non-pharmacological interventions being utilised as either an adjunct or alternative to medication therapy (Kern 2009). Low-cost treatments that decrease negative symptoms, reduce cognitive deficits and promote mental and physical quality of life and functional recovery are warranted.

Description of the intervention

Yoga originated in India as an ancient Hindu practice incorporating physical postures with breathing exercises seeking to bring about a balance between the mental and physical state (Büssing 2012; Ross 2012; Sherman 2012). The principles behind its practice were first described by Pantajali, and were believed to allow the mind and the body to be prepared for spiritual development (Ross 2012). In the Western world, yoga has now been widely adopted as both a method of relaxation and exercise. Hatha yoga is the most widely adopted practice used in the Western world (Collins 1998). Its use of postures *(*asanas*)* improves strength, flexibility, co-ordination and endurance; and its use of breathing exercises *(*pranayama*)* improves respiratory control and concentration. Mantra yoga is another well-known and widely practised form of Hindu yoga and focuses on the use of chants to achieve mental and spiritual transformation (Sherman 2012).

With its increasing popularity, research into the effect of yoga on both physical and mental health has identified key benefits of yoga. It has been shown to both reduce stress and improve cognitive function in healthy individuals (Bangalore 2012); and also to be useful as a complementary therapy for many health conditions, resulting in better blood pressure control and improvements in mental health conditions including depression and anxiety disorders (Büssing 2012).

Yoga's benefit for other mental health conditions has led to research into the role of yoga as a potential complementary therapy for the management of schizophrenia. A systematic review of randomised controlled trials indicated that yoga could also be of benefit as an add-on treatment to standard care by reducing both positive and negative symptoms of schizophrenia and improving the health-related quality of life of people with schizophrenia, although the evidence is limited as only three trials were included (Vancampfort 2012). A further review echoed the possible improvements in quality of life, but highlighted that long-term benefits are not known and the safety of the intervention was not reported (Cramer 2013). Recently it was demonstrated that yoga also improves the cognitive sub-domain of long-term memory in people with schizophrenia (Dauwan 2016).

Exercise is a subset of physical activity that is planned, structured, and repetitive (Caspersen 1985) and aims to increase one or more of the components of physical fitness (i.e. cardiorespiratory fitness, muscular strength and endurance, body composition, flexibility and neuromotor fitness), or physical activity, or to improve a physical indicator such as blood pressure. Physical fitness is a multifactorial concept comprising a set of more or less independent attributes which are related to the ability to perform physical activities. Some of these components (including cardio-respiratory fitness, muscular endurance, muscular strength and flexibility) are more closely related to health, while others (such as coordination and whole body balance) are more related to performance. Health-related physical fitness has been defined as the ability to perform daily activities with vigour and to demonstrate capacities that are associated with a lower risk of premature development of hypokinetic diseases (i.e. those associated with physical inactivity). Performance-related physical fitness refers to those components that are necessary for optimal work or sport performance (Pate 1988).

Yoga can therefore be considered a form of exercise which targets health-related physical fitness. While purist yoga-only programmes are often delivered, yoga also has the potential to be delivered as a part of a multi-modal intervention, i.e. part of a package of care. This could be alongside other exercise, which could consist of any other activity which falls under the umbrella term of exercise, encompassing broad categories of skill-related fitness, health-related fitness, body-mind fitness, as well as physical activities which are not specifically fitness focused. Yoga could also be combined with expressive therapies or talking therapies. Multi-modal interventions could consist of two components or a diverse mix of more than two elements; for example, yoga combined with other exercise combinations such as tai chi plus art therapy.

Expressive therapies include broad categories of art therapy, dance therapy, drama therapy, music therapy and writing therapy. These

represent different approaches, but the uniting principle is that these forms of therapy take place within a patient–therapist relationship.

In art therapy the patient is directed to use a range of art materials to make images, and the focus is on the relation between the image, the creator, and the therapist (Crawford 2007). Dance therapy is also sometimes referred to as dance–movement therapy (DMT) (Payne 2006), and has been used as a healing ritual since early human history, although there is no one particular therapeutic dance (Ren 2013). Drama therapists use games, storytelling and role-play (Crawford 2007). Music therapy is often perceived as a psychotherapeutic method in the sense that it addresses intra- and inter-psychic, as well as social, processes by using musical interaction as a means of communication, expression, and transformation (Mössler 2011). Writing therapy uses the act of writing and processing the written word as a therapeutic tool.

Talking therapies can be considered to consist of — but are not limited to — talking treatments, counselling, psychological therapies or treatments and psychotherapies. Cognitive behavioural therapy (CBT) is one of the most well-recognised talking therapies. In CBT, links are made between the person's feelings and patterns of thinking which underpin their distress. The participant is encouraged to take an active part in their therapy by using the following techniques (Jones 2012).

1. Challenging their habitual patterns of thinking.
2. Examining the evidence for and against their distressing beliefs.
3. Using reasoning abilities and personal experience to develop rational and personally acceptable alternative explanations and interpretations (Alford 1994); and to test these alternative explanations in real-world situations (Tarrier 1993).

As CBT has latterly developed into a 'catch-all' term for a variety of similar interventions, we will incorporate the criteria developed by Jones 2012 in this review.

How the intervention might work

Yoga has been identified as having a role in regulating the autonomic nervous system (Vancampfort 2012), decreasing sympathetic tone, and creating a reaction which is the opposite to the 'fight or flight' reaction. There is a subsequent effect on the limbic system and hypothalamic pituitary axis leading to a reduction in blood cortisol levels. This leads to a regulation of heart rate and blood pressure, which has obvious cardiovascular benefits (Damodaran 2002). Yoga also focuses on relaxed breathing and this internal concentration is thought to reduce stress by minimising mental focus on external stressors or threats (Bangalore 2012). The decrease in cortisol levels is also thought to have an effect on the better control of blood glucose, cholesterol and total lipids. Since antipsychotic medication for the treatment of schizophrenia is associated with dyslipidaemia, diabetes and obesity (Correll 2015; Vancampfort 2015), yoga may be a useful adjuvant to therapy to minimise these effects (Bangalore 2012). The improvement in the physical health of these patients could have a direct benefit for their mental health. Yoga is also identified as having a role in improving sleep (Collins 1998). There is also a link between yoga and oxytocin — a hormone related to improved mood, analogues of which have been suggested as a possible treatment for schizophrenia (Bangalore 2012; Feifel 2011) — as it has been identified that plasma levels of oxytocin are higher in people after yoga practice (Vancampfort 2012).

Mechanisms explaining the beneficial effects of exercise in people with schizophrenia are not completely clear yet. At present, the plausible mechanisms for change in positive and negative symptoms through exercise fall into one of two broad testable hypotheses: (1) biochemical changes such as increased levels of neurotransmitters (e.g. endorphins, dopamine or serotonin) which could be tested in schizophrenia-like animal models; and (2) psychological changes such as social support, sense of autonomy, improved perceptions of competence, enhanced body image, self-efficacy and distraction (Vancampfort 2014). Cardio-metabolic and neurochemical pathways between skeletal muscle, the spinal cord, and the brain offer plausible, testable mechanisms that might help explain the effects of exercise on brain health in people with schizophrenia. Previous research demonstrated that changes in hippocampal volume and cortical thickening (or less thinning) following aerobic exercise were correlated with improvements in aerobic fitness measured by change in maximum oxygen consumption (Vancampfort 2014). The underlying mechanisms of brain volume increases resulting from improved aerobic fitness are still unknown, but it was shown that increased production of brain-derived neurotrophic growth factors (BDNF) probably plays a role (Kimhy 2015). More interventional and longitudinal exploration is needed of the underlying mechanisms for brain health improvements in patients with schizophrenia following exercise. Future research could investigate whether, for example, exercise reduces the inflammatory status of the brain by increasing levels of the anti-inflammatory cytokine interleukin-10.

As expressive therapy consists of broad categories of art therapy, dance therapy, drama therapy, music therapy and writing therapy, the effects of these treatments are diverse, and are not completely known. It is not fully understood whether the healing aspect of therapy is the process of the actual expressive therapy, the relationship that develops between the therapist and the patient, or most likely, a complex fusion of the two. Generally, research into the physiological and biochemical effects of these therapies in schizophrenia is in its infancy. From a social and emotional perspective, music therapy for example can have particular motivating, relationship-building, and emotionally expressive qualities that may help those who do not respond to verbal therapy (Rolvsjord 2001; Solli 2008), while dance therapy is associated with other therapeutic benefits. Body movement dance can stimulate and release feelings, enable communication and enhance non-verbal contact. In addition, the non-critical therapeutic setting can decrease anxiety (Ren 2013).

Talking therapies are a diverse set of treatments which can be considered under the following broad categories: cognitive-behavioural, humanistic, insight-oriented, postmodernist, systemic and others. They are therefore associated with diverse effects, some of which are not fully understood. Cognitive behavioural therapy (CBT), for instance, aims to remediate distressing emotional experiences or dysfunctional behaviour by changing the way in which the individual interprets and evaluates the experience or reflects on its consequence and meaning (Jones 2012). CBT uses normalisation techniques as well as behavioural techniques to reduce distress and improve functioning. It has also been proposed by Birchwood 2006 that CBT might focus upon the following.

1. Distress reduction or the reduction of depression and problem behaviour associated with beliefs about psychotic symptomatology.
2. The emotional and interpersonal difficulty in individuals at high risk of developing psychosis.
3. Relapse prodromes to prevent relapse in psychosis.
4. 'Comorbid' depression and social anxiety, including the patient's appraisal of the diagnosis and its stigmatising consequences.
5. General stress reactivity, thereby increasing resilience to life stress and preventing psychotic relapse.
6. Increasing self-esteem and social confidence in people with psychosis.

Little research has been conducted on the effect of multi-modal interventions which encompass yoga. When delivered as part of a package of care, it is not known whether the multi-modal intervention dilutes, has an additive effect, or makes no difference to the effect of yoga. If yoga is combined with another form of exercise, the results may be different to yoga combined with expressive or talking therapies. Even combining yoga with another exercise, the effect could depend on frequency, intensity, time and type of exercise, and whether the focus is on skill-related fitness, health-related fitness, body-mind fitness, or physical activities which are not specifically fitness focused. Expressive and talking therapies are so diverse that, if combined with yoga, their combined effect could not be generalised.

Why it is important to do this review

It was originally envisaged that one Cochrane Review entitled 'Yoga for schizophrenia' would adequately map this area, but on closer evaluation it became apparent that the yoga comparison includes several distinct strands. A pragmatic decision was therefore taken to logically group comparisons into a series of independent reviews, outlined in Table 1, conducted by the same core group of authors, and to synthesise these into a future overview entitled 'Yoga for schizophrenia, an overview of Cochrane Reviews'.

Due to a growing demand from patients to use alternative or adjunct treatment to their medication (Elkins 2005), and a prevalence of poor antipsychotic compliance (van Os 2009), adjunctive non-pharmacological options are increasingly important. Yoga as part of a package of care is one such non-pharmacologically based add-on treatment in the management of people with schizophrenia. In resource-constrained times the question arises: is yoga delivered as part of a package of care more effective than another treatment — i.e. non-standard care — for people with schizophrenia? This review was planned to provide the most comprehensive answer possible to this question and thus provide guidance regarding the integration of yoga as part of a package of care into clinical practice.

OBJECTIVES

To examine the effects of yoga as part of a package of care versus non-standard care for schizophrenia.

METHODS

Criteria for considering studies for this review

Types of studies

We considered all relevant randomised controlled trials (RCTs) for inclusion and we would have included RCTs meeting our inclusion criteria and reporting useable data. We would also have considered trials that were described as 'double-blind' — in which randomisation was implied — and included or excluded trials once we had carried out a sensitivity analysis (see Sensitivity analysis). We would have excluded quasi-randomised studies, such as those that allocate the intervention by alternate days of the week. Where people were given additional treatments as well as yoga as part of a package of care, we would only have included data if the adjunct treatment was evenly distributed between groups and it was only the yoga intervention that was randomised.

Types of participants

We would have included people with a diagnosis of schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, regardless of their gender, age or severity of their illness. This included diagnoses made by any means. We were interested in making sure that information was as relevant to the current care of people with schizophrenia as possible. We therefore proposed, if information was available, to clearly highlight the current clinical state (acute, early post-acute, partial remission, remission) as well as the stage (prodromal, first episode, early illness, persistent) and whether the studies primarily focused on people with particular problems (for example negative symptoms, treatment-resistant illnesses).

Types of interventions

1. Yoga as part of a package of care

We would have included packages of care that combined yoga with another therapy, however defined by the study. Yoga can incorporate any of the major subtypes such as Mantra, Laya, Hatha and Raja and also include any of the combination of definitions including breathing exercises, meditation and body postures. We recognised that a package of care could include many diverse approaches that could be considered inappropriate to synthesise together. We proposed the following combinations of interventions, but recognised that this may not be entirely inclusive.

1.1 Yoga plus other exercise (not including yoga)

Yoga combined with another type of exercise. We have used the term 'other exercise' as yoga is also a type of exercise. 'Other exercise' can include broad categories of exercise focused on health-related fitness or performance-related physical fitness (Pate 1988).

1.2 Yoga plus talking therapy

Yoga combined with a talking therapy to form a package of care. Talking therapy can include broad categories: cognitive-behavioural; humanistic; insight-oriented; postmodernist; systemic; and other. We proposed to keep each of the above categories separate as they represent quite different approaches.

1.3 Yoga plus expressive therapies

Yoga combined with expressive therapies. These include the broad categories of art therapy, dance therapy, drama therapy, music therapy and writing therapy. We proposed to keep each of the above categories separate as they represent quite different approaches.

1.4 Yoga plus combination of above

2. Non-standard care or approaches

It is accepted that non-standard care could be considered an ambiguous term. We proposed the following interventions (as described above), but recognised that this may not be entirely inclusive.

2.1 Other exercise (not including yoga)

2.2 Talking therapy

2.3 Expressive therapies

2.4 Combination of above

If at least five trials in any of these areas of non-standard care had become available, we would have carried out an independent review.

Add-on treatment to standard care

The yoga packages of care and non-standard care interventions described above are in addition to the care participants would normally receive (standard care) or had previously received for the management of their schizophrenia (for example antipsychotic medication). This could also have included waiting-list control.

Types of outcome measures

We aimed to divide all outcomes into short term (less than six months), medium term (six to 12 months) and long term (over 12 months).

We would have endeavoured to report binary outcomes recording clear and clinically meaningful degrees of change (e.g. global impression of much improved, or more than 50% improvement on a rating scale, as defined within the trials) before any others. Thereafter, we would have listed other binary outcomes and then those that are continuous. Of note: to ensure uniformity with the portfolio of yoga reviews under construction, the following outcomes were consistent with reviews outlined in Table 1.

Primary outcomes

1. Mental state

1.1 Clinically important change in mental state (as defined by individual studies).
1.2 Any change in mental state (as defined by individual studies).
1.3 Average endpoint/change scores on mental state scales.

2. Global state

2.1 Relapse
2.2 Clinically important change in global state (as defined by each study).
2.3 Any change in global state.
2.4 Average endpoint/change scores from global state scales.

3. Social functioning

3.1 Clinically important change in social functioning (as defined by individual studies).
3.2 Any change in social functioning (as defined by individual studies).
3.3 Average endpoint/change scores on social functioning scales.

4. Adverse effects

4.1 Clinically important adverse effects.

Secondary outcomes

5. Quality of life

5.1 Clinically important change in quality of life functioning (as defined by individual studies).
5.2 Any change in quality of life (as defined by individual studies).
5.3 Average endpoint/change scores on quality of life scales.

6. Cognitive functioning

6.1 Clinically important change in cognitive functioning (as defined by individual studies).
6.2 Any change in cognitive functioning (as defined by individual studies).
6.3 Average endpoint/change scores on cognitive functioning scales.

7. Leaving the study early

7.1 Any reason.
7.2 Due to adverse effects of intervention.
7.3 Due to lack of engagement with intervention.
7.4 Due to death (suicide, natural causes, other).

8. Costs of care

8.1 Direct costs of care.
8.2 Indirect costs of care.

9. Effect on standard care

9.1 Reduction in reported adverse effects of standard care.
9.2 Change in the level of standard care required to manage condition.

10. Physical health

10.1 Clinically important change in physical health (as defined by individual studies).
10.2 Any change in physical health.

11. Service use

11.1 Acute hospital admissions.
11.2 Length of stay in hospital.

12. Disability

12.1 Important change in disability (as defined by individual studies).

13. Daily living

13.1 Clinically important change in daily living skills (as defined by individual studies).

13.2 Any change in daily living skills (as defined by individual studies).
13.3 Average endpoint/change scores on daily living scales.

'Summary of findings' table

We would have used the GRADE approach to interpret findings (Schünemann 2011); and would have used GRADEpro GDT to export data from our review to create a 'Summary of findings' table. These tables would have provided outcome-specific information concerning the overall certainty 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 rate as important to patient care and decision making. We aimed to select the following main outcomes for inclusion in the 'Summary of findings' table.

1. Mental state: clinically important change (as defined by individual studies).
2. Global state: relapse.
3. Social functioning: clinically important change (as defined by individual studies).
4. Adverse effects: any clinically important effect.
5. Quality of life: clinically important change (as defined by individual studies).
6. Costs of care: indirect or direct costs of care.
7. Physical health: clinically important change (as defined by individual studies).

If data were not available for these pre-specified outcomes but were available for ones that are similar, we would have presented the closest outcome to the pre-specified one in the table but would have taken this into account when grading the finding (Differences between protocol and review).

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Group's Study-Based Register of Trials

On 13 April 2017 and 15 May 2018, the Information Specialist searched the register using the following search strategy:

Yoga in Intervention Field of STUDY

In a study-based register such as this, searching the major concept retrieves all the synonyms and relevant studies because all the studies have already been organised based on their interventions and linked to the relevant topics (Shokraneh 2017).

This register is compiled by systematic searches of major resources (AMED, BIOSIS, CINAHL, ClinicalTrials.gov, Embase, MEDLINE, PsycINFO, PubMed, WHO ICTRP) and their monthly updates, ProQuest Dissertations and Theses A&I and its quarterly update, Chinese databases (CBM, CNKI, and Wanfang) and their annual updates, handsearches, grey literature, and conference proceedings (see Group's Module). There is no language, date, document type, or publication status limitations for inclusion of records into the register.

Searching other resources

1. Reference searching

We inspected references of all included studies for further relevant studies.

2. Personal contact

We would have contacted the first author of each included study for information regarding unpublished trials. We would have noted the outcome of this contact in the 'Included studies' or 'Studies awaiting classification' tables.

Data collection and analysis

Selection of studies

Review authors JB and DV independently inspected citations from the searches and identified relevant abstracts; a post-doctoral fellow JM independently re-inspected a random 20% sample of these abstracts to ensure reliability of selection. Where disputes arose, we acquired the full-text copy for more detailed scrutiny. JB then obtained and inspected full-text copies of the abstracts or reports meeting the review criteria. JM re-inspected a random 20% of these documents in order to ensure reliability of selection. Where it was not possible to resolve disagreement by discussion, we would have attempted to contact the authors of the study concerned for clarification.

Data extraction and management

1. Extraction

Review authors JB and JM would have extracted data from all included studies. In addition, to ensure reliability, DV would have independently extracted data from a random sample of these studies, comprising 10% of the total. We would have attempted to extract data presented only in graphs and figures whenever possible, but would have included only if two review authors independently obtained the same result. If studies were multi-centre, then where possible we would have extracted data relevant to each. We would have discussed any disagreement and documented our decisions. If necessary, we would have attempted to contact authors through an open-ended request in order to obtain missing information or for clarification. Where necessary, CEA (see Acknowledgements) would have helped clarify issues regarding any remaining problems and we would have documented these final decisions.

2. Management

2.1 Forms

We would have extracted data onto standard, pre-designed, simple forms.

2.2 Scale-derived data

We would have included continuous data from rating scales only if:

a) the psychometric properties of the measuring instrument had been described in a peer-reviewed journal (Marshall 2000);
b) the measuring instrument had not been written or modified by one of the trialists for that particular trial; and
c) the instrument had been a global assessment of an area of functioning and not sub-scores which are not, in themselves, validated or shown to be reliable. However there are exceptions:

we would have included sub-scores from mental state scales measuring positive and negative symptoms of schizophrenia.

Ideally, the measuring instrument should either have been 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; in 'Description of studies' we would have noted 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; however, calculation of change needs two assessments (baseline and endpoint), which can be difficult to obtain in unstable and difficult-to-measure conditions such as schizophrenia. We decided primarily to use endpoint data, and only use change data if the former was not available. If necessary, we would have combined endpoint and change data in the analysis, as we preferred to use mean differences (MDs) rather than standardised mean differences (SMDs) throughout (Deeks 2011).

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 would have applied the following standards to relevant continuous data before inclusion.

For endpoint data from studies including fewer than 200 participants:

a) when a scale starts from the finite number 0 (zero), we would have subtracted the lowest possible value from the mean, and divided this by the standard deviation. If this value was less than 1, it strongly suggests that the data are skewed and we would have presented these data as 'other data'. If this ratio was more than 1 but less than 2, there is a suggestion that the data are skewed: we would have entered these data and tested whether their inclusion or exclusion would have changed the results substantially. Finally, if the ratio was larger than 2 we would have included these data, because it is less likely that they are skewed (Altman 1996; Higgins 2011a).

b) if a scale started from a positive value (such as the Positive and Negative Syndrome Scale (PANSS), which can have values from 30 to 210 (Kay 1986)), we would have modified the calculation described above to take the scale starting point into account. In these cases skewed data are present if 2 SD > (S − S min), where S is the mean score and 'S min' is the minimum score.

Please note: we would have entered all relevant data from studies of more than 200 participants in the analysis irrespective of the above rules, because skewed data poses less of a problem in large studies. We would also have entered all relevant change data, as 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 or not data are skewed.

2.5 Common measurement

To facilitate comparison between trials we aimed, where relevant, to convert 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 would have made efforts to convert outcome measures to dichotomous data. This can be 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 PANSS (Kay 1986), this could be considered as a clinically significant response (Leucht 2005). If data based on these thresholds were not available, we would have use the primary cut-off presented by the original authors.

2.7 Direction of graphs

Where possible, we would have entered data in such a way that the area to the left of the line of no effect indicates a favourable outcome for yoga as part of a package of care. If keeping to this made it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'not un-improved'), we would have reported data where the left of the line indicates an unfavourable outcome and noted this in the relevant graphs.

Assessment of risk of bias in included studies

Review authors JB and JM would have worked independently to assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* to assess trial quality (Higgins 2011b). This set of criteria is based on evidence of associations between potential overestimation of effect and the level of risk of bias of the article that may be due to aspects of sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting, or the way in which these 'domains' are reported.

If the raters disagreed, we would have made the final rating by consensus. Where inadequate details of randomisation and other characteristics of trials were provided, we would have attempted to contact authors of the studies in order to obtain further information. We would have reported non-concurrence in quality assessment, but if disputes had arisen regarding the category to which a trial was to be allocated, we would have resolved this by discussion.

We would have noted the level of risk of bias in both the text of the review, Figures, and the 'Summary of findings' table/s.

Measures of treatment effect

1. Binary data

For binary outcomes we would have calculated a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI), as it has been shown that RR is more intuitive than odds ratios (Boissel 1999); and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). Although the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH), with their CIs, are intuitively attractive to clinicians, they are problematic to calculate and interpret in meta-analyses (Hutton 2009). For binary data presented in the 'Summary of findings' table/s we would have, where possible, calculated illustrative comparative risks.

2. Continuous data

For continuous outcomes we would have estimated MD between groups. We preferred not to calculate effect size measures (SMD). However if scales of very considerable similarity were 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. Authors often fail to account for intra-class correlation in clustered studies, leading to a unit-of-analysis error whereby P values are spuriously low, CIs unduly narrow and statistical significance overestimated (Divine 1992). This causes type I errors (Bland 1997; Gulliford 1999).

Where clustering had been incorporated into the analysis of primary studies, we would have presented these data as if from a non-cluster randomised study, but with adjustment for the clustering effect.

Where clustering was not accounted for in primary studies, we would have presented data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. We would have sought to contact first authors of studies to obtain intra-class correlation coefficients (ICCs) for their clustered data and to adjust for this by using accepted methods (Gulliford 1999).

We have sought statistical advice and have been advised that the binary data from cluster trials 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 ICC: thus design effect = 1 + (m − 1) * ICC (Donner 2002). We would have assumed unreported ICC to be 0.1 (Ukoumunne 1999).

If cluster studies had been appropriately analysed and had taken into account ICCs and relevant data documented in the report, we would have undertaken synthesis with other studies using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. This 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, participants can differ significantly from their initial state at entry to the second phase, 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 carry-over and unstable conditions are very likely in severe mental illness, we would only have used data from 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 would have presented the additional treatment arms in comparisons. If data were binary we would simply have added these and combined them within the two-by-two table. If data were continuous we would have combined data following the formula in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Where additional treatment arms were not relevant, we would not have reproduced these data.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss to 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 would 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 had been less than 50%, we would have addressed this within the 'Summary of findings' table/s by down-rating quality. Finally, we would also have downgraded quality within the 'Summary of findings' table/s should the loss have been25% to 50% in total.

2. Binary

In the case where attrition for a binary outcome was between 0% and 50% and where these data were not clearly described, we would have presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat (ITT) analysis). Those leaving the study early would all have been 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, the rate of those who stayed in the study — in that particular arm of the trial — would be used for those who did not. We would have undertaken a sensitivity analysis to test how prone the primary outcomes were to change when data only from people who completed the study to that point were compared to the ITT analysis using the above assumptions.

3. Continuous

3.1 Attrition

We would have used data where attrition for a continuous outcome was between 0% and 50%, and data only from people who completed the study to that point were reported.

3.2 Standard deviations

If standard deviations (SDs) were not reported, we would have tried to obtain the missing values from the authors. If these were not available, where there were missing measures of variance for continuous data, but an exact standard error (SE) and CIs available for group means, and either P value or t value available for differences in mean, we would have calculated SDs according to the rules described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). When only the SE was reported, SDs would have been calculated by the formula SD = SE * √(n). The *Cochrane Handbook for Systematic Reviews of Interventions* presents detailed formulae for estimating SDs from P, t or F values, CIs, ranges or other statistics (Higgins 2011a). If these formulae did not apply, we would have 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 have been to exclude a given study's outcome and thus to lose information. Nevertheless, we would have examined the validity of the imputations in a sensitivity analysis which would have excluded imputed values.

3.3 Assumptions about participants who left the trials early or were lost to follow-up

Various methods are available to account for participants who leave trials early or are lost to follow-up. Some trials just present the results of study completers; others use the method of last observation carried forward (LOCF); while more recently, methods such as multiple imputation or mixed-effects models for repeated measurements (MMRM) have become more of a standard. While the last two methods seem to be somewhat better than LOCF (Leon 2006), we felt that the high percentage of participants leaving the studies early and differences between groups in their reasons for doing so is often the core problem in randomised schizophrenia trials. We would therefore not have excluded studies based on the statistical approach used. However, by preference we would have used the more sophisticated approaches, i.e. we would have prefered to use MMRM or multiple imputation to LOCF, and we would only have presented completer analyses if some kind of ITT data were not available at all. Moreover, we would have addressed this issue in the item 'Incomplete outcome data' of the 'Risk of bias' tool.

Assessment of heterogeneity

1. Clinical heterogeneity

We would have considered all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We would have simply inspected all studies for participants who are clearly outliers or situations that we had not predicted would arise and, where found, discussed such situations or participant groups.

2. Methodological heterogeneity

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

3. Statistical heterogeneity

3.1 Visual inspection

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

3.2 Employing the I^2 statistic

We would have investigated heterogeneity between studies by considering the I^2 statistic alongside the Chi^2 P value. The I^2 statistic 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 the magnitude and direction of effects as well as the strength of evidence for heterogeneity (e.g. P value from Chi^2 test, or a confidence interval for I^2). We would have interpreted an I^2 estimate greater than or equal to 50% and accompanied by a statistically significant Chi^2 statistic as evidence of substantial heterogeneity (Chapter 9, *Cochrane Handbook for Systematic Reviews of Interventions*) (Deeks 2011). If substantial levels of heterogeneity were found in the primary outcome, we would have 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 the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011).

1. Protocol versus full study

We would have tried to locate protocols of included randomised trials. If the protocol had been available, we would have compared outcomes in the protocol and in the published report. If the protocol had not been available, we would have compared outcomes listed in the Methods section of the trial report with actually reported results.

2. Funnel plot

We are aware that funnel plots may be useful in investigating reporting biases, but are of limited power to detect small-study effects. We would not have used funnel plots for outcomes where there were 10 or fewer studies, or where all studies were of similar size. In other cases, where funnel plots were possible, we would have sought statistical advice in their interpretation.

Data synthesis

We understand that there is no closed argument for preferring fixed-effect models over random-effects models, or vice versa. 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 to use a random-effects model for all analyses.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

1.1 Primary outcomes

As there were no trials to include in this review, we could not conduct any subgroup analysis.

2. Investigation of heterogeneity

We would have reported if inconsistency was high. Firstly, we would have investigated whether data was entered correctly. Secondly, if data were correct, we would have inspected the graph visually and removed outlying studies successively to see if homogeneity was restored. For this review we decided that should this occur with data contributing to the summary finding of no more than 10% of the total weighting, we would have presented data. If not, we would not have pooled these data and would have discussed any 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.

If unanticipated clinical or methodological heterogeneity was obvious we would simply have stated hypotheses regarding these for future reviews or versions of this review. We did not anticipate undertaking analyses relating to these.

Sensitivity analysis

If there were substantial differences in the direction or precision of effect estimates in any of the sensitivity analyses listed below, we would not have added data from the lower-quality studies to the results of the higher-quality trials, but would have presented these data within a subcategory. If their inclusion did not result in a substantive difference, they would have remained in the analyses.

1. Implication of randomisation

If trials were described in some way as to imply randomisation, for the primary outcomes we would have pooled data from the implied trials with trials that are randomised.

2. Assumptions for lost binary data

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

3. Assumptions for missing SDs

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

4. Risk of bias

We would have analysed the effects of excluding trials at high risk of bias across one or more of the domains (see Assessment of risk of bias in included studies) for the meta-analysis of the primary outcome.

5. Imputed values

We would have undertaken 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.

6. Fixed-effect and random-effects models

We would have synthesised data using a fixed-effect model; however, we would also have synthesised data for the primary outcome using a random-effects model to evaluate whether this altered the significance of the results.

RESULTS

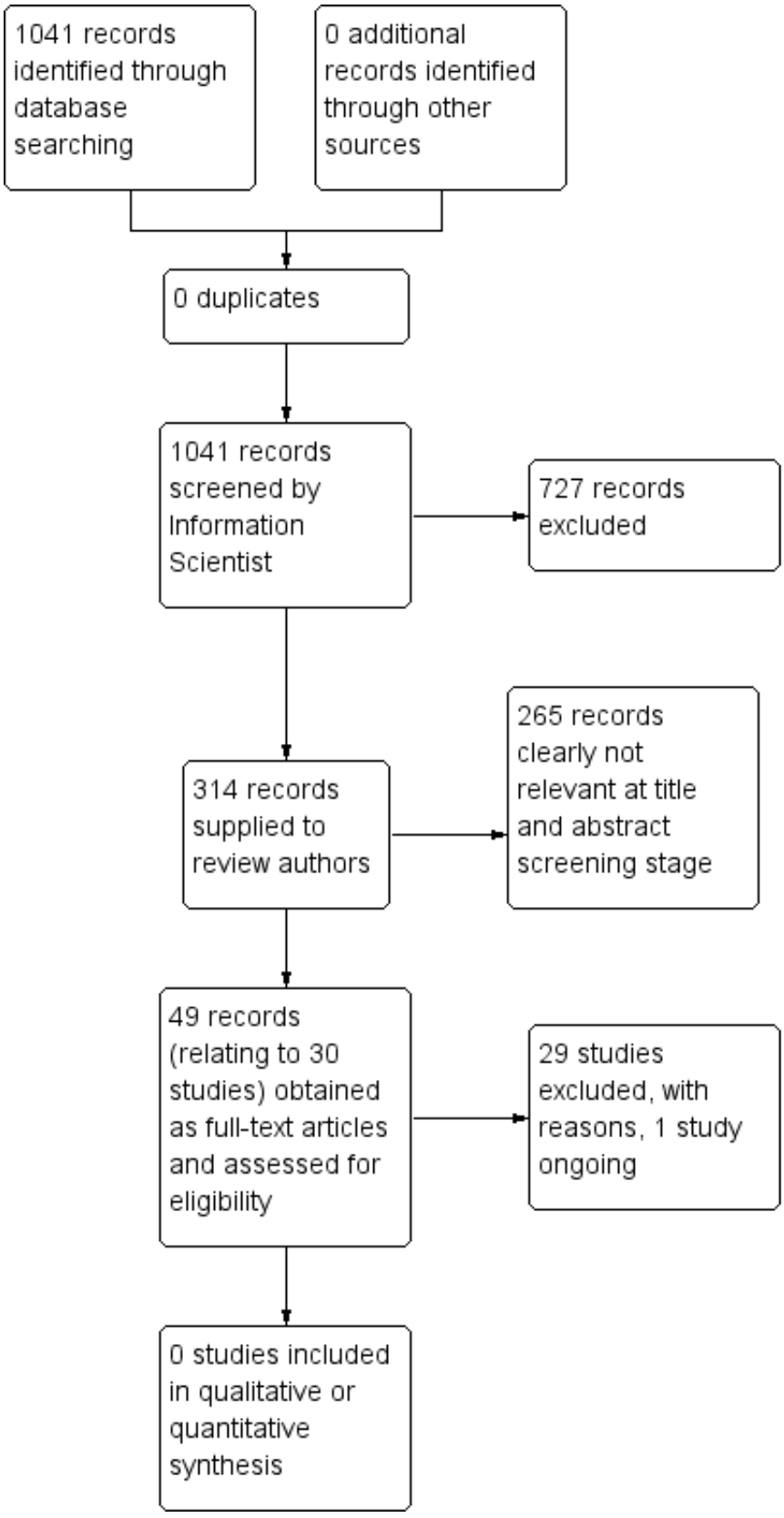
Description of studies

See also: Characteristics of excluded studies

Results of the search

Over 1000 reports (n = 1041) were identified through the initial bibliographical searches as shown in Figure 1. After screening by the Information Specialist of Cochrane Schizophrenia, 314 records were sent to the review authors. Two hundred and sixty-five of these records could be excluded by title and abstract alone. We then obtained 49 full-text articles relating to 30 studies for detailed evaluation. Thirty studies were excluded for the following reasons: four were not randomised; three did not include people with schizophrenia; 22 did not compare the intervention of yoga as part of a package of care versus non-standard care; and one study was ongoing.

Figure 1. Study flow diagram for 2018 search



Included studies

We manually checked the titles and abstracts, but none of the papers was suitable for further evaluation in the area, so we were unable to perform any analyses to assess the efficacy of yoga as part of a package of care versus non-standard care. Should trials become available, we will update the review to include them.

Excluded studies

See Characteristics of excluded studies.

Ongoing studies

One trial is ongoing. Based on available information, this trial compares yoga to "a simple exercise" so would appear not to compare yoga as part of a package of care versus non-standard care. We have contacted the corresponding authors twice but no further detail regarding this trial have so far been supplied.

Awaiting assessment

There are no trials awaiting assessement.

Risk of bias in included studies

No study met the inclusion criteria.

Allocation

No trials were available.

Blinding

No trials were available.

Incomplete outcome data

No trials were available.

Selective reporting

No trials were available.

Other potential sources of bias

No trials were available.

Effects of interventions

No trials were available.

DISCUSSION

In this review, we did not locate any eligible trials which compared yoga as part of a package of care to non-standard care.

The question arises why there are no trials in this area. Yoga as part of a package of care comprises a small sub-section of yoga-related research. As research pertaining to the clinical application of yoga for people with schizophrenia has not evolved to an advanced degree, it is not surprising that trials evaluating standard care comparators are logically evaluated firstly as an initial priority topic, summarised in the review Broderick 2015. Head-to-head comparisons of different adjunctive treatments are also warranted, summarised in a further review by the same core team of authors (Broderick 2017a). A further strand in this research field comparing yoga as part of a package of care to standard care has also been conducted (Broderick 2017b). We acknowledge that the remaining comparator pertaining to the current review, yoga as part of a package of care versus non-standard care, is lower down in the hierarchy of importance and that may be a legitimate reason why no trials have been conducted in this area to date.

Although empty reviews are considered important (Lang 2007), one may legitimately ask why this empty review was conducted, in view of the inherent difficulties of conducting empty reviews, such as a lack of specific guidance on how review authors should report the results of an empty review and the drive to minimise the number of empty Cochrane Reviews (Yaffe 2012). While empty reviews are relatively uncommon, Yaffe 2012 showed that almost 9% of reviews in the *Cochrane Database of Systematic Reviews* were empty, and this number is increasing. The decision whether or not to conduct this review, which due to authors' foreknowledge was known would be highly likely to yield an empty review, was given due consideration at an editorial level. It was decided that as this review was part of a series of reviews to populate an overview of Yoga for Schizophrenia, a thoroughly conducted series of subsidiary reviews, which includes the present review, was considered a sufficiently important catalyst to proceed with the generation of this review.

This empty review serves to highlight the gaps in the evidence to researchers and funders. As this is an empty review, we wish to highlight two main points: (1) the lack of high-quality evidence of effectiveness specifically for yoga as part of a package of care versus non-standard care; and (2) no conclusions should be drawn other than to recommend research is carried out.

Summary of main results

In the absence of suitable trials in this area, we were unable to perform any analyses.

Overall completeness and applicability of evidence

Currently, the literature does not provide any evidence for treatment with yoga as part of a package of care versus non-standard care for people with schizophrenia. It is necessary to conduct such trials for researchers and policy makers to make appropriate decisions.

Quality of the evidence

There are no clinical trials about yoga as part of a package of care versus non-standard care, so we cannot comment on the quality of evidence in this area.

Potential biases in the review process

The potential risk of bias for this review's process were limited by following Cochrane methodology. The search was carried out by an Information Specialist, and the Cochrane Schizophrenia Group register has no language, date, document type, or publication status limitations for inclusion of records. Selection of studies was carried out independently by more than one author. Risk of bias in data extraction was not an issue as no study was identified that fulfilled the selection criteria.

Agreements and disagreements with other studies or reviews

As we do not have any evidence available to discuss, it is not possible for us to agree or disagree with other trials or reviews

at this time. Our searching indicated that there are currently no trials which fulfil the inclusion criteria for a Cochrane Review on this specific topic. Other systematic reviews of yoga for schizophrenia have been conducted at review level, but yoga as part of a package of care versus non-standard care is not yet covered.

AUTHORS' CONCLUSIONS

Implications for practice

For this review we could not find any RCTs which specifically compared yoga as part of a package of care to non-standard care. Thus, there is insufficient evidence for us to establish the efficacy and acceptability of these interventions for people with schizophrenia and no conclusions can be drawn from this review.

Implications for research

1. General

In general, high-quality evidence via rigorously designed, multicentre, randomised, double-blind controlled trials is required to evaluate health care interventions. Policy makers and researchers should prioritise funding for these trials to increase the quantity and quality of these studies and provide strong evidence for the effectiveness of therapies for schizophrenia. Adverse effects should be monitored and attention should be paid to evaluation of longer-term outcomes.

2. Specific to this review

As the extent of practice of yoga as part of a package of care is not clear, it is currently difficult to comment on the importance of conducting such trials on this topic.

ACKNOWLEDGEMENTS

The Cochrane Schizophrenia Group Editorial Base at the University of Nottingham, UK, produces and maintains standard text for use in the Methods section of their reviews. We have used this text as the basis of what appears here and adapted it as required. The authors would like to thank Clive Adams (CEA) for his invaluable assistance and advice in terms of developing this protocol and review. We would also very much like to thank Claire Irving, Managing Editor and Farhad Shokraneh, Information Specialist. The authors would also like to thank Jonathan Moran (JM) for his assistance in this review.

As this is part of a family of yoga intervention reviews and as such only the interventions/objectives are different, we have used text from the background of previously published versions also written by the same core group of review authors (Broderick 2015; Broderick 2017a; Broderick 2017b).

We would like to thank Rawan Al khudari and Masahiro Banno for peer reviewing this review.

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Broderick 2017c

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Behere 2011	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Bhatia 2012	Allocation: not randomised.
Bhatia 2017	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga as a stand-alone entity, not as part of a package of care.
CTRI/2017/06/008912	Allocation: randomised. Participants: caregivers of people with schizophrenia, not people with schizophrenia.
CTRI/2017/08/009219	Allocation: randomised. Participants: people with schizophrenia. Interventions: appears to be yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
CTRI/2017/08/009505	Allocation: randomised. Participants: people with schizophrenia. Interventions: appears to be yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
CTRI/2017/09/009738	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Duraiswamy 2007	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Hu 2014	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Ikai 2013	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga plus regular day care programme versus standard care consisting of regular day care programme, not yoga as part of a package of care versus non-standard care.

Study	Reason for exclusion
Ikai 2014	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga plus regular day care programme versus standard care consisting of regular day care programme, not yoga as part of a package of care versus non-standard care.
Ikai 2017	Allocation: randomised. Participants: ICD-10 diagnosis of psychiatric disorders (F0-F9), not specifically people with schizophrenia.
Isuru 2015	Allocation: randomised Participants: people with schizophrenia Intervention: yoga as part of a package of care versus standard care, not non-standard care as specified in the protocol.
Jayaram 2013	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care versus ''[a] simple exercise''.
Kavak 2016	Allocation: 'quasi' randomised not randomised as stated in protocol.
Lin 2006	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care.
Lin 2015	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Mahal 1976	Allocation: ''double blind''. Participants: people with schizophrenia. Interventions: "Tagara" (local drug with antipsychotic properties) and "Brahmyadiyoga" (a herbal compound) versus chlorpromazine versus placebo, not yoga as part of a package of care.
Manjunath 2013	Allocation: randomised. Participants: people with schizophrenia or related disorders. Interventions: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
NCT03379480	Allocation: single blind. Participants: people with schizophrenia. Interventions: yoga as a stand-alone entity, not yoga as part of a package of care versus non-standard care.

Study	Reason for exclusion
Paikkatt 2012	Allocation: randomised Participants: people with schizophrenia Intervention: yoga as a package of care versus standard care, not non-standard care as specified in the protocol.
Ramu 1999	Allocation: ''double blind''. Participants: people with schizophrenia. Interventions: "Tagara" (local drug with antipsychotic properties) and "Brahmyadiyoga" (a herbal compound) versus chlorpromazine versus placebo, not yoga as part of a package of care.
Vancampfort 2011	Allocation: randomised. Participants: people with schizophrenia. Interventions: yoga and aerobic exercise versus control, not yoga as part of a package of care versus non-standard care.
Varambally 2012	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga as a stand-alone entity, not as part of a package of care versus non-standard care.
Varambally 2013	Allocation: randomised. Participants: caregivers of people with schizophrenia, not people with schizophrenia.
Visceglia 2011	Allocation: randomised. Participants: people with schizophrenia. Intervention: yoga as a stand alone entity, not as part of a package of care versus non-standard care control.
Wu 2014	Allocation: participants randomly selected but not randomly allocated to intervention/control group.
Xie 2006	Allocation: randomised Participants: people with schizophrenia Intervention: yoga as a package of care versus standard care, not non-standard care as specified in the protocol.
Zhang 2016	Allocation: not randomised.

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

JPRN-UMIN000013746

Trial name or title	Effects study of yoga therapy on the association of mental illness with metabolic disorders
Methods	Allocation: randomised.

JPRN-UMIN000013746 *(Continued)*	Blinding: no details given. Duration: no details given. Design: parallel.
Participants	Setting: Toyko Metropolitan Matsuzawa Hospital Diagnosis: schizophrenia (DSM-IV). History: no details given. N = 60 (target sample size). Age: 18 to 65 years. Sex: males and females. Inclusion criteria: males and females between 18 and 65 years diagnosed with schizophrenia according to DSM-IV, patients with consent capacity. Exclusion criteria: patients with diabetes, renal failure, pervasive development disorders, mental retardation.
Interventions	1. Yoga therapy: (no further details given). 2. 'A simple exercise': (no further details given).
Outcomes	Oxidative-stress markers (no further outcomes listed).
Starting date	5 December 2014.
Contact information	Masanari Itokawa (itokawa-ms@igakuken.or.jp), Hiromi Idozawa (Chiken-psy@tmhp.jp)
Notes	Contacted for study information 16.02.16 & 22.06.18: no reply.

ADDITIONAL TABLES

Table 1. Yoga reviews

Review number	Review Title	Status
1	Yoga versus standard care for schizophrenia	Broderick 2015
2	Yoga versus non-standard care for schizophrenia	Broderick 2017a
3	Yoga as part of a package of care versus standard care	Broderick 2017b
4	Yoga as part of a package of care versus non-standard care	Current review

WHAT'S NEW

Date	Event	Description
5 August 2019	Amended	Typo error in 'Plain Language Summary' corrected.

CONTRIBUTIONS OF AUTHORS

Julie Broderick – writing the protocol, trial selection, review writing.

Davy Vancampfort – modifying the protocol, trial selection, checking of draft review.

DECLARATIONS OF INTEREST

Julie Broderick: Health Research Board, Ireland. Julie Broderick was supported by a 'Cochrane Fellowship' award from the Health Research Board, Ireland. This consisted of protected time to write this review.

Davy Vancampfort: none known.

SOURCES OF SUPPORT

Internal sources

- Trinity Centre for Health Sciences, Dublin, Ireland.

  Employs lead author Julie Broderick.
- Katholieke Universiteit Leuven, Belgium.

  Employs review author Davy Vancampfort.

External sources

- Health Research Board, Ireland.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have re-ordered and renamed outcomes to be consistent with our other yoga reviews — for example, in the protocol we listed some as 'clinically significant' response and others as 'clinically important change': the relevant outcomes are now all 'clinically important change'. These changes do not affect the type of outcomes considered or type of data extracted. In line with the latest Methods template for Cochrane Schizophrenia reviews, we have clarified that outcomes in 'Summary of findings' tables should be clinically important data but if such data are not available, we will use the closest outcome available but take this into consideration when assessing the quality of evidence for such outcomes. We have also harmonised the 'Summary of findings' table outcomes to be consistent with the other yoga reviews.

INDEX TERMS

Medical Subject Headings (MeSH)

*Yoga [psychology]; Randomized Controlled Trials as Topic; Schizophrenia [*therapy]; Schizophrenic Psychology

MeSH check words

Humans