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**A research report of the therapeutic effects of yoga
for health and wellbeing.**

Prepared at ScHARR for the British Wheel of Yoga

By

**Sue Harnan, Katy Cooper, Edith Poku, Helen
B.Woods**

With input from

Elaine Jones, Lynne Jones, Pierre Bibby
of British Wheel of Yoga.

Table of Contents

Section	Page
Glossary	3
1 Introduction	6
2 Methods	7
2.1 Literature searching	7
2.2 Inclusion and exclusion criteria	7
2.3 Quality assessment	8
3 Results	10
3.1 Healthy adults	11
3.2 Osteoarthritis and osteoarthritis of the hand	19
3.3 Asthma	21
3.4 Back pain	25
3.5 Cancer	31
3.6 Depression	39
3.7 Diabetes and Cardiovascular disease	42
3.8 Menopause	50
3.9 Stress	52
3.10 Eating disorders	54
3.11 Pregnancy	57
3.12 Yoga versus exercise in healthy people and people with health conditions	62
4 Summary	63
5 Conclusion	64
6 References	64

Glossary

Words in bold appear elsewhere in the glossary.

A priori – Before a study starts, a “protocol” (plan of research) is written, which states what will be done, and what statistical techniques will be used to analyse the results. Methods that are written into the protocol are known as “a priori”. Methods that are not defined in the protocol and are added after the results have been gathered are known as “post-hoc”. A priori analyses are considered more reliable as they are chosen because they are the most theoretically sound way to analyse the data. Post-hoc analyses can be useful to explore the data and generate hypotheses, but should not be relied upon to draw conclusions. One reason for this is because they are prone to bias, where researchers choose the method of analysis that presents the results in a way that supports their hypothesis. This can go as far as changing a non significant result into a significant one.

Abstract – When research is published in a journal, each report starts with a summary of the research which describes aims, methods, results and conclusions. This is called an abstract.

Allocation concealment – making sure patients and staff do not know which group they *will* be allocated to in a randomised controlled trial, before they are randomised. Once randomisation has taken place, making sure that staff and patients do not know which group they are in is called **blinding**.

ANOVA – Analysis of variance - a statistical test

Before-after analysis/comparison – See **between group analysis/comparison**

Between group analysis/comparison – **Randomised controlled trials** have two or more groups. A before-after analysis (pre-test to post-test analysis) compares how well the patients in each group are before having treatment to how well they are after they have had treatment. This shows whether they have got better during the study. However, it does not prove that they got better due to the treatment. It may be that the group would have got better without treatment. For example, if you have a cold, you usually get better within a few days anyway. To show that the improvement is because of the treatment and not just naturally getting better, it should be compared to the improvements seen in a similar group who had a different treatment, no treatment, or **placebo** (dummy) treatment. This is known as a between-group analysis and is the only way to really show that the treatment has had an effect.

Bias – Any sort of systematic error in a piece of research that may affect the results. This could be to do with differences in the types of patients included in each group, differences in the way people (including patients, medical staff and research staff) behave when they know which treatment a patient is receiving (eg if a patient does not believe a treatment will work, they may report that they are more ill than if they thought it would work), or the expectations a researcher approaches the results with when they draw their conclusions. There are many types of bias, and they can work to make a treatment look better or worse, can be small or large and their effects can often be unpredictable.

Blind/Blinding – Patients, medical staff and the people conducting a study may have prior beliefs about whether the intervention they are testing works. This can lead people to act differently according to their beliefs. For example, a person who is ill with arthritis and is given a herbal therapy may not believe that the therapy works, and may therefore perceive that their pain as not changing. Equally, a nurse who does not believe the therapy does not work may give the patient more attention, and provide more painkillers, obscuring the true effect of the treatment. Finally, when analysing results statistically, prior beliefs can influence which tests are used, and which tests are emphasised in the write up. To prevent prior beliefs about a therapy affecting the results, people in the study and conducting the study can be “blinded” to which group a person is in. This is achieved by concealing which group a patient *will be* allocated to (**allocation concealment**) and which group they then *are* allocated to (**blinding**) by, for example, allocating them a number rather than naming the group. This is done at the same time as randomisation, and the key to the numbers is held in a concealed list or on a computer which patients, medics and study personnel do not have access to. Sometimes, a **placebo** (dummy) treatment is used to try to conceal differences between treatments which would allow people to “break” the blinding, and work out which group they are in. Sometimes it is not possible to conceal which group people are in because of the nature of the treatment being obviously different and a convincing **placebo** not really being possible. Examples include surgery, physiotherapy, counselling and yoga. In these cases, it should still be possible to blind the staff who analyse the results at the very least, if not medical personnel as well.

Clinical significance – Sometimes a change in a measurement may be seen, but it may not in actual fact mean that a person is considered to be any better in medical terms, or feel noticeably better in themselves. For example, a small fall in a measure of depression may still mean that the person is severely depressed. Just because a result is **statistically significant**, it does not mean it is clinically significant.

Intervention – The treatment that is being investigated. This can be a pharmaceutical drug, surgery, a physical therapy such as physiotherapy, a talk therapy such as counselling, or even an activity such as walking or drawing. For this report, the intervention is yoga.

Outcome – This is the measured result in the study. Examples include weight, blood pressure, hormone levels, levels of depression or anxiety and so on. Often, more than one outcome is measured in a study.

Placebo and placebo effect – placebos are dummy (inactive) medicines or treatments given to help prevent study participants from knowing which group they have been randomised to (see **blinding**). In addition, some research shows that just “treating” someone can make them feel better. For example, giving a person a pill and telling them it is paracetamol (when really it contains no paracetamol) can make their headache feel less severe. So the group that is given the placebo medicine may also report improvements in their condition. This is known as the placebo effect. When the placebo group is compared to the group that has been given the real treatment, the effects of the real treatment may not seem so large, because both groups experience the placebo effect. However, there is some debate about whether the placebo effect really exists, with arguments that it is simply that some people within a group get better naturally. Some people believe that the placebo effect is valuable and should be harnessed to help people feel better.

Post-hoc – See a priori

Power calculation, statistical power – Random variation means that people vary, results vary and therapies behave differently in different people. As such, results are never exactly the same in everyone. This means that small effects can get lost in the results, as they look like random variation rather than an effect. Large differences are easier to detect. To make sure enough patients are recruited to a trial to detect a small effect, a calculation can be done to predict how many patients are needed. This is known as a power calculation, and the number of patients needed is known as the **sample size**. If this calculation has not been done, and a study does not find an effect, it will be unclear whether this is because there is no effect, or because there were not enough participants to detect the effect.

Pre-test to post-test analysis/comparison – See between group analysis/comparison

Quality assessment In some cases, research is conducted badly. This can introduce **bias**, and the results should be treated with caution. Quality assessment aims to assess whether the study is at risk of **bias**. It is usually assessed using a list of questions with “yes/no/can’t tell” answers.

Random sequence – When patients are recruited to a **randomised controlled trial**, they are randomly assigned to a treatment group. There are various ways of randomising, from tossing a coin, to using computer generated random numbers. This is known as the “random sequence”. The methods used to generate the sequence should be truly random, and not based on some characteristic of the patient such as date of birth or appointment day, as these may result in more of one type of patient ending up in one group than the other. For example, if all patients who had a particular type of cancer were usually seen in a cancer clinic on the same day, and all were randomised to the same group, any difference in the way that cancer responded to treatment, or differences in the prognosis for people with that cancer, could affect the results for that group. This would be a form of bias.

RCT – Randomised controlled trial – These trials are the best way of finding out if a treatment is effective, as the trial design prevents many types of bias that are difficult to exclude from other types of studies. Trial participants are randomly assigned to two (or more) groups. One group receives the treatment (e.g. yoga) and the other group receives no treatment or a different treatment. The health of the participants in the treatment group can then be compared with that of the other group.

Sample size – See **power calculation**.

SF36 and SF12 – Questionnaires completed by patients which measure health-related quality of life. SF stands for “short form”, and these questionnaires are used widely across the world. The questionnaires have been validated and tested for reliability. The questionnaire is a generic health questionnaire, and may not be sensitive enough to pick up some changes, for example, in sleep quality.

SR – Systematic review – This is a type of literature review which uses rigorous methods to maximise the number of relevant studies that are found. They are reported in such a way that they could be replicated by another researcher. They include **quality appraisal** of the research included to see how reliable the results are. Systematic reviews may include a

meta analysis, where results from different studies are combined to get an overall picture of effectiveness.

Statistical significance – Because results vary within a study due to random variation, statistical tests are applied to data to see whether the results are likely to have occurred by chance. If the results of a study are not statistically significant, it may indicate that the treatment has no effect. It may also indicate that the study does not have enough participants to detect the effect (see **power calculation**), or that the intervention or study was not well designed. If the results are statistically significant, and there is a low risk of bias, it means that there is a very good chance that the intervention works.

1 Introduction

This is the first British Wheel of Yoga (BWY) Research Report. This report was commissioned from the School for Health and Related Research (SchHARR) by BWY to summarise key recent research on the therapeutic effects of Yoga on adults aged 18-65 years. The aims of this document are

- To inform and strengthen the evidence base for yoga in an unbiased way
- To support and further professional knowledge and understanding about yoga
- It also provides a platform for further research

The British Wheel of Yoga is a registered charity and has recently become incorporated as a limited company. It is the largest yoga organisation in the UK having nearly 8000 members and has been running for over 40 years. The BWY has a tripartite role as a membership organisation, a teaching organisation, and it is recognised by the Sport and Recreation Alliance (previously CCPR) and Sport England as the National Governing Body for Yoga (NGB).

SchHARR is a large school within the Faculty of Medicine, Dentistry and Health at the University of Sheffield. This School covers all aspects of health research from conducting clinical trials to collating and synthesising existing research evidence. The authors of this report regularly conduct high quality systematic reviews for the National Institute of Health and Clinical Excellence (NICE) and the National Instituted for Health Research Health Technology Assessment Programme (NIHR HTA).

If you are a health or social care practitioner with an interest in any of the conditions listed below, or a yoga teacher who would like to know more about yoga research, this report will be a useful source of up to date information for you.

We have included research on healthy adults aged 18 to 65, as well as studies on yoga for people with some common health conditions (in the same age range) including:

- Arthritis
- Asthma
- Back pain
- Cancer
- Cardiovascular disease
- Depression and Anxiety
- Diabetes
- Menopause
- Pregnancy
- Healthy adults

Yoga is an ancient physical and mental practice, which has been used in the East for thousands of years. Over the last century, yoga has gained popularity in the West, and is now practiced by many thousands of people across the UK. Yoga is practiced in varying forms and styles, but generally consists of four main practices; physical exercise (poses or “asana”), relaxation, meditation, and breathing techniques (pranayama). This research report aimed to include all forms of yoga, regardless of the style or practice used.

2 Methods

This report does not intend to be a full systematic review, but does intend to be unbiased, systematic, explicit and reproducible in its methods. Many of the key elements of systematic review are present, such as literature searching, reproducible inclusion and exclusion criteria and quality assessment.

2.1 Literature searching

Key biomedical databases were searched including Medline and Medline in Process, Embase, Cinahl, Assia, Cochrane Library, Science Citation Index, Psychinfo, Cameol, Amed, British Nursing Index (and Archive) and Sport Discus. Searches were conducted using key words and thesaurus terms (where available) for yoga and filtered by study type using established filters. The keywords were yoga, yogic, prana, pranic, pranayama, dhyana, dharana, asana, pratyahara and hatha. Databases were searched in April 2011 from inception, and results were limited to English Language and humans.

2.2 Inclusion and exclusion criteria

Studies were selected for inclusion in a two stage process. In stage one, pre-set (a priori) criteria were used to short list eligible studies on the basis of their title and abstract. In stage two, key study characteristics were extracted into an excel database and coded. Post-hoc exclusion criteria were developed by the academic research team and expert members of British Wheel of Yoga, based on the study characteristics reported in the abstract (without reference to the study results), with the aim of bringing the number of selected studies down to 40. The resulting inclusion and exclusion criteria are listed in table 1.

Table 1. Pre-set inclusion criteria and post-hoc exclusion criteria

	Pre-set inclusion criteria	Post-hoc exclusion criteria
Study type	<ul style="list-style-type: none"> • Randomised controlled trial (RCT) or systematic review. 	<ul style="list-style-type: none"> • Excluded systematic reviews if a more recent or more comprehensive review found. • Exclude RCTs if already reported in an included systematic review. • Excluded dissertations, unless published in a peer reviewed journal as a research paper. • Excluded qualitative studies
Population	<ul style="list-style-type: none"> • Adults aged 18 to 65 years old. 	<ul style="list-style-type: none"> • Excluded studies of patients with health conditions that have low prevalence in the general population. • Excluded studies in very specific populations (e.g. archers)
Intervention	<ul style="list-style-type: none"> • Any yoga intervention including yoga meditation, relaxation, postures and breathing techniques. • Excluded laboratory-based studies. 	<ul style="list-style-type: none"> • Excluded yoga mixed with other interventions (eg meditation based stress reduction (MBSR)). • Excluded breathing devices. • Excluded studies judged to have sub-therapeutic exposure to yoga. • Excluded interventions not replicable in UK e.g. Yoga camps.
Comparator	<ul style="list-style-type: none"> • Compared to any type of control group. 	
Outcomes	<ul style="list-style-type: none"> • Any health outcome. 	<ul style="list-style-type: none"> • Excluded specific/non health outcomes e.g. Glossolalia (speaking in tongues).

Once a study was selected for inclusion, the full text of the study was obtained. The full text was used to create the summaries contained in this research report.

2.3 Quality assessment

Not all research is of a good quality. Sometimes this is because the study has been badly designed and conducted; sometimes a study has not been well reported and the quality

cannot be determined. The main concern is whether bias has been introduced to the results. Bias is where results have been influenced in one direction or the other, either by an error in the design or conduct of the study, or an error in the way the results have been analysed and interpreted. For RCTs, the main types of bias we have looked for are as recommended by the Cochrane Collaboration¹ and consider:

- *How the random sequence was generated:* Randomisation aims to provide two or more groups with an equal balance of patient characteristics that may affect how the group will react to the intervention. Characteristics include factors such as age, gender and how well participants are. Poor randomisation can lead to unequal groups, which can affect results.
- *Whether anyone could tell which group a participant would end up in before being randomised (allocation concealment):* for example, very ill participants may refuse to take part if they know they will be in the control arm, but will participate if they are in the intervention arm. This would lead to a much more ill set of patients in the intervention arm and possibly affect results.
- *Whether participants and study personnel knew which group they were in and which intervention they were receiving (blinding):* participants or personnel may provide or ask for more or different care because of their own perceptions about the effectiveness of the intervention they are receiving, if they know which group they are in. This can affect results as one group may get better or worse care as a consequence.
- *Whether outcome assessors knew which group participants were in:* where participants or study personnel know which intervention they are receiving, this may consciously or subconsciously affect the results they report.
- *How data from drop outs or missed sessions are dealt with in the analysis:* where missing data can affect the results either positively or negatively, e.g. if all the most ill people die or drop out, this may make the intervention look more effective than it is.
- *Whether all planned measurements are reported:* if it is clear that some of the outcomes that were planned are not reported, it might be because they were negative results. This may make the intervention look more effective than it is.

For Systematic reviews, we have used the CASP checklist,² which checks the potential for bias in how the review was conducted. The relevant questions in this checklist related to:

- Were studies of the best design included (in this case, this should always be RCTs as they are the only studies that can robustly estimate how effective an intervention is)
- Checking the literature search to see if it would catch most or all relevant studies
- Whether the quality of the studies was assessed

3. Results

The initial search retrieved 1960 citations, 170 of which were identified by the search filters as RCTs or systematic reviews. Of these, 116 were included on the basis of the pre-set inclusion criteria and their title and abstract. A further systematic review was identified by hand searching, and. After data extraction of study characteristics, and development of the post-hoc exclusion criteria, 42 studies were included. Of these, three were unobtainable in the time available to complete the report, leaving 39 includable studies. A further RCT study published after the search was also included, making the total number of included studies 40.

3.1 Healthy Adults.

We found six RCT studies which look at the effects of yoga on healthy adults. Some of these looked at how yoga could help those at work, whilst some studies focussed on specific psychological (e.g. stress, wellbeing) or physical (e.g. heart rate) outcomes.

3.1.1 Summary of yoga for healthy adults.

The majority of the research on yoga for healthy adults is positive. However, there are problems with the research as it stands, which need addressing in future studies. Often, statistical analyses were poorly done or poorly reported, with no between group comparisons being made. Some studies were subject to a large number of drop outs, and these were not properly accounted for in the results. However, these problems do not entirely detract from the largely positive results that have been found, which include benefits such as psychological benefits including improvements in anxiety and mood, wellbeing benefits, improvements in cardiovascular function and improvements in comfort and strength for computer users.

3.1.2.1 Harinath K, Malhotra AS, Pal K, Prasad R, Kumar R, Kain TC, et al.³

Effects of Hatha yoga and Omkar meditation on cardiorespiratory performance, psychologic profile, and melatonin secretion. J Altern Complement Med 2004 Apr;10(2):261-8.

Study design and location. Randomised controlled trial, India.

Number of participants: 30

Objective. To evaluate effects of Hatha yoga and Omkar meditation on cardiorespiratory performance, psychologic profile, and melatonin secretion.

Methods. 30 healthy male participants (army soldiers) aged 25 to 35 years were included and randomised to control group or yoga group, each with 15 participants. People with endocrine disease or who had previous experience of yoga were excluded. The control group performed routine army training exercises, including body flexibility exercises for 40 minutes and slow running for 20 minutes during morning hours and games for 60 minutes during evening hours. The yoga group practised selected yogic asanas (postures) for 45 minutes and pranayama for 15 minutes during the morning, whereas during the evening hours these subjects performed preparatory yogic postures for 15 minutes, pranayama for 15 minutes, and meditation for 30 minutes daily. Both groups participated for 3 months.

Yoga practices used. Yoga was practised under the supervision of two qualified instructors from Morarji Desai National Institute of Yoga, New Delhi. Yoga asana were held for 2 minutes, with savasana practiced for 2 minutes between every fourth asana. Participants were asked to practise in a relaxed state of mind being fully conscious of the physical movements. Pranayamas included Bhastrika and Bhramari pranayama (mornings) and Sheetal, Sheetkari, Bhramari and Nadi Sodhan in the evenings. Evening meditation was Omkar meditation, performed in padmasana (lotus pose) and involved concentrating on Agna/ajna Chakra and Sahasrara Chakra and chanting Om softly.

Outcomes studied. Outcomes included physiological measurements including heart rate (HR) and blood pressure (measured lying down and 3 minutes after standing up), respiratory

rate (when lying down), orthostatic tolerance (faintness when standing up) and lung function measurements. Other measures included the IPAT anxiety scale questionnaire to measure anxiety and the Minnesota Multiphase Personality Inventory (MMPI) to measure depression. A further questionnaire to assess general wellbeing which consisted of questions about general health, quality of sleep, mental condition and feeling towards peers and superiors. Blood samples were also taken to measure melatonin levels (melatonin is a hormone thought to mediate the relaxing effects of yoga as well as various other physiological benefits).

The results. When comparing the results before and after the 3 month intervention, blood pressure measurements (systolic, diastolic and mean arterial pressure), orthostatic tolerance, lung function measurements and wellbeing were statistically significantly improved in the yoga group but not the control group. Respiratory rate, heart rate, anxiety and depression remained unchanged in both groups. The yoga group had significantly higher melatonin levels at 2am, 3am and 4am after the yoga intervention than before and this correlated with wellbeing scores. Statistical comparisons between the groups were not reported, making it difficult to be sure the change from the beginning to end of the study is due to the intervention.

Is the research good quality and free of bias? The details needed to assess the quality of this study are mostly not reported by the study authors. Randomisation was done well, but it is not clear if allocation concealment was attempted, nor whether study personnel and outcome assessors were blind to which group participants were in, or whether there was any missing data and if so how this was dealt with in statistical analyses. This means it is unclear whether the study is at risk of bias. It is also not clear whether there were enough participants to detect an effect.

Conclusions. This study reports some promising results for yoga, but interpretation is limited by some problems and omissions. Comparisons between the yoga group and the control group were not made, so it is not possible to draw firm conclusions as to the efficacy of yoga. Also, the participants were all army soldiers and compliance is likely to have been higher than for the general population. As only 15 participants were in each group, it is likely that any changes seen would not have reached statistical significance in analysis due to under-powering. However, the results are encouraging and the authors of the study conclude that yogic practices can be used as psychophysiological stimuli to increase secretion of melatonin, which, in turn, might be responsible for an improved sense of well-being.

3.1.2.2 Khalsa SB, Shorter SM, Cope S, Wyshak G, Sklar E.⁴

Yoga ameliorates performance anxiety and mood disturbance in young professional musicians. Appl Psychophysiol Biofeed 2009 Dec;34(4):279-89.

Study design and location. Randomised controlled trial, USA.

Number of participants: 45

Objective. To evaluate the benefits of yoga and meditation for musicians.

Methods. Initially, 31 participants, all elite musicians attending the Tanglewood Music Centre, were recruited and randomised to two yoga intervention groups (n=15 each). One participant was randomised to the control group. A further 14 participants were recruited

separately upon invitation to the no-intervention control group. The authors of the study note that this is therefore not a fully randomised study, as those in the control groups were only recruited once randomisation had effectively been performed, and can be assumed to have less interest in yoga than those in the active groups. This was a pragmatic approach because fewer musicians initially volunteered than was expected.

Yoga practices used. There were two yoga intervention groups. One group received yoga and meditation classes, whilst the other received the yoga and meditation classes and an additional yoga lifestyle intervention. The yoga and meditation classes consisted of classical yoga postures, multiple breathing techniques and meditation following the Kripalu system. This system emphasises the rich experience of internal physical sensations and offers less anatomical alignment than some other forms of yoga (e.g. Iyengar). Participants in both groups were asked to attend three yoga and/or meditation classes per week for the duration of the eight week study. In addition, those in the yoga lifestyle group received a two day intensive retreat which included practice sessions, discussions of yoga practice and philosophy, meditation techniques, breath control and conscious eating. They also attended a weekly problem-solving group discussion which focussed on how yogic philosophy relates to life as a musician, followed by yoga practice, and an individual one hour session to focus on specific questions relating to posture, breath and mediation work. Those in the yoga group were also invited but not required to attend an individual session.

Outcomes studied. Outcome measures used include the Performance Anxiety Questionnaire (PAQ), which focuses on anxiety related to practice, group and solo performances; the Profile of Mood States (POMS) questionnaire; the Performance-Related Musculoskeletal Disorders (PRMD) questionnaire; the Perceived Stress Scale (PSS); and the Pittsburgh Sleep Quality Index (PSQI).

The results. Results from PAQ showed that scores were significantly improved from the start to the end of the 8 week intervention period for the yoga only group in terms of music practice, group performance and solo performance, and for the yoga lifestyle intervention group for group performance and solo performance. Improvements in group performance and solo performance were maintained at 1 year follow-up for the yoga lifestyle group only. The actual mean changes reported showed the yoga groups performed better than the control groups, but these values failed to reach significance at either time point when the groups were compared to each other. A trend towards a difference was seen after the 8 week intervention when results from both yoga groups were combined and compared to the control group. This may indicate that there were too few participants in the study to detect an effect (study may have been underpowered).

Results from the POMS questionnaire are somewhat poorly reported, with results from several different statistical tests making it difficult to see clearly what effect the intervention had. The actual mean changes reported showed the yoga groups performed better than the control groups in all POMS measures, but these values failed to reach significance at either time point when the groups were compared to each other. There appear to be some statistically significant decreases in tension/anxiety and anger/hostility in the yoga groups, depending on which analysis is used.

No statistically significant differences were found for PRMD and PSQI. Low initial scores for PRMD and PSS indicate that there may not have been any significant problems with musculoskeletal disorders or sleep to start with, making an improvement unlikely.

Is the research good quality and free of bias? This study has several methodological flaws. Randomisation and allocation concealment were compromised as those in the control group were recruited after randomisation had taken place. No blinding of any study personnel was attempted, and it is unclear how missing data was handled. The range of statistical approaches used to analyse the results was not clearly justified. All these leave the study at considerable risk of bias. In addition, the study was underpowered, making it unlikely that a real effect would be detected at a statistically significant level. It is unclear in which direction these problems would affect the results overall.

Conclusions. The raw data from this study suggests some positive effects of yoga on performance anxiety and mood. However, these results generally fail to reach statistical significance in between group analyses, unless the two yoga groups are combined to increase statistical power. This suggests the study may be underpowered to detect any effects of yoga. In addition, the study is at risk of bias from several factors. The raw data indicates that there is justification to further investigate the effects of this type of yoga intervention in this type of group.

3.1.2.3 Telles S, Dash M, Naveen KV.⁵

Effect of yoga on musculoskeletal discomfort and motor functions in professional computer users. Work, 33;2009: 297-306

Study design and location. Randomised controlled trial, India

Number of participants: 291 randomised (118 analysed)

Objective. To examine the impact on professional computer users of 60-days of yoga practice on musculoskeletal discomfort, motor functions including speed and strength, and hip and lower back flexibility.

Methods. 291 computer software developers undertaking complex tasks, aged 21 to 49 years were randomised to yoga and 'wait-list' control groups. Only participants with right-handed dominance were included. Individuals reporting symptoms of neck, shoulder, hand and/or arm discomfort of a musculoskeletal origin as well as those requiring analgesics for such symptoms were excluded from the study.

The yoga group [n=146] attended a 1-hour yoga session, 5 days a week for 60 days. Yoga sessions were taught and monitored by a qualified instructor in a designated room on the company's premises. The control group [n=145] continued with their usual recreational activities in the company's recreation centre. These activities included watching television, chatting with friends, playing indoor games and exercising in the gym.

Yoga practices used. Yoga postures (asanas), joints and back exercises (sithilikarana vyayama), breathing exercises (pranayamas), visual cleansing exercises (tratata) and a relaxation period.

Outcomes studied. Both groups were assessed at baseline and after 60 days. Outcomes studied included musculoskeletal discomfort, hand grip strength, tapping speed, low back and hamstring flexibility.

The results. Assessments at the end of 60 days were based on findings in 118 participants [62 in the yoga group; 56 in the 'wait-list control' group]. Compared to the control group, participants who attended yoga sessions had a significant decrease in self-reported

musculoskeletal discomfort, an increase in bilateral hand grip strength, right hand tapping strength, low back and hamstring flexibility.

Is the research good quality and free of bias? Overall, this study was of moderate quality. Inclusion and exclusion criteria were explicitly described. Randomisation of participants was adequate, however allocation concealment was unclear. Although, all relevant outcomes were reported by blinded outcome assessment, the reliability and validity of a number of assessment tools (e.g. for tapping strength and hand grip strength) was not reported. There was a high number of drop-outs in both study groups. Reasons given for this finding included transfer of workers and busy schedules at work. Analyses of results were not on an intention-to-treat basis and included a number of post-hoc analyses.

Conclusions. This study suggests beneficial effects of yoga in individuals whose work involve the performance of complex computer-related tasks. There were trends towards decrease in musculoskeletal discomfort and improvements in motor functions compared with a control group. It may be useful to perform a sufficiently powered study to evaluate the effects of yoga using more objective measures for relevant outcomes in an identical study population.

3.1.2.4 Shelov DV, Suchday S, Friedberg JP.⁶

A pilot study measuring the impact of yoga on the trait of mindfulness. Behavioural and Cognitive Psychotherapy. 2009;37:595-598

Study design and location. Pilot randomised controlled trial, USA

Number of participants: 46 randomised (34 analysed)

Objective. To evaluate the effect of yoga on the state of mindfulness in a healthy population.

Methods. The 46 study participants were staff and students of the Ferkauf Graduate School of Psychology (FGS) and the Albert Einstein College of Medicine (AECOM), aged 22 to 65 years. Participants were randomised to a yoga group or a wait-list control group.

The yoga group took part in a 60-minute hatha yoga practice once a week for 8 weeks.

It was unclear which activities those assigned to the wait-list control group received during the 8-week study period. However, the report suggests that these individuals started a yoga intervention 10 weeks after an initial interview. Timing of this interview was not explicitly described.

Yoga practice used. Yoga sessions consisted of yoga postures, breathing exercises and shavasana relaxation.

Outcomes studied. The primary outcome, mindfulness, was assessed using the Freiburg Mindfulness Inventory (FMI). Overall mindfulness scores were derived by summing scores from responses to a 30-item questionnaire assessing four subscales including accepting and open attitudes towards experience; paying attention without distraction; process oriented understanding and disidentifying attentional processes of mindfulness.

The results. Statistically significant changes from baseline to follow-up were seen in both groups for overall mindfulness, with the yoga group showing a numerically superior mean change of 4.7. However the statistical significance of the difference between the two groups was not reported. In the yoga group, the subscales of disidentifying attentional processes,

accepting and open attitude towards experience, and process oriented understanding were significantly improved from baseline to follow-up, whilst in the control group, only process oriented understanding was significantly improved.

Is the research good quality and free of bias? Overall, this study has an unclear risk of bias. Methods of recruitment, blinding and group allocation were unclear or partially reported and may be at risk of bias. The study also had a drop-out rate of over 20% (n=12/46), and it was not clear how these drop outs were dealt with in the final analysis, which may have been a further source of bias.

Conclusions. This study shows before-after improvements in mindfulness in a healthy population following 8 weeks of hatha yoga. However, it is not clear if the improvement was due to yoga as a between group comparison has not been reported. Also, the study may be at some risk of bias. It would be helpful to undertake more work in this area using rigorous and transparent research methods.

3.1.2.5 Streeter CC, Whitfield TH, Owen L, Rein T, Karri SK, Yakhkind A, Perlmutter R, Prescott A, Renshaw P, Ciraulo DA, Jensen JE.⁷

Effects of yoga versus walking on mood, anxiety and brain GABA levels: A randomised controlled MRS study. The Journal of Alternative and Complementary Medicine. 2010; 16 (11):1145-1152.

Study design and location. Randomised controlled trial, USA

Number of participants: 52 randomised (34 analysed)

Objective. To investigate the changes in mood, anxiety and gamma-aminobutyric acid (GABA) levels in relation to yoga practices and a metabolically matched walking intervention.

Methods. 52 participants recruited through newspaper and other related advertisements were randomised to yoga and a metabolically similar walking regime. Participants were aged between 18 and 45 years and had no on-going Axis 1 disorder (mental health conditions). Exclusion criteria for this study included those with previous or current history of yoga practice, existing involvement in any mind-body practices including psychotherapy, recent treatment with drugs that affect GABA levels including pharmacological agents, tobacco and alcohol. Those for whom magnetic resonance imaging was contraindicated were also excluded from the study. The yoga group received 60-minute Iyengar yoga practice three times per week. After 4 weeks of supervised yoga practice with a trained instructor, participants received printed lists and pictures of postures to use at home. The control group exercised by walking for 60 minutes at a rate of 2.5 miles per hour on a level surface at 3.0 metabolic equivalents (METs). Both interventions (yoga and walking) were limited to a maximum of 36 sessions during the study period.

Yoga practice used. Iyengar yoga

Outcomes studied. The main outcomes of this study were mood scores, anxiety scores and levels of GABA in the left thalamus.

The results. Assessment of mood and anxiety were at baseline, week 4, week 8 and week 12. Mood was assessed with the Exercise-Induced Feeling Inventory (EIFI) while anxiety scores were derived from the Spielberger State-Trait Anxiety Inventory (STAI). Magnetic resonance scans were at baseline (scan 1), after the 12-week study period (scan 2). This

was followed immediately by the assigned intervention and then a final scan (scan 3). Compared to the control group, participants who were involved in yoga sessions had a reported decrease in anxiety and increased mood and thalamic GABA levels. Correlations between GABA levels and mood/anxiety scores were also investigated, and some positive correlations were found.

Is the research good quality and free of bias? Overall, this study was of moderate to high quality. Although, for all relevant outcomes reported, blinded outcome assessment was unclear. There was a high number of drop-outs in both study groups. Analyses of results were not on an intention-to-treat basis.

Conclusions. This study suggests beneficial effects of yoga on mood and anxiety in healthy individuals. The correlations between thalamic GABA levels and improved mood and decreased anxiety levels suggest GABA may mediate the responses seen. Further studies are needed to examine the role of GABA.

3.1.2.6 Hartfiel N, Havenhand J, Khalsa SB, Clarke G, Kraye A.⁸

The effectiveness of yoga for the improvement of well-being and resilience to stress in the workplace. Scandinavian Journal of Work 2011.

Study design and location. Randomised controlled trial, UK.

Number of participants: 48

Objective. This study examined the effectiveness of yoga in enhancing emotional well-being and resilience to stress among university employees.

Methods. 48 university employees were recruited via email and flyers. People with at-risk health conditions such as recent surgery or first trimester pregnancy were excluded. People already practising yoga regularly were allowed to attend class but were not included in the analysis. Participants were randomised to receive yoga classes or to a wait list control group who received no intervention during the study period.

Yoga practices used. Participants were offered Dru Yoga. They were asked to attend at least one 60 minute lunchtime session for six weeks. Classes were taught by a senior Dru Yoga instructor and participants were provided with a CD of a guided 35 minute home practice. Home practice frequency and duration was recorded by the participants using a form. Classes consisted flowing movements, directed breathing and relaxation techniques that included affirmation and visualization.

Outcomes studied. Two questionnaires were used to measure outcomes. These were the Profile of Mood States Bipolar (POMS-BI) and the Inventory of Positive Psychological attitudes (IPPA). Both scales focus on both positive and negative emotional states and are more appropriate for use with participants who are considered "normal".

The results. Participants attended an average of 1.15 classes per week. Participants who attended less than 6 sessions were excluded from the analysis. When the change in scores from the start to the end of the trial were compared between groups, those in the yoga group were less anxious, confused, depressed, tired, and unsure, had a greater sense of life purpose and satisfaction and were more self-confident during stressful situations. Scores for the yoga group improved two to five times more than those in the control group across these

outcomes. Although the yoga group reported feeling more agreeable (less hostile) than the control group at the end of the program, this difference was not statistically significant.

Is the research good quality and free of bias? Whilst certain elements of this study were well conducted, there is a risk of bias from participants and study personnel knowing which group participants were in. The study also excluded participants who did not comply fully with the intervention, which may bias the results and mask reasons for dropping out. A second analysis including these participants should have been done. It is not clear if the size of the effect was clinically meaningful.

Conclusions. Whilst there are problems with this study which may have lead to bias in the results, they are nevertheless promising. Future studies on healthy participants should provide a more robust analysis and should make more attempts to conceal allocation and blind study personnel as to which group participants are in.

3.2 Osteoarthritis and Osteoarthritis of the hand

3.2.1 What is Osteoarthritis?

Osteoarthritis is a disease which causes stiffening, inflammation and pain in the joints. It most commonly occurs in the hips, knees, joints in the hands and at the base of the big toe. It usually occurs in people aged over 50 years of age, and more women than men suffer from it. It can also occur in young people, often as a result of injuries. It is thought to affect around 8 million people in the UK.⁹

3.2.2 Studies found.

We found two systematic reviews of osteoarthritis. Both focussed on multiple therapies. One review focussed on osteoarthritis of the hand only, the other focussed on any osteoarthritis. Both reviews found the same RCT of yoga for hand osteoarthritis.

3.2.3 Summary for Osteoarthritis. There is some evidence that yoga is effective for osteoarthritis of the hand.

3.2.4.1 Mahendira DT and Towheed TE.¹⁰

Systematic review of non-surgical therapies for osteoarthritis of the hand: an update. Osteoarthritis and Cartilage 2009;17(10):1263-8. (This study is an update of Towheed TE.¹¹ Systematic review of therapies for osteoarthritis of the hand. Osteoarthritis and Cartilage 2005;13: 455-462.)

3.2.4.2 Brosseau L, Pelland L, Wells G, Macleay L, Lamothe C, Michaud G, et al.¹²

Efficacy of Aerobic Exercises for Osteoarthritis (part II): A Meta-analysis. Physical Therapy Reviews 2004 Sep;9(3):125-45 2004.

Study design and location. Systematic reviews, Canada.

Number of RCTs included: 1 RCT

Objective. To evaluate non-surgical therapies for osteoarthritis of the hand (Mahendira & Towheed , 2009). To examine the efficacy of aerobic exercise among individuals with osteoarthritis. (Brosseau et al, 2004)

Methods. Mahendira and Towheed 2009 searched 6 key electronic databases (Medline, Premedline, Embase, Amed, Cinahl, EBM review including Cochrane database of systematic reviews, DARE, ACP journal club and Central Cochrane Database) in 2008. Reference lists of retrieved articles were also searched. Brosseau et al 2004 searched Medline, Embase and Cochrane Controlled Trials Register. Mahendira and Towheed 2009 included RCTs recruiting patients with diagnosed or undiagnosed osteoarthritis. Studies were excluded if the therapy was surgical, and if the language was not English and not enough information was provided in the english language abstract. Data extraction was conducted independently by two reviewers and differences were resolved by discussion. Quality was assessed using the Jadad scale, with an extra item on allocation concealment. Similarly, Brosseau et al, 2004, used the Jadad scale, with some additional questions relating to RCT design, data collection and statistical analyses.

Yoga practices used. Both reviews identified only one study which related to yoga, and this was for hand osteoarthritis. Brosseau et al, 2004, described the practice as yoga and relaxation techniques with patient education, delivered as eight weekly sessions of 60 minutes. Strengthening and stretching exercises emphasising extension and alignment were taught, along with group discussions, supportive encouragement and general questions and answers.

Outcomes studied. The study¹³ that was identified reported pain and mobility measures.

The results. The included study recruited 26 participants, one of whom dropped out. Participants were offered a ten week therapy programme consisting of eight hourly sessions, with a “no therapy” control group. Statistically significant changes in tenderness of the right and left hand were reported, though these changes were not clinically significant. Range of motion and pain during activity were also statistically significantly improved in the right hand, but not the left. The improvements in range of motion and pain were clinically significant. There were no statistically significant changes for hand pain at rest, hand swelling, grip strength and hand function. However, a clinically significant improvement was seen in the right hand for pain at rest.

Is the research good quality and free of bias? Both reviews are of good quality. RCTs were included, all major sources have been searched, and quality assessment was included. Whilst the quality assessment tool (Jadad scale) used has been criticised, an additional question relating to allocation concealment was added to improve this.

Conclusions. Mahendira and Towheed 2009 conclude that there is at least some evidence for the efficacy of yoga for hand osteoarthritis. Bosseau et al 2004 conclude similarly that there is evidence to support yoga for (hand) osteoarthritis. As the one included study was small, it can be inferred that a larger study would help to confirm these results.

3.3 Asthma

3.3.1 What is Asthma?

Asthma is a chronic disease of the airways, which leads to inflammation, tightening of the muscles around the airways, and sometimes the build up of mucus and phlegm. All of these symptoms result in narrowing of the airways which makes it difficult to breathe. Coughing, wheezing and tightening of the chest are common signs of an asthma attack. Attacks are usually triggered by irritants. In some people, asthma is triggered by exercise, but with care, this can be managed so that people with asthma can take part in exercise.¹⁴ Asthma can be controlled with pharmaceutical drugs, but surprisingly three people per day are thought to die from asthma.¹⁵

3.3.2 Studies found.

We found three studies; one systematic review which included 3 relevant RCTs and which was published in 2002, and two RCTs that have been published since then.

3.3.3 Summary for Asthma. Across the five RCTs, there are some positive results for improvement of some subjective symptoms, the number of attacks, drug use, mental state, and lung function, but not all reached statistical significance. This may be due to sample size in some cases. There are some weaknesses in the methods used which could have affected results in either direction. There was a great deal of variety in the type of yoga taught, and how long it was practiced for. When future researchers design their studies, they may want to carefully consider how many weeks it should take to see an effect, how long sessions should last, how many sessions should be given in a week, and whether pranayama on its own is the most appropriate yoga intervention. In the absence of any evidence of negative effects, yoga appears to be a potentially beneficial therapy for people with asthma.

3.3.4.1 Steurer-Stey C, Russi EW, Steurer J.¹⁶

Complementary and alternative medicine in asthma: do they work? Swiss Med Wkly 2002;132(25-26):338-44.

Study design and location. Systematic review, Switzerland.

Number of RCTs included: 3

Objective. To summarise the most popular alternative treatments in asthma and the evidence of their effectiveness.

Methods. Three electronic database (Medline, Embase and Cochrane Library), were searched to May 2002. Bibliographies of retrieved studies were also searched. Studies in English and German were included. The review included studies on acupuncture, homeopathy, yoga, herbal and nutritional therapies. Studies do not seem to have been quality assessed formally. RCTs and systematic reviews were included.

Yoga practices used. Details of the practices used in the studies are not provided, except for one study which used a device to learn pranayama. The length of time yoga was given for varied but included 54 months, 16 weeks, and 3 weeks.

Outcomes studied. Outcomes mentioned in the review included number of asthma attacks in a week, drug treatment score, use of drugs, lung function (using a spirometer), mental state and subjective symptoms.

The results. Results varied across the three studies. The long term study (54 months, 106 participants)¹⁷ showed a significant improvement for number of asthma attacks per week, a decrease in drug use and an increase in a measure of lung function (peak flow rate). The 16 week trial¹⁸ with 17 participants showed a positive trend towards reduced use of drugs, improvement in lung function and symptom score, but the results were not significant, possibly due to the small number of participants. The three week trial¹⁹ with 36 patients showed a statistically significant improvement in mental state and subjective symptoms, but not in lung function.

Is the research good quality and free of bias? Overall, this review is likely to be relatively free of bias, but failed to assess the quality and risk of bias of the studies it found, or report the results in their entirety. It is therefore unclear what the risk of bias is for these two RCTs.

Conclusions. The review does not draw conclusions about the yoga RCTs on their own. From the results that are reported it would seem there is some evidence that yoga may be effective for improvement of some subjective symptoms, number of attacks, drug use, mental state, and lung function.

3.3.4.2 Sodhi C, Singh S, Dandona PK.²⁰

A study of the effect of yoga training on pulmonary functions in patients with bronchial asthma. Indian J Physiol Pharmacol 2009 Apr;53(2):169-74.

Study design. Randomised controlled trial

Number of participants: 121

Objective. To assess the outcome of yoga training on pulmonary function in patients with bronchial asthma.

Methods. 121 patients with mild to moderate bronchial asthma who were not smokers and aged 17 to 50 were included. Patients remained on their usual prescribed treatments during the study. Patients with a number of serious conditions were excluded, as were patients already engaged in exercise or training. Those included were randomised to a yoga training group or a control group. Those in the yoga group received one 45 minute training session per week for 8 weeks, and were instructed to practice at home for 45 minutes twice daily, and to keep a practice diary.

Yoga practices used. Various deep breathing techniques (pranayamas), kapalabhati (cleaning breath), bhastrika (rapid and deep respiratory movements), ujjayi (loud sound producing pranayama) and sukha purvaka pranayama (easy comfortable breathing).

Outcomes studied. Lung function, using a computerised spirometer to measure peak expiratory flow rate (PEFR), forced expiratory volume in the first second (FEV1), forced vital capacity (FVC), forced mid expiratory flow in 0.25 to 0.75 seconds (FEF25-75), and FEV1/FVC% ratio at 4 and 8 weeks.

The results. Between group comparisons for all outcomes showed a trend towards better results in the yoga group, but these did not reach statistical significance except in three

cases (FEV1 at week 4 and 8, FEV/FVC at week 8). However, increases in PEFR, FEV1, FVC, FEF25-75 and FEV1/FVC% ratio between baseline and 4 weeks and 8 weeks were statistically significant for the yoga group for all measures, but not for the control group.

Is the research good quality and free of bias? Overall, this study did not provide enough information to assess the quality and potential for bias. In addition, it is not clear whether there were enough participants in the trial to detect the full effect as no power calculation is reported, and it is not clear what size of effect is clinically useful.

Conclusions. Results from this study are promising for yoga for asthma, with positive trends and statistically significant results being reported. However, it is unclear whether the study was of good quality, and the results generally failed to reach statistical significance when the two groups were compared to each other. A better reported trial, with enough participants to detect a clinically relevant effect is needed to confirm the results of this study.

3.3.4.3 Sabina AB, Williams AL, Wall HK, Bansal S, Chupp G, Katz DL.²¹

Yoga intervention for adults with mild-to-moderate asthma: a pilot study. Ann Allergy Asthma Immunol 2005 May;94(5):543-8.

Study design and location. Randomised controlled trial, USA.

Number of participants: 62 recruited, 45 completed.

Objective. To determine the effectiveness and feasibility of a yoga and breath work intervention for improving clinical factors and quality of life in adults with mild to moderate asthma.

Methods. 62 patients aged 18 years and older with mild to moderate asthma, and who were taking standard asthma medications were included. Smokers, recent ex-smokers and ex-smokers who used to smoke heavily were excluded as they are likely to have irreversible lung damage. Pregnant women, those with exercise induced asthma, those who practised yoga in the previous 3 years and those with other significant medical problems were also excluded. Those included were randomised to intervention and control groups. The yoga group received yoga classes but were only told that they were receiving complementary care body conditioning. The control group received stretching classes taught by exercise physiologists, which was considered a suitable control as previous research showed muscular and general aerobic fitness did not impact on asthma. Contact and planned practice time was the same for the two groups.

Yoga practices used. The yoga practice consisted of 4 weeks of twice weekly, 90 minute classes taught by an experienced Iyengar yoga teacher. Participants were taught asana (postures), pranayama (breathing) and dhyana (meditation) and were asked to continue practising at home for 20 minutes per day, 3 times per week for the next 3 months.

Outcomes studied. The main outcome was frequency of rescue inhaler use, measured as puffs per day. The Mini Asthma Quality of Life Questionnaire was also used. A secondary outcome was lung function measured using a spirometer. Outcomes were recorded at the beginning of the study, at the end of the 4 weeks of classes and again at the end of the additional 3 month period.

The results. Participants in the yoga group had worse lung function at the start of the trial. There was a significant drop-off in attendance and compliance in both groups. Neither

intervention significantly altered rescue inhaler use, nor was there any difference in use between the two groups at either time point. Both groups showed a significant improvement in one measure of lung function (FEV1), but no other lung function measures, and there was no difference in the beneficial effect between the two groups. Quality of life scores did not differ between groups, but at 16 weeks, patients in the control group had significantly better scores than at the beginning of the study. There was an improvement in morning asthma symptoms in both groups at 4 weeks and 16 weeks.

Is the research good quality and free of bias? Overall, this study was of good quality in many ways, but there were some problems. Patients in the yoga group had significantly worse lung function at the start of the study, which may have biased results in either direction. In addition, it is not clear how the results dealt with data for the patients who dropped out, which might affect results in either direction. It is not clear if there were enough patients to detect small effects.

Conclusions. Results from this study suggest that yoga does not have an effect on inhaler use for patients with mild to moderate asthma. Both yoga and stretching exercises may have improved one measure of lung function (FEV1). However, there were problems with the study that may have biased results against yoga and because of the small number of participants, it is difficult to be sure that the results can be relied upon. A larger study with a better balance of patients in each group would be needed to confirm the conclusion that yoga is not effective.

3.4 Back Pain

3.4.1 What is back pain?

Back pain is suffered by as many as 80% of adults at some point in their life, and in the UK around 49% of adults report lower back pain that lasted more than 24 hours in the last year²². Back pain with a specific cause can be due to slipped discs, ankylosing spondylitis or sciatica. Non-specific back pain is usually caused by sprains, strains, minor injuries or pinched or irritated nerves.²³

3.4.2 Studies found.

We found one systematic review and three RCTs published after the review. All are on chronic low back pain.

3.4.3 Back pain summary. Whilst smaller trials failed to pick up an effect, larger, well conducted trials indicate that vinyoga, Iyengar yoga and yoga delivered by British Wheel of Yoga teachers can be effective for chronic low back pain and some of its side effects such as loss of function and depression.

3.4.4.1 Chou R, Huffman LH, et al.²⁴

Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med 2007 Oct 2;147(7):492-504. [Erratum changes applied to online version]

Study design and location. Systematic review, USA.

Number of RCTs included: 3

Objective. To assess benefits and harms of various therapies including yoga for acute or chronic low back pain (with or without leg pain).

Methods. Two electronic databases (Medline and Cochrane Database of Systemic Reviews), were searched for systematic reviews. The primary source of data was systematic reviews and where no evidence was found from reviews, further searches were conducted in Medline, the Cochrane Central Register for Controlled Trials and PEDro to identify RCTs. Reference lists were searched and experts consulted for additional citations. The Oxman criteria were used to assess the quality of included reviews, and the Cochrane Back Review Group criteria to assess the quality of RCTs. Studies were included if they reported pain outcomes, back-specific function, general health status, work disability or patient satisfaction.

Yoga practices used. Any type of yoga was included in the review. Of the three RCTs identified, the style of yoga taught was Viniyoga¹ and Iyengar yoga.^{2,3}

Outcomes studied. Pain outcomes, back-specific function (assessed by Roland–Morris Disability Questionnaire (RDQ)), general health status, work disability or patient satisfaction.

The results. Three trials were identified, including a total of 183 participants. One high quality trial of Viniyoga²⁵ (101 participants) which lasted 6 weeks found vinyoga to be slightly superior to conventional exercise and moderately superior to a self-care education book for back specific function (RDQ) when followed up 12 weeks after the start of the study. At 26 weeks, vinyoga was superior only to the self-care education book. Symptom “bothersomeness” was similar across the three groups at 12 weeks, but yoga was superior to the self-care book at 26 weeks. Medication use was lower in the yoga group (21% of

patients vs 50% in the exercise group, and 59% in the self-care group), but care provider visits not altered. The two lower quality and smaller trials of Iyengar yoga were less conclusive^{26:27}. One trial (60 participants) found yoga to be more effective at reducing disability, though pain reduction was only significant when results were corrected for differences in patient characteristics at the start of the study between the groups. The other small study (22 participants) found no differences between yoga and standard exercise.

Is the research good quality and free of bias? This review is generally of good quality though may have missed some studies. No meta analysis was attempted and it is unclear if this may have been possible.

Conclusions. The review concludes that there is evidence to support the effectiveness of vinyoga for back pain, but does not draw a conclusion for yoga as a whole or for Iyengar yoga. More large studies of good quality are needed to draw further conclusions.

3.4.4.2 Williams K, Abildso C, Steinberg L, Doyle E, Epstein B, Smith D, et al.²⁸

Evaluation of the effectiveness and efficacy of Iyengar yoga therapy on chronic low back pain. Spine 2009 Sep 1;34(19):2066-76.

Study design and location. Randomised controlled trial, USA, Canada.

Number of participants: 90 (an additional analysis of only those who followed the schedule (per protocol) was also provided, and included 74 patients)

Objective. To evaluate Iyengar yoga therapy on chronic low back pain. Yoga subjects were hypothesized to report greater reductions in functional disability, pain intensity, depression, and pain medication usage than controls.

Methods. 90 patients with lower back pain judged by a physician to be due to musculoskeletal causes were included. Patients who were English speaking, able to attend class, who agreed not to seek other bodywork treatments and who would attend a minimum of 40 classes in at least 20 of the 24 weeks of instruction and would practise at home for 30 minutes per day on non-class days. Patients with back pain not due to musculoskeletal causes, who were pregnant or who had one of a range of other debilitating conditions were excluded. Those included were randomised to intervention or control. Those in the yoga group received classes, equipment, a manual and a DVD for home practice. Those in the wait list control group continued with self-directed medical care and were offered the yoga classes 6 months after the conclusion of the study.

Yoga practices used. Participants were taught Iyengar yoga by a qualified Iyengar instructor with two experienced class assistants. The yoga therapy was designed in consultation with two senior Iyengar instructors and approved by B.K.S. Iyengar. Participants were taught specific poses selected and modified for lower back pain. Relaxation (savasana) was included in the postures.

Outcomes studied. Outcomes were assessed at the start of the trial (baseline) then at 12, 24 and 48 weeks after the start of the trial. The primary outcomes were functional disability measured by the Oswestry Disability Index (ODI), pain measured using a visual analogue scale (VAS), depression using the Beck Depression Inventory II (BDI-II) and self reported medication usage.

The results. 90 participants aged between 23 and 66 years were recruited. Patient characteristics were similar at the start of the study, though more African Americans were randomised to the yoga group and the average number of months since the first back pain episode was longer in the control group. 16 participants from the yoga group did not complete the trial. When analysing all participants (an intention to treat analysis) and using a patient's previous measurement to replace missing measurements (last observation carried forward), ODI improvements were very nearly significant when results at 12 and 24 weeks were included in the analysis. When baseline to 24 week data was included in the analysis, the results were significant indicating that disability and VAS were improved in the yoga group (29% and 42% greater reduction compared to control, respectively) at this time point. However, these outcomes were not significant when baseline to 12 weeks change was considered. BDI-II was significantly improved at both 12 and 24 week analyses (28.3% and 45.7% greater reduction compared to control, respectively). There was no statistically significant difference in the change in medication usage between the two groups, however the trend was for a greater decrease in the yoga group. When analysing only participants who completed the trial (per-protocol analysis), improvements in the yoga group were more pronounced in all outcomes. At 48 weeks, 68% of participants in the yoga arm were still practicing yoga. Improvements in outcomes were still statistically significant in the yoga group, though a little lower than at 24 weeks.

Is the research good quality and free of bias? This is a high quality RCT which used a good method to randomise participants and to keep group allocation secret until the participants were enrolled. Study personnel who recorded outcomes did not know which group participants were in, and missing data was handled appropriately. The study had enough participants to detect an effect. The results of this study should be free from most sources of bias. However, it should be noted that the control group did not receive as much attention as the yoga group, and this may have contributed to the effects seen.

Conclusions. Results from this high quality study suggest that yoga can be an effective approach to managing chronic lower back pain and can result in decreased functional disability, pain and depression. It may also help some patients to reduce medication usage.

3.4.4.3 Cox H, Tilbrook H, Aplin J, Semlyen A, Torgerson D, Trehwela A, et al.²⁹

A randomised controlled trial of yoga for the treatment of chronic low back pain: Results of a pilot study. Complement Ther Clin Pract 2010;16(4):187-93.

Study design and location. Pilot randomised controlled trial, UK.

Number of participants: 20 (analysed)

Objective. To conduct a pilot trial of yoga for the treatment of chronic low back pain to inform the feasibility and practicality of conducting a full-scale trial in the UK; and to assess the efficacy of yoga for the treatment of chronic low back pain.

Methods. 20 patients who were aged 18 to 65 years, had a score of 4 or more on the Roland and Morris Disability Scale (RDQ), had presented to their GP in the previous 18 months with lower back pain who could attend yoga classes (times and dates) and were sufficiently physically mobile were included. Patients who were pregnant, had psychosis or recent substance abuse, who were already participating in yoga or a trial for their lower back pain, were not currently suffering an episode of lower back pain, had previous spinal

surgery, or had clinical indications of serious spinal or neurological pathology were excluded. Those included were randomised to yoga intervention or control. Those in the yoga group received the yoga intervention alongside usual care and written advice on back pain management. Those in the control group received usual care and written advice on back pain management.

Yoga practices used. The yoga intervention consisted of 12 weekly 75-min classes. It was devised by an Iyengar Yoga teacher (IYAUK) and lower back pain yoga specialist, in collaboration with a British Wheel of Yoga teacher (BWY), who delivered the intervention. Each class took a different element of yoga philosophy as the theme and taught students relaxation and various asanas (postures) including standing and seated poses.

Outcomes studied. The main outcome was functional limitations as measured by the RDQ which asks participants to answer questions about their lower back pain and dysfunction for that day. The minimum clinically significant difference is thought to be a two to three point reduction. Clinical status as measured by the Aberdeen Back Pain Scale (ABPS), general health status measured using the SF-12, the EQ-5D health index, Pain self-efficacy as measured by the Pain Self-Efficacy Questionnaire (PSEQ), and the number of days (i) spent in bed due to lower back pain, (ii) with restricted activity attributed to lower back pain, and (iii) whether medication was used for lower back pain over the previous four weeks. Measurements were taken at the start of the trial (baseline), at 1 month and at 3 months.

The results. 20 participants were recruited and randomised, 10 to each group. Participants in the yoga group were younger (average 12 years younger), had had their back pain for less time, were more likely to be employed and more were women when compared to the control group. There was generally poor attendance to the classes, most of which seemed to be to do with scheduling, and fewer yoga participants completed the measurements. This is likely to affect estimates of efficacy. The only statistically significant result was for pain at 4 weeks, where the yoga group reported a greater decrease in pain as measured by the ABPS (yoga group, -10.39; usual care group -2.00 on 100 point scale). Whilst some other measures showed larger improvements in the yoga group, these were not statistically significant. Equally, some other measures were more improved in the control group, but not statistically significantly so.

Is the research good quality and free of bias? The study is of mixed quality. Randomisation was done well, but participants and study personnel may have been able to tell which group they would be in before joining the trial, which can introduce bias. It was not clear if outcome assessors were blind. The main problems with this trial are: that the group patient characteristics were very different at the start of the trial with older and less well participants in the control group; a large percentage of participants did not provide data in the yoga group; and there were a high number of missed classes in the yoga group. These factors could have influenced results in either direction, or both, making results very difficult to draw conclusions from. In addition, this study is a pilot study, and is unlikely to be powered to detect an effect. Non-statistical results do not necessarily indicate the intervention does not have an effect.

Conclusions. Results from this study show some benefit from yoga in terms of reduction in pain at 4 weeks, but not at 3 months. However, this study is a pilot study with very few participants and it is unsurprising to find mixed results. The main aim of the trial was to identify methodological issues to help design the larger trial, published subsequently and reported below (Tilbrook 2011).

3.4.4.4 Tilbrook HE, Cox H, Hewitt CE, Kang'ombe RA, Chuang LH, Jayakody S, Aplin JD, Semlyen A, Trehwela A, Watt I and Torgerson DJ.³⁰

Yoga for Chronic Low Back Pain. A randomised trial. Ann Intern Med. 2011;155:569-578.

Study design and location. Randomised controlled trial, UK.

Number of participants: 313

Objective. To compare the effectiveness of yoga and usual care for chronic or recurrent low back pain.

Methods. Patients who had visited their GP with low back pain in the last 18 months and were aged 18 to 65 were invited to Participate. 313 patients who had a score of 4 or more on the RMDQ (Roland-Morris Disability Questionnaire), musculoskeletal pain bounded by the lowest ribs and gluteal folds and were able to attend 1 of the yoga venues were included. Patients were excluded if they 1) did not return a baseline questionnaire 2) had performed yoga in the previous 6 months, 3) could not get off the floor unaided, 4) could not use stairs, 5) were pregnant, 6) had life-threatening comorbid conditions, 7) had previously undergone spinal surgery, 8) had severe documented psychiatric problems or alcohol dependency, and 9) had indications of serious spinal neurologic abnormality. Those included were randomised to intervention and control. 156 participants were assigned to the yoga group and received taught sessions, home practice materials and usual care (including a back health booklet). 157 participants were assigned to the control group and received usual care (including a back health booklet).

Yoga practices used. The yoga intervention was for twelve weeks, with one taught session per week. Teachers were either Iyengar teachers, or British Wheel of Yoga teachers. Each class was 75 minutes long. At the first session, participants were given a student manual, a mat and a relaxation CD. Home practice sheets were also distributed at 4 week intervals during class. Participants were encouraged to practice 30 minutes daily, or twice per week at home. Practices included asana (postures), pranayama (breathing), relaxation techniques, mental focus and philosophy. Poses targeted stiff, weak and uneducated areas of the whole body, to improve mobility, strength and posture, and reduce pain.

Outcomes studied. Outcomes were studied via postal questionnaires, and were given a small (£5) financial incentive to return the questionnaire. The primary outcome was back function as measured by the RMDQ at 3 months. Secondary outcomes were back function at 6 and 12 months, physical and mental health as measured by the Short Form -12 (SF-12) Health Survey components, back pain scores on the Aberdeen Back Pain Scale (ABPS), self-efficacy scores on the Pain Self-Efficacy Questionnaire (PSEQ), beliefs, expectations, and preferences for treatment at baseline, class attendance and use of yoga at home. Additional outcomes were recorded, (EuroQoL-5D health index, number of days spent in bed and number of days with restricted activity, economic data, including medication use over the previous 4 weeks and other health care use)but will be reported separately.

The results. Attendance was moderate, with 60% of those in the yoga group attending at least half of the first six sessions, and any three of the following six sessions. A further 26% attended at least one session, and 15% did not attend any class. There was no association

between attendance and attitude to yoga. An intention to treat analysis of RMDQ scores, where missing data was replaced with average values, showed that the difference between the change in the yoga group and control group was statistically in favour of the yoga group at 3, 6 and 12 months. Additional analyses were performed, where missing data was replaced with the very lowest scores (worst case scenario) or the very highest scores (best case scenario). Yoga was not effective in the worst case scenario analysis, but was very effective in the best case scenario analysis. Other outcome measures were mixed. ABPS recorded a near-significant trend ($P=0.06$) for improvement in pain in the yoga group at 3 months, and results were also non-significantly in favour of yoga at 6 and 12 months. The SF-12 physical and mental summary scores were also more improved in the yoga group, but the difference between groups was not significant. The PSEQ difference in improvement between the yoga group and the control group was significantly in favour of yoga at 3 and 6 months, but non-significantly in favour of yoga at 12 months. 12 patients in the yoga group reported adverse events. In the yoga group, one of these events was a serious back pain event, possibly or probably related to yoga. Other adverse events were non-serious and of these, 4 were not related to yoga and 7 were possibly or probably related to yoga.

Is the research good quality and free of bias? This study is of generally high quality. Randomisation was done well, study personnel could not tell which group participants would be assigned to, and the statisticians were blind to which group data came from. Participants were not blind to which group they were in, and patients who did not complete the baseline questionnaire were excluded from the trial. This may account for a small imbalance in the baseline characteristics, where there are fewer patients who expressed a preference for yoga in the control group (61% versus 72%). This may introduce a small amount of bias to the results. Missing data were handled very well, with best and worse case scenario assessments. Some outcomes are reported elsewhere, and it is not possible to comment on these in this report.

Conclusions. The primary outcome showed that yoga is an effective intervention for improving disability due to back pain, at a level that is clinically significant. This effect was maintained over a year, even though the intervention was only delivered for 12 weeks. Yoga was associated with an increase in adverse events, but these were mostly non-serious. Self efficacy for dealing with back pain was also significantly improved in the yoga group compared to the control group at 3 and 6 months. Other results were numerically in favour of yoga, but results did not reach statistical significance. This may be because the study was not powered for these outcomes. This study adds to the body of evidence which supports the use of yoga to treat lower back pain.

3.5 Cancer

3.5.1 What is cancer?

Cancer is a very common life threatening disease which can affect most parts of the body. It is the uncontrolled proliferation of cells, which can invade and damage tissues and organs of the body. Treatments for cancer include surgery, chemotherapy and radiotherapy, depending on the type of cancer. The treatments themselves often have unpleasant side effects, and the mental and emotional pressure of a cancer diagnosis can severely affect people's quality of life. It is these side effects and emotional difficulties that therapies such as yoga aim to address.

3.5.2 Studies found

We found 1 systematic review of yoga for people with cancer, and a further 8 RCTs. Breast cancer is the most studied condition, with 5 of the RCTs reported in the review and 6 of the subsequent RCTs focussing on this.

3.5.3 Cancer summary.

Most studies were carried out in women with or recovering from breast cancer. The systematic review was unable to draw a conclusion because of very mixed results. However, across the RCT studies published subsequently, those that tested for Quality of Life and aspects of mood consistently reported positive results for yoga (between group and/or before-after comparisons), except in one case where there was no change. Other positive results included improvements in intrusive thoughts, hot flushes, joint pain, anxiety and depression. Mixed results were obtained for Cortisol levels, with one good sized high quality study reporting significant changes, and one small study of unknown quality reporting no significant changes. Overall, however, there seem to be significant benefits of yoga for people with cancer.

3.5.4.1 Smith KB, Pukall CF.³¹

An evidence-based review of yoga as a complementary intervention for patients with cancer. Psychooncology 2009 May;18(5):465-75.

Study design and location. Systematic review, Canada.

Number of RCTs included: 6

Objective. To conduct an evidence-based review of yoga as an intervention for patients with cancer. Specifically, this paper reviewed the impact of yoga on psychological adjustment among cancer patients.

Methods. 10 electronic databases (including EMBASE; PsycINFO; PsycARTICLES; Psychology (SAGE); Medline; and The Cochrane Library) were searched. Studies were included if they assessed psychological functioning (e.g. quality of life) and the intervention was yoga on its own rather than yoga as part of an intervention programme. RCTs and non-controlled studies were included, but this report will focus on the RCTs. Quality was assessed using a tool developed by Suydam (1968), and the CONSORT checklist.

Yoga practices used. The style and type of yoga varied, and included amongst others Hatha yoga, Tibetan yoga, Iyengar yoga and Yoga of awareness. Yoga was taught in classes, and home practice encouraged in most cases.

Outcomes studied. The review focussed on psychological outcomes such as anxiety, depression and stress and also included quality of life.

The results. Six RCT studies³²⁻³⁷ were included, as well as four non-controlled studies. The number of participants in the studies ranged from 13 to 398, and numbered 905 in total. However, only 343 were from RCT studies. Participants were either entirely or majority women. Of the RCT studies, 5 recruited women with breast cancer,^{32;33;35-37} and one recruited patients with lymphoma.³⁴

Overall, the RCT studies were thought to be of generally high quality, with standardised measures being used in most cases and comparisons being made between the two study arms for statistical significance. Outcomes reported included anxiety, depression, stress, distress, fatigue, sleep quality, mood, quality of life, spiritual wellbeing and awareness. There was variation between results, with significant and non-significant changes being reported across the outcomes. No clear answer as to the effectiveness of yoga for psychological adjustment in people with cancer emerged. The trials only recruited small number of patients (five of the six studies recruited less than 65 patients), and this may have been too few to detect treatment effects. The authors of the study suggest that further research into what type of patient benefits most (for example, those currently undergoing treatment), and which aspects of yoga practice are most beneficial, is needed.

Is the research good quality and free of bias? Overall, this review was of good quality and free of bias, with a good analysis of the strengths and weaknesses of the included trials, and an appropriately cautious conclusion drawn, given the available evidence. Meta analysis was not attempted, but may have been possible.

Conclusions. The review notes that some positive outcomes are reported, but that generally there is a great deal of variability in results. A thorough search for literature seems to have been done, and a good narrative analysis given. Meta analysis may have been possible but was not discussed or attempted. The review authors conclude that more research into which patient subgroups are most likely to benefit, and which aspects of yoga are most effective is needed.

3.5.4.2 Carlson LE, Culos-Reed N, Daroux LM.³⁸

The effects of therapeutic yoga on salivary cortisol, stress symptoms, quality of life and mood states in cancer outpatients: a randomized controlled study. Annual meeting of the American Psychosomatic Society 2005; Abstract 1342.

Study design and location. Randomised controlled trial, pilot study.

Number of participants: 20 (analysed)

Objective. To assess the effects of yoga on salivary cortisol, stress symptoms, quality of life and mood states in cancer outpatients.

Methods. 20 cancer outpatients who had completed treatment were included and randomised to either yoga group (10 participants) or control group (10 participants).

Yoga practices used. Details about the yoga practice were not given, but were described as therapeutic yoga. The sessions were provided for seven weeks.

Outcomes studied. Salivary cortisol levels were measured from saliva samples, and quality of life, stress symptoms and mood states were measured using questionnaires.

The results. Changes in salivary cortisol levels from the start to the end of the study were not significantly different between the two groups, indicating there was no benefit for the yoga group compared to the control group. Participants in the yoga group reported significant improvements in quality of life and mood disturbance from the beginning to the end of the study. A statistical comparison between the groups is not reported, so only a cautious conclusion as to efficacy can be drawn.

Is the research good quality and free of bias? This study is only reported as a conference abstract and not enough information is provided to assess the risk of bias. As the study is a pilot study with small numbers, it is unlikely to produce statistically significant results.

Conclusions. As the study is a pilot study with small numbers, it is unlikely to produce statistically significant results, and the results should be viewed in this light. The detection of an improvement in quality of life and mood disturbance in the yoga group from the start to the end of the study is promising. Larger studies with between group comparisons are needed to confirm these results.

3.5.4.3 Cohen L, Thornton B, Perkins G.³⁹

A randomized trial of a Tibetan yoga intervention for breast cancer patients. Annual meeting of the American Psychosomatic Society 2005; Abstract 1607.

Study design and location. Randomised controlled trial.

Number of participants: 58 (analysed)

Objective. Effects of a Tibetan yoga intervention for breast cancer patients on intrusive thoughts and avoidance behaviours, cancer related symptoms, mood, sleep disturbances and quality of life.

Methods. Fifty eight patients with stage I to III breast cancer were included. Those included were randomised to Tibetan yoga or wait list control.

Yoga practices used. The intervention consisted of a seven week Tibetan yoga programme which included controlled breathing, visualisation/meditation and postures from Tibetan yoga practices.

Outcomes studied. Patients filled in questionnaires at the start of the study, after one week, and at one and three months. The questionnaires measured intrusive thoughts and avoidance behaviours (Impact of Events Scale - IES), cancer-related symptoms (M.D. Anderson Symptom Inventory), mood, sleep disturbances and quality of life.

The results. Of the 58 included patients, 48% were undergoing active treatment. Patient characteristics were balanced across the two groups. A mixed model analysis revealed a group by time effect for the IES score. Multivariate linear regression, controlling for baseline, showed the yoga group had significantly better cancer-related symptom scores at 1 week, but no other significant changes were noted for mood, quality of life or sleep disturbances.

Is the research good quality and free of bias? This conference abstract did not provide enough information to assess the quality of the study. It is unclear if there were sufficient participants to detect a clinically relevant effect in all outcomes.

Conclusions. Results from this study are promising for beneficial effects of the Tibetan yoga programme for invasive thoughts and avoidance behaviours. No significant changes were seen for quality of life, mood or sleep disturbances and only in the first week for cancer-related symptoms. A full assessment of the quality of this study is not possible as it is only published as a conference abstract, and it is unclear whether enough participants were recruited to detect small effects.

3.5.4.4 Carson JW, Carson KM, Porter LS, Keefe FJ, Seewaldt VL.⁴⁰

Yoga of Awareness program -for menopausal symptoms in breast cancer survivors: results from a randomized trial. Support Care Cancer 2009 Oct;17(10):1301-9.

Study design and location. Randomised controlled trial, USA.

Number of participants: 37 (analysed)

Objective. To evaluate the effects of a yoga intervention on menopausal symptoms in a sample of survivors of early-stage breast cancer (stages IA–IIB).

Methods. Thirty seven early-stage breast cancer survivors, who were experiencing at least one hot flush per day, four days or more per week and who were currently disease-free and not receiving chemotherapy or hormone replacement therapy were recruited. Non-English speaking women, women who could not attend or already attended yoga and women with serious psychiatric disorders were excluded. Even though anti-depressants can reduce hot flushes, women who were taking them were not excluded, so long as they fell within the other inclusion criteria. Other treatments for menopausal symptoms were acceptable, so long as the dose of these had been stable for the previous 3 weeks. Those included were randomised to the yoga group or the wait-list control group. Those in the yoga group received the yoga intervention straight away. Those in the control group were offered the intervention 6 months later.

Yoga practices used. The yoga style followed was Yoga of Awareness. Those in the yoga group received eight weekly classes of 120 minutes. The classes were taught by a certified yoga teacher and a researcher who had undergone comprehensive training; both were experienced in teaching yoga and meditation to medical patients. To standardise delivery, a manual was developed with detailed class guidelines. Classes included asana (poses, for 40 minutes), pranayama (breathing, for 10 minutes), meditation (for 25 minutes), study of pertinent topics (for 20 minutes) and group discussion (for 25 minutes). Participants were encouraged to practise at home and were given a CD and handouts to refer to, and applications to daily life were given each week (e.g. in the moment acceptance of hot flushes).

Outcomes studied. Outcomes were measured at the start of the study (baseline), at the end of the eight weeks of classes and again 3 months after the classes ended. The primary outcome was hot flushes score (frequency per day multiplied by severity, both scored on a 0 to 9 scale by the participants). Other symptoms scored on a 0 to 9 scale included: joint pain, fatigue, negative mood, sleep disturbance, night sweats and bother (menopausal symptom

related distress). Therapeutic process was assessed by scoring relaxation, vigour and acceptance. All were scored using a daily diary, which participants submitted via an interactive telephone voice system.

The results. Between the two groups, participants were statistically similar in terms of age, socio-economic and demographic characteristics, disease stage and treatment type. The average age was 54 years. Statistical tests (multilevel modelling regression analysis) demonstrated significant improvements in the yoga group versus the control group at the end of the eight weeks of classes, for hot flush frequency, severity and overall score. There were also significant improvements in the yoga group for daily joint pain, fatigue, vigour, sleep disturbance and symptom-related bother. Negative mood and acceptance showed a trend towards improvement, whilst night sweats and relaxation were not significantly improved. When three control participants who were practising yoga elsewhere were excluded from the analyses, negative mood and acceptance became significantly improved. At 3 months post intervention, sleep disturbance, night sweats and relaxation were not significantly improved but all other outcomes were.

Is the research good quality and free of bias? This study was very well conducted and should be free from most sources of bias. Blinding of participants and instructors was not possible, but outcome assessors were blind to which treatment group participants were in. Incomplete data was well handled and the statistical analyses seem appropriate. The main drawback is the small number of participants which marginally missed the number needed to detect a moderate effect.

Conclusions. This high quality pilot study reports very promising results which suggest yoga may be an effective treatment for hot flushes and most menopausal symptoms in women who have survived breast cancer. The study was a pilot study; results from a larger study are required to confirm these encouraging findings.

3.5.4.5 Danhauer SC, Mihalko SL, Russell GB, Campbell CR, Felder L, Daley K, et al.⁴¹

Restorative yoga for women with breast cancer: findings from a randomized pilot study. Psychooncology 2009 Apr;18(4):360-8.

Study design and location. Randomised controlled trial, USA.

Number of participants: 44 (analysed)

Objective. To determine the feasibility of implementing a restorative yoga intervention for women with breast cancer; and to examine group differences in self-reported emotional, health-related quality of life, and symptom outcomes.

Methods. Forty four patients with breast cancer who were 18 years or older and were between 2 and 24 months post-primary treatment, and/or had had a recurrence in the last 24 months were included. Patients who were not physically able to attend, could not understand English or who had medical contraindications were excluded. Those included were randomised to a yoga group, or a waiting list control group. Those in the yoga group received yoga classes. Those in the control group remained on the waiting list and were offered classes after the end of the study. All participants completed questionnaires at the beginning and after the last session (10 weeks).

Yoga practices used. Sessions focussed on restorative yoga and were taught by a qualified instructor who was also a cancer survivor. Participants were taught asana (postures), pranayama (breathing) and deep relaxation (savasana). Ahimsa (non-violence), one of the five yamas (ethical guiding principles), was emphasised during practice. This translates as being gentle with oneself and avoiding positions which cause pain. Sessions were 75 minutes long and were provided for ten weeks. Attention to breath was also encouraged.

Outcomes studied. Health related quality of life using SF-12 and FACT-B questionnaires; Fatigue, using FACT-Fatigue questionnaire; Spiritual wellbeing, using FACIT-Spirituality; Depression, using Centre for Epidemiologic studies depression scale (CES-D); Sleep quality, using Pittsburgh sleep quality inventory (PSQI); Mood, using Positive and Negative affect schedule (PANAS). The programme was evaluated through participant feedback and the feasibility assessed by examining recruitment, attendance and drop out rates, adverse events and programme satisfaction. These outcomes are not reported here.

The results. Of the 44 women who participated, most had minimal previous experience of yoga. The mean age was 56 years. The mix of participants in terms of age, socio- economic and demographic characteristics, disease stage, treatment type and attendance at classes was statistically similar between the groups. Outcomes were mixed. Health related quality of life was statistically significantly more improved in the yoga group when just the mental health section of the SF-12 was considered. Results for the physical health section were not statistically significantly different. Likewise, results for the positive affect (mood) section of PANAS were improved, and for the peace/meaning section of FACIT-Spirituality, whilst results for the role of faith section were not. Other measures were not significantly more improved in the yoga group, but in most cases the trend was for yoga participants' scores to be better. Other analyses of the data suggest some patients benefit more from yoga than others, for example those with lower emotional wellbeing and worse mood at the start.

Is the research good quality and free of bias? Overall, this study did not provide enough information to assess the quality and potential for bias. Statistical analyses were well planned and appropriate, though conclusions were limited by the number of participants and pilot nature of the study. Whilst all outcomes have been reported, some results for particular sections of questionnaires seem to be missing.

Conclusions. Results from this study are generally positive, and whilst not all analyses reached statistical significance, the trends in the data suggest there are potentially important benefits for yoga in this population. Patients with worse mood and lower emotional wellbeing may benefit more. A larger trial with better reporting (methods of randomisation, blinding etc) could be performed to explore these results in different subsets of patients.

3.5.4.6a Vadiraja HS, Rao MR, Nagarathna R, Nagendra HR, Rekha M, Vanitha N, et al.⁴²

Effects of yoga program on quality of life and affect in early breast cancer patients undergoing adjuvant radiotherapy: a randomized controlled trial. Complement Ther Med 2009 Oct;17(5-6):274-80.

3.5.4.6b Raghavendra RM, Vadiraja HS, Nagarathna R, Nagendra HR, Rekha M, Vanitha N, et al.⁴³

Effects of a yoga program on cortisol rhythm and mood states in early breast cancer patients undergoing adjuvant radiotherapy: A randomized controlled trial. Integr Cancer Ther 2009 Mar;8(1):37-46.

These two publications are based on the same study, but Vadiraja et al (2009) reports quality of life and mood (affect) data, whilst Raghavendra et al (2009) reports data on cortisol rhythms and mood states (stress, anxiety and depression).

Study design and location. Randomised controlled trial, India.

Number of participants: 88 (analysed)

Objective. This study compares the effects of an integrated yoga program with brief supportive therapy in breast cancer outpatients undergoing adjuvant radiotherapy at a cancer centre.

Methods. Eighty eight patients with stage II and III breast cancer outpatients who were newly diagnosed with operable breast cancer, were scheduled to have radiotherapy, were between 30 and 70 years of age and had a high school education were included. Patients with concurrent conditions including psychiatric illness were excluded, as were patients who had known metastases or were prescribed concurrent chemotherapy. Those included were randomised to yoga intervention group and control group. Those in the yoga group received an integrated yoga programme designed to promote a sense of calmness and relaxation with a perceptible change in coping with day to day stresses. Participants were expected to attend a minimum of three sessions per week for six weeks and to practice at home on the other days. Those in the control group received the brief supportive therapy with education that is routinely offered to patients as a part of their care in the study center. Participants and their carers received three or four 15 minute sessions (once every ten days). This was thought to control for non-specific aspects of yoga such as attention, support and a sense of control.

Yoga practices used. The yoga intervention consisted of a set of asanas (postures), pranayama (breathing), meditation, and yogic relaxation techniques with imagery (mind sound resonance technique and cyclic meditation).

Outcomes studied. Vadiraja et al (2009) reported results from the Positive and Negative Affect Schedule (PANAS) which measures aspects of mood and state of mind, and the European Organisation for Research and Treatment of Cancer-Quality of life C30 (EORTCQoL C30) which measures health related quality of life in people with cancer. Raghavendra et al (2009) reported results from the Hospital Anxiety and Depression Scale (HADS) and the Perceived Stress Scale (PSS). Levels of cortisol (a stress hormone) were also measured from saliva both before and after radiotherapy in both groups.

The results. The 88 participants were randomised with 44 in each group. The groups seem to be similar at the start of the trial in terms of age, histopathology, treatment type and marital status, though there seem to be more patients with grade III cancer in the control group. Statistical analysis is not provided for baseline characteristics. The publication by Vadiraja et al (2009) reports that statistical ANOVA analysis between yoga and control groups showed the yoga group had significantly better results than the control group for positive affect, decreased negative affect, improved emotional function and cognitive function. There was no significant change in social function and role function in either group. The publication by Raghavendra et al (2009) reports that the yoga group had significantly

lower cortisol levels than the control group at 6am in the morning, but not at 9am and 9pm. Both groups showed a significant decrease in anxiety, stress and depression scores, and the yoga group fared significantly better when compared to the control group.

Is the research good quality and free of bias? Overall, this study was reasonably free of bias, but failed to score well for some aspects of blinding. Whilst participants were impossible to blind, some study personnel who could have been blinded were not. This may have lead to patients being treated differently according to which group they were in, though this may not have had a big effect on outcomes. Data analysis seems to have been handled well. There were just enough patients recruited for there to be enough to detect a moderate effect.

Conclusions. Results from this study are very promising. Yoga improved aspects of mood (affect), and emotional and cognitive functioning as measured by the EORTCQoL C30 when compared to the control group. No improvements in social or role function were seen in either group. Salivary cortisol levels show a decrease in the stress hormone at 6am in the morning, but not at other times. Depression and anxiety decreased significantly more in the yoga group than the control group.

3.6 Depression

3.6.1 What is depression

Depression is a mental health condition which is characterised by feelings of sadness and low spirits which last for more than a few weeks, or recur often. Symptoms can range from mild to severe. At their mildest, people feel sad and everything is more of an effort. At their worst, people may feel suicidal and lose the will to live. Depression has many causes, including life events such as a traumatic experience or bereavement, illness, giving birth (post natal depression), and personality traits such as low self esteem.⁴⁴ Lifestyle choices such as not taking enough exercise, eating a poor diet, or using recreational drugs can also contribute. Treatments for depression include prescription medications, talking therapies and exercise.⁴⁵

3.6.2 Studies found. We found two systematic reviews of yoga for depression. One was published in 2005 and a different group of researchers updated that review in 2010. No further studies were found since 2010. Both reviews are reported here.

3.6.3 Depression summary

Both reviews draw positive conclusions about yoga for people with depression, and one of these reviews was of very high quality. Whilst the evidence is not conclusive, and questions about which groups benefit most and which aspect or aspects of yoga are most beneficial, the evidence suggests yoga may be of benefit to at least some people with depression.

3.6.4.1 Pilkington K, Kirkwood G, Rampes H, Richardson J.⁴⁶

Yoga for depression: The research evidence. J Affect Disord 2005 Dec;.89(1-3).

Study design and location. Systematic review, UK.

Number of RCTs included: 5

Objective. The aim of this study is to systematically review the research evidence on the effectiveness of yoga for depression.

Methods. 12 electronic databases (including Medline, CINAHL, AMED and Cochrane databases) were searched from inception to 2004. Randomised controlled trials which included patients with depression or depressive disorders, and used a yoga intervention were eligible for inclusion. Studies which used meditation alone or a complex intervention with non-yoga elements (such as MBSR) were excluded. Quality assessment was performed using a set of questions adapted from the 2001 version of the Centre for Reviews and Dissemination guidelines, which is a well regarded quality assessment tool. Data extraction and quality assessment were performed by two reviewers separately, and discrepancies resolved by discussion.

Yoga practices used. Any yoga style was eligible for inclusion. Amongst the studies found, practices included a yoga relaxation technique called Broota yoga,⁴⁷ a study of the benefits of Savasana,⁴⁸ two studies^{49;50} of the benefits of SKY (Sudarshan Kriya Yoga, which consists mainly of pranayama/breathing exercises) and a study of Iyengar yoga⁵¹ (which

consisted mainly of asanas/postures). The interventions varied in length from three days to regular sessions over five weeks.

Outcomes studied. Depression as measured by depression rating scales.

The results. 5 studies were included,⁴⁷⁻⁵¹ with a total of 183 participants across the studies. All studies reported that yoga was effective when comparing depression levels at the start and end of the trial in the yoga groups. However, between group comparisons were only reported for the study of savasana, where yoga was statistically significantly better than the control group. One three-arm trial⁴⁹ of yoga, electroconvulsive therapy (ECG) and imipramine showed yoga (SKY) was not as effective as ECG, but was comparable to drug therapy with imipramine. In the other studies, yoga performed better than the comparator in pre-post tests.

Is the research good quality and free of bias? This is a high quality systematic review that includes a thorough search of the literature and good considerations of the limitations of the included studies. The authors conclude that the methods used in the studies are poorly reported and there is a risk of bias having been introduced to the results. Meta analysis was not done and this was appropriate because the study populations and interventions were not similar enough to do so.

Conclusions. The authors conclude that yoga interventions are potentially beneficial for people with depression, but add a few cautions: the interventions were not well described, and used mixed techniques, making it difficult to tell whether all or just some aspects are active; the populations were of differing severities and different ages, so it is unclear whether some populations may derive more benefit than others, and whether the results can be generalised to the whole population; the doubt about study quality and risk of bias means results should be interpreted with caution. Overall, the authors are enthusiastic about the potential benefits of yoga as a low risk, non-pharmacological treatment for depression, that is worthy of further study.

3.6.4.2 Mehta P, Sharma M.⁵²

Yoga as a complementary therapy for clinical depression. Complementary Health Practice Review 2010 Oct;.15(3).

Study design and location. Systematic review, USA.

Number of RCTs included: 10

Objective. To examine research regarding the benefits of yoga for depression.

Methods. Three electronic database (CINAHL, Medline and ERIC), were searched from 2005 to 2010. Studies were included if they were in English, measured depression or depressive symptoms, used yoga as an intervention and were either a randomised controlled trial (RCT), a quasi-experimental study, or a pretest-posttest design. This summary will focus on the results from the RCTs . No quality assessment was performed.

Yoga practices used. Yoga practices varied across the ten studies, and included Iyengar yoga (asana/poses pranayama/breathing, relaxation), SKY (Sudarshan Kriya Yoga, which consists mainly of pranayama/breathing exercises), Sahaj yoga (meditation), Yoga as part of a programme (Inner resources programme which included guided imagery and mantra repetition as well as Hatha yoga practices), Silver yoga (hatha yoga for the elderly), Integral

yoga (asana/poses with breathing/pranayama and awareness), Ashtanga yoga and Integrated yoga (asana/poses, breathing/pranayama, meditation, relaxation with imagery).

Outcomes studied. Depression as measured by depression rating scales.

The results. Ten RCTs were included in the study, but the number of participants in the studies was not reported. Some studies only included those with depression,⁵³⁻⁵⁷ whilst other studies looked at the effects of yoga on depression levels in people with other conditions such as cancer (Culos-Reed et al 2006 and Danhauer 2009 reported elsewhere in this report),^{35;41;58} alcohol dependency,⁵⁹ and back pain (Williams et al, 2009, also reported elsewhere in this report)²⁸ where depression is a common co-morbidity. Control groups included wait-list, usual care, ayurveda herbal treatment, hypnosis, psychoeducation and antidepressants.

Results were often expressed as pre to post test differences, rather than differences between the changes seen in each group. Eight out of the ten studies reported significant decreases in levels of depression for the yoga group, and in all cases the yoga group fared better than the control groups. Of the four studies which did express results as differences in the change in each group, all showed yoga to be significantly better than the control groups (which comprised usual care, psychoeducation with and without hypnosis, wait list or supportive therapy). There was no discussion about the clinical significance of the changes seen.

Is the research good quality and free of bias? This review is of fairly low quality. Some studies may have been missed due to a limited search strategy, and more importantly, no quality assessment was performed on the included studies. As such, the risk of bias of individual studies and the body of evidence as a whole is unknown. Results were poorly organised, and an overall conclusion based on RCTs alone not given.

Conclusions. Whilst this review is of a generally poor quality and the risk of bias within the included studies is unknown, the overwhelming majority of studies found some beneficial effects of yoga for depression. Conclusions have to be drawn with caution as between group comparisons were not always performed, but it is likely that yoga is of benefit to people suffering depression.

3.7 Diabetes and Cardiovascular disease

3.7.1 What are diabetes and cardiovascular disease?

Diabetes and cardiovascular disease are highly related conditions. Those with diabetes are five times more likely to suffer from cardiovascular disease. This is because long term fluctuations in blood glucose affect the lining of the arteries and increase the chances that furring of the arteries will occur. In addition, many of the risk factors which lead to diabetes such as poor diet are also highly associated with cardiovascular disease.⁶⁰

3.7.2 Studies found

We found one systematic review which considered yoga for insulin resistance syndrome and cardiovascular disease, and three RCTs published subsequently which focussed on type 2 diabetes. We found a further three RCTs relating to cardiovascular health.

3.7.3 Diabetes and cardiovascular disease summary

The systematic review reported that results suggest yoga has positive benefits in reducing risk factors for diabetes and cardiovascular disease in healthy people and those with risk factors, but that further large high quality studies are needed. The three RCTs which looked at yoga for reduction of risk factors in those with metabolic syndrome, those at high risk of type 2 diabetes, and those with type 2 diabetes found mostly positive trends toward improvements, but these trends did not reach significance. The studies reporting the least positive results also had the most problems with attendance. Motivation and adherence is a problem in this patient group, and future research should attempt to improve these factors to get a better picture of the potential benefits of yoga for prevention and treatment of type 2 diabetes.

Two of the RCTs which studied yoga for cardiovascular disease recruited patients with hypertension, whilst one study recruited people who had experienced heart failure. All three studies reported positive results for yoga in these groups, including improvements in blood pressure, pulse rate, fitness and stress and in flexibility and blood serum markers. Positive trends were found for girth, quality of life and BMI. One study extended its recommended use of yoga only to mild and moderate cases of hypertension.

3.7.4.1 Innes KE, Bourguignon C, Taylor AG.⁶¹

Risk indices associated with the insulin resistance syndrome, cardiovascular disease, and possible protection with yoga: a systematic review. J Am Board Fam Pract 2005;18(6):491-519.

Study design and location. Systematic review, USA.

Number of RCTs included: 22

Objective. This systematic review assesses the effects of yoga on risk factors associated with insulin resistance syndrome (metabolic syndrome) and cardiovascular disease, and on related clinical endpoints. The review includes studies in healthy people and people with or at risk for cardiovascular disease.

Methods. Four electronic databases (MEDLINE, PubMed, PsycINFO and IndMED) were searched for English-language studies published from 1970 to 2004. Randomised controlled trials (RCTs) and non-randomised studies were included. Quality was assessed according to criteria. Data were not pooled in a meta-analysis due to differences between studies.

Yoga practices used. Yoga interventions ranged from 2 days to 12 months. Some included single or multiple components of yoga (such as postures, breathing, or relaxation) while others combined yoga with interventions such as lifestyle advice, diet, stress management.

Outcomes studied. Changes in cardiovascular risk factors such as weight, blood pressure, insulin resistance, and lipid profiles; oxidative stress and coagulation profiles; and clinical endpoints such as medication use and CVD progression.

The results. The review included 22 RCTs^{3,62-82} (Murugesan et al 2000,⁶⁶ Harinath et al 2004³ also reported elsewhere in this report) and 48 non-randomised studies. Studies were of variable quality, most were small, and almost 70% were conducted in India. Most were conducted in healthy adults (50%) or adults with or at risk for cardiovascular diseases (30%).

The included studies showed beneficial effects of yoga on cardiovascular risk factors. Of 13 studies assessing insulin resistance, most reported improvements, with 2 of 2 small RCTs showing trends for improvement versus controls. Of 14 studies assessing lipid profiles, most reported improvements, with 4 of 5 RCTs showing improvements (some significant) versus controls. Of 18 studies assessing body weight, most reported improvements, with 5 of 6 RCTs showing improvements versus controls. Of 37 studies assessing blood pressure, over 75% reported improvements, with 11 of 14 RCTs showing significant improvements versus controls. There were improvements in outcomes such as oxidative stress and coagulation profiles, and clinical endpoints such as medication use and CVD progression.

Is the research good quality and free of bias? Overall, this review was of high quality. Several databases were searched, results were presented for both randomised and non-randomised studies, several outcomes were reported, and study quality was considered.

Conclusions. Collectively, the included studies suggest that yoga may reduce risk factors for insulin resistance syndrome and cardiovascular disease and improve clinical outcomes, both in healthy populations and in people with or at risk for cardiovascular disease. However, the variability in study quality, lack of studies in western populations, and small sample sizes suggest that further high quality RCTs are needed to confirm these findings.

3.7.4.2 Cohen BE, Chang AA, Grady D, Kanaya AM.⁸³

Restorative yoga in adults with metabolic syndrome: a randomized, controlled pilot trial. Metab 2008;6(3):223-9.

Study design and location. Pilot randomised controlled trial, USA.

Number of participants: 24 (analysed)

Objective. To determine whether a restorative yoga intervention was feasible and acceptable in underactive, overweight adults with metabolic syndrome.

Methods. 26 underactive, overweight adult men and women aged 30 to 65 with metabolic syndrome (increased risk of diabetes and cardiovascular disease) were randomised to yoga and control groups, and 24 completed the study. The yoga group attended 15 yoga sessions

of 90 minutes each over 10 weeks, were instructed to practice at home for 30 minutes three times per week, and received a log book, yoga props, manual and CD. The control group received no intervention (and were placed on a waiting list for yoga classes).

Yoga practices used. Restorative yoga, a form of yoga that emphasises relaxation and uses props to provide total support of the body. Each class consisted of brief warm-up stretches and breathing exercises followed by 10 poses held for 5–10 minutes each.

Outcomes studied. This pilot study assessed adherence to and acceptability of the yoga intervention, measures of well-being, and metabolic outcomes e.g. weight, body mass index (BMI), blood pressure, insulin sensitivity, blood glucose and lipid levels, over 10 weeks.

The results. Of 26 participants, 24 (92%) completed the trial. Attendance at yoga classes and adherence to home practice were good. All yoga participants reported being “very satisfied” with the yoga intervention, and the majority (87%) felt that the yoga poses were easy to perform. In the yoga versus control group, changes in blood pressure (-9.2mmHg), weight (-2.3kg) and BMI (-0.9kg/m²) favoured the yoga group, though differences were not statistically significant. There was a significant increase in energy level and trends towards improvement in well-being and stress in the yoga versus control group. Laboratory measures (insulin sensitivity, blood glucose, triglycerides and cholesterol), physical activity and dietary intake did not differ significantly between groups.

Is the research good quality and free of bias? Overall, this study was of reasonable quality, with all relevant outcomes reported, though blinding of outcome assessors was not clear. This was a pilot study assessing feasibility of yoga in this patient group, and probably did not include enough participants to detect significant differences in all clinical outcomes.

Conclusions. Restorative yoga was a feasible and acceptable intervention in underactive, overweight adults with metabolic syndrome in this pilot study. There were trends towards improvements in some clinical and psychological outcomes compared with a control group, but these did not reach statistical significance and would benefit from further testing in a larger trial.

3.7.4.3 Skoro-Kondza L, Tai SS, Gadelrab R, Drincevic D, Greenhalgh T.⁸⁴

Community based yoga classes for type 2 diabetes: an exploratory randomised controlled trial. BMC Health Serv Res 2009;9.

Study design and location. Exploratory randomised controlled trial, UK.

Number of participants: 59 (analysed)

Objective. To explore the feasibility of community-based yoga classes in patients with type 2 diabetes.

Methods. 59 adult men and women with type 2 diabetes, not taking insulin, and living in one of two multi-ethnic boroughs in London (UK) with average and low socio-economic deprivation scores, were randomised to yoga and control groups. The mean age was 60 years. The yoga group were offered 24 yoga classes of 90 minutes, twice-weekly for 12 weeks, and received a yoga mat and belt, leaflet of yoga exercises, and audiotape. The control group received no intervention (and were placed on a waiting list for yoga classes). Both groups received advice and leaflets on healthy lifestyle and were encouraged to exercise.

Yoga practices used. Primarily breathing and relaxation (pranayama), plus gentle stretching and postures (asanas). Classes were run by an experienced yoga teacher who adapted the exercises to the needs and abilities of the participants.

Outcomes studied. Plasma glucose (HbA1c), weight, waist circumference, lipid levels, blood pressure, UKPDS cardiovascular risk score, diabetes-related quality of life, measured at 12 weeks and 6 months, plus adherence to and acceptability of the yoga intervention.

The results. Two-thirds of patients on general practice diabetic registers were ineligible, and 90% of the remainder declined to participate. Attendance at classes was 50%, and no participants did the exercises regularly at home. Participants reported enjoying the classes and feeling much better after a class. However, several patients required tailoring of the exercises, and yoga teachers felt that most participants were unsuitable for 'standard' yoga exercises because of limited flexibility, lack of basic fitness, co-morbidity, and lack of confidence. 80% of participants showed a fall in blood glucose during the class. There was a small decrease in plasma glucose (HbA1c) in the yoga group at 12 weeks, but this was not statistically significant and was not sustained six months later. There were no statistically significant differences between the yoga and control groups on any outcomes.

Is the research good quality and free of bias? Overall, this study was of reasonable quality, with all relevant outcomes reported, though blinding of outcome assessors was not clear. This was an exploratory study assessing feasibility of yoga in this patient group, and it was unclear if there were enough participants to detect significant differences in outcomes.

Conclusions. This exploratory trial of community-based yoga classes in type 2 diabetes did not show statistically significant differences in outcomes compared with a control group. Possible explanations include recruitment challenges; practical and motivational barriers to class attendance; barriers to engaging in the exercises; inadequate intensity and/or duration of yoga intervention; and insufficient personalisation of exercises to individual needs. All these factors should be considered when designing future trials.

3.7.4.4 Yang K, Bernardo LM, Sereika SM, Conroy MB, Balk J, Burke LE.⁸⁵

Utilization of 3-month yoga program for adults at high risk for type 2 diabetes: A pilot study. Evidence-based Complementary and Alternative Medicine 2578;2011 , 2011. Article Number:257891.

Study design and location. Pilot randomised controlled trial, USA.

Number of participants: 23 (analysed)

Objective. To assess the feasibility of a 12-week yoga program among adults at high risk for type 2 diabetes, to begin examining whether yoga improves cardio-metabolic risk factors, and to examine the effect of yoga on exercise self-efficacy.

Methods. 23 adults (2 male, 21 female) at high risk for type 2 diabetes, age 45 to 65, currently undertaking little exercise, were randomised to yoga and control groups. The yoga group attended 24 yoga sessions of 60 minutes each, twice per week for 12 weeks, were instructed to practice at home and received an instructional CD. The control group received general health educational materials every 2 weeks including diet and exercise advice.

Yoga practices used. Vinyasa style yoga (based on hatha yoga but more fitness-based), including a warm-up, physical postures (asanas) modified to meet participants' needs, breathing exercises (pranayamas), and a relaxation period.

Outcomes studied. Clinical outcomes (blood pressure, blood glucose, insulin, lipid levels, weight, BMI), adherence to and acceptability of the yoga programme, and exercise self-efficacy (confidence in ability to engage in day-to-day exercise), measured at 12 weeks.

The results. All yoga group participants completed and expressed high satisfaction with the program, and session attendance ranged from 58% to 100%. Compared with the education group, the yoga group showed trends for improvements in weight, blood pressure, insulin and triglycerides, though these did not reach statistical significance, while fasting glucose level and HDL and LDL cholesterol showed small or no changes. The yoga group showed a non-significant trend for improvement in exercise self-efficacy versus the education group.

Is the research good quality and free of bias? Overall, this study was of fairly high quality, with all relevant outcomes reported and blinded outcome assessment. This was a pilot study aiming to assess feasibility of yoga in this patient group, and probably did not include enough participants to detect significant differences in clinical outcomes.

Conclusions. This pilot study indicates that a yoga program was a feasible and acceptable intervention for underactive adults at high risk for type 2 diabetes. There were trends towards improvements in some clinical outcomes compared with a control group, as well as in exercise self-efficacy (confidence in ability to engage in day-to-day exercise), but these did not reach statistical significance and would benefit from further testing in a larger trial.

3.7.4.5 McCaffrey R, Ruknui P, Hatthakit U, Kasetsoomboon P.⁸⁶

The Effects of Yoga on Hypertensive Persons in Thailand. Holistic nursing practice 2005;19(4):173–18.

Study design and location. Randomised controlled trial*, Thailand (academic collaboration with USA).

Number of participants: 54 (analysed)

Objective. To determine the effectiveness of a yoga programme on blood pressure and stress amongst people with hypertension in Thailand.

Methods. 61 patients with (BP>140/90 mm Hg) who were not taking antihypertensive medications were included, though 7 did not complete the study due to lack of time (5 from yoga group), commencing medication (1 from control group) and moving away (1 from control group). Those included were randomised to yoga group or control group, using stratified randomisation to ensure that patient characteristics were balanced across groups. Characteristics that might affect yoga practice (emotional or physical stress crisis, smoking and alcohol use and excessive salt consumption) were measured at baseline and at follow-up. Patients with these confounding factors were dropped. Those in the yoga group received booklets and a cassette tape. Those in the control group received usual care, which included advice about diet and exercise.

Yoga practices used. The booklets and cassette tapes contained yoga advice and instructions about hypertension and stress management. The programme was to be

practiced three times per week for eight weeks and included pranayama (breathing), deep relaxation and 14 yoga asana postures.

Outcomes studied. The Stress Assessment Questionnaire (SAQ), modified from the Stress of Symptom Inventory (SOS) was used to determine stress levels. Physiological data, including blood pressure (systolic and diastolic), heart rate and body weight (body mass index (BMI)), were taken from the patient's medical records. Those in the yoga group kept a Yoga Practice Record Form. Outcomes were recorded at the start of the study and every two weeks until the end of the intervention period (8 weeks).

The results. 54 patients completed the study, but it is not clear if the confounding factors listed above lead to any participants being dropped from data analysis. Patient characteristics at the start of the study were balanced across groups. Repeated-measures ANOVA analysis of stress scores showed they were significantly improved in the yoga group at the end of the 8 weeks compared to the control group. Likewise, Systolic blood pressure, diastolic blood pressure and heart rate were significantly improved at 2,4,6 and 8 weeks and body mass index was significantly improved at 6 and 8 weeks in the yoga group but not the control group. When the mean values were compared between groups at each time point, the significance was maintained for all outcomes except BMI reduction, though a trend towards reduced BMI was maintained.

Is the research good quality and free of bias? This study did not provide enough information to assess the quality and potential for bias. There is a lack of clarity around which patients were included in the analysis, and the whole study is poorly written up. In addition, a power calculation was not provided so it is not possible to tell whether enough patients were included and whether the positive effects seen are clinically significant.

Conclusions. Results from this study suggest that this yoga programme had positive effects on blood pressure and heart rate in hypertensive patients. The effects on body mass index are less robust, which may be due to length of follow up or small sample numbers. It was not possible to assess this study's risk of bias due to poor reporting. These positive and promising results require confirmation in a larger study of better quality.

3.7.4.6 Murugesan R, Govindarajulu N, Bera TK.⁶⁶

Effect of selected yogic practices on the management of hypertension. Indian J Physiol Pharmacol 2000 Apr;44(2):207-10.

Study design and location. Randomised controlled trial, India.

Number of participants: 33 (11 in each of 3 groups)

Objective. To assess the effect of selected yogic practices on the management of hypertension.

Methods. 33 patients with hypertension who were aged 35 to 65 years were included. Those included were randomised to either a control group who received no intervention but careful monitoring, an experimental group who received a yoga intervention, and another experimental group who received anti-hypertensive drugs (beta-blockers, sympatholytic calcium channel blockers, ACE inhibitors). The study lasted 11 weeks.

Yoga practices used. The yoga intervention was given morning and evening for one hour each, 6 days per week, for 11 weeks. The intervention consisted of a set of asana (postures), Nadi-sodhana pranayama (breathing), chanting Om and meditation.

Outcomes studied. The outcomes measured were systolic blood pressure, diastolic blood pressure, pulse rate and body weight.

The results. Between group comparisons showed that the change in blood pressure, pulse rate and body weight were all significantly better in the yoga group compared to the anti-hypertensive group. In addition, all outcomes were better in the yoga group compared to the control group, and in the drug group compared to the control group.

Is the research good quality and free of bias? This study did not provide any information about measures taken to avoid bias. The risk of bias is therefore unknown. The number of patients included is small, and the study population inclusion criteria are poorly defined, and rely on clinician opinion.

Conclusions. This study shows very promising results for the use of yoga in hypertensive patients. However, the authors point out that only mild and moderate cases should be managed without drugs, and as the study population was not clearly defined in terms of severity of hypertension, it is unclear who is most likely to benefit and how this might vary with severity of hypertension.

3.7.4.7 Pullen PR, Thompson WR, Benardot D, Brandon LJ, Mehta PK, Rifai L, et al.⁸⁷

Benefits of yoga for African American heart failure patients. Med Sci Sports Exerc 2010 Apr;42(4):651-7.

Study design and location. Randomised controlled trial, USA.

Number of participants: 40 (analysed)

Objective. To assess the effects of low-intensity yoga on medically stable heart failure patients.

Methods. 40 patients with systolic and diastolic heart failure (New York Heart Association class I to III) who were medically stable, able to walk unaided, and on stable therapy for at least 3 months previously were included. Patients who had a life expectancy less than 6 months, were pregnant or breast-feeding, were unable to attend twice a week or who were addicted to drugs or alcohol were excluded. All patients received standard medical care, which included education and a brochure about home walking to follow. Those included were randomised to either the yoga group or the control group. Those in the yoga group received a hospital based yoga programme. Those in the control group received standard care.

Yoga practices used. The yoga classes were taught by a qualified instructor (Yoga Alliance, USA) who had 20 years experience in the field of cardiac rehabilitation. Classes were one hour in length and participants were expected to attend 16 sessions in an eight to 10 week period. The practice included breathing (pranayama), asanas (postures, including standing poses, seated poses, balances, forwards and backwards bends, and twists), meditation and relaxation. Postures were adapted to individual needs, with use of the wall for standing poses, and a chair where required.

Outcomes studied. A primary outcome was not identified, but a number of outcomes were measured. Fitness tests included a graded treadmill test, electrocardiogram to measure heart activity, blood pressure, flexibility (sit and reach test) and girth (waist and hips) at the start of the study and at the end (two months later). Blood tests included measures of serum markers IL-6, hs-CRP and EC-SOD. Quality of life was measured with the MLwHFQ (Minnesota living with heart failure questionnaire).

The results. 40 patients were included, 17 females and 23 males. Ages ranged from 31 to 76 years and 95% were African American. 21 patients were randomised to the yoga group, 19 to the control group. Three participants from each group did not complete the study. Patient clinical characteristics were similar in each group, though slightly more had diastolic dysfunction in the control group. Patients in the yoga group improved significantly more ($P=0.002$) than those in the control group (who did not improve at all) when performing treadmill tests at the start and end of the study (yoga group increased treadmill time by 22% compared to control group who increased treadmill time by 5%). Likewise, changes in V_{O_2} peak values (volume of oxygen consumed) were significantly better ($P=0.003$) in the yoga group than the control group, who showed a trend towards worsening V_{O_2} peak values. All serum markers were significantly more improved in the yoga group, as was flexibility, though quality of life results and girth measures failed to show a significant difference.

Is the research good quality and free of bias? Overall, this study did not provide enough information to assess the quality fully, though some things were done well. It is not clear how randomisation was achieved or if allocation concealment was attempted. Outcome assessors were blind, and all results seem to have been reported. It is not clear if the number of patients included were enough to detect small or clinically significant changes. The study may be underpowered, and some bias may have occurred through lack of blinding and allocation concealment. A more robust study outcome may have been mortality at one year.

Conclusions. Results from this study suggest yoga for African Americans with heart failure may be beneficial to overall fitness, flexibility, and serum markers of cardiovascular health, though conclusions should be confirmed by further better quality and larger studies. Benefits to quality of life and girth were not reported, though it is possible that the length of follow-up and/or the size of the sample were inadequate to detect such an effect.

3.8 Menopause

3.8.1 What is menopause?

Menopause is the time in a women's life when menstruation gradually comes to a stop. The average age of menopause is 52. Because of hormonal changes, menopause is often accompanied by symptoms such as hot flushes, night sweats and irritability. Treatments for severe symptoms include Hormone Replacement Therapy (HRT), clonidine and antidepressants.⁸⁸ Many women seek to control symptoms through self help, such as yoga.

3.8.2 Studies found.

We found one systematic review on yoga for women going through the menopause.

3.8.3 Menopause summary.

Evidence from the two RCTs found by the review show statistically significant improvements in some aspects of cognitive function and perceived stress for those practicing integrated yoga. Surprisingly, there were no statistically significant differences between intervention and control groups for overall menopausal symptoms, quality of life, mood, depression, satisfaction with life and sleep quality. Some non-significant trends were observed and improvements in the integrated yoga group for GCS, VCL and neuroticism were seen. This may indicate that there is some therapeutic benefit for patients.

3.8.4.1 Innes KE, Selfe TK, Vishnu A, Innes KE, Selfe TK, Vishnu A.⁸⁹

Mind-body therapies for menopausal symptoms: a systematic review. Maturitas 2010 Jun;66(2):135-49.

Study design and location. Systematic review, USA.

Number of RCTs included: 21 papers in total, 2 RCT on Yoga, 5 uncontrolled clinical trials (UCT).

Objective. To systematically review the peer-reviewed literature regarding the effects of self-administered mind-body therapies on menopausal symptoms.

Methods. 10 electronic database (MEDLINE, CINAHL, Academic Search Complete, Cochrane Library (Cochrane Central Register of Controlled Trials), PsycINFO, PsycARTICLES, Alt HealthWatch, IndMED, Health Source: Nursing/Academic Edition, and SPORTDiscus with Full Text.) were searched from inception to November 2009. Additional hand searching was also performed. Studies regarding the effects of any self-administered mind-body therapy (relaxation and stress-reduction therapies, e.g. biofeedback, imagery, yoga and meditation, breathing exercises, tai chi, qigong, pilates, mindfulness-based stress reduction programs, progressive muscle relaxation, etc) on menopausal symptoms were included. Studies that evaluated only conventional exercise or cognitive behavioural therapy programs, did not specifically target menopausal symptoms, or were not available in English were excluded. Quality assessment was performed using a checklist for mind-body therapies.

Yoga practices used. The two RCT studies of yoga used integrated yoga^{90;91} and Iyengar yoga.^{92;93} The integrated approach included 1 hour classes 5 days per week for 8 weeks, with poses, breathing, meditation and lectures. The Iyengar approach included two 90 minute classes per week with results recorded over 4 months. Weekly home practice sheets

were given to encourage home practice. Practice included poses and meditation and used props.

Outcomes studied. Outcomes studied across the two RCTs include Greene Climacteric Scale (GCS; includes psychosocial, somatic, vasomotor, sexual), Utian Quality of Life Scale (UQOL), Vasomotor Symptom Checklist (VCL; includes hot flushes, night sweats, disturbed sleep, daily interference and symptom related bother), Pittsburgh Sleep Quality Index, and various cognitive and psychological tests for stress and/or depression.

The results. The two included RCTs reported both between group and within group comparisons. Between group comparisons from the Chattha studies of integrated yoga^{90;91} showed statistically significant differences in improvement between the control group and intervention group for cognitive tests and stress. Near-significant trends towards improved GCS and VCL were also noted, with one significant result for vasomotor symptoms as measured by the GCS questionnaire. No significant differences between groups were found for neuroticism. Within group comparisons showed that the intervention group participants were statistically significantly improved at the end of the study for GCS, VCL and neuroticism, but not for night sweats or psychosocial functioning. Between group comparisons from the Elavsky study of Iyengar yoga^{92;93} showed no statistically significant differences between groups for any outcome (GCS, UQOL, mood, depression, satisfaction with life and sleep quality). However, within group comparisons showed that the intervention and control group participants showed a non-significant trend towards improvement for some GCS subcategories.

Is the research good quality and free of bias? The review is generally of good quality, though the inclusion of non-RCTs and uncontrolled studies is not necessary as two RCTs were available. As such, only the RCT results are presented here. Quality assessment of studies was performed, but not reported in a way that allows the reader to see which studies were of good quality.

Conclusion

See summary at start of section.

3.9 Stress

3.9.1 What is stress?

Stress is a response to too much emotional or mental pressure. Possible symptoms of stress include amongst others: irritability and short temper, anxiety, racing thoughts, headaches, breathlessness, sweating and dizziness. Stress can lead to depression and anxiety. GPs may suggest self help techniques such as exercise or a talking therapy to alleviate stress.⁹⁴

3.9.2 Studies found

One RCT relating to yoga for stress was found.

3.9.3 Stress summary

This study suggests that yoga and relaxation are both effective treatments for stress in the short term, though it is not clear how effective they are, and whether this represents a meaningful improvement. Yoga appears to be more effective in the short term at improving overall mental health. In the long term, fewer participants continued their yoga practice, and improvements in social function, mental health and vitality were significantly better in the relaxation group, perhaps as a result of more sustained practice.

3.9.4.1 Smith C, Hancock H, Blake-Mortimer J, Eckert K.⁹⁵

A randomised comparative trial of yoga and relaxation to reduce stress and anxiety. Complement Ther Med 2007 Jun;15(2):77-83.

Study design and location. Randomised controlled trial, Australia.

Number of participants: 131

Objective. To compare yoga and relaxation for the reduction of stress, anxiety, blood pressure and the improvement of quality of life.

Methods. 131 patients aged between 18 and 65 years, experiencing mild or moderate levels of stress (as determined by the General Health Questionnaire-12 (GHQ-12)), and able to attend and participate in the classes. Subjects were excluded if they scored less than 2 on the GHQ-12, were physically unable to do yoga or attend class, were currently doing yoga or were pregnant. Those included were randomised to intervention or control. Those in the yoga group received hatha yoga classes. Those in the control group received progressive muscle relaxation classes. Both groups received classes for 1 hour per week over 10 weeks.

Yoga practices used. The yoga practice incorporated asana (poses), pranayama (breathing), meditation and relaxation, with the aim of removing external concerns, achieving focus and becoming sensitive to internal feelings.

Outcomes studied. Anxiety was measured by the State Trait Personality Inventory subscale for anxiety. Psychological stress was measured by the GHQ12, and health related quality of life was measured using the SF-36 questionnaire. Patients were followed up at the end of the 10 weeks of intervention and again six weeks later to see if changes were maintained over time.

The results. The authors report that there was an improvement in stress and anxiety scores in both groups. However, the actual values and statistical significance of these improvements is not given, so it is not clear how effective either intervention was. Between group differences were given and yoga was found to be as effective as relaxation at reducing stress and anxiety and on seven domains of the SF-36 from baseline to the end of the intervention. Yoga was found to be more effective than relaxation for improvements in mental health at the end of the intervention. There was no change in blood pressure. At the follow up point six weeks after the intervention had finished, there were no differences between groups in stress, anxiety and on five domains of the SF-36. Respondents from the relaxation group achieved significantly higher mean scores for social functioning, mental health and vitality at the end of the 6 week follow-up compared to those from the yoga group. 64% continued practising in the relaxation group compared with 42% continuing to practice in the yoga group.

Is the research good quality and free of bias? This study has some strengths and some weaknesses. Randomisation and allocation concealment were done well, and the statistician was blind to the treatment groups. However, there were drop outs and it is not clear how these were dealt with, which may affect the results. In addition, the study did not recruit enough participants to be sure that it would detect a clinically significant result, and the clinical significance and statistical significance of the improvements seen in both groups is not at all clear.

Conclusion

See summary at start of section.

3.10 Eating disorders

3.10.1 What are eating disorders?

Eating disorders include anorexia (not eating enough), bulimia (vomiting after eating) and binge eating. Causes of disordered eating are complex and include social, psychological and biological factors.⁹⁶ They may indicate underlying depression, anxiety or difficult emotions. Treatments include psychological therapy, dietary advice and prescription medication such as antidepressants.

3.10.2 Studies found

We found two RCTs relating to eating disorders.

3.10.3 Eating disorders summary

The two studies found focussed on very different types of people. One study recruited women who were dissatisfied with their bodies, but did not necessarily have an eating disorder. The other study recruited overweight and obese women, all of whom had been tested for binge eating. Only the study which recruited women with eating disorders found that yoga had an effect, though this effect was large and statistically significant. Yoga seems to have a positive effect on overweight women with problems with binge eating. Further studies are needed to see if this positive effect extends to other eating disorders.

3.10.4.1 Mitchell KS, Mazzeo SE, Rausch SM, Cooke KL.⁹⁷

Innovative interventions for disordered eating: evaluating dissonance-based and yoga interventions. Int J Eat Disord 2007 Mar;40(2):120-8.

Study design and location. Randomised controlled trial, USA.

Number of participants: 93 analysed after 20 withdrawals.

Objective. This study compared the effectiveness of cognitive dissonance and yoga programs for reduction of symptomatology and risk factors of disordered eating. No a priori hypotheses were made as to the expected differences between the two groups.

Methods. 93 female university students who responded to a flyer advertising a study for women dissatisfied with their bodies were recruited. 30 were randomised to a control group, 33 to the yoga group and 30 to the cognitive dissonance group. The yoga and dissonance groups each met once a week for 45 minutes over a 6-week period. The cognitive dissonance therapy focused on group discussion of the origin and perpetuation of the thin-ideal as well as its the negative consequences. Media images were presented, and the concepts of fattism and self-objectification introduced. Feminist perspectives of the history of thinness and oppression of women were discussed.

Yoga practices used. The yoga intervention followed the Integral yoga approach and was taught by an instructor certified by the National Yoga Alliance (USA). No further details of the practice were reported.

Outcomes studied. Several outcome measures were used; the eating disorder diagnostic scale (EDDS), the binge eating scale (BES), the State-Trait Anxiety Inventory (STAI), subscales relating to body dissatisfaction and drive for thinness from the Eating Disorder Inventory (EDI), the Ideal body Stereotype Scale-Revised (IBSS-R), the three-factor eating

questionnaire (TFEQ), the Toronto Alexithymia Scale (TAS-20) and the Body Shape Questionnaire-Revised-10 (BSQ-R-10).

The results. Of the 93 females recruited, 21.3% displayed symptoms of moderate binge eating and 5.6% displayed symptoms of severe binge eating. The rest had no or mild binge eating as scored by BES. After randomisation it was found that the average BES score at the start of the study was higher (worse) in the dissonance group than in the yoga and control groups, indicating that there was more binge eating in the dissonance group from the start. There were some positive effects noted in the dissonance group compared to the control group, but not in the yoga group compared to the control group.

Is the research good quality and free of bias? Whilst this research has used a thorough battery of tests and appears to be well conducted, several key aspects are poorly reported and it is not possible to tell to what extent the results are at risk from bias. In addition, it is not clear whether there were enough participants in each group to detect an effect, and the authors note that the yoga intervention may not have been delivered often enough or for long enough to have an effect.

Conclusions. Results from this study show that a 45 minute lesson each week for 6 weeks does not appear to impact on disordered eating or its risk factors. However, results from this study cannot be taken as an indication that yoga cannot have an effect as the duration of classes seem unlikely to be effective, and the number of participants with disordered eating in each group was probably too small to detect small but clinically relevant effects. More research is needed to draw a firm conclusion.

3.10.4.2 Mclver S, O'Halloran P, McGartland M.⁹⁸

Yoga as a treatment for binge eating disorder: a preliminary study. Complement Ther Med 2009 Aug;17(4):196-202.

Study design and location. Randomised controlled trial, Australia.

Number of participants: 90 recruited, 50 analysed

Objective. To examine the efficacy of a 12-week yoga program aimed at reducing binge eating severity in overweight or obese women.

Methods. 90 obese or overweight women aged between 25 and 65 and with a score greater than 20 on the Binge Eating Scale (BES) were recruited and randomised. Women who already practiced yoga, were pregnant or lactating and those attending weight loss clinics were excluded. Participants were randomised to a waitlist control group or a yoga group. The waitlist control group were offered classes at the end of the initial intervention period.

Yoga practices used. Each 60-min class typically included 5 min of *pranayama*, 45 min of *hatha yoga*, and 10 min of *yoga nidra* (deep relaxation). Participants were encouraged to develop a daily practice in three distinct, overlapping domains: physical awareness through movement and stillness (*asana*), breath awareness (*pranayama*) and concentrative meditation (*dharana* and *dhyana*), including eating mindfully. Daily home practice was supported with a CD featuring a 30 minute session and an illustrated manual.

Outcomes studied. Several outcomes were measured: Binge eating severity using the BES; physical activity, using the International Physical Activity Questionnaire (IPAQ); Body mass index (BMI); and waist and hip measurements.

The results. Binge eating and physical activity were statistically significantly better in the yoga group when compared to the control group. These effect sizes were considered large by statistical tests. These changes appear to have been maintained over three months. In addition, BMI, hips and waist measurements were also statistically significantly more improved in the yoga group when compared to the control group, but these improvements were not as large. The results were sustained when participants who left the study were included in the analysis.

Is the research good quality and free of bias? This study is of reasonable quality. Its strengths include a well designed randomisation strategy, some consideration of the size of the effect, and a robust analysis of the data which includes appropriate handling of missing data from participants who dropped out. The intervention appears well designed. The main weakness of the study is that no blinding of study personnel and outcome assessment/analysis appears to have been attempted, which may put results at risk of bias.

Conclusions. This study shows that yoga appears to have a very positive effect on overweight and obese women with eating disorders. There is some room for bias to have occurred, and a fairly large number of women dropped out (as is usual in studies of exercise in obese populations). But generally speaking these results indicate yoga is an effective treatment overall, and especially for women who persevere with the treatment.

3.11 Pregnancy

3.11.1 What is pregnancy?

Pregnancy is not really a health condition, but does bring with it experiences that women seek assistance with, both during gestation and during the birth itself. Many women use yoga prenatally to aid with comfort and to prepare both mentally and physically for giving birth.

3.11.2 Studies found

We found one systematic review and three RCTs which looked at yoga for pregnancy, both before and during giving birth.

3.11.3 Pregnancy summary

The results from the three RCTs are very positive for the benefits of yoga for women both before and during giving birth. Benefits include increased comfort and decreased pain during labour, decreased length of labour, pre-natal improved quality of life and decreased pre-natal stress.

3.11.4.1 Beddoe AE, Lee K.⁹⁹

Mind-body interventions during pregnancy. Journal of Obstetric, Gynecologic, & Neonatal Nursing: Clinical Scholarship for the Care of Women, Childbearing Families, & Newborns 2008 Mar;.37(2).

Study design and location. Systematic review, USA.

Number of RCTs included: 0, 2 non-RCTs reported.

Objective. To examine published evidence on the effectiveness of mind-body interventions during pregnancy on perceived stress, mood, and perinatal outcomes.

Methods. Four electronic database (PubMed, Cinahl, PsycINFO, and the Cochrane Library) were searched from 1980 to February 2007. Prospective studies were included if they investigated a mind-body modality with adult pregnant women, contained quantitative data, were published in English in peer-reviewed journals and reported outcomes related to psychological stress. Interventions designed for use in labour, in depressed women or which were not a mind-body therapy were excluded. This review did not conduct a formal quality assessment of studies.

Yoga practices used. Any yoga practice was included in the review. In the two studies reported, the yoga was transcendental-style meditation, yogic breathing, and yoga postures.

Outcomes studied. Any outcome was considered as includable in the review. The two studies included reported birth outcomes.

The results. No randomised controlled trials were found, but two quasi experimental studies were reported, both conducted in India.^{100;101} One study reported statistically significant results for improved birth weight, decreased intrauterine growth restriction, fewer babies born prior to 37 weeks gestation and fewer women suffering hypertension with intrauterine growth restriction.¹⁰⁰ Fewer caesareans were needed in the yoga group, but this was not statistically significant. The second study was a subset of women with Doppler

abnormalities.¹⁰¹ Birth weights were significantly higher in the yoga group, and there was a trend towards fewer birth complications.

Is the research good quality and free of bias? The review was of mixed quality. It is likely that all relevant papers were found, but these were not quality assessed so the risk of bias of the studies is unknown. This makes the results difficult to interpret.

Conclusions. This review did not find any randomised controlled trials. The two non-randomised studies found are very promising for the effects of yoga for pregnancy. However, no conclusions can be drawn as both studies were subject to bias; better quality randomised studies are needed to confirm these results.

3.11.4.2 Chuntharapat S, Petpichetchian W, Hatthakit U.¹⁰²

Yoga during pregnancy: effects on maternal comfort, labor pain and birth outcomes. Complement Ther Clin Pract 2008 May;14(2):105-15.

Study design and location. Randomised controlled trial, Thailand.

Number of participants: 66 analysed

Objective. To examine the effects of a yoga program during pregnancy, on maternal comfort, labour pain, and birth outcomes.

Methods. 74 pregnant women who were: at least 18 years old; able to communicate and write in Thai; without serious illness or high-risk complications during pregnancy; receiving antenatal care from the start, or at least from the second trimester, of pregnancy; and, without prior experience of practising yoga were included in the study. Those included were randomised to the intervention or control group. Those in the yoga group received supervised yoga sessions. Those in the control group received usual care with casual conversation for 20 to 30 minutes at each scheduled hospital visit.

Yoga practices used. The yoga practice consisted of six sessions each an hour long at the 26–28th, 30th, 32nd, 34th, 36th, and 37th week of gestation. The classes included education about anatomy of pregnancy, yoga asana (poses), chanting, breathing, yoga nidra and meditation. Participants were provided with a booklet and tape cassette and asked to practice at home at least three times per week for 10 to 12 weeks. Participants kept a practice diary, and weekly telephone calls were made by investigators to each subject to check home practice.

Outcomes studied. Several outcomes were studied, including: a visual analogue scale to total comfort (VASTC), to measure maternal comfort in the first stage of active labour; the maternal comfort questionnaire (MCQ; modified from the General Comfort Questionnaire) to measure maternal comfort 2 hours post delivery; the visual analogue sensation of pain scale (VASPS) given with the VASTC; the pain behavioural observation scale (PBOS), filled in by the investigator; birth outcomes measured using Apgar scores of the baby's physical condition; and the length of labour.

The results. Women in the yoga group scored better for comfort during labour as measured by the VASTC, and at 2 hours after labour as measured by the MCQ, when compared to the control group. Pain during labour (VASPS and PBOS) was also statistically significantly lower in the yoga group compared to the control group. The first stage of labour and the total length of labour was found to be shorter in the yoga group, though no significant difference

was found in the second stage of labour, the Apgar scores or the use of augmentation and pethidine.

Is the research good quality and free of bias? The quality of this study is largely unknown due to poor reporting. Randomisation was done well, but it is unclear whether study personnel and outcome assessors were blind to which group participants were in, which leaves the study at risk of bias. There are also a number of participants unaccounted for, and it is unclear how the analysis dealt with the missing data, though it appears they may have been excluded. This leaves the study at further risk of bias, as, in the worst case scenario, the participants who dropped out may have fared worse than the rest of the participants.

Conclusions. The results from this study indicate that yoga can improve maternal comfort, decrease experience of pain and shorten the length of labour, but are to be interpreted with considerable caution owing to the unknown and possibly high risk of bias introduced by missing patient data and outcome assessment. Whilst the results are very encouraging, they should be replicated elsewhere before firm conclusions can be drawn.

3.11.4.3 Rakhshani A, Maharana S, Raghuram N, Nagendra HR, Venkatram P.¹⁰³

Effects of integrated yoga on quality of life and interpersonal relationship of pregnant women. Qual Life Res 2010 Dec;19(10):1447-55.

Study design and location. Randomised controlled trial, India.

Number of participants: 102 (analysed)

Objective. The objective of this study was to investigate the effects of integrated yoga on the quality of life and interpersonal relationships in normal pregnant women.

Methods. 102 pregnant women between 18 and 20 weeks of gestation with a normal pregnancy and aged 20 to 35 were included. Patients with medical conditions which might lead to pregnancy complications and increase stress (eg diabetes, hypertension), patients with IVF or multiple pregnancies and patients with a history of intrauterine growth restriction, preeclampsia or other severe pregnancy complications were excluded, as were patients with maternal structural abnormalities, where ultrasound showed foetal abnormalities or where the participant had previously practised yoga. Those included were randomised to the yoga group or the control group. Those in the yoga group received supervised classes. Those in the control group received standard supervised antenatal exercise classes. Both groups were given one hour classes three times per week for the first month, then were expected to practise at home with a pre-recorded cassette. Refresher classes were provided periodically and participants kept an exercise diary to monitor practice.

Yoga practices used. The yoga practice followed was in the “integrated approach to yoga” style, which is a holistic approach to well-being at physical, emotional, mental and spiritual levels. The classes consisted poses suitable for pregnant women, lectures on yoga lifestyle including diet, thinking, feeling and behaviour, breathing exercises (pranayama) and relaxation.

Outcomes studied. Quality of life was measured using the WHOQOL-100 instrument which covers physical health, psychological health, level of independence, social relationships, environment, spirituality/religion/personal beliefs. Interpersonal relationships were measured

using the Fundamental Interpersonal Relations Orientation (FIRO) - B questionnaire, which covers aspects of inclusion, control and affection.

The results. There were 51 participants in each group. Characteristics of participants were statistically similar between the groups at the start of the trial, except for profession, with more employed women in the yoga group. Results from the WHOQOL-100 showed participants in the yoga group improved significantly more than the control groups in all aspects except, surprisingly, the spiritual domain. FIRO-B showed statistically significant improvements in the “expressed inclusion” and “wanted control” elements when comparisons were made between the yoga and control groups. Whilst changes in other elements of the FIRO-B were not significantly different between the groups, the changes from the beginning to the end of the study in expressed and wanted inclusion, expressed and wanted control and wanted affection were significant in the yoga group but no significant changes were observed in the control group. This suggests there may be effects worthy of further investigation with a larger group of people, or in specific subsets of people.

Is the research good quality and free of bias. Overall, this study was relatively free of bias, but failed to score well on a couple of points. It was not clear if participants or study personnel could tell which group they would end up in before being enrolled in the study, and it was not clear how any missing data was dealt with, or whether there was any missing data. The study was of a fairly good size for detecting an effect, but it is not clear if the effects detected were clinically relevant.

Conclusions. Results from this study suggest yoga is beneficial to quality of life in normotensive women with a normal pregnancy. There may also be advantages to interpersonal relationships, but a larger trial would provide more clarity around any such effects. The study was of generally good quality, though it is unclear if there was any missing data and if so how this was dealt with. Overall, these results indicate that yoga is beneficial for this group.

3.11.4.4 Satyapriya M, Nagendra HR, Nagarathna R, Padmalatha V.¹⁰⁴

Effect of integrated yoga on stress and heart rate variability in pregnant women. Int J Gynaecol Obstet 2009 Mar;104(3):218-22.

Study design and location. Randomised controlled trial, India.

Number of participants: 122

Objective. To study the effect of integrated yoga practice and guided yogic relaxation on both perceived stress and measured autonomic response in healthy pregnant women.

Methods. 122 pregnant women, who were aged 20 to 35 years and between the 18th and 20th weeks of pregnancy, were randomized to the yoga or the control group. Women in the following categories were excluded from the study: multigravida when the participant had no living child; multiple pregnancy; maternal physical abnormalities; obesity; psychiatric problems; pregnancy-associated medical problems such as diabetes and hypertension; pregnancy from in vitro fertilization; intrauterine growth restriction in a previous pregnancy; foetal abnormality on ultrasound scanning; and previous exposure to yoga. Those in the yoga group received supervised classes. Those in the control group received standard supervised antenatal exercise classes. Both groups were given two hour classes three times

per week for the first month, and were expected to practice at home for an hour with a pre-recorded cassette. Refresher classes and telephone check-up calls were provided periodically and participants kept an exercise diary to monitor practice.

Yoga practices used. The yoga group successively practised 2 modules of integrated yoga, specifically designed for the second and third trimesters of pregnancy. These included breathing exercises (pranayama), asanas (poses), meditation and deep relaxation.

Outcomes studied. The outcomes studied were stress as measured by the Perceived Stress Scale (PSS) and heart rate variability (HRV).

The results. PSS scores decreased statistically significantly more in the yoga group than the control group (31.57% decrease in the yoga group, 6.6% increase in the control group, $p=0.001$). HRV scores were also statistically significantly more improved in the yoga group during deep relaxation, which is interpreted as indicating that yoga modified the autonomic response to stress favourably.

Is the research good quality and free of bias? This study is of high quality. Randomisation and allocation concealment were done very well so there is very little chance of bias affecting which group a participant was allocated to. Blinding was not possible for participants, but the outcome assessors and statistician were blinded. There were some drop outs from the groups, and it is not clear how these were dealt with in the results. However, statistical power was maintained and drops out were even in each group, so the risk of bias may be less.

Conclusions. Results from this study show that yoga reduced stress in healthy pregnant women when compared to an exercise and education control. These results are very promising and if replicated elsewhere indicate that yoga is of benefit to healthy pregnant women in reducing stress.

3.12 Yoga versus exercise in healthy people and people with health conditions.

We found one systematic review which compared yoga to exercise.

3.12.1 Ross A, Thomas S.¹⁰⁵

The health benefits of yoga and exercise: a review of comparison studies. J Altern Complement Med 2010;16(1):3-12.

Study design and location. Systematic review, USA.

Number of RCTs included: 8

Objective. This systematic review aims to look at the health benefits of yoga, primarily yoga asana (postures) when compared to exercise in healthy people or people with a health condition.

Methods. One electronic database (Medline via PubMed), restricted to core journals, was searched. Quality was assessed and low quality studies excluded.

Yoga practices used. The elements of yoga used in the RCT studies included asana in all cases. Four studies also included pranayama (breathing), two further studies also included meditation and one study included asana, pranayama and meditation.

Outcomes studied. The review looked at all the effects reported by the included studies. This included a wide range of outcomes, from mood and quality of life to cholesterol levels and heart rate.

The results. The review included eight RCT studies, as well as four studies using methods of lower quality. Three of the RCT studies included only healthy people.^{67;106;107} The other five RCTs focused on either people going through the menopause (Chattha et al 2008, reported elsewhere in this report),⁹⁰ people with schizophrenia,¹⁰⁸ people with multiple sclerosis,¹⁰⁹ people receiving haemodialysis¹¹⁰ or people with type 2 diabetes.¹¹¹ It is not clear where the eight studies were from or how many participants were in them.

The results of the included studies generally showed that yoga was similar or more beneficial than exercise in a range of outcomes including fatigue, heart rate, cholesterol levels, stress and quality of life.

Is the research good quality and free of bias? Overall, this review did not score well on quality assessment. More could have been done to search for relevant studies as only one database was searched and no other methods were used. The review included studies other than RCTs which are likely to be of lower methodological quality. Whilst the quality of the included studies was considered, this was used to exclude some studies, but it is not clear how many or for what reasons. As such, the review may have missed or excluded relevant studies. A meta-analysis was appropriately not attempted, but some information about the studies is missing, such as the quality of the study and number of participants, which makes it difficult to interpret the results.

Conclusions. This review suggests yoga has a number of benefits in both healthy people and people with a health condition, however the quality of the included studies is not known so the results should be interpreted with caution.

4. Discussion

4.1 Key findings

This research report outlines some of the key recent research on yoga for both healthy adults and people with health conditions.

Many studies included in the review reported statistically significant positive outcomes, and this is very encouraging for an intervention as complex and variable as yoga, applied across such a wide range of conditions. Further studies reported trends and non-significant outcomes in favour of yoga, though a few studies did report no change (and very rarely a decrease) in the yoga groups.

Conditions that are highly studied include cancer (14 studies, mainly in breast cancer survivors), depression (15 studies) and in those at risk/diagnosed with diabetes and cardiovascular disease (28 studies). For cancer, studies published since 2005 have been consistently positive for quality of life and aspects of mood, as well as for intrusive thoughts, hot flushes, joint pain, anxiety and depression. Prior to 2005, results seemed more mixed for all outcomes. There is a suggestion in the research that some patients may benefit more than others, for example, those still undergoing treatment compared to those in recovery or remission. For those with depression, a similar question regarding which groups benefit most was raised. Results are largely supportive of yoga for depression, though there were problems with studies relying on pre-post test comparisons rather than between group comparisons. The studies of diabetes and cardiovascular disease often reported proxy outcomes relating to risk factors for disease such as weight loss and lipid profiles. This is usual for studies into these conditions. Results across studies were mixed, but often displayed at least positive trends towards yoga.

Groups which seem to respond consistently well to yoga in the literature include pregnant women, and healthy adults. Larger, better quality studies of back pain show positive effects.

4.2 Limitations

There are several limitations to the studies reported in this review, and to this study itself that should be borne in mind when interpreting these results:

1. This research report has not considered all the evidence, and cannot therefore draw an overall conclusion as to the efficacy of yoga.
2. Much of the research suffers from methodological weaknesses. Common problems include:
 - Not enough participants to expect to be able to detect an effect. Studies should be larger.
 - Inadequate analyses, focussing on before-after comparisons rather than between group comparisons. This means conclusions about efficacy cannot be drawn.

- Significant numbers of drop-outs, which have not always been dealt with well in statistical analyses.
- Yoga interventions that may not have been given for long enough or often enough to realistically be expected to produce an effect.
- Poor reporting made it difficult to assess bias in many cases.
- Few studies attempted to blind study personnel and outcome assessors.
- Most studies rely on self-reported outcomes, which are subject to bias, especially as it is not possible to blind participants to yoga interventions.
- Few studies attempted to conceal allocation, leaving studies open to bias
- Few studies considered whether the results reached clinical significance as well as statistical significance. By this, we mean whether the effect seen would constitute an improvement when judged by a clinical expert, or be noticeable by the participant themselves.
- Few studies addressed attendance issues.

3. Differences in the forms of yoga taught, the techniques focussed on and even the teachers themselves may impact on the results. This will be impossible to standardise, but may account for the variety in results. Statistical analyses and research design could in some cases draw out these differences where, for example, two or more teachers contributed to lessons.

4. Often studies recruited people who have no former interest in yoga. This is a difficult issue to address, as researchers and clinicians like evidence that can be applied to the general population. However, in the real world, yoga is usually attended by choice, and in the context of a medical intervention, a doctor would only ever be recommending yoga as a choice. It is therefore likely that studies which do not select patients who have chosen to do yoga will underestimate the benefits of yoga for people who chose it and are self-motivated to attend. In this sense, the positive results seen are even more encouraging.

5. Very few of the encountered studies recorded adverse events. Whilst intuitively it seems unlikely that yoga will have any severe or serious side effects, this is still a very important consideration, and must be addressed by future research.

4.3 Future research

We strongly recommend that any future research should attempt to address the issues listed in section 4.2 above.

In addition, further primary research could focus on:

- Osteoarthritis – we found only one study on hand osteoarthritis
- Development of an outcome measure which captures the benefits of yoga more accurately. This should be preference based to allow for the incorporation of the results into a cost-effectiveness model
- Whether the motivation and attitude people come to yoga with affects the results they are likely to see

- Determining what conditions people turn to yoga for, and focussing on these in future research studies

Whilst further secondary research may include:

- Developing a “logic model”, as used in public health interventions,
- Conducting a “realist synthesis” (a novel approach to complex interventions) of the evidence.
- Meta analysis, drawing and building on the results of this review. Though it should be noted that it is unclear whether this would be possible; meta analysis requires that study design, interventions, outcome measures and study participants are very similar and there may not be sufficient similar studies to warrant this.
- Meta synthesis of the qualitative literature, which could incorporate aspects of logic modelling and/or realist synthesis.

5. Conclusion

In conclusion, there is a healthy and thriving community of researchers attempting to assess the benefits of yoga for health and wellbeing. Whilst there are flaws and many gaps in the current body of evidence, there is much to support the use of yoga for both mental and physical health, in both the healthy general population and for people with some common health conditions.

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Yoga for health and wellbeing.

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