# RESEARCH PAPERS ON DIABETES

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**S-VYASA**

**Swami Vivekananda**

**Yoga Anusandhana Samsthana**

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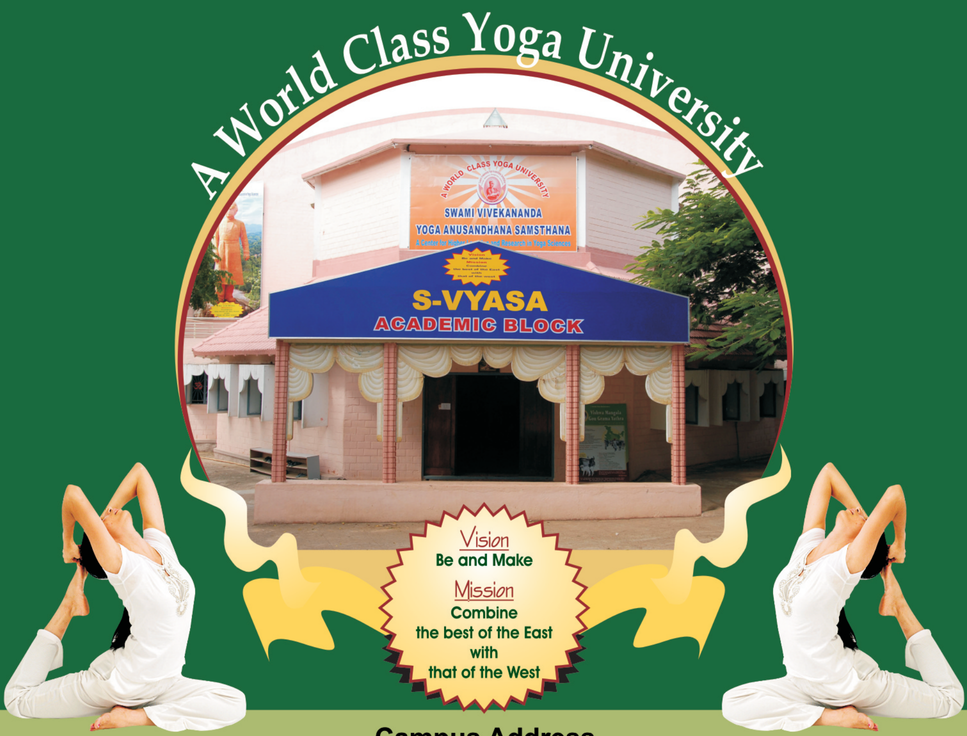


**Campus Address**

**PRASHANTI KUTIRAM**

Giddenahalli, Jigani Hobli, Anekal Taluk, Bengaluru - 562 106

Ph: 080-27825385, 27825122, 22609999

**Address for Correspondence**

**EKNATH BHAVAN**

# 19, Gavipuram Circle, Kempegowda Nagar, Bengaluru - 560 019,

Ph: 91-080-2661 2669 Telefax: 91-080-2660 8645

**e-mail: svyasa@svyasa.org website: www.svyasa.org**

## CONTENTES

# Original research

## Yoga therapy for NIDDM: a controlled trial

Robin Monro, Joyce Power, Anil Coumar, R Nagarathna and P Dandona

Summary

*Objective* – *To study the potentials of yoga therapy as an aid to the management of non-insulin-dependent diabetes mellitus (NIDDM).*

*Design* – *A randomised trial comparing the policy of offering yoga classes with that of non-intervention.*

*Setting* – *Royal Free Hospital, London.*

*Patients* – *21 patients with NIDDM, taking medication (13) or on diet control alone (8).*

*Intervention* – *Patients were randomised to control (11) and yoga (10) groups. Both continued their normal medication and diet. The control group had no additional intervention. The yoga group was offered yoga classes with a standard set of postural, breathing and relaxation exercises; most patients attended one or two classes per week and practised one or more times per week at home.*

*Main outcome measures* – *Fasting blood glucose (FBG) and glycated haemoglobin (HbAlc), assayed before randomisation and after 12 weeks of yoga.*

*Results* – *Both FBG and HbAlc improved significantly ($P < 0.05$) in the yoga group, compared to the controls. Three patients in the yoga group were able to reduce their medication. Most patients in the yoga group wanted to continue attending yoga classes, and reported feeling better, less anxious and more in control of themselves. No adverse effects were observed.*

*Conclusions* – *Offering yoga classes to NIDDM patients at a diabetic clinic attracted significant numbers of patients and led to improved glucose homeostasis. Further work is required to (a) optimise the yoga effect, (b) assess its range of applicability, (c) compare its efficacy to that of other behavioural interventions and (d) determine its mode of action.*

### Introduction

Yoga offers a largely unexplored, widely available resource for the management of stress-related ailments. Research has demonstrated its effectiveness for hypertension[1], bronchial asthma[2] and several other conditions[3]. The recent report that a combination of diet, exercise and yoga can reverse coronary heart disease[4] has drawn widespread interest. There is evidence[3,5] that yoga can also benefit people with non-insulin-dependent diabetes mellitus (NIDDM). We report here the first randomised, controlled trial of yoga for NIDDM. We have simply compared yoga with non-intervention, omitting controls for attention and exercise. While these may well contribute to the effects of yoga, they are themselves known to be complex phenomena, and we consider it to be judicious to make a preliminary confirmation that yoga is feasible and beneficial before embarking on expensive investigations into all its possible modes.

### Methods

We recruited 21 volunteers with NIDDM through the Royal Free Hospital outpatient clinic and the local media, excluding those with end stage liver or kidney disease, or congestive cardiac failure. Thirteen were taking medication for NIDDM, the remainder were on diet control alone. Only one had practised yoga previously (not recently). Volunteers were allocated to yoga and control groups without stratification by drawing lots. *Table 1* gives biodata for the two groups.

*Table 1:*
**Biodata of patients**

| | *Yoga* | *Control* |
|---|---|---|
| *No. of cases* | 11 | 10 |
| *No. of men/women* | 5/6 | 5/5 |
| *Age: range* | 45-67 | 46-66 |
| *Age: mean (SD)* | 53 (6.0) | 57 (7.3) |
| *No. taking medication* | 8 | 5 |

The control group continued with normal medical treatment only. The yoga group in addition to normal treatment was offered five yoga classes per week at the hospital. Most patients attended one or two classes per week and practised one or more times per week at home. The 90-minute classes utilised a standard sequence of simple postural, breathing and relaxation exercises, taking appropriate precautions for patients with hypertension or lower back pain[6].

Fasting blood glucose (FBG) and glycated haemoglobin (HbAlc)[7] were assayed before randomisation and after 12 weeks of yoga. Covariate analysis was carried out with BMDP Statistical Software. A simple questionnaire on subjective responses to yoga was administered by post to the patients in the yoga group (100% response).

### Results

*Table 2* shows that FBG decreased in the yoga group but increased in the controls, the difference between the changes in the two groups being 0.60 - (– 1.20) = 1.80 ($P < 0.05$; 95% confidence limits 0.27-3.33). The corresponding changes in

HbAlc were 1.56 - (− 0.20) = 1.76 ($P < 0.05$; 95% confidence limits 0.20-3.32). *Table 3* shows that similar confidence limits for the changes were obtained using the final values for FBG (or HbAl) adjusted by covariate analysis for sex, age and initial FBG (or HbAl).

*Table 2:*
Fasting blood glucose (FBG) and glycated haemoglobin (HbAlc) before and after 12 weeks of yoga

| | FBG (SD) (mmole/1) | | HbAlc (SD) (% Hb) | |
|---|---|---|---|---|
| | *Yoga* | *Control* | *Yoga* | *Control* |
| *No. of cases* | 11 | 10 | 11 | 10 |
| *Mean before* | 8.7 (3.9) | 7.6 (1.9) | 10.3 (3.4) | 8.9 (2.3) |
| *Mean after* | 8.1 (4.1) | 8.8 (3.0) | 8.7 (2.4) | 9.1 (1.2) |
| *Difference* | 0.60 (1.6) | − 1.20 (1.8) | 1.56 (1.8) | 0.20 (1.6) |

*Table 3:*
Mean changes in FBG and HbAlc (after minus before 12 weeks of yoga), adjusted by covariate analysis for sex, age and initial FBG. 95% CL = 95% confidence limits

| | FBG (SD) | HbAl (SD) |
|---|---|---|
| *Yoga* (11) | 7.7 (1.7) | 8.3 (1.2) |
| *Control* (10) | 9.3 (1.7) | 9.5 (1.2) |
| *Diff* (95% CL) | 1.576 (0.01,3.15) | 1.205 (0.13,2.29) |

Since FBG reflects glucose control at the time of blood sampling, and HbAlc reflects average glucose levels over the previous (approximately) six weeks, it follows that glucose levels in the yoga group fell significantly, relative to the controls, both at a single time point, after 12 weeks of yoga, and over the preceding (approximately) six weeks. Three of the patients in the yoga group were able to reduce their dose of tablets, since their blood glucose levels fell markedly following the initiation of yoga therapy. It follows that glucose homeostasis improved in the yoga group compared to the non-intervention group.

Questionnaires, administered by post, indicated that all the patients in the yoga group, except one, wanted to continue attending yoga classes, and the majority felt better, less anxious and more in control of themselves. Two reported improved mobility. No adverse effects were observed.

## Discussion

The fasting blood glucose and HbAlc assays show that glucose homeostasis improved in the yoga group, compared to the controls, over the 12-week period of the trial. The three reductions of medication in the yoga group, with no reductions in the control group, strengthen this conclusion.

Our yoga 'package' included several different components, known to help with glucose control in NIDDM, including exercise, diet, relaxation and counselling. The effect of exercise in increasing glucose utilisation would have been small, since the yoga employed is very gentle and the average heart rate over a yoga session is about the same as the resting level; exercise therapy for diabetes involves at least half an hour of active exercise with heart rate well above the resting level.

Surwit and Feinglos[8] reported that relaxation training led to improved glucose tolerance in NIDDM patients without affecting insulin sensitivity or glucose-stimulated insulin secretory activity. This could be mediated by decreases in sympathetic and adrenal cortical activity. Yoga presumably has similar effects but may also act in other ways, since it includes postural and breathing exercises in addition to simple relaxation.

It might be argued that attention, alone, could have caused the observed effects, since the control group did not have periods of attention, matching those of the yoga classes. It would be difficult to rule out such a possibility, since attention is a complex process, and the quality of attention provided by a yoga instructor undoubtedly contributes to the effectiveness of the therapy. To study this scientifically will require considerable sophistication, since attention in a yoga class cannot readily be dissociated from the practices being taught; controls for attention cannot be administered like placebo tablets in drug trials. However, this methodological difficulty does not detract from the evidence that yoga can benefit people with NIDDM. The potentials of yoga as a therapy for NIDDM must stand upon comparison with other therapies (including those based primarily on attention). Before this can critically be accomplished, yoga therapy for NIDDM must be further characterised.

The absence of adverse effects is consistent with observations by one of us (RN), at her yoga therapy clinic, on hundreds of cases of diabetes. It might be thought that yoga could exacerbate the tendancy to neuropathic arthropathy in people with diabetes but, contrary to popular misconceptions, therapeutic yoga uses very gentle exercises (with body awareness), and avoids putting any strain on the musculoskeletal system. Indeed, yoga may offer a viable alternative to exercise therapy in cases of arthropathy, and might actually benefit the condition.

Yoga therapy for NIDDM should now be studied to (a) optimise it, (b) determine the extent to which the effects are due to exercise, relaxation, 'attention placebo' or other factors and (c) compare its efficacy and range of applicability to those of other behavioural interventions.

Robin Monro PhD
Joyce Power B
*Yoga Biomedical Trust*
*Cambridge*
Anil Coumar MBBS
P Dandona FRCP
*Royal Free Hospital*
*London*
R Nagarathna MRCP(
*Vivekananda Kendra Yoga Research Foundation*

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# Community based yoga classes for type 2 diabetes: an exploratory randomised controlled trial

Lana Skoro-Kondza, Sharon See Tai, Ramona Gadelrab, Desanka Drincevic and Trisha Greenhalgh*

Address: Research Department of Primary Care and Population Health, University College London, London, N19 5LW, UK

Email: Lana Skoro-Kondza - l.skoro-kondza@pcps.ucl.ac.uk; Sharon See Tai - s.seetai@pcps.ucl.ac.uk; Ramona Gadelrab - ramonagadelrab@hotmail.com; Desanka Drincevic - m.rigby@pcps.ucl.ac.uk; Trisha Greenhalgh* - p.greenhalgh@pcps.ucl.ac.uk

* Corresponding author

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## Abstract

**Background:** Yoga is a popular therapy for diabetes but its efficacy is contested. The aim of this study was to explore the feasibility of researching community based yoga classes in Type 2 diabetes with a view to informing the design of a definitive, multi-centre trial

**Methods:** The study design was an exploratory randomised controlled trial with in-depth process evaluation. The setting was two multi-ethnic boroughs in London, UK; one with average and one with low mean socio-economic deprivation score. Classes were held at a sports centre or GP surgery. Participants were 59 people with Type 2 diabetes not taking insulin, recruited from general practice lists or opportunistically by general practice staff. The intervention group were offered 12 weeks of a twice-weekly 90-minute yoga class; the control group was a waiting list for the yoga classes. Both groups received advice and leaflets on healthy lifestyle and were encouraged to exercise.

Primary outcome measure was HbA1c. Secondary outcome measures included attendance, weight, waist circumference, lipid levels, blood pressure, UKPDS cardiovascular risk score, diabetes-related quality of life (ADDQoL), and self-efficacy. Process measures were attendance at yoga sessions, self-reported frequency of practice between taught sessions, and qualitative data (interviews with patients and therapists, ethnographic observation of the yoga classes, and analysis of documents including minutes of meetings, correspondence, and exercise plans).

**Results:** Despite broad inclusion criteria, around two-thirds of the patients on GP diabetic registers proved ineligible, and 90% of the remainder declined to participate. Mean age of participants was 60 +/- 10 years. Attendance at yoga classes was around 50%. Nobody did the exercises regularly at home. 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. There was a small fall in HbA1c in the yoga group which was not statistically significant and which was not sustained six months later, and no significant change in other outcome measures.

**Conclusion:** The benefits of yoga in type 2 diabetes suggested in some previous studies were not confirmed. Possible explanations (apart from lack of efficacy) include recruitment challenges; practical and motivational barriers to class attendance; physical and motivational 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.

**Trial registration:** National Research Register (1410) and Current Controlled Trials (ISRCTN63637211).

## Background

Type 2 diabetes has reached epidemic levels and its incidence and costs continue to rise. Physical activity is an effective intervention, but few patients engage in it regularly (see discussion). Yoga is popular, has many hypothetical benefits, and may be a more acceptable than sporting activity for some sectors of the population.

> Yoga and diabetes
>
> 'Yoga' as an intervention varies widely. While many researchers conceptualize yoga as a form of physical activity, others argue that yoga is a holistic intervention incorporating body postures (asanas), breathing techniques (pranayamas), meditation, cleansing, nutrition, modification of attitudes and behaviour, and mental discipline. [1]
>
> The advantages of yoga as option for physical activity in diabetes include (a) the holistic philosophy in which physical exercises are linked to a wider a lifestyle package that also includes diet, relaxation and what western practitioners would call stress management; (b) low cardiovascular demands relative to other forms of exercise; (c) low impact, hence meets a need for people who are obese, have difficulties in mobilisation, or contra-indications (e.g. proliferative retinopathy) to strenuous exercise; and (d) it provides an alternative identity option (yoga practitioners do not see themselves as "sporty").

Five previous randomised trials have been published of yoga in Type 2 diabetes. [2-6] The only UK trial recruited 21 participants from a hospital clinic and showed a highly significant fall in mean HbA1c (1.6%) in the yoga group over a three-month intervention period. [3] A US study based in primary care randomised 60 patients and showed no significant impact of yoga overall, though a subgroup of patients with high initial HbA1c levels showed a significant fall. [6] Three trials from India, in which a total of 310 patients were randomised, all showed a positive but statistically non-significant impact of yoga on glycaemic control. [2,4,5] Two recent systematic reviews concluded that current evidence suggests (but does not prove) that yoga may be efficacious in Type 2 diabetes; that publication bias may have occurred; and that an adequately powered, well-designed randomised controlled trial is needed to remedy the methodological deficiencies of previous studies. [7,8]

Yoga can be thought of as a 'complex intervention', for which the Medical Research Council recommends an extensive development period to achieve a robust, theory-based mechanism of action (phase 1), optimise the coordination and delivery of components (phase 2), and test these in exploratory trials (phase 3) before undertaking a definitive randomised trial (phase 4). [9] This exploratory trial was designed as a 'phase 3' study in the development of the intervention. As such, the trial was intentionally underpowered, since the purpose of the study was not to obtain a definitive effect size but to optimise processes and address the fidelity of the intervention in a real-life setting.

## Methods

### *Project management and governance*

Research Ethics Approval was granted by Barnet, Enfield and Haringey Local Research Ethics Committee, REC Number 04/Q0509/32. The trial was prospectively registered on the National Research Register (ID 1410) and Current Controlled Trials (ISRCTN63637211). A steering group with representation from academics, local GP surgeries, yoga therapists, and a statistician met regularly through the study, considered emerging data, and approved ongoing modifications to the protocol.

### *Setting*

The study was conducted in two north London boroughs. Borough A was in the lowest quartile for socio-economic deprivation, and 55% of the population were from ethnic groups other than white British. Borough B was more affluent, and its ethnic mix was close to the London average (40% from non-white British groups). Yoga classes at Borough A were held at a local leisure centre and at Borough B in a meeting room at one of the general practice surgeries.

### *Study design*

Exploratory randomised controlled trial with in-depth process evaluation, informed by the Medical Research Council framework. [9] The study was designed to generate data on (a) how best to recruit GP practices and patients; (b) operational aspects of delivering the yoga (e.g. where, when and how often); (c) what sort of yoga exercises to would be acceptable and efficacious; (d) how to maximise attendance and acceptability of the classes; (e) patients' and therapists' qualitative experiences; (f) the feasibility of different outcome measures; and (g) an estimate of effect size to inform the sample size calculation in a definitive trial. The design is summarised in Figure 1.

### *Sampling and recruitment*

In Borough A, we wrote to 60 general practices inviting them to participate. Those showing interest were visited and a standard information pack given. Participating practices agreed to recruit eligible patients opportunistically; posters were provided to put up in these surgeries. Because of low recruitment using this method, we adopted a more pro-active approach in Borough B. We approached two general practice surgeries whom we knew to be interested

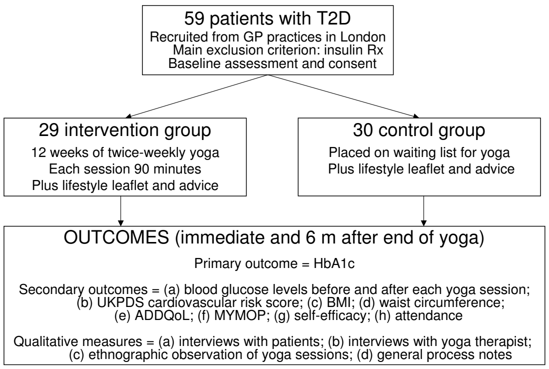


**Figure 1**
**Summary of study design**.

in both diabetes and research. We obtained a practice list of diabetic patients and drafted an invitation letter on practice headed notepaper for the general practitioner to send to potentially eligible patients. We followed up non-responders in Borough B by letter and telephone call.

### *Inclusion and exclusion criteria*

We included all diabetic patients over 18 with diabetes not treated with insulin. We excluded insulin treated patients because precipitous falls in blood glucose levels may occur during yoga in patients on insulin. [10] Exclusion criteria were contra-indication to physical exercise (e.g. unstable or under-investigated coronary heart disease, disseminated cancer, severe osteoporosis), inability to join in a yoga class (e.g. a relevant mental illness), or inability to understand English sufficiently to participate in the class (major cognitive deficit, poor English fluency).

### *Assessment and randomisation*

Interested patients were invited to an assessment visit at their general practice or a local surgery, at which the study was explained and informed consent obtained before performing a baseline physical examination and ordering blood tests. We also recorded self-assessed ethnicity and Index of Multiple Deprivation of the person's home postcode (derived from national census data and scored from 0.6 to 86 with a national mean of 21 and median of 17, in which a higher score means greater deprivation[11]). Eligible participants were randomised using opaque sealed envelopes to either yoga or a waiting list control arm; all participants eventually had 12 weeks of yoga classes. Because of the small numbers a block randomisation design was used to ensure equal numbers in each group.

### *Intervention*

The intervention group was encouraged to attend a total of 24 90-minute yoga classes over 12 weeks. Classes were run by an experienced yoga teacher who used judgement to adapt the exercises to the needs and abilities of the participants. The exercises focused primarily on breathing and relaxation (pranayama) but also included gentle stretching and postures (asanas). All participants in the yoga group were given their own yoga mat and belt, a leaflet of yoga exercises, and an audiotape by a yoga therapist; the waiting list control participants also received these after the end of the study period. In addition, both intervention and control groups were given a leaflet about exercise in diabetes and encouraged to take regular exercise.

### *Outcome measures*

The primary outcome measure was HbA1c. Secondary outcome measures (predefined before the study began) were UKPDS cardiovascular risk score (a composite of blood pressure, smoking status, lipid ratio, presence of atrial fibrillation, and HbA1c which has high predictive value in diabetes),[12] and three candidate psychometric scales: quality of life (using the diabetes-specific ADDQoL instrument[13]), self-efficacy (using a diabetes-specific adaptation[14]), and MYMOP (Measure Yourself Medical Outcome Profile[15]). These measures were taken at baseline, immediately on completion of the yoga class (or control period), and six months later. In addition, we monitored fingerprick blood glucose levels before and after each yoga class.

### *Process measures*

We held two focus groups with each group of participants – one before the start of the yoga class and one on the day of the last class. In the first of these we explored their hopes, expectations and concerns about the yoga class. In the second, we asked open-ended questions about the class (e.g. "how did it go?" "what do you think you got out of it?" "were there any problems?") and whether expectations had been met.

Because of low attendance at the Borough A class, we decided to introduce prompting for the Borough B class. With consent, a telephone or text reminder was sent the day before the class. For those who had chosen to be contacted by text, we sent another text the day after the class asking "how was the class?". Text responses were included in our qualitative data set. In addition, ten of the 29 participants randomised to yoga consented to having an individual semi-structured interview, at which we asked similar questions to those in the focus group (but with the opportunity for a private reply), and also asked specifically about factors affecting their attendance at the classes and ability to follow the exercises set.

Members of the research team (LS-K and RG) attended a total of 10 yoga classes and wrote up brief ethnographic field notes after each class.

We conducted a semi-structured interview with each yoga teacher towards the end of the series of classes, in which we encouraged them to comment on the motivation and ability of the participants; which exercises had been given and why; perceptions of barriers to effective participation, and what they would advise us when designing a further trial.

The data sources for the process analysis are summarised in Table 1.

### *Data processing and analysis*

All quantitative analyses were conducted in SPSS Version 12 using paired sample t tests to compare paired measures (physiological and biochemical measures, questionnaire scores, pairing before and after measures in each participant) and analysis of covariance to compare trend over time in the following variables (all of which were approximately normally distributed in the sample): HbA1c, body mass index, waist-hip ratio, systolic and diastolic blood pressure, lipid levels (total cholesterol, LDL, HDL, triglycerides), UKPDS risk score, and scores on the psychometric instruments (self efficacy, MYMOP and ADDQOL).

Interview and focus group data were transcribed and analysed for themes using the constant comparative method (i.e. as qualitative data were generated, themes in the new data were compared with those already identified from older data, thus iteratively refining the themes). [16] This process was aided by the use of an Excel spreadsheet for framework analysis,[17] and by regular discussions between researchers.

## Results

### *Recruitment*

Recruitment was difficult and slow. Of 60 general practices approached in Borough A, only 12 were interested and nine of these recruited very few participants. In Borough B, where we used practice diabetes registers, recruitment was much quicker but most patients on the register proved ineligible (because of insulin treatment, ischaemic heart disease, cerebrovascular disease, or other co-morbidity). In one practice, for example, only 53 out of 187 adult patients on the register were eligible and only six of these (3% of those the register) agreed to participate. Reasons given for declining included not interested (most commonly), too busy, not keen on the research aspect of the study, anxieties about their ability to do yoga ("not bendy enough"), and already attending a yoga class (two patients).

### *Participants*

The 59 participants comprised 13 men and 36 women. Mean age was 60 (SD 10) years, and mean duration of diabetes 30 (SD 5) years. Their self-assessed ethnicity was white British (10); other European or Mediterranean (4); African (14); and Asian (31). The mean deprivation score was 20.5, median 28.3, and range 4.2 to 60.0, indicating a wide range of socio-economic backgrounds but skewed towards the more deprived sectors.

### *Attendance*

Overall, attendance at the classes was 50%, with the number of classes attended ranging from zero to 24. The commonest reason given for not attending was that the class was at an inconvenient time (especially for those at work or studying) or conflicted with another appointment (e.g. dentist, picking up a child). Text and phone

**Table 1: Data sources for process analysis**

| Source of data | Type and quantity of data | Insights from these data |
|---|---|---|
| Yoga participants | Attendance records for all classes<br>4 focus groups (2 before class began, 2 after last class)<br>10 semi-structured interviews<br>Text messages from 7 participants | Whether people attended and if not, why not<br>Hopes and fears for yoga<br>Evaluation of their own performance and perceptions of barriers to yoga exercise<br>Confidence and motivation to continue |
| Yoga teachers | 2 semi-structured interviews (one with each teacher) | Type of individual who might benefit<br>Type of exercise that might be beneficial<br>Suggestions for intensity and duration of exercise sessions |
| Ethnographic observation | Field notes from researchers' attendance as participant observers at yoga class | Participants' engagement with the class<br>Practical constraints e.g. noise, room size |
| Documentary sources | Letters, emails, and file notes relating to setting up and running the project<br>(e.g. relating to gaining access to practices, recruitment, linking with clinical care) | Operational challenges and how they might be reduced or avoided next time |

reminders did not substantially increase attendance, mainly because very few people gave forgetting as the usual reason for non-attendance, though a minority of participants found the reminders helpful.

#### *Observation of the yoga groups*

Participants appeared to engage with and enjoy the yoga classes, where much of the time was spent on relaxation exercises. One of the yoga teachers spent considerable time 'tailoring' exercises for each participant so that everyone could join in somehow (e.g. if a person could not lie on the floor, a chair-based alternative was negotiated). Several participants in the other teacher's group spent parts of the class not participating at all. Pre-and post-yoga fingerprick blood glucose tests showed that 80% of participants experienced a fall in their blood glucose level during the class (mean change -2.1 mmol/L; SD 1.9 mmol/L; $p < 0.0001$), and one in 20 participants had a dramatic drop of 5 mmol/L or more.

#### *Participants' perspective*

All participants had high hopes that yoga would improve their general well-being and help control their diabetes. All were nervous before the course that they would not cope with the classes, and some expected to be asked to undertake complex contortions. They enjoyed the classes (which they found much gentler than they had feared), spoke highly of the teacher, and said they felt much better after a class. This was true both for high and low attenders. Participants said found it much easier to do yoga in a group than alone. They valued the social aspects of the group, and some expressed disappointment that there was no opportunity for socialising immediately after the class (because the venue had been booked for a limited time).

#### *Yoga teachers' perspective*

Yoga teachers felt that participants benefited from the classes, but that very few would have been suited to a 'general' yoga class because of frailty, stiffness, lack of fitness, lack of confidence, or co-morbidity. Both teachers felt that all participants should have a personalised plan of yoga exercise which took into account their physical fitness, comorbidity and confidence. They also felt that sessions should be longer than an hour (whilst the venue had been booked for 90 minutes, only 60 minutes was spent exercising), and that the course should last at least six months. They were unhappy with the venues provided, which were perceived to be too noisy and not conducive to the spiritual aspects of yoga (for example, the sports centre venue was characterised by repeated intercom announcements). Teachers were surprised that participants had not undertaken any yoga exercises at home and felt that in future research, agreement to practise regularly at home should be a precondition for inclusion in the trial and this aspect of the intervention should be given more emphasis in class.

#### *Impact of the yoga intervention*

On an intention to treat basis, there was no difference in any outcome measure between the two groups. In the intervention group, HbA1c fell slightly from 7.06 to 6.86 immediately after the course (mean change -0.02; 95% CI -0.40–0.001), but rose again to 7.01 six months later (mean change -0.05; 95% CI -0.26–0.16). The corresponding figures for the control group were 7.03 to 6.95 (mean change -0.07; 95% CI -0.21–0.007) and 7.30 six months later (mean change -0.28; 95% CI -0.10–0.66 95%CI). None of these differences was statistically significant. No other outcome measure showed a significant change. In terms of psychometric scales, the ADDQoL proved easy to administer and produced reliable data (though no changes were observed in score), but the diabetes self-efficacy scale was difficult to complete and analyse, and the MYMOP scale was very unreliable (because participants' goals were not stable over time).

### Discussion

This exploratory trial, which failed to demonstrate a significant impact of yoga in Type 2 diabetes, suggests that recent reports about the benefit of this intervention may have been premature. [1,10] The negative finding of this study may be explained either by lack of efficacy (yoga has no effect on glycaemic control or other cardiovascular risk factors) or by a number of factors that combined to attenuate the impact of a potentially effective intervention. In a future, larger study, a prospective per-protocol analysis (in addition to the main intention-to-treat analysis) might help to adjudicate between lack of efficacy of the intervention and poor attendance.

Our process data suggest that factors which could have contributed to a possible under-estimate of the efficacy of the intervention may have included good background control in the population targeted (the mean HbA1c of the adult diabetic population in participating practices was 6.9 mmol/L and few patients with poor glycaemic control entered the study); practical and motivational barriers to class attendance; physical and motivational barriers to engaging in the exercises; inadequate intensity and/ or duration of yoga intervention; and insufficient personalisation of exercises to individual needs.

The trade-off between 'personalising' exercises and delivering a 'standardised' intervention raises questions about fidelity of intervention which should also be considered in future trials, perhaps with attention to Hawe's writing on achieving a theoretically coherent 'core' intervention but applying flexibility to individual needs. [18]

A striking finding in our qualitative data was the mismatch between what people said about the yoga classes (enjoyable, make me feel better, improves my diabetic control) and their lack of commitment to attending them or continuing the exercises at home. It would appear that whilst participants *valued* the yoga class, they did not *prioritise* it, and some only attended if nothing else came up in the time slot. In this respect, attending the yoga class was rather like 'going to the gym' and did not have the same medical significance for participants as (say) an appointment with a health professional. Whilst 'community based' yoga may have a more holistic ethos, a previous randomised trial showing dramatic impact of yoga on HbA1c (in which attendance was very high) was held in a hospital clinic and the yoga course "prescribed" by the patient's diabetologist (Monro R, personal communication). [3]

Changing one's lifestyle, especially from sedentary to physically active, is difficult. Compliance with exercise regimens in diabetes is notoriously low, [19-22] especially in 'free living' community settings,[21,23,24] extremes of age, [25-28] and minority ethnic groups. [29-31] Exercise programmes offered in research studies are rarely sustained beyond the intervention phase. [21,22] Barriers to taking regular exercise in diabetes include low motivation[19,21] a personal identity that does not embrace athleticism,[32,33] and lack of social capital and social support. [34] Whether yoga should be 'medicalised' (e.g. as a 'prescription for exercise' intervention) to increase the priority given to it by patients is not an easy question to answer. Whilst this move may improve attendance, it also sits oddly with the ethos of a 'holistic' intervention intended to transform mind, body and spirit.

A recent review article by Alexander et al considered the uptake of yoga in diabetes from the perspective of the social determinants of health. [1] Promoting behavioural interventions such as physical activity for diabetes, they argue, implicitly places responsibility (and, where relevant, blame) on the individual, and diverts attention from the economic, social and cultural barriers to partaking in such activity. Participation in yoga has a very strong class, ethnicity and age bias (like other complementary and alternative medicine interventions, it is undertaken predominantly by the relatively young, educated, white middle classes, despite its origins in the East). [1] Our finding that most people with Type 2 diabetes who are eligible and willing to attend yoga classes in our London setting are from non-white ethnic groups, lower socio-economic backgrounds, and close to or above retirement age suggests that a key component of a future trial should probably be 'marketing' the idea of yoga to a group who might not otherwise be drawn to this activity.

## Conclusion

Taking into account the process data generated by this study, we make the following recommendations for the design of future trials:

### *Recruitment*

• Must be simple and involve no additional work for general practitioners or their staff

• Greatest interest is likely to come from the recently retired (60–69) as they have time to attend and may be well motivated

### *Venue*

• Must be 'fit for purpose' – ideally a quiet centre where yoga classes are already being held

• Must provide 'social' incentive e.g. meeting space to chat, lunch after the session

### *Maximising attendance*

• Pay careful attention to convenience of sessions

• Text or phone reminders may help some participants but most non-attendance is not due to forgetting

• Use yoga teacher to increase motivation

### *The exercises*

• Each participant should have a 'personalised' package tailored to their individual needs and motivation

• Strenuous physical exercises or those needing flexibility are unsuitable for most diabetic people

• Monitor blood glucose levels closely as precipitous drop may occasionally occur even in those not taking insulin

### *How often should yoga be done?*

• Aim should be several times a week for at least 90 minutes each time, but because of problems with attendance, most of this must be done at home

• Participants must agree to practice at home as a precondition for inclusion*

• Teachers must motivate people to exercise at home and give specific 'homework'

• Home 'yoga kit' (e.g. mat, belt, block) seems to be valued but supplying it will not automatically lead to yoga being done at home

### *Process/outcome measures*

• It is very important to measure attendance

• HbA1c and other blood tests are feasible but should be linked in with people's routine diabetes checks to avoid over-investigating

• ADDQoL appears a robust and acceptable measure (but may not be sufficiently sensitive to change)

• Further ethnographic observation would provide additional insights on what sort of yoga exercises are helpful for what sort of patient

## Competing interests

The authors had no competing interests. The sponsor of this study, Novo Nordisk Research Foundation, to whom we are grateful for financial support, had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

## Authors' contributions

LS-K conceptualised the study, led the recruitment of practices and patients, undertook assessment and randomisation of participants, and led collection of data. RG and DD assisted with assessments and data collection, and RG led the sub-study of text and phone prompting. SST led the quantitative analysis. TG provided methodological support and led the analysis of qualitative data with assistance from RG and LS-K. TG and LS-K wrote the paper. All authors read and approved the final manuscript.

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# Contextualizing the Effects of Yoga Therapy on Diabetes Management:

## A Review of the Social Determinants of Physical Activity

**Gina K. Alexander, MPH, RN**, **Ann Gill Taylor, EdD, RN, FAAN**, **Karen E. Innes, PhD, MSPH**, **Pamela Kulbok, DNSc, MS, RN, APRN,BC**, and **Terry K. Selfe, DC, PhD**
From the Center for the Study of Complementary and Alternative Therapies (Ms Alexander and Drs Taylor, Innes, and Selfe); and the Department of Family, Community, & Mental Health Systems (Dr Kulbok), University of Virginia School of Nursing, Charlottesville.

## Abstract

This article provides a review of literature both to identify the effects of yoga-based therapy on the management of type 2 diabetes mellitus and to examine the social context of physical activity. Findings from the review indicate that yoga has a positive short-term effect on multiple diabetes-related outcomes; however, long-term effects of yoga therapy on diabetes management remain unclear. The context of the social environment, including interpersonal relationships, community characteristics, and discrimination, influences the adoption and maintenance of health behaviors such as physical activity, including yoga practice. Further research is necessary to determine the extent of this influence.

### Keywords

discrimination; physical activity; social environment; type 2 diabetes mellitus; yoga

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The prevalence of type 2 diabetes mellitus (also referred to as *diabetes*) is increasing nationwide. From 1980 to 2005, prevalence of diabetes among the US population rose from 5.8 million to 14.7 million.[1] Approximately 9.6% of Americans aged 20 years or older (a total of 20.6 million people) have diabetes.[2]

There are clear ethnic and racial disparities in the prevalence of diabetes and diabetes-related complications. Rates of prevalence of diabetes among ethnic minorities older than 20 years are as follows: 12.8% to 15.1% among American Indians/Alaskan natives, 13.3% among African Americans, and 9.5% among Hispanic/Latino Americans; these rates contrast with the prevalence of 8.7% among non-Hispanic Whites.[3] Long-term complications such as blindness, end-stage renal disease, and lower extremity amputation are much higher among ethnic minorities than among non-Hispanic Whites with diabetes.[4]

Healthcare professionals and policy makers agree that reducing racial and ethnic disparities in diabetes and other health-related outcomes is a national priority; however, debate persists about root causes and taking appropriate action. Some argue that cultural practices are to blame, although culture itself is often defined poorly, if at all.[5] Others purport that a viable solution

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Corresponding author: Gina K. Alexander, MPH, RN, University of Virginia School of Nursing, PO Box 800905, Charlottesville, VA 22908 (e-mail: E-mail: gka8c@ virginia.edu).

is the promotion of cultural competence among healthcare providers.[6,7] Still others point to the lack of practical interventions tested among individuals with diabetes, particularly for the promotion of lifestyle changes in the form of physical activity (PA) and nutrition recommendations.[8,9] Given the increasing prevalence of diabetes, enduring health disparities, dissatisfaction with conventional approaches, and growing public interest in complementary and alternative medicine (CAM), researchers have begun to study the effects of various CAM modalities on diabetes management.

The purpose of this review is 2-fold: (1) to probe the published research literature to identify current understanding of yoga-based therapy as a CAM modality for diabetes management and (2) to situate these findings in a broader context through a review of the social determinants of health behavior and lifestyle change, particularly PA. The primary aim of this integrative review is to examine key factors of the social environment that affect the practice of PA, including yoga, among adults with or at risk for type 2 diabetes mellitus.

## BACKGROUND AND SIGNIFICANCE

To investigate the best means of improving health status among those with diabetes, researchers have targeted specific health behaviors for lifestyle change, namely, nutrition and PA, in the design of randomized clinical trials, measuring outcomes such as food intake, PA patterns, changes in body habitus (decreased body mass index, weight, or waist circumference), and improved glycemic control.[10–15] Unfortunately, most of these studies do not address the mechanisms for maintenance of lifestyle change, nor do the studies have data points beyond 1 year postintervention.

Further complicating the challenge to improve health status among those with diabetes, a growing body of evidence suggests additional racial/ethnic disparities in the practice of dietary behavior and PA.[16] In particular, only 25% of African Americans aged 18 years or older engage in consistent PA of moderate intensity in comparison with 35% of non-Hispanic Whites of the same age.[17]

Yoga therapy, as applied in western culture, is an innovative form of PA and stress management; this mind–body practice is a CAM modality that has become increasingly popular in recent years.[18,19] Among adults with diabetes, yoga therapy has been associated with multiple benefits and few adverse effects.[20] Yet, studies that investigate yoga therapy and its outcomes rarely report data beyond 1 year postintervention, and few, if any, examine aspects of the social environment that may contribute to yoga practice as a lifestyle to prevent or minimize complications from diseases such as diabetes.

Social conditions such as poverty, discrimination, socioeconomic status, and ecologic resources influence the risk and trajectory of disease; yet, the focus of intervention is often upon behavioral risk factors at the level of the individual.[21] Examining the social determinants of PA holds relevance for the advancement of science in the fields of public health, nursing, and CAM modalities. Until the effects of the social environment are more clearly understood, innovative programs to improve health will have limited effectiveness in real-world settings. Indeed, randomized controlled trials that emphasize intervention efficacy to the exclusion of intervention reach, adoption, and maintenance over time inevitably narrow the possibility of research translation into practice.[22]

## METHODS

This review focuses on published research articles indexed in the CINAHL, PubMed, MEDLINE, Web of Science, and PsycINFO databases and relevant articles obtained through the ancestry approach. Search criteria included research articles written in English, published between 1985 and April 2007, and concerning studies conducted among adult humans. For the first aim of the review (yoga-based therapy in diabetes management), the key words were "yoga" and "diabetes mellitus." For the second aim of the review (social determinants of PA), the key words included "diabetes mellitus," "physical activity," "social support," "social environment," "stigma," "prejudice," and "discrimination."

Exclusion criteria included articles that were not written in English and those with a target population of children, young adults, or pregnant women. Among the articles describing study findings, those excluded were those with outcomes less than 6 months postintervention or those lacking a focus on diabetes-related outcomes. After application of inclusion and exclusion criteria, 73 articles were eligible for review. Additional articles were retrieved from the reference lists of the eligible articles. Most of the articles included in the review were based on research in the United States, although articles based on research in other countries were included if they were written in English and pertained to the aim of the review.

## YOGA THERAPY IN DIABETES MANAGEMENT

Although considered an ancient tradition in Indian culture, yoga therapy falls within the domain of CAM in American society. Public interest in CAM continues to grow; consequently, it behooves healthcare professionals to be informed and to engage their patients in open discussion regarding CAM use.[23,24]

According to a study drawn from analysis of the 2002 National Household Interview Survey,[24] persons with diabetes use CAM at rates of prevalence equal to those with-out diabetes. Although this study is subject to self-report and recall bias, its findings are clinically important: those with diabetes are more likely to practice prayer than those with-out diabetes, but they are less likely to use herbs, consume vitamins, or practice yoga therapy.[24]

Current projections of undiagnosed diabetes are quite high, so true patterns of CAM use or yoga practice among those with diabetes are difficult to abstract. One readily discernible trend, however, is the increased experimentation with yoga practice in the United States in recent years. In 2004, findings from a nationwide survey indicated that 7.5% of a nationally representative sample had practiced yoga at some point in their lives, with almost 4% having practiced yoga in the past year; interestingly, 90% of the sample expressed the belief that yoga was very helpful in improving or maintaining health, or both.[25] Although the low response rate and low proportion of yoga users necessitate the judicious interpretation of these data, the evidence base for yoga therapy as an efficacious strategy for chronic illness management continues to expand.

The implementation of yoga therapy varies widely. While many researchers conceptualize yoga as a form of PA, others argue that comprehensive yoga, an approach incorporating body postures (*asanas*), breathing techniques (*pranayamas*), meditation, cleansing, nutrition, attitudinal and behavioral modification, and mental discipline, is more beneficial and loyal to its ancient tenets.[19,26–28] Nonetheless, western forms of yoga primarily emphasize components of exercise and stress management.[18,19]

Yoga therapy has been associated with a multitude of benefits and few adverse effects according to a recent systematic review of the effects of yoga on physiologic and clinical risk factors in adults with diabetes.[20] Benefits include significant reductions in fasting and postprandial blood glucose levels, hemoglobin $A_{1c}$, total cholesterol and low-density lipoprotein, triglycerides, coronary stenosis, oxidative stress, blood pressure, body weight, waist-to-hip ratio, heart rate, catecholamine levels, need for medication relative to baseline, and psychosocial risk factors.[18–20,26–28] Yoga is also associated with decreased weight gain in healthy adults, a matter of significance in the prevention and management of many chronic

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illnesses, including diabetes.[29] Although intervention studies reveal similar positive findings, many have a poor study design, lack an adequate control group, and offer an insufficient description of sampling and statistical analysis techniques.[20]

Yoga-based therapy is clearly a promising intervention for primary and secondary prevention of diabetes, given the multiple health benefits attributed to the practice of yoga. However, the literature is unclear regarding the most beneficial forms of yoga, the possibility of a dose–response relationship in managing diabetes, and the most labor-effective, cost-effective, and time-effective manner in which to train patients. Moreover, no studies were identified that measured factors contributing to the maintenance of yoga practice over time. An exploration of the social determinants of PA in general will provide a logical basis for understanding factors that may contribute to yoga practice as well.

## SOCIAL DETERMINANTS OF PHYSICAL ACTIVITY

Little has been published regarding the factors that contribute to the adoption and maintenance of yoga therapy as a form of PA. The focus of the extant literature on the initiation and maintenance of PA in general is largely upon factors at the level of the individual person, with limited consideration of environmental factors.[30] Researchers agree that self-efficacy, for example, is a fundamental element of PA adoption and maintenance.[31–38] In addition, there is ample evidence linking demographic factors with PA. For example, long-term maintenance is less likely for older, ethnic minority women who reside in the southern or northeastern regions of the United States.[35–37,39–41] It appears that the intensity of PA is also predictive of its longevity in practice; activities that emphasize moderate intensity conducive to lifestyle integration are more likely to be maintained over time.[33,35]

The initiation and maintenance of PA do not depend solely upon individual factors, however; environmental factors are critical determinants as well.[33,35,37,39,42] Environmental factors include physical features and social characteristics. Social environmental factors constitute the focus of this integrative review.

A uniform definition of the social environment is difficult to pinpoint, although scientists would generally agree that key features of the social environment, such as social norms, social stressors, and social constraints on individuals' opportunities and choices, shape health behaviors such as PA.[43] The authors of *Healthy People 2010* emphasize the role of social environmental factors in healthy living and highlight the influence of 2 aspects of socioeconomic status—income and education—on leading health indicators, one of which is PA.[40]

Social support is the most widely investigated social environmental factor in the health literature; encouragement or assistance from family and friends constitutes a form of proximal support that affects lifestyle changes in diabetes management, including PA.[34,44–46] Social resources in the neighborhood and community, on the other hand, provide distal support for PA maintenance, which is equally important for sustained lifestyle change.[31,39,41,44,47–49] These resources may be either stress-buffering or stress-inducing qualities of the environment. Moreover, certain social environmental factors ("leverage points") exert a disproportionate influence on behavior and well-being.[50–52]

### Social influence of interpersonal support

Findings from the literature suggest that social support is a critical determinant of health status and serves as a protective factor for those suffering with or at risk for chronic illness.[53–56] Some view their family members as a reliable source of emotional support, especially in times of illness.[57] Individuals with diabetes often report that family members provide instrumental support, encouraging them to engage in self-management behaviors, including exercise, judicious grocery shopping, meal preparation, and foot care— activities that can help them to achieve better glycemic control over time.[58–60] Mechanisms by which social support influences PA include the establishment of social norms that promote the adoption and maintenance of health behaviors, such as exercise, and the provision of helpful ideas and material resources to overcome barriers to PA.[34]

Family members, however, are not always a positive source of support. In direct contrast to reports that characterize family members as seemingly idyllic encouragers, some individuals testify that their family members have a tendency to make matters worse by engaging in regulatory or nagging behavior.[56,61] Participants in one study emphasize that some family members are in denial or simply do not understand; they provide poor healthcare advice, particularly with regard to food choices.[62] Regarding PA, it appears that working women who remain physically active report lower family support but higher levels of social support from friends than women who are inactive.[35]

Family conflict can mitigate the positive aspects of social support and increase the stress faced by those living with diabetes. Because of differential forms of conflict measurement and analysis of outcomes, research findings regarding the influence of unresolved family conflict are contradictory. While some assert that addressing conflict leads directly to improved clinical outcomes and reduced healthcare costs, others indicate that conflict management does not appear to affect clinical measures directly.[57,63] Still others determined that family conflict is related to depression, which, in turn, influences quality of life and attitude toward diabetes self-management.[64]

A recent review of controlled trials testing the effects of social support interventions determined that the role of social support in diabetes management remains unclear.[56] Varying definitions, divergent measurement, and contradictory findings limit the understanding of social support mechanisms in promoting lifestyle changes. Among those with diabetes, the effect of social support appears to vary by gender; men tend to prefer spousal and family support, whereas women favor the support of friends or extended family networks.[56] Emotional and instrumental support are commonly reported, but further research is necessary to explore the types of social support that are most beneficial for sustaining lifestyle changes necessary for diabetes management and prevention.

### Social influence of the neighborhood and community

Environmental variables that capture characteristics of neighborhoods and communities are beginning to gain the attention of researchers, yet the expanding evidence base of PA determinants focuses more heavily on psychosocial and behavioral factors at the individual level.[30] The influence of the social environment is widely recognized in health behavior research, yet the primary focus of the published literature pertains to the influence of the physical environment.[34] Although physical and social aspects of the environment have independent effects, social processes inevitably mediate the influence of the physical environment.[52]

Social cohesion enhances the collective social capital of communities, which is, in turn, related to increased PA.[34] Yet, the few studies that investigate social and environmental aspects of neighborhoods and communities predominantly focus upon neighborhood deprivation as opposed to neighborhood assets.[34] The extent to which a given environment provides opportunities for the development of supportive interpersonal relationships will determine the growth of social cohesion, commitment, and innovation for changes within that neighborhood or community.[52]

A large, cross-sectional phone-based survey of middle-aged and older women revealed that neighborhood characteristics are significantly related to physical inactivity. Among the 4 ethnic groups responding, in particular African American women, the infrequent observations of others exercising in the neighborhood greatly increased one's odds of having an inactive lifestyle.[30] Not only do social norms influence PA but psychosocial hazards within a neighborhood may also affect the practice of PA. A recent review of the literature on PA maintenance among women high-lighted the importance of environmental variables such as neighborhood safety, climate, and accessibility of trails or facilities for PA.[35]

Studies that examine the influence of perceived neighborhood safety on PA reveal contradictory findings. Results from a survey of almost 3,000 multiethnic women across the United States reveal that perceived safety of one's neighborhood is not a significant predictor of PA.[30] In contrast, a cross-sectional analysis of baseline data from a multilevel cohort study of community-dwelling older adults ($N$ = 1,140) revealed that visible, stable features of neighborhood environments evoking fear or alarm among residents are significantly related to less PA and less healthy diets.[65] Likewise, a report from the Centers for Disease Control and Prevention on the analysis of 1996 Behavioral Risk Factor Surveillance System data from Maryland, Montana, Ohio, Pennsylvania, and Virginia indicates that neighborhood safety contributes to the physical inactivity of Americans across many regions of the United States.[66]

The relationship between the social environment and PA is complex and needs further clarification through research among various population groups. Moreover, it is vital to both assess individuals' perceptions of environmental influence on PA and provide objective assessment of the environment.[30] Additional suggestions for the assessment of the social influence of neighborhoods and communities on PA include enumeration of the resources in the community that promote exercise, such as community walking clubs or local media reports addressing the benefits of PA.[34]

### Social influence of discrimination

Another aspect of the social environment is social discrimination. For purposes of this article, *social discrimination* is defined as any form of prejudice or stigma based on physical traits such as race, weight, and age. In recent years, researchers have examined the effects of social discrimination on health-related outcomes. Specifically, scientists have documented the negative effects of racial discrimination on stress, depression, blood pressure level, substance abuse, and satisfaction with medical care.[67–72]

Racial discrimination is a present and historical reality for many Americans, and a recent review of community-based studies confirmed its positive association with outcomes in mental and physical health status.[71] Racial discrimination has a dual description: *individual perceptions*, resulting in emotional distress and greater risk of chronic illness over time; and *institutional racism*, resulting in reduced access to optimal healthcare, increased exposure to hazardous conditions in the physical environment (related to housing and occupational opportunities), and aggressive advertising of both legal and illicit drugs and substances in segregated neighborhoods.[34]

Measurement difficulties continue to impede progress in this line of research, particularly the broad range of instruments designed to measure discrimination and the extent to which specific health-related out-comes of interest have been based largely on self-report, including self-rated physical health, stress, and depressive symptoms. Although subject to bias, such measures remain important, for they capture qualities of the social environment that have been overlooked by researchers for decades. Future research is necessary to determine the influence of racial discrimination on PA and other health-related behaviors, as few, if any, such studies have been published in the research literature.[34] To date, the primary behaviors that have a documented association with racial discrimination are alcohol and tobacco use.[71]

In addition to racial bias, an "antifat" bias is apparent in American society. This bias poses a significant problem for those with diabetes because the association between obesity and diabetes is clearly established in the literature.[73–75] Documented correlates of weight-based discrimination include healthcare avoidance, depression, and low self-esteem. [76–82] The literature regarding the influence of weight-based discrimination on health-related outcomes is accumulating, but measures used to assess the phenomenon have been categorical and, in some cases, dichotomous, which limits data analysis. Even so, it is important to note the findings from a large study of a convenience sample, indicating that more than 20% of women and 17% of men report weight-related mistreatment, not only from their spouse or loved one but also from strangers.[78] Furthermore, significant amounts of antifat bias are pervasive among healthcare professionals who work with obese patients or conduct obesity research.[81] Some healthcare providers attribute negative characteristics to obese patients, and society as a whole often perceives obese individuals as deviant and having flaws in character that lead to their condition.[76]

A recent study of 216 women revealed that obesity is associated with increased healthcare avoidance and delay in seeking medical attention.[76] This particular study is limited because of its reliance on self-reported data. One of the key findings, however, is that women avoid visiting healthcare providers because they simply do not want to be weighed in the clinic, nor want to be told to lose weight.[76] The authors indicate that healthcare avoidance may be especially pronounced if women perceive that their obese condition disproportionately affects their treatment through the lack of diagnostic evaluation and further testing or if healthcare providers focus solely on weight to the exclusion of apparent symptoms.[76] Although the evidence base is insufficient to draw conclusions, it is logical that weight-based discrimination could influence health behaviors such as PA or limit access to unbiased education and healthcare.

Ageism affects health behavior and health-related outcomes as well. Studies indicate that physicians are less likely to recommend PA to older adults, that sedentary behavior stems from sociocultural attitudes and prejudice toward aging, and that negative stereotypes of aging influence physiologic function important for lifelong PA.[83–85]

In particular, it is proposed that biologic changes inherent in the aging process, coupled with societal values and cultural attitudes regarding the activity of older adults, significantly affect the PA patterns of older adults.[83] As they age, women in particular often report a delicate balance among factors such as avoiding the risk of injury, desiring to meet sociocultural ideals for beauty and longevity, and seeking to maintain an independent lifestyle as they pursue PA. Others simply hold subtle societal beliefs that suggest that their aging bodies are incapable of handling the exertion of PA.[83]

In a study of community-dwelling men and women aged between 63 and 82 years, investigators reported significant increases in walking speed and other improvements in gait among those who were exposed to positive stereotypes of aging and no changes in those exposed to negative stereotypes of aging. The authors conclude that stereotypes of aging have a profound impact on gait and other aspects of physiologic function.[84] A recent review of the literature regarding ageist stereotypes indicates that healthcare providers likely propagate aging myths by being less aggressive in both their treatment of conditions and their recommendations for health-promoting behaviors.[85] In particular, physicians may be less likely to recommend PA, in spite of known benefits, simply because they perceive older adults as having earned rest and repose.[85]

Discrimination is pervasive in modern society. Evidence suggests that anywhere between 70% and 100% of adults report racial discrimination, more than 20% of adults report mistreatment related to weight, and more than 80% of Americans aged 50 or older report experiencing some form of ageism.[78,85,86] Recent research suggests that the internalization of negative stereotypes and discrimination poses a significant threat to health and is related to glucose intolerance, abdominal obesity, elevated blood pressure level, and physical inactivity.[68,85,87,88] Although the social stigma caused by perceived discrimination may affect the adoption and maintenance of health behaviors such as PA, this relationship is rarely measured.[89] In fact, no such studies were retrieved in a recently published review of the literature regarding the social environment and PA.[34]

A clear gap exists in the literature regarding the social influence of discrimination on PA. Further research is necessary to inform practice and build the knowledge base for appropriate levels of intervention to promote health and PA among all people, regardless of their background or physical appearance.

## DISCUSSION

The 2-fold purpose of this review was to identify from the published research literature the effects of yoga therapy as a CAM modality for diabetes management and provide context for these findings through an examination of the social determinants of PA. The implications for yoga-based research are evident. Although wide variations in the design and implementation of yoga therapy preclude the possibility of meta-analysis at this point, findings indicate that yoga has a positive short-term effect on multiple health-related out-comes. It would be prudent for healthcare providers to encourage exploration of yoga therapy as an option for PA and stress management for all patients, including those with diabetes; however, yoga is not considered a substitution for medical care but rather an adjuvant approach for health promotion. The long-term effects of yoga therapy on diabetes management remain unclear, a reflection of the lack of longitudinal research with data points beyond 1 year postintervention.

The social determinants of PA and associated implications are myriad. Simply put, further research is necessary to clarify the effects of the social environment on PA. Unfortunately, diverse measurements of social support and discrimination inhibit firm conclusions about the respective influence of these variables on the adoption and maintenance of PA. The social influence of neighborhoods and communities remains unclear, although a growing body of evidence points to the importance of social connectedness and cohesion, which can then influence social norms in favor of PA. For too long, research on neighborhoods and communities has focused on deprivation, crime, and fear, without assessing social assets or the capacity for social cohesion. It is essential to acknowledge the influence of deficits in the social environment, but identifying social ecologic leverage points for change is equally important.[52]

Disparities in diabetes and other health-related outcomes warrant the investigation of researchers and the attention of practitioners. The findings of this review support the assumption that complementary and alternative approaches, particularly yoga therapy, are efficacious in health promotion and diabetes management, yielding many benefits with few adverse effects. However, an intervention in isolation, no matter how innovative it may be, is not adequate to ensure long-term behavior change. Environmental factors are critical determinants of health behavior, and social influences are clearly important for the practice of all forms of PA, including yoga, and other lifestyle changes necessary for optimal diabetes management. Behavioral interventions are more likely to make an appreciable impact on the public's health when the interventions apply a conscientious appraisal of the social context of

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behavior to the meaningful development of strategies that enhance social assets while minimizing social hazards and inequalities, thereby achieving greater ecologic depth.

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# Effect of exercise therapy on lipid profile and oxidative stress indicators in patients with type 2 diabetes

Lorenzo A Gordon*[1], Errol Y Morrison[2], Donovan A McGrowder[3], Ronald Young[4], Yeiny Terry Pena Fraser[1], Eslaen Martorell Zamora[5], Ruby L Alexander-Lindo[2] and Rachael R Irving[2]

Address: [1]Department of Medicine, University of the West Indies, Kingston 7, Jamaica, [2]Department of Basic Medical Sciences, University of the West Indies, Kingston 7, Jamaica, [3]Department of Pathology, University of the West Indies, Kingston 7, Jamaica, [4]Faculty of Pure and Applied Science, University of the West Indies, Kingston 7, Jamaica and [5]Department of Saturnino Lora Hospital, Santiago de Cuba, Cuba

Email: Lorenzo A Gordon* - lorenzogordon@yahoo.com; Errol Y Morrison - errol.morrison@uwimona.edu.jm; Donovan A McGrowder - dmcgrowd@yahoo.com; Ronald Young - ronald.young@uwimona.edu.jm; Yeiny Terry Pena Fraser - yeinita@yahoo.com; Eslaen Martorell Zamora - gordonsatish@yahoo.com; Ruby L Alexander-Lindo - lisa.lindo@uwimona.edu.jm; Rachael R Irving - rachael.irving@uwimona.edu.jm

* Corresponding author

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## Abstract

**Background:** Yoga has been shown to be a simple and economical therapeutic modality that may be considered as a beneficial adjuvant for type 2 diabetes mellitus. This study investigated the impact of Hatha yoga and conventional physical training (PT) exercise regimens on biochemical, oxidative stress indicators and oxidant status in patients with type 2 diabetes.

**Methods:** This prospective randomized study consisted of 77 type 2 diabetic patients in the Hatha yoga exercise group that were matched with a similar number of type 2 diabetic patients in the conventional PT exercise and control groups. Biochemical parameters such as fasting blood glucose (FBG), serum total cholesterol (TC), triglycerides, low-density lipoprotein (LDL), very low-density lipoproteins (VLDL) and high-density lipoprotein (HDL) were determined at baseline and at two consecutive three monthly intervals. The oxidative stress indicators (malondialdehyde – MDA, protein oxidation – POX, phospholipase A2 – PLA2 activity) and oxidative status [superoxide dismutase (SOD) and catalase activities] were measured.

**Results:** The concentrations of FBG in the Hatha yoga and conventional PT exercise groups after six months decreased by 29.48% and 27.43% respectively ($P < 0.0001$) and there was a significant reduction in serum TC in both groups ($P < 0.0001$). The concentrations of VLDL in the managed groups after six months differed significantly from baseline values ($P = 0.036$). Lipid peroxidation as indicated by MDA significantly decreased by 19.9% and 18.1% in the Hatha yoga and conventional PT exercise groups respectively ($P < 0.0001$); whilst the activity of SOD significantly increased by 24.08% and 20.18% respectively ($P = 0.031$). There was no significant difference in the baseline and 6 months activities of PLA2 and catalase after six months although the latter increased by 13.68% and 13.19% in the Hatha yoga and conventional PT exercise groups respectively ($P = 0.144$).

**Conclusion:** The study demonstrate the efficacy of Hatha yoga exercise on fasting blood glucose, lipid profile, oxidative stress markers and antioxidant status in patients with type 2 diabetes and suggest that Hatha yoga exercise and conventional PT exercise may have therapeutic preventative and protective effects on diabetes mellitus by decreasing oxidative stress and improving antioxidant status.

**Trial Registration:** Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12608000217303

## Background

Diabetes mellitus is a worldwide health problem predisposing to markedly increased cardiovascular mortality and morbidity [1]. Lipid abnormalities significantly contribute to the increased risk of cardiovascular disease and other morbidity in diabetics [2]. There is a growing body of evidence showing that hyperglycaemia and dyslipidaemia are linked to increased cardiovascular risk [3]. It has been demonstrated that high levels of serum TC, triglycerides, LDL, VLDL, glycated haemoglobin ($HbA_{1c}$), microalbuminuria, hypertension, low concentration of HDL and increased body mass index (BMI) are significantly associated with coronary heart disease [4].

Oxidative stress induced by reactive oxygen species (ROS), which is generated by hyperglycaemia, is one of the major foci of recent research related to diabetes mellitus [5]. Diabetes mellitus is characterized by hyperglycaemia together with biochemical alterations of glucose and lipid peroxidation [6]. There are several studies that have evaluated free radical induced lipid peroxidation and the antioxidants in diabetic patients [7,8]. Some complications of diabetes mellitus are associated with increased activity of free radical-induced lipid peroxidation and accumulation of lipid peroxidation products [9]. Mechanisms that contribute to increased lipid peroxide formation in diabetic patients include: hyperglycaemic-induced glucose autooxidation, non-enzymatic glycation of proteins and lipids, increased sorbitol pathway activity, oxidation of advanced glycation end-products (AGEs) and cyclooxygenase dependent formation of prostaglandin H2 ($PGH_2$) [10]. A variety of natural antioxidants exist to scavenge oxygen free radicals and prevent oxidative damage to biological membranes. One group of these antioxidants is enzymatic (intracellular), which includes superoxide dismutase (SOD), glutathione peroxidase and catalase [11]. In addition to enzymatic antioxidants, are the major natural antioxidants, most of them derived from natural sources by dietary intake and include vitamin A, vitamin C, vitamin E and carotenoids [12]. Abnormally high levels of peroxidation and the simultaneous decline of antioxidant defense mechanisms can lead to damage of cellular organelles and oxidative stress [13].

Exercise is a major therapeutic modality in the treatment of diabetes mellitus [14]. Regular physical exercise has been reported to be effective in the prevention and delay of onset of type 2 diabetes, increases insulin sensitivity, and ameliorates glucose metabolism [15]. Yoga has become increasingly popular in Western cultures as a means of exercise and training fitness [16]. It has been used clinically as a therapeutic intervention and its practice includes muscle stretching, breathing exercises, behavioural modification, and dietary control through mental discipline [17]. A growing number of research studies have shown that Hatha yoga can improve strength and flexibility, and may help control physiological variables such as blood pressure, respiration and heart rate, and metabolic rate to improve overall exercise capacity [18,19]. Studies carried out on medium or long-term effect of yoga exercise on oxidative stress parameters and antioxidant status in type 2 diabetic patients are sparse. The aims of the present study were therefore to investigate the effects of Hatha yoga as well as conventional physical training (PT) exercise interventions on lipid profile, oxidative stress parameters and antioxidant status after 3 and 6 months of intervention in patients with type 2 diabetes mellitus.

## Methods

This prospective randomized control study was conducted at The National Institute of Endocrinology and The "Hermanos Ameijeiras" Hospital, Havana, Cuba from September 1998 to February 1999. The patients were selected according to the CONSORT declaration [20] and include only those with type 2 diabetes who had been trained in diabetes education and instruction, exercise, diet and medication according to the recommendations of the International Diabetes Federation (IDF), for a minimum of 3 months, and who met the following criteria for the study. These criteria were: type 2 diabetes mellitus without malnutrition or severe complications of the disease (cardiovascular, renal, visual and cerebral), between 40–70 years old, duration of the disease between 1–10 years, good psychological condition (in accordance with the psychologist's consideration), non-smoker and non-alcoholic. The study was approved by The "Hermanos Ameijeiras" Hospital ethics committee and informed consent was obtained from all patients who participated in the study.

The managed groups (Hatha yoga and conventional PT exercise) were trained for 24 weeks in basic exercise techniques, diabetes education and instructions. The yoga class was designated by a certified Hatha yoga instructor and a physician. The programmes were carefully illustrated through workshops and subjects were required to attend one yoga class weekly for twenty four weeks along with home exercise. None of the subjects in the Hatha yoga group were exposed to yogic practices. Each yoga session consisted of 20 minutes of pranayamas (breath-control exercises), 25 minutes of dynamic warm-up exercises, 60 minutes of asanas (yogic postures), and 15 minutes of supine relaxation in savasana (corpse pose). Subjects were given a booklet illustrating the specific pose to help with their independent practice [21].

Subjects in the conventional exercise PT exercise group also attended classes and were engaged mainly in aerobic exercise for 2 hours. A certified exercise instructor directed the conventional PT exercise intervention arm of the study. The conventional PT exercises consisted of one class per week for 24 weeks along with home exercise. The conventional PT sessions consisted of 15 minutes of warm up exercises, 30 minutes of aerobic walking on an outdoor 400-meter track, 20 minutes of body flexibility exercises, 20 minutes of aerobic dance, 25 minutes of games and 10 minutes of warm down exercises. Daily home exercise 3 – 4 times per week for 1 hour in the same Rate of Perceived Exertion was encouraged for subjects in both the Hatha yoga and conventional PT exercise classes. Intensity of exercise was determined by measurement of the pulse rate, and heart rate before, during and after exercises in subjects in the Hatha yoga and conventional PT exercise groups. Target heart rate was initially estimated as 70% of maximum based on morning resting heart rate and age. The measurement of perceived exertion during and immediately following exercise was done in the Hatha yoga and conventional PT groups by using the modified Borg Rate of Perceived Exertion Scale [22]. A questionnaire with statements as given in Borg's rating scale was used to assess the magnitude of exertion during and immediately after exercise. The Perceived Exertion Scale consisted of statements between 6 and 20 ('no exertion at all' to 'maximum exertion'). Subjects were instructed to exercise at a level of 8 – 10 on the Perceived Exertion Scale. Each managed group fulfilled a specific weekly programme that included the following: medical and psychological evaluation of patients and instructions on: education, diet, specific treatments, personal care and exercises (conventional PT or Hatha yoga). Subjects were also given a booklet in which they noted dietary compositions, medications taken daily, signs and symptoms, daily blood pressure, weekly glycaemia and information on adherence to home-based exercise programmes. Compliance with the interventions was assessed by having study participants complete daily 1-week log sheets that recorded whether or not they exercised or practiced yoga and for how long. The booklets were reviewed weekly by personnel blinded to the study. Class attendance was also recorded. The control group followed a treatment plan as recommended by their clinics or general physicians and was never seen by the personnel of this study for diabetes management. They were not engaged in any kind of active exercise intervention during the entire study period. All subjects were encouraged to see their attending physician regularly.

Figure 1 gives a description of the selection of type 2 diabetic patients in the study. A total of 231 subjects were recruited for this prospective randomized study: 77 type 2 diabetic patients in the Hatha yoga exercise group (62 females and 15 males) that were matched with 77 type 2 diabetic patients in the conventional PT exercise group (62 females and 15 males) and another 77 type 2 diabetic patients serving as the control group (62 females and 15 males). All 231 patients completed the study.

Measurement of the weekly variations of clinical and metabolic parameters was used to check the effectiveness of both interventions (Hatha yoga exercise or conventional PT). Baseline assessment of outcome measures and parameters were performed before the subjects were randomized and occurred 1 to 14 days before classes started. On the baseline visit, medical history was reviewed, demographic data were recorded, and blood samples taken for biochemical investigations. Blood was drawn from an antecubital vein at baseline, 3 months and 6 months for biochemical investigations, in post absorptive state. The blood was drawn between 7:30 am and 9:00 am, without stasis, and the serum was separated within an hour of collection. On the day of the blood collection, subjects were asked to abstain from Hatha yoga or conventional PT exercises. The biochemical investigations that were determined included lipid profile – serum TC, triglyceride, HDL, LDL and VLDL. Fasting blood glucose was measured before exercises. Oxidative stress indicators included: concentration of MDA, PLA2 activity and POX. The antioxidant status parameters were SOD and catalase activities.

All laboratory determinations were carried out at the "Hermanos Ameijeiras" Hospital. The personnel of the laboratories were blinded to the study. The fasting blood glucose concentration for each group was determined by using the Reflolux S type 1172115 glucometers (Boehringer Mannheim, Germany) [23]. This is based on the glucose-oxidase method [24]. Fasting venous blood was taken from each subject at baseline, at the third and sixth months. Total cholesterol, triglyceride and HDL were determined by enzymatic methods [25]. High density lipoprotein was measured after precipitating VLDL and LDL cholesterol in the presence of magnesium ions. The LDL fraction was calculated by the Friedwald formula [26].

Malondialdehyde concentration in the serum was measured spectrophotometrically according to Yagi [27] and PLA2 activity in serum was determined according to the method described by Lobo and Radbani [28]. Protein oxidation is based on the detection of the carbonyl group that appears as a result of the oxidation of lateral chains of certain amino acids. Plasma carbonyl group levels were evaluated following the 2,4-dinitrophenylhydrazine (2,4-DNP) assay [29], and were expressed as nanomoles per milligram of protein. The protein concentration was determined using bovine serum albumin as standard, according to Bradford's method [30]. The SOD activity was determined by inhibition of pyrogallin (formed due to auto-oxidation of pyrogallol) [31] and catalase activity

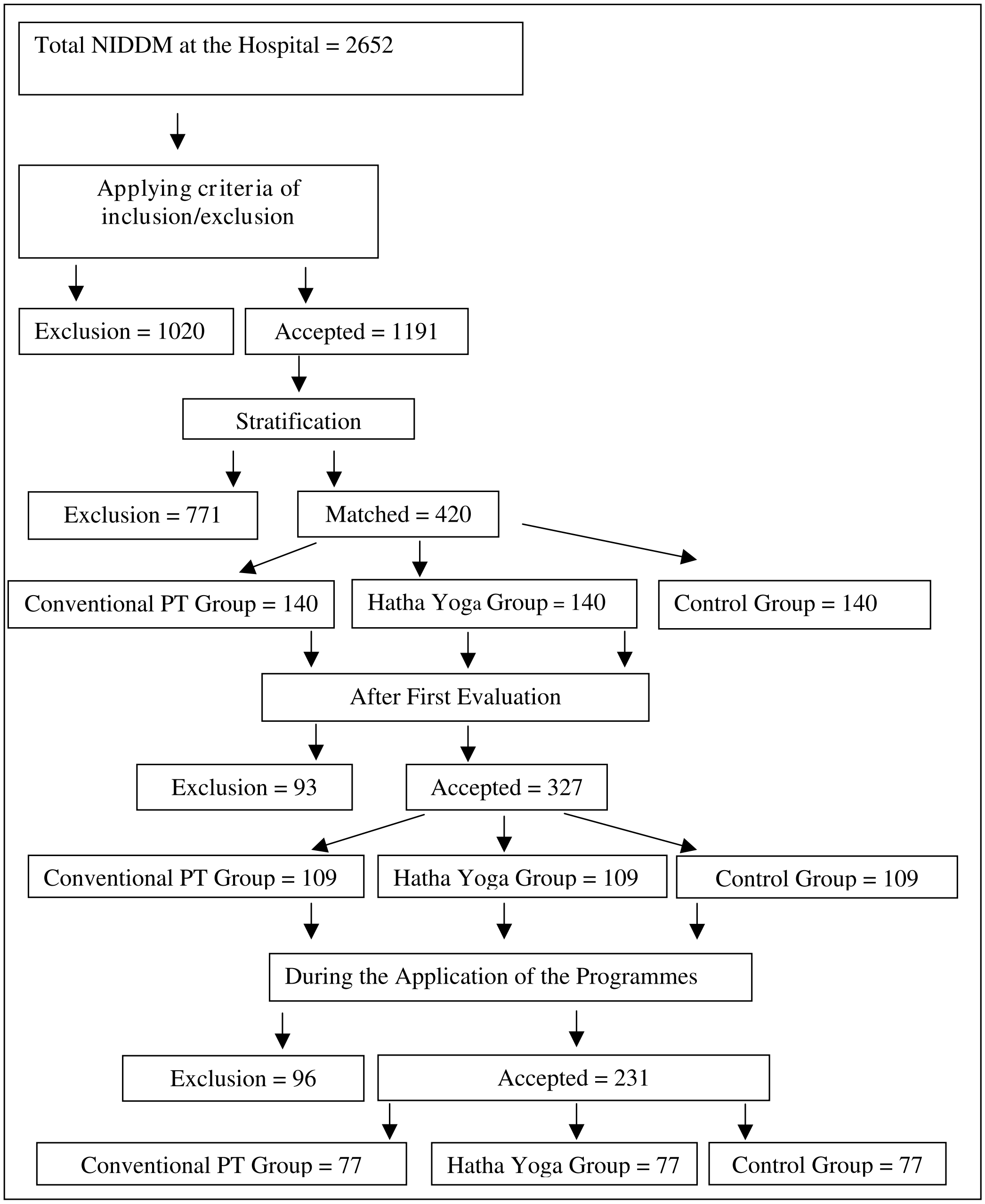


**Figure 1**
**Schematic diagram representing the study design.**

was measured by ultraviolet method, based on the transformation of hydrogen peroxide [32].

The data were collected and recorded on questionnaires, and a database was developed in Microsoft Excel 2000. The calculations were carried out with the soft-wares EPI-INFO Version 6.0 and SPSS Version 10.0 with a level of statistical significance of 95%. The individual variables were evaluated to determine the changes in the three groups (Hatha yoga, conventional PT and control) during the different periods (baseline, third or sixth month). To investigate the effects of a variable within a group the Within – Subjects factors analysis, and the effects between the groups Between – Subjects analysis were used according to Two Way ANOVA with a 95% confidence interval. Two Way ANOVA was applied to detect differences among groups (Hatha yoga, conventional PT exercise and control) and within groups over the duration of treatment. According to the behaviour of the variables, each table was represented by the mean and the standard error of the mean (SEM). As the three groups were of equal sizes then the Tukey's Honestly Significant Difference (Tukey HSD, available in SPSS) was used for posthoc comparisons. Differences were considered significant if $P < 0.05$.

## Results

There were 231 type 2 diabetic patients, 186 (80.5%) females and 45 (19.5%) males. Subjects matched according to age and sex and the mean ages were very similar in the three groups according to gender (Table 1). There was no significant gender-specific difference in demographic and biochemical parameters measured in the study. All 231 patients completed the study by participating in the 6-month assessment. Compliance with home-based exercise in the Hatha yoga and conventional PT groups was in the range from 80 – 85% and averaged attendance at classes was 90 – 95%. In the Hatha yoga and conventional PT exercise groups there were significantly decreased concentrations of FBG at the third ($P < 0.0001$) and sixth months of exercise ($P < 0.001$) compared to baseline values (Table 2). The concentrations of FBG in the Hatha yoga and conventional PT exercise groups decreased by 29.48% and 27.43% respectively compared to a reduction of 7.48% in the control group. There were significant differences in FBG between the managed exercise groups and the control group at the third and sixth months ($P < 0.0001$).

There was a significant reduction in serum TC in the Hatha yoga and conventional PT exercise groups at the end of six months ($P < 0.0001$). In the Hatha yoga exercise group the TC concentration decreased from $4.39 \pm 0.14$ mmol/L to $4.33 \pm 0.15$ mmol/L, whilst in the conventional PT exercise group it decreased from $4.32 \pm 0.13$ mmol/L to $4.29 \pm 0.14$ mmol/L. The mean concentrations of TC significantly differed between the managed exercise groups and the control group ($P < 0.001$) and in latter group it increased from $4.37 \pm 0.13$ mmol/L at baseline to $5.11 \pm 0.13$ mmol/L after 6 months. The concentration of serum triglyceride was not significantly decreased in the managed exercise groups, with a reduction of 6.0% and 7.1% in the Hatha yoga and conventional PT exercise groups respectively ($P = 0.432$). The concentration of serum triglyceride in the control group increased by 5.0% and there was no significant differences between this group and the managed exercise groups ($P = 0.068$; Table 2).

No significant differences were found in the concentrations of LDL and HDL in the Hatha yoga and conventional PT exercise groups after six months when compared with baseline value or control group (Table 3; $P < 0.05$). The concentrations of VLDL in the managed group significantly differed at the sixth month from baseline values. In the Hatha yoga and conventional PT exercise groups the concentrations of VLDL decreased from $0.83 \pm 0.05$ mmol/L at baseline to $0.77 \pm 0.05$ mmol/L after six months ($P = 0.036$). However, there was no significant difference in the concentration of VLDL in the managed exercise groups and the control group ($P = 0.788$).

Lipid peroxidation as indicated by MDA significantly decreased in the managed exercise groups after six months, with reductions of 19.9% and 18.1% in the Hatha yoga and conventional PT exercise groups respectively ($P < 0.0001$). There were significant differences in the concentrations of MDA between the managed exercise groups and the control group ($P = 0.004$), with no change in this parameter for the latter group after six months (Table 4).

The activity of PLA2 in the Hatha yoga exercise group increased by 7.1% and markedly increased by 16.2% in the conventional PT exercise group after six months ($P > 0.05$). There was no significant difference in activity of PLA2 between the managed exercise groups and control group ($P = 0.057$). No significant difference was found in the concentration of POX in the managed exercise groups after six months or when compared with the control group (Table 4).

The activity of SOD significantly increased by 24.08% and 20.18% in the Hatha yoga and conventional PT exercise groups respectively ($P = 0.031$; Table 5), while it decreased by 5.35% in the control group after six months. There was no significant difference in the activity of SOD in the managed exercise groups compared to the control group ($P = 0.118$) after six months. The activity of catalase increased

**Table 1: Frequency of treated type 2 diabetic subjects according to group, sex and age**

| Group | Female | | | Male | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. | % | Mean Age | No. | % | Mean Age | No. | % | Mean Age |
| Conventional | 62 | 80.5 | 63.5 | 15 | 19.5 | 65.6 | 77 | 100.0 | 63.9 |
| Hatha yoga | 62 | 80.5 | 63.8 | 15 | 19.5 | 64.7 | 77 | 100.0 | 64.0 |
| Control | 62 | 80.5 | 63.8 | 15 | 19.5 | 62.5 | 77 | 100.0 | 63.6 |

**Table 2: Comparison of FBG, cholesterol and triglyceride concentrations amongconventional PT exercise, Hatha yoga exercise and control type 2 diabeticpatients over a 6-month period**

| Variable/Group | Baseline | 3 Months | 6 Months |
|---|---|---|---|
| FBG (mmol/L) | | | |
| Conventional PT | 11.74 ± 0.34 | 8.71 ± 0.24**ab | 8.52 ± 0.24**ab |
| Hatha yoga | 11.84 ± 0.45 | 8.58 ± 0.44**ab | 8.35 ± 0.44**ab |
| Control | 11.77 ± 0.44 | 12.79 ± 0.37 | 10.89 ± 0.39 |
| Cholesterol (mmol/L) | | | |
| Conventional PT | 4.32 ± 0.13 | 4.29 ± 0.14**ab | 4.27 ± 0.14**ab |
| Hatha yoga | 4.39 ± 0.14 | 4.33 ± 0.16**ab | 4.33 ± 0.15**ab |
| Control | 4.37 ± 0.13 | 4.93 ± 0.14 | 5.11 ± 0.13 |
| Triglyceride (mmol/L) | | | |
| Conventional PT | 1.83 ± 1.11 | 1.78 ± 1.10 | 1.70 ± 1.11 |
| Hatha yoga | 1.83 ± 1.13 | 1.76 ± 1.14 | 1.72 ± 1.13 |
| Control | 1.81 ± 1.13 | 1.83 ± 1.12 | 1.90 ± 1.12 |

Values represent Mean ± S.E. **$p < 0.0001$; a: significantly different from baseline; b: significantly different from control.

by 13.68% and 13.19% in the Hatha yoga and conventional exercise groups respectively (P = 0.144), but their differences with those of the control group were not statistically significant (P = 0.744).

## Discussion

The present study confirmed the positive effects of Hatha yoga as well as conventional PT exercises on biochemical, oxidative stress and oxidant status in type 2 diabetics over six months. Type 2 diabetic patients engaged in Hatha yoga exercise and conventional PT exercises demonstrated lower fasting blood glucose, serum TC and VLDL concentrations. Malondialdehyde concentration, a lipid peroxidation product and marker of oxidative stress significantly decreased. The activities of SOD an enzymatic oxidant significantly increased and this was accompanied by a non-significant increase in that of catalase. The results of this study are similar to that of Bijlani et al. where yoga significantly decreased FBG, serum TC, LDL, VLDL, triglycerides and TC/HDL ratio in individuals attending a lifestyle education based program for 9 days [33]. Other researchers have reported that yoga sanas significantly reduced FBG and serum MDA in patients with type 2 diabetes mellitus [34]. This study suggests that Hatha yoga exercise is as effective as conventional PT exercise in substantially improving biochemical, oxidative stress profile and antioxidant status in type 2 diabetic patients over a period of six months.

The beneficial effects of yoga on glycaemic control are well documented. In this study, Hatha yoga exercise significantly reduced FBG concentrations after six months. This result is in accordance with previous studies by Malhotra et al. who showed that yoga asanas significantly decreased FBG concentrations in type 2 diabetic patients after forty days [35]. A similar study by Jain et al. over the

**Table 3: Comparison of HDL, LDL and VLDL among conventional PT exercise, Hathayoga exercise and control type 2 diabetic patients over a 6-month period**

| Variable/Group | Baseline | 3 Months | 6 Months |
|---|---|---|---|
| HDL (mmol/L) | | | |
| Conventional PT | 0.93 ± 0.04 | 0.94 ± 0.04 | 0.94 ± 0.04 |
| Hatha yoga | 0.94 ± 0.04 | 0.97 ± 0.04 | 0.97 ± 0.05 |
| Control | 0.93 ± 0.93 | 0.93 ± 0.04 | 0.91 ± 0.04 |
| LDL (mmol/L) | | | |
| Conventional PT | 3.02 ± 0.12 | 3.00 ± 0.12 | 3.00 ± 0.12 |
| Hatha yoga | 3.09 ± 0.14 | 3.01 ± 0.15 | 3.01 ± 0.14 |
| Control | 3.07 ± 0.12 | 3.17 ± 0.13 | 3.24 ± 0.12 |
| VLDL (mmol/L) | | | |
| Conventional PT | 0.83 ± 0.05 | 0.78 ± 0.05 | 0.77 ± 0.05*a |
| Hatha yoga | 0.83 ± 0.07 | 0.79 ± 0.07 | 0.77 ± 0.07*a |
| Control | 0.84 ± 0.06 | 0.84 ± 0.06 | 0.84 ± 0.06 |

Values represent Mean ± S.E. *$p < 0.05$; a: statistically significant different from baseline.

**Table 4: Comparison of MDA, PLA2 and POX concentrations among conventional PTexercise, Hatha yoga exercise and control treated type 2 diabetic patients over a6-month period**

| Variable/Group | Baseline | 3 Months | 6 Months |
|---|---|---|---|
| MDA (nmol/L) | | | |
| Conventional PT | 2.32 ± 0.12 | 2.23 ± 0.12 | 1.90 ± 0.10**a*b |
| Hatha yoga | 2.36 ± 0.20 | 2.21 ± 0.15 | 1.89 ± 0.16**a*b |
| Control | 2.35 ± 0.12 | 2.36 ± 0.12 | 2.37 ± 0.13 |
| PLA2 (IU) | | | |
| Conventional PT | 1.97 ± 0.08 | 2.19 ± 0.08 | 2.29 ± 0.09 |
| Hatha yoga | 2.10 ± 0.08 | 2.12 ± 0.07 | 2.25 ± 0.07 |
| Control | 2.06 ± 0.09 | 2.16 ± 0.09 | 2.15 ± 0.09 |
| POX (nmol/mg) | | | |
| Conventional PT | 2.25 ± 0.12 | 2.21 ± 0.14 | 2.34 ± 0.15 |
| Hatha yoga | 2.19 ± 0.13 | 2.20 ± 0.14 | 2.34 ± 0.13 |
| Control | 2.21 ± 0.13 | 2.23 ± 0.15 | 2.25 ± 0.16 |

Values represent Mean ± S.E. **$p < 0.0001$; *$p < 0.05$; a: significantly different from baseline; b: significantly different from control.

**Table 5: Comparison of the activities of superoxide dismutase (SOD) and catalaseamong conventional PT exercise, Hatha yoga exercise and control type 2 diabetic patients over a 6-month period**

| Variable/Group | Baseline | 3 Months | 6 Months |
|---|---|---|---|
| SOD (U/mL) | | | |
| Conventional PT | 11.25 ± 0.86 | 11.66 ± 0.82 | 13.52 ± 0.96*a |
| Hatha yoga | 11.17 ± 1.18 | 11.64 ± 1.15 | 13.86 ± 1.11*a |
| Control | 11.01 ± 1.05 | 11.03 ± 0.98 | 10.42 ± 0.93 |
| Catalase (U/mL) | | | |
| Conventional PT | 80.28 ± 5.57 | 85.44 ± 5.54 | 90.87 ± 5.13 |
| Hatha yoga | 80.36 ± 7.02 | 85.53 ± 3.77 | 91.35 ± 5.21 |
| Control | 82.10 ± 5.89 | 81.44 ± 4.67 | 82.11 ± 5.34 |

Values represent Mean ± S.E. *$p < 0.05$; a: significantly different from baseline.

same time period demonstrated a significant reduction in hyperglycaemia measured by FBG and oral glucose tolerance [36]. Sahay et al. reported significant reduction in fasting and post-prandial blood glucose concentrations within three months of yoga exercise in type 2 diabetic patients [37]. Mercuri et al. found significantly decreased glycaemia after three months of yoga exercise in a similar group of patients [38]. The results of this study and others indicate the positive effect of yoga exercise on glycaemia control and suggest that such would be beneficial for the treatment of diabetes mellitus.

Lipoprotein abnormalities play an important role in the causation of diabetic atherosclerosis [39]. Dyslipidaemia causes morbidity and mortality in patients with type 2 diabetic mellitus and the most common pattern in type 2 diabetic patients is elevated triglyceride and LDL, and decreased HDL cholesterol concentrations [40]. The modifications of LDL lipoprotein increase atherogenicity and available data suggest that LDL is more atherogenic in individuals with type 2 diabetes mellitus [41]. In this study Hatha yoga and conventional PT exercises significantly reduced serum TC and VLDL concentrations with no significant change in triglyceride, LDL or HDL concentrations. Agrawal et al. reported significant improvement in glycaemic control and lipid profile in type 2 diabetic patients exposed to yoga exercise where there was significant reduction in serum TC, triglyceride and LDL concentrations associated with concomitant significant increase in HDL concentrations after three months [42]. Agte and Tarwadi observed statistically significant reduction by *Sudarshan kriya yoga* (SKY) on serum TC and triglycerides in type 2 diabetic patients after four months [43]. These authors suggested a promising potential for SKY as a complementary treatment for patients with diabetes [43]. The results of this study and others point to benefits for persons with diabetes mellitus with relationship to the risks associated with dysfunction of the lipid profile such as: macrovascular complications, endothelin-1 [44], coronary heart disease and oxidative stress [45].

Diabetic patients have been generally described as having high levels of oxidative stress [46]. Oxidative stress generally causes damage to the membrane polyunsaturated fatty acids leading to the generation of MDA, a thiobarbituric acid reacting substance (TBARS). Increased lipid peroxidation products in diabetic subjects with vascular complications, have been reported [47]. Some authors have shown that high concentration of glucose may be associated with the presence of oxidative stress as reflected by the increase of intracellular lipoperoxides [48]. Serum MDA levels are higher in patients with newly diagnosed type 2 diabetes mellitus [49] and its concentration is elevated in poorly controlled type 2 diabetic patients [50]. The serum MDA concentrations in controls, which remained unaltered over the six month period was significantly higher than that of the managed exercise groups. Other researchers have found significant reduction in plasma MDA *by Sudarshan kriya yoga* (SKY) in type 2 diabetic patients after four months [43]. In our study the decreased concentration of MDA by the third and sixth months in type 2 diabetic patients in Hatha yoga and conventional PT exercise groups indicated that there was a reduction in lipoperoxidation diabetes mellitus. The control of glycaemia and the decreased lipid profile parameters using yoga exercises are important influences on the decrease of this oxidative stress parameter and provide more support for the rational of a possible protective effect of yoga exercise against oxidative stress in diabetics.

Protein oxidation, in contrast to lipid peroxidation, does not have the features of chain reactions. The plasma proteins destructed by peroxidation have a quite long period. Therefore, the evaluation of POX in plasma is a respected marker of free radical intensity [51]. Reactive oxygen species modify amino acid side chains of proteins such as arginine, lysine, threonine and proline residues to form protein carbonyls [52]. Carbonyl group formation is considered an early and stable marker for POX, and elevated protein carbonyl levels are detected in type 2 diabetes mellitus and well correlated with the complications of diabetes [53]. The POX non-significantly increased in diabetic patients in the managed exercise groups, with minor increase in the control group. This indicates carbonyl group formation and thus evidence of free radical modification of proteins over the six months [54].

Exercise is a major therapeutic modality in the treatment of diabetes mellitus [55]. Exercise training has been known to be effective in type 2 diabetes mellitus by increasing insulin sensitivity [56], and regular exercise can strengthen antioxidant defenses and may reduce oxidative stress [57]. Exercises including yoga postures have been shown to play a role in preventing type 2 diabetes [58]. The yoga postures are slow rhythmic movements which emphasize the stimulation of the organs and glands by easy bending and extensions which do not over-stimulates muscles but concentrate on glandular stimulation [59]. A major benefit of non-exhaustive exercise such as yoga is to induce a mild oxidative stress that stimulates the expression of certain antioxidant enzymes. This is mediated by the activation of redox-sensitive signaling pathways [60]. For example, gene expression of SOD is enhanced after an acute bout of exercise preceded by an elevation of NF-kappaB and AP-1 binding. An increase in *de novo* protein synthesis of an antioxidant enzyme such as SOD or catalase usually requires repeated bouts of exercise [61]. This could explain the increase in the activity of SOD in the Hatha yoga and conventional PT exercise groups at the end of six months.

Cellular intracellular enzymes such as SOD and catalase along with non-enzymatic antioxidants (glutathione) act as primary line of defense to cope with the deleterious effects of reactive oxygen species [62]. Superoxide dismutase detoxifies superoxide radicals and converts them to hydrogen peroxide which is further converted to water by catalase and glutathione peroxidase. Reduced scavenging of free radicals by SOD, decreased glutathione and decreased activity of catalase are associated with diabetes and vascular pathology [46]. Reduced capacities of antioxidant enzymes lead to increased oxidative stress in diabetes [63]. Turk et al. reported an increase in SOD activity and decreased catalase activity and suggested that these alterations may be owing to the compensatory mechanisms of the antioxidant system in type 2 diabetics [64]. In our study, evaluation of antioxidant status demonstrated significant increase in SOD activity and non-significant increase in catalase activity with a concomitant significant reduction in MDA in the Hatha yoga and conventional PT groups after six months. The improved antioxidant status due to these exercise regimens may point to adaptive response to oxidative stress reflecting free radical production and increased enzyme biosynthesis [65]. Furthermore, in oxidative stress when excessive superoxide formation may be accompanied by increased nitric oxide levels, elevated SOD activity may play a protective role in preventing cells from peroxynitrite formation [66].

Exercise intensity, for diagnostic or exercise prescription purposes, has been expressed in terms of oxygen consumption ($VO_2$), heart rate (HR), and/or ratings of perceived exertion [67]. Maximal oxygen consumption ($VO_{2max}$) is generally accepted as the criterion measure of cardio-respiratory capacity [68]. Accordingly, recommended intensity levels for particular purposes may be accurately expressed in terms of $VO_{2max}$. One of the limitations of the study is the lack of investigation of this parameter and the measurement of lactate. There were budgetary constraints and the authors recognized that the measurement of $VO_{2max}$ is generally restricted to sophisticated research settings due to the specialized equipment required. In this study, heart rate and Rating of Perception Exertion was used as valid indicators of exercise intensity. Changes in $VO_{2max}$ during different types of yoga breathing practices (pranayama) have previously been reported. Ray and colleagues reported that there is significant increase in $VO_{2max}$ in healthy individuals who practiced yogic exercise one hour every morning (6 days per week) for six months [69]. Another study showed decreased $VO_{2max}$ during Ujjayi pranayama practice in subjects who were practicing yoga for more than six months [70]. Carroll and colleagues found no relationship between heart rate and $VO_{2max}$ although there was mild increase in blood lactate in a group of yoga practitioners with yoga experience of 3 – 36 months [71].

## Conclusion

The findings of the study demonstrate the efficacy of Hatha yoga exercise on fasting blood glucose, lipid profile, oxidative stress markers and antioxidant status in patients with type 2 diabetes. The response observed using Hatha yoga exercise in type 2 diabetic patients was similar to that of conventional physical training exercise. These findings suggest that Hatha yoga exercise has therapeutic preventative and protective effects in type 2 diabetes by decreasing oxidative stress. This may have direct impact on the use of Hatha yoga exercise as a safe therapeutic modality in diabetes mellitus.

## Competing interests

The authors declare that they have no competing interests.

## Authors' contributions

LAG, EYM, EMZ were responsible for the study concept, coordinating research activities, the development of method, analyzing the data and writing the manuscript. DAMcG, RY, YTPF, RLA-L and RRI were involved in literature search, statistical analysis, data interpretation and writing the manuscript. All authors read and approved the final manuscript.

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Study protocol



# Psychological, social and biological determinants of ill health (pSoBid): Study Protocol of a population-based study

Yoga N Velupillai*[1], Chris J Packard[2], G David Batty[3], Vladimir Bezlyak[4], Harry Burns[5], Jonathan Cavanagh[6], Kevin Deans[7], Ian Ford[4], Agnes McGinty[8], Keith Millar[6], Naveed Sattar[9], Paul Shiels[10] and Carol Tannahill[1]

Address: [1]Glasgow Centre for Population Health, Level 6, 39 St Vincent Place, Glasgow, G1 2ER, UK, [2]NHS Greater Glasgow and Clyde, Glasgow Royal Infirmary, Dept. Vascular Biochemistry, 4th Floor University Block, 10 Alexandra Parade, Glasgow, G31 2ER, UK, [3]MRC Social and Public Health Sciences Unit, 4 Lilybank Gardens, Glasgow, G12 8RZ, UK, [4]Robertson Centre for Biostatistics, University of Glasgow, Level 11, Boyd Orr Building, University Avenue, Glasgow, G12 8QQ, UK, [5]Scottish Executive, St. Andrew's House, Regent Road, Edinburgh, EH1 3DG, UK, [6]Section of Psychological Medicine, Faculty of Medicine – University of Glasgow, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, UK, [7]NHS Greater Glasgow and Clyde, Glasgow Royal Infirmary, Dept. of Clinical Biochemistry, Macewen Building, 84 Castle Street, Glasgow, G4 0SF, UK, [8]Rosehill, Munros Street, Alexandria, Dunbartonshire, G83 0PU6, UK, [9]University of Glasgow, Division of Cardiovascular and Medical Sciences based at Vascular Biochemistry, 4th Floor QEB, Glasgow Royal Infirmary, 10 Alexandra Parade, Glasgow, G31 2ER, UK and [10]University of Glasgow, Faculty of Medicine, University Dept. Surgery, Level 2, Q.E.B, Glasgow Royal Infirmary, 10 Alexandra Parade, G31 2ER, UK

Email: Yoga N Velupillai* - Yoga.Velupillai@drs.glasgow.gov.uk; Chris J Packard - chris.packard@btinternet.com; G David Batty - david-b@sphsu.mrc.ac.uk; Vladimir Bezlyak - vladimir@stats.gla.ac.uk; Harry Burns - cmo@scotland.gsi.gov.uk; Jonathan Cavanagh - J.Cavanagh@clinmed.gla.ac.uk; Kevin Deans - kevindeans@nhs.net; Ian Ford - ian@stats.gla.ac.uk; Agnes McGinty - A.McGinty@clinmed.gla.ac.uk; Keith Millar - K.Millar@clinmed.gla.ac.uk; Naveed Sattar - nsattar@clinmed.gla.ac.uk; Paul Shiels - p.sheils@clinmed.gla.ac.uk; Carol Tannahill - carol.tannahill@drs.glasgow.gov.uk

* Corresponding author

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## Abstract

**Background:** Disadvantaged communities suffer higher levels of physical and mental ill health than more advantaged communities. The purpose of the present study was to examine the psychosocial, behavioural and biological determinants of ill health within population groups in Glasgow that differed in socioeconomic status and in their propensity to develop chronic disease especially coronary heart disease and Type 2 diabetes mellitus.

**Methods:** Participants were selected at random from areas known to be at the extremes of the socioeconomic continuum in Glasgow. Within the categories of least deprived and most deprived, recruitment was stratified by sex and age to achieve an overall sample containing approximately equal numbers of males and females and an even distribution across the age categories 35–44, 45–54 and 55–64 years. Individuals were invited by letter to attend for assessment of their medical history, risk factor status, cognitive function and psychological profile, morbidity, and carotid intima-media thickness and plaque count as indices of atherosclerosis. Anonymised data on study subjects were collected from the General Practice Administration System for Scotland to analyse characteristics of participants and non-participants.

**Results:** 700 subjects were recruited. The response (active participants per 100 invitation letters) in the least deprived group was 35.1% and in the most deprived group was 20.3%. Lowest response was seen in young males (least deprived 22.4% and most deprived 14.1%).

**Conclusion:** This cross-sectional study recruited the planned sample of subjects from least deprived and most deprived areas within Glasgow. As evident in other studies response differed between the most and least deprived areas. This study brought together researchers/academics from diverse disciplines to build a more sophisticated understanding of the determinants of health inequalities than can be achieved through unidisciplinary approaches. Future analyses will enable an understanding of the relationships between the different types of measure, and of the pathways that link poverty, biology, behaviour and psychology and lead to health inequalities.

## Background

Heart disease, diabetes, some cancers, rheumatoid arthritis and mental illness are examples of the burden of ill-health that is carried disproportionately by deprived communities[1]. Not only is the prevalence and incidence of disease higher in areas of deprivation but also the nature of the problem appears to be qualitatively different, and treatment less successful[2]. This inequality in disease risk can partially be explained by the higher prevalence of classical risk factors in deprived areas, but this explanation fails to account for the totality of the variations [3-5].

There are social gradients in a range of biological and psychosocial variables which indicate that living in a deprived environment may increase the propensity to develop chronic disease, through as yet unknown mechanisms[6,7]. A potential underlying cause of increased prevalence of disease is chronic inflammation. This has been observed to be more common in deprived than affluent populations, [8-12] linked to coronary heart disease[13,14], increased risk of type 2 diabetes[15,16] and other disorders[17], as well as cognitive dysfunction and altered psychological profile [18-21]. Atherosclerosis is now understood to be an inflammatory disorder with key components of the innate immune system being intimately involved in the initiation and progression of plaques on the artery wall, and in triggering an acute coronary event such as myocardial infarction[14]. The aetiology of diabetes appears also to involve activation of innate immunity with high levels of inflammatory biomarkers such as C reactive protein being associated with increased risk of developing the disorder[15]. Because of the aetiological links, some suggest that coronary heart disease and type 2 diabetes arise from a 'common soil'[22].

The cause of increased activation of the innate immune system in individuals from deprived populations is not clear. It may be linked to poor living and working conditions such as exposure to pathogens, or to increased levels of obesity. There is abundant evidence linking the accumulation of abdominal fat to raised levels of inflammatory cytokines in the plasma[23,24]. Further it is noteworthy that the relationship between body fat and inflammation is present even in children[25] suggesting that propensity to some adult chronic diseases may begin early in life. Abdominal obesity is believed to be a major precipitating factor in the development of insulin resistance and ultimately in the development of type diabetes[26]. For this reason the present 'epidemic' of obesity in many countries around the world is a significant concern for public health authorities and healthcare providers.

Chronic inflammation, central obesity and insulin resistance have been associated in population surveys and in experimental studies with impaired cognitive function and with an altered (negative) mental outlook. Depression appears to be more frequent in overweight individuals[27,28] and type 2 diabetes is recognised increasingly as a risk factor for accelerated cognitive decline in the elderly[29,30]. Prospective studies have shown inflammatory markers to predict cognitive decline in initially-healthy elderly subjects over follow-ups of between one and ten years[19,30], and that those of lower socio-economic status and poorer educational attainment are more vulnerable to such inflammation-related decline[31]. Recently investigators have reported that a further feature of central obesity/metabolic syndrome is an altered mental state associated with depression and "loss of control"[31,32]. It has also been recognised that depression is commonly found in subjects with CHD and is an important factor to overcome as part of recovery from a myocardial infarction [33-35].

These aetiological links need further exploration as potential explanations of the burden of physical and mental ill health in deprived communities. From a public health perspective it is important to establish if those who need to take on board messages advocating lifestyle change (weight loss, physical activity) are in a position affectively and intellectually to receive them. Equally, certain personality and other individual difference factors modify responses to stress and challenge, conferring both vulnerability and protection, and must be accounted for as moderating variables.

Glasgow is a particularly appropriate setting for a study of the effects of deprivation on ill-health because of the strong socioeconomic gradient within the conurbation, the fact that deprived communities make up a substantial proportion of the population and the associated variation in mortality and morbidity[7]. The present study is to determine the extent to which the syndrome of central obesity/chronic inflammation explains the socioeconomic gradient in vascular disease and whether the syndrome is associated with alterations in the mental state.

## Methods

### *Aims and Hypotheses*

The study for the most part was an exploratory pilot for a large scale investigation of the genotypic and phenotypic determinants of ill health in deprived communities The overall aim was to determine the extent to which the linked syndrome of central obesity/chronic inflammation explains the social gradient in vascular disease and whether the syndrome is associated with alterations in the mental state.

The hypotheses to be tested were summarised as follows in the study protocol:

"Socioeconomic gradients in health are influenced by adverse environmental conditions, work, relationships, community, knowledge and practice of health-promoting or health-damaging behaviours. Hormonal and metabolic responses to the above stressors, while protective in the short term, in the long term causes adverse changes (e.g. hyperplasia of visceral adipose tissue and central obesity) that leads to chronic disease (e.g. atherosclerosis). Further consequences are a heightened response to stress and a tendency towards depression and altered mental function".

### *Research questions*

The following questions were addressed:

1) Do deprived sections of the community display increased prevalence of features of a condition termed metabolic syndrome (i.e. central obesity and insulin resistance) and chronic inflammation compared to affluent sections?

2) Do deprived groups exhibit higher levels of serum endotoxin, revealing increased exposure to bacterial pathogens (as a result for example of damp housing) compared to affluent groups?

3) Do deprived groups differ from affluent ones in psychological profile (affective state and cognition) and to what extent can this be related to the presence of the central obesity/insulin resistance/chronic inflammation syndrome?

4) Is sub-clinical atherosclerosis (as detected by carotid ultrasound analysis) more prevalent in deprived groups? To what extent is the prevalence explained by classical risk factors (smoking, blood pressure, cholesterol) and to what extent is it related to the presence of metabolic syndrome?

In addition, we sought to ascertain the feasibility of a large scale population study by determining response rate, drop out rate, time taken by respondents to complete the questionnaires and the visits, any discomfort experienced by respondents to the various medical assessments, numbers volunteering for the Magnetic Resonance Imaging (MRI) Scan etc, and how the above were affected by age group, sex and deprivation category.

### *Ethical approval and confidentiality*

Ethical approval for the study was obtained from Glasgow Royal Infirmary Research Ethics committee. In all study records (electronic and paper) subjects were identified only by their study number. Information linking identity (name, address, general practitioners) to study number was held securely by the Glasgow Centre for Population Health[36] (GCPH; the coordinating centre). Only anonymised data were obtained from General Practice Administration System for Scotland[37] (GPASS) records on practice computers. The Health Board's Caldicott Guardian approved the study process and GPs with the approval of the ethics committee consented to the use of Community Health Index[38] and anonymised GPASS data.

The Health Information and Technology (HIT) section of the Greater Glasgow Health Board (GGHB) was responsible for sample selection and assignment of a study number to each subject (from 0001 to 3,600).

### *Subjects*

Selection was based on the Scottish Index for Multiple Deprivation[39] (SIMD) which identified the least and most deprived areas in the Glasgow conurbation area. Five general practitioners (GP) practices with the highest percentage of patients aged 35–64 years living in areas classified as being in the bottom 5% of SIMD [most deprived (MD)] were approached and all agreed to participate in the recruitment process. A further five practices with the highest percentage of patients aged 35–64 years living in areas classified as being in the top 20% of SIMD [least deprived (LD)] also agreed to participate.

HIT generated a target population of 21,672 people from the GP lists of these ten practices (Table 1). From this tar-

**Table 1: pSoBid target population by age and sex identified SIMD 2004**

| | Males | | | | Females | | | | Both Sexes |
|---|---|---|---|---|---|---|---|---|---|
| Number of subjects living in: | 35–44 years | 45–54 years | 55–64 years | Total | 35–44 years | 45–54 years | 55–64 years | Total | 35–64 yrs |
| 20% Least Deprived area* | 2,124 | 2,169 | 2,024 | 6,317 | 2,278 | 2,335 | 2,074 | 6,687 | 13,004 |
| 5 % Most Deprived area* | 1,931 | 1,482 | 949 | 4,362 | 1,849 | 1,366 | 1,091 | 4,306 | 8,668 |
| Total | 4,055 | 3,651 | 2,973 | 10,679 | 4,127 | 3,701 | 3,165 | 10,993 | 21,672 |

* The most deprived sample was drawn from the category 5% most deprived by SIMD. The least deprived sample was drawn from subjects living in areas classed by SIMD as in the 20% least deprived category

get population 12 groups of 300 each were selected according to strata defined by the combination of category, sex and age-group (35 to 44, 45 to 54, and 55 to 64 years) (Table 1) giving a total sampling frame of 3,600 subjects. As the study progressed, over-sampling of subjects from the most deprived group was required (due to the lower response rate) and the HIT section was approached to select randomly further potential subjects from the target population. GPs were able to exclude persons from the sample who had recently expired or who had a terminal illness. Due to the nature of the psychological questionnaires and cognitive assessment, only those who understood and spoke English were invited to participate in this pilot study. The eligibility of subjects was checked by GPs and Practice Managers before letters were sent.

If the participant had had an illness which was likely to increase CRP levels acutely (e.g. urinary tract infection, upper respiratory tract infection, etc.) during the two weeks prior to his/her appointment this was recorded but assessments proceeded on the scheduled date.

***Recruitment Procedure***

Invitation letters to selected subjects were sent in batches of 150 every two weeks. Accompanying the letter was a form for the subject to return (in a reply paid envelope) recording their contact details and indicating their willingness to consider participation. Subjects who agreed to receive further information about the study were sent the pSoBid participant information booklet[40]. If there was no response after two weeks, a reminder was sent. The Research Nurse contacted those who received the participant information booklet, and if after reading the information booklet they decided to participate in the study, they were invited to come for the first visit at their GP's clinic on a mutually agreed day and time (see Additional file 1 for flowchart). This process continued until approximately equal numbers for the 12 groups were recruited.

***Protocol***

The study comprised two visits, each lasting about an hour and a half to two hours. Arrangements were made for taxi transfers to and from the participants' homes. Posters advertising the study were displayed in GP Clinics and also in local community centres and libraries. Two free telephone numbers were set up one in the coordinating centre and one in the Glasgow Royal Infirmary (GRI) where the research nurses were based.

At Visit 1 the study was explained to participants and informed consent obtained. The visit involved completion of lifestyle and psychology questionnaires, assessment of health status and measurement of blood pressure, pulse rate and indices of obesity (height, weight, hip, waist and mid thigh circumference). Lung function was measured by Forced Expiratory Volume in one second ($FEV_1$) and Forced Vital Capacity (FVC). Questionnaires completed at this visit examined affective state and control/coping i.e. the General Health Questionnaire[41] (which has been used previously in this context by other research groups[31,42]), the Generalised Self-Efficacy Scale[43], the Sense of Coherence Scale[44] and Beck Hopelessness Scale[45]. An appointment was made for the second visit (in the morning and fasting) to be carried out at GRI on a date convenient to the participant.

At Visit 2, a fasting blood sample was taken to measure cholesterol, triglycerides, very low density lipoprotein (VLDL), low density lipoprotein (LDL) and high density lipoprotein (HDL), markers of diabetes and obesity (glucose, insulin, leptin and adiponectin), markers of inflammation and clotting [C-reactive protein (CRP); inerleukin-6, (IL6); fibrinogen, D dimer; tissue plasminogen activator (tPA) antigen], and markers of endothelial dysfunction [Intercellular Adhesion Molecule (ICAM); von Willebrand Factor (vWF)]. Then, after breakfast, participants completed further psychological and cognitive function tests, and underwent ultrasound assessment of carotid intima media thickness and plaque count. Previous research has shown an association between eating breakfast and mood and performance, with the effects due in part to experimental manipulation of the normal morning routine[46,47]. In this study as far as possible breakfast was provided according to an individual's normal routine (or abstinence, if relevant), so that any effects

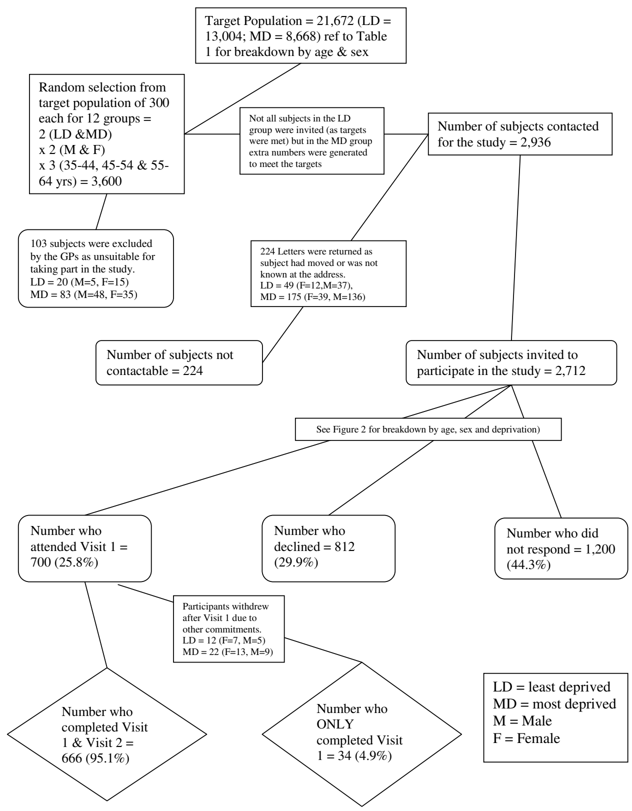


**Figure 1**
**Recruitment flowchart for the pSoBid study**. LD = Least Deprived; MD = Most Deprived. M = Male; F = Female.

on performance and affective state would be those observed in real life.

Psychology questionnaires completed by the participants at Visit 2 provided indices of personality and individual differences in self-esteem. The personality factor of neuroticism is known significantly to affect emotional responsiveness and adjustment. Assessment involved self-completion of the Eysenck Personality Scales[48] and the Rosenberg Self-Esteem Scale[49]. Cognitive assessment involved the following main domains of cognition: executive function (tested by Trails Test[50] and Stroop Test[51]), memory (tested by Auditory Verbal Learning Test) and cognitive performance (estimated from the NART-2[52] which provided a proxy measure of "IQ"). Attention and speed of processing were tested by Choice Reaction Time[53].

Male participants were asked if they would be interested in participating in MRI scanning (Visit 3). From a total of 327 male participants, 140 volunteered, and 40 of these were randomly selected (stratified by age group and deprivation category). These scans will be completed by spring 2008.

Before each visit the participants were contacted by telephone on the previous day to confirm their attendance and to ensure that the taxi arrangements were in place. At the end of the study all participants were sent a letter thanking them for their participation in the study and were informed that they would all receive an executive summary of the study findings. After each visit participants were asked to complete a feedback form detailing their opinion of the study and their experiences.

#### *Lifestyle questionnaire*

This questionnaire had 13 sections including basic demographic data, past and present health status, current medications, oral health, smoking history, alcohol intake, diet, physical activity levels, childhood situation, birth weight and place of birth, their parents' age and father's occupation, education levels, employment history and income levels.

#### *Carotid intima media thickness*

Measurement of the intima media thickness of the carotid artery by high resolution ultrasound is now a widely accepted, non-invasive, surrogate measure of atherosclerosis and a reliable indicator of future risk of a major coronary event[54,55]. Carotid intima media thickness provides a suitable continuous outcome measure for atherosclerosis, enabling association studies to be performed on fewer numbers (i.e. hundreds of subjects compared to classical surveys using endpoints such as MI which require sample sizes in the thousands). Recent carotid intima media thickness studies have evaluated the extent to which sex differences in CHD are explained by central obesity, the relationship between degree of atherosclerosis (intima media thickness) and inflammation status (CRP levels)[55,56] and the relationship of periodontal disease to carotid intima media thickness[57]. Ultrasound examination of the carotid arteries also allows presence and number of plaques to be determined[58,59]. Carotid plaque count has previously been found to be a predictor of myocardial infarction[58] and stroke[60]. The carotid ultrasound examination lasted 20 to 30 minutes. Doppler velocity in right and left internal carotid arteries was recorded in order to identify any significant internal carotid artery stenosis. Images of the distal 1 cm of the common carotid artery, the carotid bulb and the proximal internal carotid artery were recorded on the left and right side, and intima-media thickness of the far wall of the artery determined using the software package Etrack. The number of carotid plaques at each of the six sites was determined using published procedures[58]. M-mode ultrasound of the distal common carotid artery was recorded to assess arterial stiffness. Reading of the scans was performed off-line by a reader who was blinded to the identity of the participants.

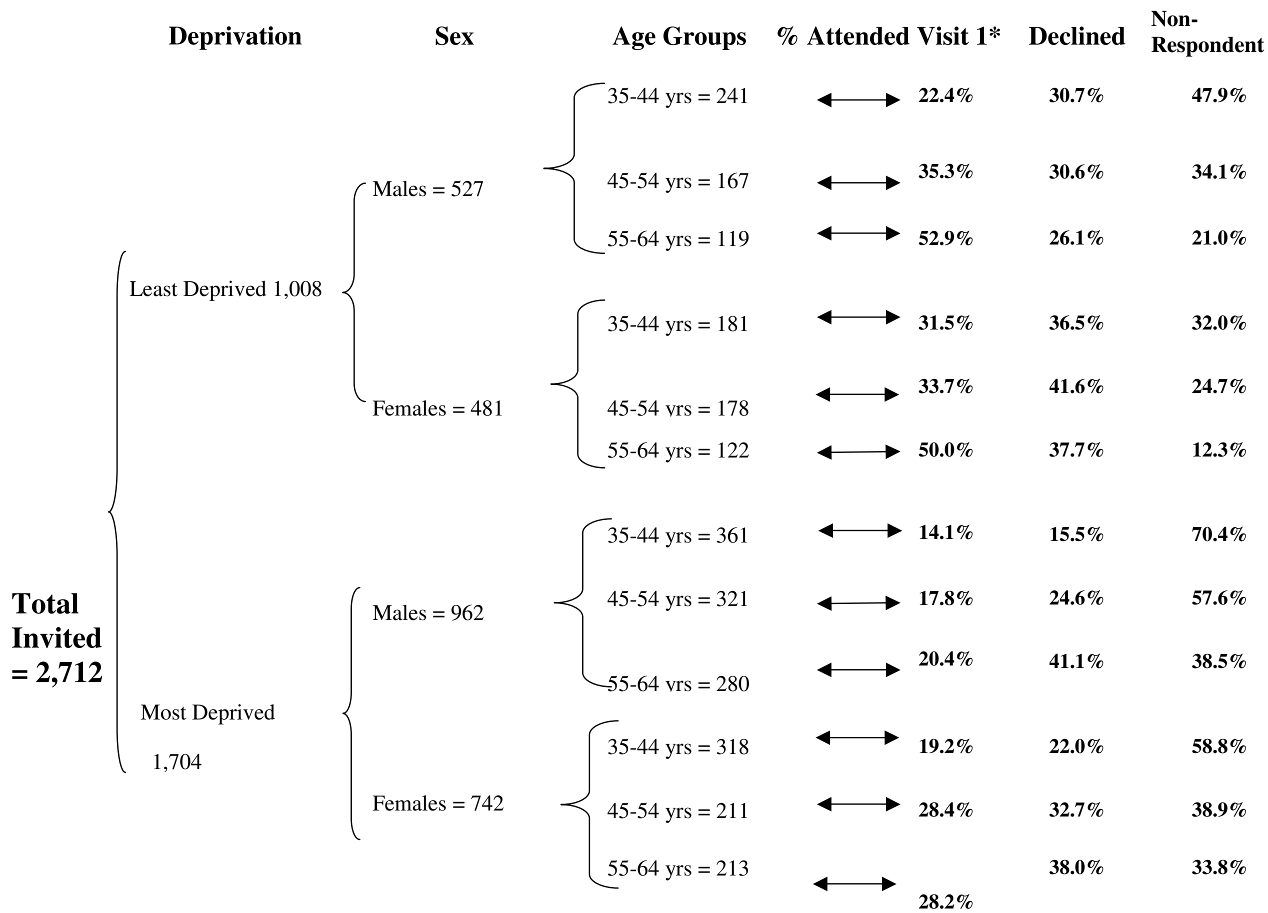


**Figure 2**
**Basic characteristics of subjects included in the pSoBid study by deprivation, sex and age**. * = Included in these % are 34 participants who ONLY completed Visit 1.

***GPASS Extraction Process***
GPASS was used to evaluate the characteristics of those who were invited to participate in the study. Eight of the ten GP practices (four in the LD area, four in the MD area) selected for the study use GPASS to record their routine data. Anonymised data were collected on smoking status and current prescription for statins, aspirin, antihypertensives, antidepressants and anti-diabetic drugs as evidence of the prevalence of chronic disease. Data were collected separately for those who attended visit 1 (Group 1), those who declined to attend (Group 2) and non-respondents to the invitation (Group 3). Non-participants (Group 4) were defined as the combination of groups 2 and 3.

***Statistical analysis***
Sample size in the LD and MD groups was estimated on the assumption that 90% would attend both visits and have CRP measured and that a maximum of 10% would not have good quality intima media thickness measurements. The power calculations were based on perceived clinically meaningful differences and assumed a 1.1 mg/L standard deviation for the natural logarithm of CRP measurements[61] and a 0.163 mm standard deviation for carotid intima media thickness[62]. Power calculations indicated that a sample size of 350 per group would provide 84% power to detect a 30% difference in mean CRP levels and 82% power to detect a 0.04 mm difference in mean carotid intima media thickness.

Categorical data are presented as counts and where appropriate as percentages. Where formal comparisons of percentages have been carried out, chi-squared tests have been used.

## Results
From the sampling frame of 3600 subjects a total of 2,712 invitations were issued to recruit a cohort of 700 (25.8%) participants. Out of the 2,712 invitations sent, 812

**Table 2: Breakdown of pSoBid study subjects**

| Sex/Depcat | Age Group | Completed Visit 1 & 2 | Withdrew after Visit 1 | Replied 'No' | Non-Respondents | Sent Letters |
|---|---|---|---|---|---|---|
| **LD Female** | **35–44** | 55 (30.4%) | 2 (1%) | 66 (36.5%) | 58 (32.1%) | 181 (100%) |
| **LD Female** | **45–54** | 56 (31.5%) | 4 (2.2%) | 74 (41.6%) | 44 (24.7%) | 178 (100%) |
| **LD Female** | **55–64** | 60 (49.2%) | 1 (0.8%) | 46 (37.7%) | 15 (12.3%) | 122 (100%) |
| **LD Female** | **Total** | **171 (35.6%)** | **7 (1.4%)** | **186 (38.7%)** | **117 (24.3%)** | **481 (100%)** |
| **LD Male** | **35–44** | 52 (21.6%) | 2 (0.8%) | 74 (30.7%) | 113 (46.9%) | 241 (100%) |
| **LD Male** | **45–54** | 58 (34.7%) | 1 (0.6%) | 51 (30.6%) | 57 (34.1%) | 167 (100%) |
| **LD Male** | **55–64** | 61 (51.2%) | 2 (1.7%) | 31 (26.1%) | 25 (21.0%) | 119 (100%) |
| **LD Male** | **Total** | **171 (32.4%)** | **5 (1%)** | **156 (29.6%)** | **195 (37.0%)** | **527 (100%)** |
| ***LD Participants*** | | ***342 (33.9%)*** | ***12 (1.2%)*** | ***342 (33.9%)*** | ***312 (31%)*** | ***1008 (100%)*** |
| **MD Female** | **35–44** | 55 (17.3%) | 6 (1.9%) | 70 (22.0%) | 187 (58.8%) | 318 (100%) |
| **MD Female** | **45–54** | 55 (26%) | 5 (2.4%) | 69 (32.7%) | 82 (38.9%) | 211 (100%) |
| **MD Female** | **55–64** | 58 (27.2%) | 2 (1%) | 81 (38.0%) | 72 (33.8%) | 213 (100%) |
| **MD Female** | **Total** | **168 (22.6%)** | **13 (1.8%)** | **220 (29.6%)** | **341 (46.0%)** | **742 (100%)** |
| **MD Male** | **35–44** | 49 (13.6%) | 2 (0.5%) | 56 (15.5%) | 254 (70.4%) | 361 (100%) |
| **MD Male** | **45–54** | 53 (16.5%) | 4 (1.3%) | 79 (24.6%) | 185 (57.6%) | 321 (100%) |
| **MD Male** | **55–64** | 54 (19.3%) | 3 (1.1%) | 115 (41.0%) | 108 (38.6%) | 280 (100%) |
| **MD Male** | **Total** | **156 (16.2%)** | **9 (0.9%)** | **250 (26.0%)** | **547 (56.9%)** | **962 (100%)** |
| ***MD Participants*** | | ***324 (19.0%)*** | ***22 (1.3%)*** | ***470 (27.6%)*** | ***888 (52.1%)*** | ***1704 (100%)*** |
| **GRAND** | **TOTAL** | **666 (24.6%)** | **34 (1.3%)** | **812 (29.9%)** | **1,200 (44.2%)** | **2712 (100%)** |

**LD = Least Deprived**.
**MD = Most Deprived**
The total response rates were calculated by combining those who completed Visit 1 & 2 (column 3) with those who withdrew after Visit 1 (column 4).

(29.9%) people declined to participate and 1,200 (44.3%) did not respond (Figure 1). Data collection was completed in April 2007 and data quality was tested over the summer of 2007. For calculation of response rate the denominator used was the total number invited to participate in the study.

There were 224 people in the sample who were not contactable. Letters were returned by the postal services because the addressee had moved or was not known at that address (Figure 1). Males in the MD category were more often not contactable (12.4%) compared to the other subjects (6.6% LD males, 5% MD females and 2.4% LD females).

GPs removed 103 subjects from the sample as they felt that the subjects were not able to complete the study (house bound, too ill to participate, terminal illness or literacy problems). Eighty-three were from the MD subjects (35 females and 48 males) and 20 were from the LD subjects (15 females and 5 males).

### *Response*

The number of letters sent in each of the 12 groups to recruit a target of 60 subjects was varied according to the group's response rate (Table 2). The highest number of letters (361) was sent to 35–44 year old males in the MD group (response rate = 14%); the fewest (119 and 122 respectively) were sent to 55–64 year old males and females in the LD participants (response rate 52.9% and 50% respectively – Figure 2). Although the initial target was 60 per group (720 in total), we stopped recruitment at 700 (in line with the power calculation) due to time constraints.

Of the 700 subjects who participated in the study only 34 (4.9%) did not complete both visits. Of these, 12 were 35–44 years old; 14 were 45–54 years and 8 were 55–64 years (Table 2).

There were 171 male and 171 female participants in the LD group and 168 females and 156 males in the MD group (Table 2). The response rate was 33.9% for LD and 19.0% for MD participants, and response rate by age group was 31.7% in 35–44 year olds, 33.3% in 45–54 year olds and 35% in 55–64 year olds.

A total of 812 subjects (Table 2) in the sample declined (replied NO to the invitation). There were more females who declined (LD = 38.7% and MD = 29.6%) than males (LD = 29.6% and MD = 26.0%). In the MD group (35–44 year olds were less likely to respond than were 55–64 year olds, but this age difference was not seen in the LD subjects.

A total of 1,200 people in the sample did not respond to the letter; the non-response was 52.1% for MD and 30.9% for LD subjects. More males did not respond (LD = 37%

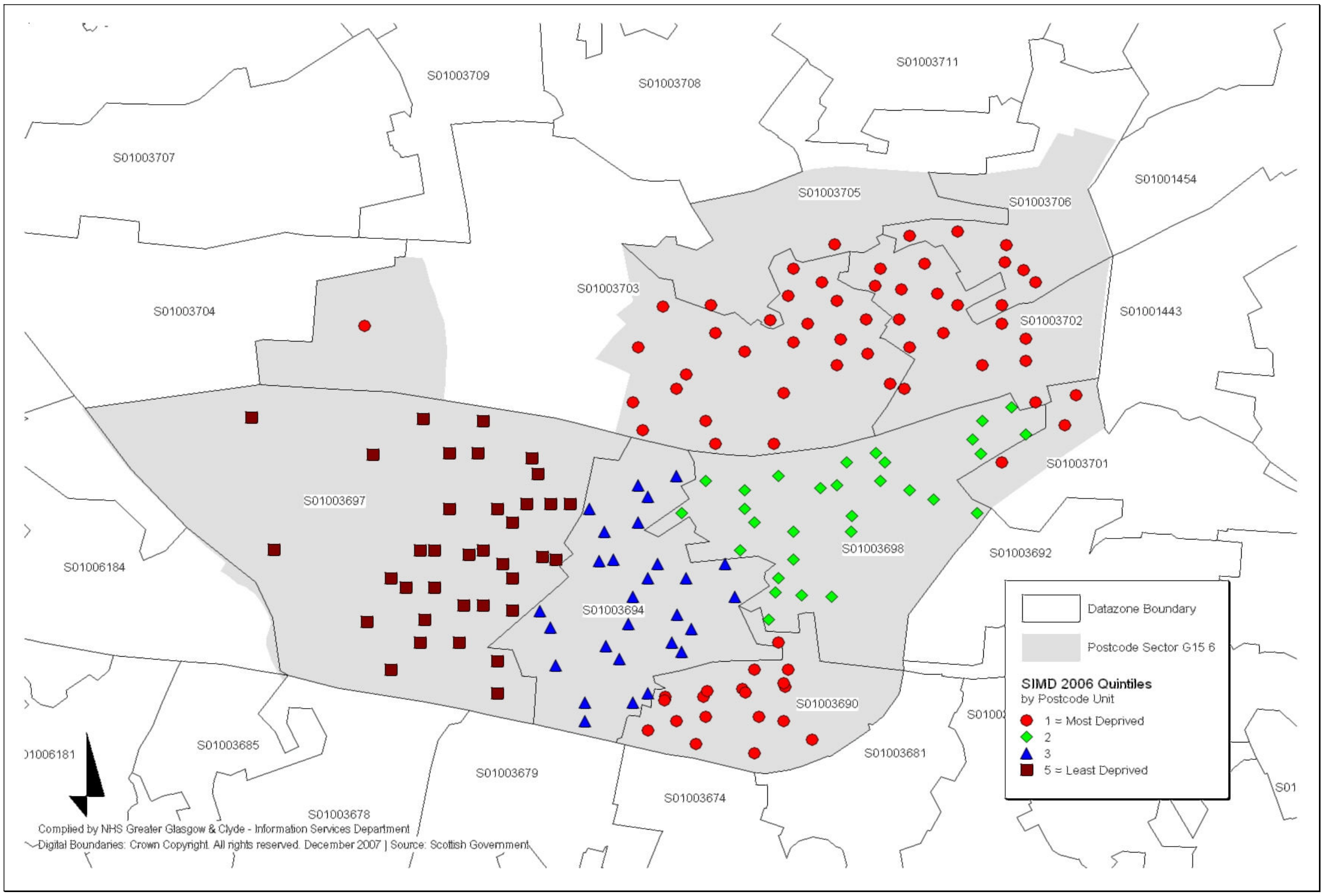


**Figure 3**
**Map showing Postcode Sector G15 6 by DECPAT and SIMD Data Zones**. SIMD = Scottish Index for Multiple Deprivation.

and MD = 56.9%) compared to females (LD = 24.3% and MD = 46%). There was an age difference for both males and females (non-response rate higher for 35–44 compared to 55–64 year olds) in both MD and LD subjects.

## Discussion

The study was successful in recruiting subjects of the desired sex and age profile from the most and least deprived areas of Glasgow. Data zones in SIMD were the preferred choice for our sampling process because each covers a smaller area and population (750–1,000) than the Postcode sectors which were used in a previous, well used deprivation classification (DEPCAT)[63]. This is illustrated in Figure 3 which shows the Postcode sector G15 6 (DEPCAT 6) and the same area by data zones (SIMD quintiles 1–5). The G15 6 area has nine data zone areas which have clear boundaries between the various quintiles in the SIMD and consists of least and most deprived areas. The Information Services Division (ISD) Scotland has recommended that routine and in-depth NHS Board level analyses from 1997 onwards use SIMD measure of deprivation[64].

In recruiting for the present study we found similar patterns of response to those observed in earlier surveys. In the Scottish Health Survey of 2003 (SHS 2003) from the co-operating households, response was lowest among those aged 16–24. Among men, response was highest among those aged 65 plus, while among women those aged over 24 gave a consistently high response rate[65]. In SHS 2003, men aged below 35 years were slightly under-represented at both interview and nurse visit relative to their proportions in the population while men aged 55 and over were slightly over-represented. Women aged below 25 years were under-represented at both stages, while women aged 45–74 were overrepresented[65].

The availability of the GPASS information allowed us to examine at least some potential bias inherent in our recruitment strategy. Of particular concern was the possibility that, of those invited, the 'worried well' and 'healthy deprived' would preferentially volunteer, so minimising potential differences between the least and most deprived communities.

A further methodological concern was the impact on participation of the number of questionnaires, investigations and the prospect of having to attend two visits of 1 1/2 hours each for this study. Only 34 participants failed to complete both visits and the full set of evaluations. Participants stated on a feedback questionnaire that they were highly satisfied with the study process and some saw it as an opportunity to have a complete medical check-up

### *Strengths and Limitations*

The study achieved its recruitment objectives in terms of the sample size and the nature of the recruits. The depth and range of the evaluations performed will provide important information concerning the relationships between deprivation, obesity, inflammation, atherosclerosis and mental outlook. This will enable us to address the hypothesis that the increased prevalence of coronary heart disease, type 2 diabetes and negative mental outlook in a deprived population is attributable in large part to an increased frequency of chronic inflammation, endothelial dysfunction and insulin resistance linked to the more challenging social environment.

There are limitations to the design of pSoBid[66]. Since the sample was stratified by age and sex, it is not a true representation of the general population; further, there is bias due to the variation in response rate. The sample was selected from the extremes of deprivation so as to maximise any observed differences and, therefore, provides no information about population gradients. The cross-sectional nature of the study means that it will not be possible to identify causal pathways or the temporal relationship between variables.

That said, the breadth and depth of data collected, linkage to NHS records, and the population-based nature of pSoBid make it an important resource, now and in prospect, for building understanding about the mechanisms that help to explain deprivation-related ill-health.

## Conclusion

The multidisciplinary approach employed in this study will enable a more holistic understanding of the diverse characteristics of individuals who reside in affluent and deprived communities and their influence on health and health inequalities. This study also illustrates the willingness of subjects to volunteer for a variety of investigations involving psychological, behavioural, sociological and medical questions and tests including blood analysis. As in other studies it was easier to enrol females than males, older compared to younger people, and the more affluent participants. Linkage to medical records allowed comparison of the health characteristics of participants and non-participants, yielding an insight into aspects of volunteer bias in studies of this type. This study also brought together researchers/academics from diverse disciplines to build a more sophisticated understanding of the determinants of health inequalities than can be achieved through unidisciplinary approaches. Future analyses will enable an understanding of the relationships between the different types of measure, and of the pathways that link poverty, biology, behaviour and psychology and lead to health inequalities.

This article has outlined the study background, design and recruitment. The findings from this study will be presented in future articles.

## Competing interests

The author(s) declares that they have no competing interests.

## Authors' contributions

YV, CJP, DGB, HB, JC, KD, IF, KM, NS, PS and CT contributed equally to conception, design and final approval of the version to be published. YV, CJP and CT have been involved in drafting the manuscript and revising it critically for important intellectual content. VB performed the statistical analysis. AM supervised the recruitment of subjects and data collection.

## Additional material

Additional file 1
*Flow chart for subjects in pSoBid.*
Click here for file
[http://www.biomedcentral.com/content/supplementary/1471-2458-8-126-S1.doc]

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**Review**

# The Influence of Yoga-Based Programs on Risk Profiles in Adults with Type 2 Diabetes Mellitus: A Systematic Review

**Kim E. Innes[1,2] and Heather K. Vincent[2]**

[1]Center for the Study of Complementary and Alternative Therapies and [2]Department of Physical Medicine and Rehabilitation, University of Virginia Health Systems, Charlottesville, VA, USA

There is growing evidence that yoga may offer a safe and cost-effective intervention for Type 2 Diabetes mellitus (DM 2). However, systematic reviews are lacking. This article critically reviews the published literature regarding the effects of yoga-based programs on physiologic and anthropometric risk profiles and related clinical outcomes in adults with DM 2. We performed a comprehensive literature search using four computerized English and Indian scientific databases. The search was restricted to original studies (1970–2006) that evaluated the metabolic and clinical effects of yoga in adults with DM 2. Studies targeting clinical populations with cardiovascular disorders that included adults with comorbid DM were also evaluated. Data were extracted regarding study design, setting, target population, intervention, comparison group or condition, outcome assessment, data analysis and presentation, follow-up, and key results, and the quality of each study was evaluated according to specific predetermined criteria. We identified 25 eligible studies, including 15 uncontrolled trials, 6 non-randomized controlled trials and 4 randomized controlled trials (RCTs). Overall, these studies suggest beneficial changes in several risk indices, including glucose tolerance and insulin sensitivity, lipid profiles, anthropometric characteristics, blood pressure, oxidative stress, coagulation profiles, sympathetic activation and pulmonary function, as well as improvement in specific clinical outcomes. Yoga may improve risk profiles in adults with DM 2, and may have promise for the prevention and management of cardiovascular complications in this population. However, the limitations characterizing most studies preclude drawing firm conclusions. Additional high-quality RCTs are needed to confirm and further elucidate the effects of standardized yoga programs in populations with DM 2.

**Keywords:** blood pressure – cardiovascular disease – coagulation – glycemia – insulin resistance – lipids – lung function – oxidative stress – sympathetic activity

## Introduction

Type 2 Diabetes mellitus (DM 2) is a leading cause of death and disability in the United States (US) and other industrialized nations (1–3) as well as in a growing number of developing countries (4–6). In the United States, newly diagnosed cases of DM 2 have increased ~50% in the past 10 years alone (2). As of 2002, DM 2 was estimated to affect ~16 million Americans, with 1.3 million new cases diagnosed each year (2). An additional 41 million or more people have impaired glucose tolerance or impaired fasting glucose, collectively referred to as prediabetes, a powerful predictor of clinical DM 2 (1,2,7). Both diabetes and prediabetes dramatically increase risk for cardiovascular disease (CVD) and stroke, and for death due to CVD-related causes (2,7,8). Leading to premature morbidity and mortality, and to preventable disability and work loss, DM 2 is clearly of pressing clinical and economic significance, with direct medical expenditures for DM 2 in the United States totaling over $92 billion in 2002 alone (1,2).

While diabetes is a glycemic disorder, diagnosed on the basis of elevated blood glucose levels, it is a complex

For reprints and all correspondence: Heather K. Vincent, The Center for the Study of Complementary and Alternative Therapies, The Blake Center, Suite G113, PO Box 800905, University of Virginia Health Systems, Charlottesville, VA 22908-0905, USA. Tel: +1-434-243-9933; Fax: +1-434-243-9938; E-mail: kei6n@virginia.edu

condition characterized by multiple, underlying and interrelated metabolic abnormalities linked to insulin resistance (3,9,10). These alterations, together comprising the insulin resistance or metabolic syndrome, collectively and independently predict the development of DM 2 (1,9–11) and related vascular disorders, including atherosclerosis and CVD (1,9,11–16). Core features of the insulin resistance syndrome (IRS) are glucose intolerance, insulin resistance, atherogenic dyslipidemia, visceral adiposity and high blood pressure (12,14,16,17). Other abnormalities associated with the IRS and linked to the pathogenesis and progression of DM 2 (10,18–21) include hypercoagulation (10,14,20,21), chronic inflammation (8,14,16,17,19,21), endothelial dysfunction (8,10,14,20–22), oxidative stress (18,22) and impaired lung function (23–25). Increased sympathetic activity, enhanced cardiovascular reactivity and reduced parasympathetic tone have also been implicated in the pathogenesis of IRS (14,21,26–30) and in the development and progression of DM 2 and related cardiovascular complications (21,31,32). In addition, there is mounting evidence that chronic psychological stress and negative mood states are strongly associated, in a bidirectional manner, with insulin resistance (33–37), glucose intolerance (34,38), central obesity (39–41) dyslipidemia (34,37,42), hypertension (43–47) and other components of the IRS (33,39,48–54). Likewise, prospective studies have shown depression, a common comorbidity in diabetic populations (55,56) and a powerful predictor of CVD morbidity and mortality (45,52,57–62), to increase risk for developing DM 2 by 2- to 3-fold (56,63,64).

Clearly, there is a need to identify cost-effective prevention and management strategies for DM 2 that address the multiple interrelated factors underlying this complex, devastating and increasingly common disorder. In light of the strong influence of psychosocial factors on the development of IRS and DM 2, the role of sympathetic activation in the pathogenesis of insulin resistant states, and the bi-directional relationships of these and other IRS-related risk factors, mind–body therapies may hold particular promise for both the prevention and treatment of DM 2. Of particular interest in this regard is yoga, an ancient mind–body discipline that has been widely used in India for the management of diabetes, hypertension and related chronic insulin resistance conditions (65–69).

Originating in India over 4000 years ago, the practice of yoga has been rising steadily in the United States and other industrialized countries during recent decades (70–72). Of the seven major branches of Hindu yoga, Hatha (or forceful) yoga, Raja (Royal or classical) yoga, and Mantra yoga are perhaps the best known and most commonly practiced forms. Mantra yoga, emphasizing the use of specific sounds or chants to achieve mental and spiritual transformation, was popularized in the West by Maharishi Mahesh Yogi, the founder of Transcendental Meditation (TM). Raja yoga, Patanjali's eight limb system of meditation, contemplation and renunciation, seeks self-realization and transformation through progressive control of the mind (73). Hatha yoga, the branch of yoga most widely practiced in the Western industrialized world, approaches self-realization and healing through the physical body and its energetic (pranic/etheric) template, with a focus on breath control (pranayama) and specific postures (asanas), including both active and relaxation poses (73). Hatha yoga also incorporates mental concentration (dharana), and meditation (dhyana), mantras or chants, cleansing exercises (kriyas), and specific hand gestures (mudras) (74). With no appreciable side effects and multiple collateral lifestyle benefits (70,72,75,76), yoga appears safe, is simple to learn, and can be practiced by even ill, elderly or disabled individuals (77). Yoga is also easy and inexpensive to maintain, requiring little in the way of equipment or professional personnel, with some studies indicating excellent long-term adherence and benefits (78–80). Notably, there is growing evidence that yoga practice may aid in the prevention and management of DM 2, reduce IRS-related risk factors associated with DM 2, and may improve the prognosis and attenuate signs of those with clinical DM 2 (69,81–85).

In this paper, we critically review the published scientific literature regarding the influence of yoga on metabolic perturbations of DM 2 and on related clinical outcomes, taking into account the major limitations and biases of these studies. Relevant findings from non-diabetic populations regarding observed effects of yoga on IRS-related risk factors for CVD and associated clinical outcomes, reviewed in depth in a previous publication (82), are also summarized, and the implications of these findings for the primary and secondary prevention of DM 2 are discussed.

## Methods

We conducted a thorough search of the published medical literature to identify studies regarding the effects of yoga in adults with diabetes. The search was restricted to English language articles published after 1970 and available in US libraries, and to original studies specifically evaluating the effects of yoga (alone or in combination with other interventions) on metabolic, anthropometric or clinical profiles of adults with DM. Because DM is so often associated with CVD (9,10), studies targeting populations with or at risk for cardiovascular disorders that explicitly included adults with DM were also evaluated. Original studies were included in the review if they reported outcome data and evaluated the effects of yoga and yoga-based interventions on clinical measures of insulin resistance, lipid profiles, body weight or composition, blood pressure, oxidative stress, coagulation/fibrinolytic profiles, lung function, or on markers of sympathetic activation and cardiovagal function. We also included studies assessing the influence of yoga and yoga-based programs on relevant clinical outcomes, including medication use, DM- or CVD-related events and hospitalizations, and measures of CVD progression.

Since the etiology and management for Type 1 diabetes differs from that of type 2 diabetes, studies targeting only populations with type 1 diabetes were excluded. Case studies, abstracts from conference proceedings and anecdotal reports were also eliminated, as were studies with intervention group sizes of less than four subjects. Articles were identified using MEDLINE, PubMED and psycINFO, three commercially indexed, scientific databases. Because the majority of studies investigating the effects of yoga therapy have been conducted in the Indian subcontinent and these databases offer only incomplete capture of articles published in Indian medical journals, IndMED, a bibliographic database of over 75 major Indian biomedical journals, was also searched. Search words included yoga, yogic, relaxation, mind–body and meditation. In addition, the citation sections of all identified articles, including review papers, were scanned to identify relevant papers not indexed in PsycINFO, PubMED, MEDLINE or IndMED.

Each eligible study (i.e. each study identified that met our inclusion criteria) was classified into one of three design categories: randomized controlled trials (RCTs), non-randomized controlled trials (NRCTs) and uncontrolled (pre-post) trials. In RCTs, an investigator randomly allocates a yoga or yoga-based program to one group (the experimental or yoga group) and no intervention, usual care, or another intervention to one or more other groups (controls). Both groups are then evaluated to determine change over time in specific indices of CVD risk. In NRCT, the experimental design and analytic strategy are similar to that of RCTs, but the allocation to a given treatment is not performed randomly. In uncontrolled (pre–post) studies, all subjects participate in a yoga or yoga-based program, and change over time (baseline to post-intervention) in specific indices of CVD risk is evaluated.

Study quality was evaluated using criteria based on those utilized in recent systematic reviews regarding the effects of yoga (82) and other popular mind–body therapies (86,87). Criteria included (i) adequate sample size; (ii) explicit eligibility criteria and/or adequate description of study population; (iii) single, well-defined intervention; (iv) appropriate control group(s) or comparison condition(s); (v) randomization of treatment allocation; (vi) blinding of outcome assessment; (vii) adequate accounting for confounders; (viii) statistical methods well described and appropriate; (ix) outcome measures well-defined and point estimates and measures of variability presented; (x) adequate follow-up/drop-out rate reported; and (xi) conclusions supported by findings.

Clinical measures and outcomes evaluated were categorized into several different domains (Table 2). For each domain, we summarized findings from relevant studies. Due to the heterogeneity of study designs, settings, interventions and outcomes, we did not conduct a meta-analysis.

## Results and Discussion

The literature search identified a total of 25 eligible studies investigating the influence of yoga-based interventions on physiologic/anthropometric indices of DM 2 and/or related clinical outcomes, including 15 uncontrolled clinical trials, 6 NRCTs and 4 RCTs (Table 1). Of these studies, 13 uncontrolled studies, 2 NRCTs, and 2 RCTs specifically targeted adults with DM. A majority (77%) of identified studies were published between 1990 and 2006, and most were small in size, with over 40% having study populations numbering under 25 subjects. Seventy-nine percent of total eligible studies, and almost 90% of those specifically investigating diabetic populations were conducted in India (Table 1). Yoga-based interventions used in these studies ranged in duration from 8 days to 12 months. Some studies evaluated the effects of single ($n = 2$) or multiple components of yoga practice ($n = 12$) alone, while others assessed comprehensive yoga-based programs that included a special diet, lifestyle education, non-yogic exercise, stress management or other interventions ($n = 11$) (Table 1). Table 2 lists the characteristics of eligible studies identified. The findings of these studies regarding the effects of yoga-based interventions on specific IRS-related physiologic and anthropometric indices and relevant clinical outcomes are reviewed below.

### Influence of Yoga on Core Indices of the IRS

Twenty-five eligible published studies from four countries have investigated the potential influence of yoga and yoga-based programs on one or more core indices of the IRS, including measures of insulin resistance and glucose metabolism, lipid profiles, body weight and composition, and blood pressure. Of these studies, 20 examined the influence of yoga-based interventions on clinical markers of insulin resistance (including 14 uncontrolled clinical trials, 3 NRCTs and 3 RCTs), 12 evaluated the influence of yoga on blood lipid profiles (including 4 uncontrolled clinical trials, 5 NRCTs and 3 RCTs), and 10 assessed the influence of yoga on body weight or composition (including 4 uncontrolled trials, 5 NRCTs and 1 RCT). In addition, we identified six eligible studies evaluating the effects of yoga on blood pressure, including three uncontrolled analyses, two non-randomized controlled studies and one RCT. Findings of these are summarized in Tables 2–4 and are discussed briefly below.

#### *Markers of Insulin Resistance*

Of the 20 eligible studies evaluating the effects of yoga on markers of insulin resistance, all but one documented significant, post-intervention improvement in one or more clinical measures following the practice of yoga either alone or in combination with other therapies (Tables 3 and 4). Interventions ranged in length from 8 days (88) to 12 months (89,90), and all but one (91) incorporated yoga asanas or poses. All 14 uncontrolled studies targeting adults with DM 2 (65,83,91–101), hypertension (68) and/or other chronic conditions (88) reported significant improvement post-intervention in indices of insulin resistance relative to baseline values. Documented changes included reductions in fasting (65,68,83,88,91,94–100) and post-prandial glucose (65,83,91–99), and in fasting glycated hemoglobin (83,97,98,100) (Table 2). Likewise, non-randomized controlled studies of adults with diabetes (102,103) or confirmed coronary artery disease (CAD) (89) reported reductions in fasting glucose (89,102,103) and fructosamine (102) among subjects receiving a yoga-based

**Table 1.** Characteristics of eligible studies investigating the effects of yoga-based programs in adults with Diabetes mellitus (DM)

| | Uncontrolled clinical trial | | Non-randomized controlled trial | | Randomized controlled trial | | Totals | |
|---|---|---|---|---|---|---|---|---|
| | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | *n* | % |
| Target population: adults with DM | | | | | | | | |
| DM 2 only | 3 | 2 | | 1 | 1 | | 7 | 41.2 |
| DM 1 and 2 | 2 | 2 | | | 1 | | 5 | 29.4 |
| Unspecified DM | 4 | | 1 | 1* | | | 5 | 29.4 |
| Total targeting DM | 9 | 4 | 1 | 1 | 2 | | 17 | |
| Sample size | | | | | | | | |
| <25 | 7 | 1 | | | 1 | | 9 | 52.9 |
| 25–40 | 2 | 2 | | 1 | 1 | | 6 | 35.3 |
| 41–60 | | | | | | | 0 | 0.0 |
| >60 | | 1 | 1 | 1* | | | 2 | 11.8 |
| Location | | | | | | | | |
| India | 9 | 2 | 1 | 1 | | | 13 | 76.5 |
| US | | | | | | | 0 | 0.0 |
| Europe | | | | | 2 | | 2 | 11.8 |
| Year published | | | | | | | | |
| 2000–05 | 3 | | | 1 | 1 | | 5 | 29.4 |
| 1990–99 | 1 | 2 | 1 | 1* | 1 | | 5 | 29.4 |
| 1980–89 | 5 | 1 | | | | | 6 | 35.3 |
| 1970–79 | | 1 | | | | | 1 | 5.9 |
| | | | | | | | 17 | |
| Target population: adults with CAD/hypertension and/or various chronic illnesses including | | | | | | | | |
| DM 2 | | 1 | | 1 | | 1 | 3 | 42.9 |
| Unspecified DM | | 1 | | 3 | | 1 | 5 | 71.4 |
| DM N not stated | | | | 1 | | 1 | 2 | 28.6 |
| Total | | 2 | | 4 | | 2 | 8 | |
| Sample size | | | | | | | | |
| <25 | | 1 | | | | | 1 | 14.3 |
| 25–40 | | | | | | | 0 | 0.0 |
| 41–60 | | | | | | 2 | 2 | 28.6 |
| >60 | | 1 | | 4 | | | 5 | 71.4 |
| Location | | | | | | | | |
| India | | 2 | | 1 | | 1 | 4 | 57.1 |
| US | | | | 2 | | 1 | 3 | 42.9 |
| Europe | | | | 1 | | | 1 | 14.3 |
| Year published | | | | | | | | |
| 2000–05 | | 2 | | 2 | | 2 | 6 | 85.7 |
| 1990–99 | | | | 2 | | | 2 | 28.6 |
| 1980–89 | | | | | | | 0 | 0.0 |
| 1970–79 | | | | | | | 0 | 0.0 |
| Sample size | | | | | | | | |
| <25 | 7 | 2 | 0 | 0 | 1 | 0 | 10 | 41.7 |
| 25–40 | 2 | 2 | 0 | 1 | 1 | 0 | 6 | 25.0 |
| 41–60 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 8.3 |
| >60 | 0 | 2 | 1 | 4 | 0 | 0 | 7 | 29.2 |
| Location | | | | | | | | |
| India | 9 | 6 | 1 | 2 | 0 | 1 | 19 | 79.2 |

**Table 1.** *Continued*

| | Uncontrolled clinical trial | | Non-randomized controlled trial | | Randomized controlled trial | | Totals | |
|---|---|---|---|---|---|---|---|---|
| | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | *n* | % |
| US | 0 | 0 | 0 | 2 | 0 | 1 | 3 | 12.5 |
| Europe | 0 | 0 | 0 | 1 | 2 | 0 | 3 | 12.5 |
| Year published | | | | | | | | |
| 2000–05 | 3 | 2 | 0 | 3 | 1 | 2 | 11 | 45.8 |
| 1990–99 | 1 | 2 | 1 | 2 | 1 | 0 | 7 | 29.2 |
| 1980–89 | 5 | 1 | 0 | 0 | 0 | 0 | 6 | 25.0 |
| 1970–79 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 4.2 |
| Totals | 9 | 6 | 1 | 5 | 2 | 2 | 25 | |

CAD, coronary artery disease; DM 1, Type 1 Diabetes mellitus; DM 2, Type 2 Diabetes mellitus.
*Two yoga-based interventions tested within same study (100).

intervention versus controls receiving enhanced usual care (89), a low fat vegetarian diet alone (102) or a light to moderate exercise program that included walking (103). In a small RCT of British adults with DM 2, Monro *et al.* (101) demonstrated significant declines in both fasting glucose and glycated hemoglobin (HbA1c) among participants attending structured yoga classes relative to usual care controls. In a second RCT of 37 adults with poorly controlled DM, of whom 14 had type 1 diabetes, those attending biweekly yoga classes for 16 weeks demonstrated similar, but non-significant declines in $HbA_1c$ (84). In contrast, in a small RCT of American seniors, a subanalysis of those at risk for CVD did not demonstrate significant reductions in $HbA_1c$, fasting glucose or fasting insulin in those completing a comprehensive integrative medicine program relative to controls receiving usual care or an active exercise and diet intervention. However, sample sizes in this analysis of seniors were very small ($n = 6$, 3 and 3, respectively) (90). Overall, yoga practice was associated with a 6.1–34.4% reduction in fasting glucose, 23.9–32.8% reductions in post-prandial glucose and 10.5–27.3% reduction in $HbA_1c$, with the percentages varying by study population and design (Table 4).

While the evidence for a beneficial effect of yoga on indices of insulin resistance appears generally consistent across studies, most studies (60%) had no comparison groups (65,68,83,88,91–100), and many had small sample sizes (65,68,83,84,93–98,101) or reduced power due to stratified analyses (65,90,99,102). Others lacked detailed information on eligibility criteria or study population characteristics (65,83,92,95–98,100,102–104), including type of diabetes (90,95,96,105–107). Blinding of the outcome assessment was reported in only one (90). The study sample selection process was unclear in several studies (83,93,95–98,100, 102,103), and in others, potential selection bias (93,97), loss to follow-up (89,93–96) and uncontrolled confounding factors such as demographic, anthropometric and lifestyle characteristics (65,83,88,91,92,95–97,99,100) may have been influential. The intervention was not well-described (65,91,93,95) or appeared to vary in duration or intensity (91–94,101) in some studies; others included multiple interventions (68,79,88–90, 94,99,100,103,105), rendering detection of the effect of a specific component difficult. Most studies did not adequately detail the analytic methods used (68,92,97–99,101,103,108), some presented no statistical analysis for some or all of the outcome measures (68,91,92,99,103), and many appeared to suffer other methodological deficiencies, including lack of adequate point estimates for key outcome measures (68,88,92,94,103,104), failure to adjust for multiple comparisons (68,83,84,88,90–92,94,97,98,100,102), confusing data presentation (65,68,91) and other potential analytic problems (65,90,95). Among the controlled studies, additional limitations included lack of randomization (89,102,103), failure to describe treatment allocation methods (89) or adjust for differing baseline characteristics (79,102) and/or absence of intergroup comparisons (103,107).

### *Blood Lipid Profiles*

Of the 12 identified studies that assessed the potential effects of yoga on blood lipid concentrations, all suggested that the practice of yoga and yoga-based programs may improve lipid profiles (Table 3). Four uncontrolled studies targeting adults with diabetes (100,109) and/or other chronic conditions (68,88), demonstrated significant positive changes in blood lipid levels following yoga-based interventions that ranged from 8 days (109) to 3 months (109) in duration. Observed improvements in blood lipid fractions included reductions in cholesterol (68,88,100,109), triglycerides (88,100,109), low-density lipoprotein (LDL) (88,109), and very LDL levels (88,109), increases in high density lipoprotein (HDL) levels (68,109), and reduced LDL/HDL ratio (88) relative to baseline levels and/or control values (89,110,111). Similarly, five controlled, non-randomized studies (102,104,106,112,113) and two RCTs (79,84) investigating the effects of yoga alone (102) or in combination with diet (79,102,106,112,113), education (84), stress management (89,106,113) and other therapies (79,89,106,113) demonstrated significant improvement in lipid profiles relative to controls receiving enhanced

**Table 2.** Characteristics and relevant measures and outcomes of eligible studies

| Reference, location | Sample size (yoga, controls) | Duration | Study population | Comparison group/ condition | Intervention | Clinical measures | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | IR indices | Lipids | Body size/ comp | BP | Coagulation | Oxidative stress | SNS/PSN activity | Lung function | Other clinical outcomes |
| **Studies targeting adults with Diabetes mellitus†** | | | | | | | | | | | | | | |
| *Uncontrolled clinical trials* | | | | | | | | | | | | | | |
| (92), India | 52 | 6+ months, 45 min per day | Adults 17–70 years with uncomplicated DM for 3+ years (11 DM 1, 38 obese) | Ss own controls | Yoga (AS, SH); obese also on low cal diet | X+ | | X+ | | | | | | X+ |
| (93), India | 14 (7 DM; 7 normal) | 6 months 40 min per day | White collar men aged 25–63, white collar, 7/10 with hx of DM for 6 months to 11 years (3 drop out first 2 weeks; 6 DM 2, 1 DM 1 complete study); 7 non-DM | Ss own controls | Yoga (AS, SH, PR) | X+ | | X+ | | | | | | |
| (109), India | 32 (5–8 per group) | 10–12 weeks, 45–60 min day | 27 men, 5 women with DM; avg 47.5 (M), 43 years (F); randomized to 5 different yoga routines | Ss own controls | Yoga training (AS, PR, SH) | | X+ | | | | | | | |
| (65), India | 16 | 28 days | Adults with DM assigned to 1 of 3 yoga routines | Ss own controls | Yoga AS | X+ | | | | | | | | |
| (91), India | 35 | Not stated | Adults with DM (31 DM 2, 4 DM 1) | Ss own controls | Yoga PR | X+ | | | | | | | | X+ |
| (94), India | 9 (2 DM 1, 7 DM 2) | 5 weeks, 1 h 2× per day | 9 hospital pts 25–50 years (DM 5–10 years) naïve to yoga; 4 on insulin, others on oral drugs | Ss own controls | Resid. yoga training (AS, PR, KR, SH) +low cal, fat diet | X+ | | X+ | X+ | | | | | X+ |
| (95), India | 20 (10 DM, 10 normal) | 6 months | I. 10 non-DM men 30–35 years, 10 DM men 32–37 years, on oral meds and special diet. Analyses stratified by DM status | Ss own controls | Yoga training and practice (AS, SH/R) | X+ | | | | | | | | |
| (96), India | 20 (10 DM, 10 normal) | 6 months | I. 10 non-DM men 34–37 years, 10 non-obese DM men 34–37 years, on oral meds and special diet. Separate analyses | Ss own controls | Yoga training and practice (AS, SH/R) | X+ | | | | | | | | |
| (99), India | 149 | 40 days, 2.5 h per day | 149 outpatients with DM 2, avg 45.9 years, 22–23 BMI | Ss own controls | Residential (hosp-ital) yoga AS, KR, PR, SH+ veg diet | X+ | | X+ | | | | | | X+ |
| (100), India | 30 | 40 days | Hospitalized men with DM 2; 22 on oral drugs, mean 59.5 years, 17 years DM duration, 22.5 BMI | Ss own controls | Residential (hosp-ital) yoga AS, KR, PR, SH+ veg diet | X+ | X+ | X+ | | | | | | |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (97), India | 19 | 40 days, 2.5 h per day | Non-smoking adults 30–60 years w/uncomplicated DM 2?, on drug and diet control | Ss own controls | Yoga (AS, PR, M) | X+ | | | | | X+ | | | |
| (98), India | 24 | 40 days, 30–40 min per day | Adults 30–60 years old; with un-complicated DM 2 (0–10 years) | Ss own controls | Supervised yoga AS, SH, PR | X+ | | | | | | | | |
| (83), India | 24 | 40 days | Adults 30–60 years with un-complicated DM 2 (1–10 years) on meds, diet | Ss own controls | Yoga (AS, SH): 13 poses in standard sequence | X+ | | | X+ | | | X+ | | X+ |
| *Non-randomized controlled trials* | | | | | | | | | | | | | | |
| (103), India | 20, 20 | 40 days | 30–60 years; DM 2 for 0–10 years; controls similar age, DM severity | Medication, light-moderate exercise | Supervised yoga AS, PR, SH+ medication, diet | | | | | | | | X+ | |
| (102), India | 80 (20,20,20,20) | 3 months, 2× per day, 25–35 min | 60 patients from Indore diabetic clinics (intervention), 20 non-DM matched on age, sex; 40–70 years on vegetarian diet | No intervention (non-DM adults); Strict diet alone (20 DM adults) | (i) Yoga AS,SH only center(ii) Yoga +strict diet | X+ | X+ | X+ | | | | | | |
| *Randomized controlled trials* | | | | | | | | | | | | | | |
| (101), UK | 21 (11,10) | 12 weeks, 90 min 1–5× per week | Uncomplicated type 2 DM controlled with meds ($n$ = 13; 8 Yoga group) or diet ($n$ = 8); 45–67 years, avg 53 (Y), 57 (C) | Usual care (continue on medication, diet) | Yoga classes (PR, AS, SH) + usual care | X+ | | | | | | | | X+ |
| (84), UK | 37* | 16 weeks | Poorly controlled insulin-treated DM (14 with DM 1) from Hospital DM clinic, avg 60–61 years | Education, simple exercise | Education, Hatha yoga classes | X+ | X+ | | X- | | | | | X+ |
| **Studies including but not targeting adults with DM 2** | | | | | | | | | | | | | | |
| *Uncontrolled clinical trials* | | | | | | | | | | | | | | |
| (68), India | 20 | 78 sessions, 1 h per day | Adults with mild to moderate hypertension, 35–55 years. Include 4 Ss with DM (age 39–50 years) | Ss own controls | Yoga (AS, PR, M,SH) +education | X+ | X+ | | | | X+ | X+ | | X+ |
| (88), India | 98 (20 with DM) | 8 days, 3–4 h per day with weekend off | 67 male, 31 female clinic out-patients aged 20–74 (avg 46) years with CV disorders, DM, obesity or other chronic condition | Ss own controls | Yoga (AS, SH, M, PR)+ education, advice, group support, stress management | X+ | X+ | | | | | | | |
| *Non-randomized controlled trials* | | | | | | | | | | | | | | |
| (111), Germany | 154 (118,36)[¥] | 3 months | Lifestyle program participants (58 men, 48 women 18–64 years); analyses incl. 36–72 Ss; Ss with DM included, N unknown | Non-participants matched on age, gender, specific risk factors | Residential program: Kriya yoga+ vegetarian diet | | X+ | X+ | X+ | X+ | | X+ | | |

**Table 2.** *Continued*

| Reference, location | Sample size (yoga, controls) | Duration | Study population | Comparison group/ condition | Intervention | Clinical measures: IR indices | Lipids | Body size/ comp | BP | Coagulation | Oxidative stress | SNS/PSN activity | Lung function | Other clinical outcomes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (112), US | 333 (194,139), 62 with DM | 12 months, 72 4 h sessions | Adults with confirmed CAD, eligible for revascularization; 263 men, 70 women | Usual care | Usual care +Session: 1h each: stress management (incl Yoga AS, M); exercise, group support, meal | | X+ | X+ | | | | | | X+ |
| (106), US | 440 (91 with DM)**; 342 complete | 12 months | Adults with confirmed CAD, eligible for revascularization. 347 men, 93 women in intervention arm (68 women, 274 men complete); mean age 58 (men)-59 (F) y. 55 men, 36 women with DM at baseline | Usual care** | 1 h per day stress management: Yoga AS, R, M + low fat vegetarian diet, group support 2× per week, exercise 3+h per week+usual care | | X+ | X+ | X+ | | | X+ | | |
| (104), India | 113 (71,42) | 12 months, 21 sessions | Adults 30–70 years with confirmed CAD, incl. 33 with DM 2. 71/80 in yoga group, 42/60 controls complete study | Usual care: AHA diet, moderate exercise, medication (incl statins) | Yoga + medication (except statins), low fat diet, walking, stress management | X+ | X+ | X+ | | | | | | X+ |
| *Randomized controlled trials* | | | | | | | | | | | | | | |
| (90), USA | 43 (20,9,14) 15 high risk (6,3,6) | 12 months | Adults 65+ y, avg 74 years; complete reliable data for 43 of original 57 Ss; high risk group includes Ss with DM (N not stated) | (1) Usual care; (2) Usual care+ diet,exercise, education, supplements | Yoga M, AS + walking, diet | X+ | | | X+ | | | | | X+ |
| (79), India | 42 (21,21) (7,5 with DM 2) | 4 days training+ 1 year | Men with CAD & chronic stable angina, 32–72 years. Yoga and control groups similar in age, weight, lesion severity | Usual care:AHA diet, moderate exercise; regular evaluations | Yoga: (PR, AS, K, M)+ diet, exercise, regular evaluations | | X+ | X+ | | | | | | X+ |

Under each category, a plus indicates a beneficial change in at least one measure; a negative sign indicates no change in any of the measures in a specific category.

AHA, American Heart Association; AS, yoga asanas or postures; avg, average; BF, biofeedback; BP, blood pressure; CAD, coronary artery disease; cal, calorie; Clin, clinical; comp, composition; comp, composition; d, day, DM, Diabetes mellitus; F, female; h, hour; IR, insulin resistance (markers of); KR, kriyas or cleansing exercises; M, meditation; MBSR, mindfulness-based stress-reduction program; mo, month; PMR, progressive muscle relaxation; PR, pranayama or yogic breathing exercises; R, relaxation poses (non-specified); Resid, residential; SH, shavasana or corpse pose, a traditional yoga relaxation pose; SNS/PNS, markers of sympathetic/parasympathetic activation, including heart rate and catecholamine levels; Ss, subjects; veg, vegetarian; week, week; y, year.

†Excluding studies exclusively targeting Type 1 Diabetes mellitus.

*N's for each group not given.

**Data for intervention group only presented in this study; number with DM 2 completing study not stated, although drop-outs similar to completers in medical risk factors.

¥36–72 analyzed in matched analyses.

**Table 3.** Summarized findings of studies (1970–2006) investigating the effects of yoga-based programs on insulin resistance, lipid profiles, and body size and composition, and blood pressure, stratified by study design and intervention (yoga alone versus in combination with other interventions)

| Findings, by clinical measure | Study design | | | | | |
|---|---|---|---|---|---|---|
| | Uncontrolled clinical trials | | Non-randomized controlled clinical trials | | Randomized clinical trials | |
| | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions |
| Measures of insulin resistance | | | | | | |
| Fasting glucose | | | | | | |
| Reduced | **(65,83,91,95–98)** | **(68,88,94, 99,100)** | **(102)*** | **(103,104)**† | **(101)** | |
| No change | | | | | | (90)* |
| Post-prandial glucose | | | | | | |
| Reduced | **(65,83,91–93, 95–98)** | **(94,99)** | | | | |
| No change | | | | | | (90) |
| Reduced fructosamine | | | **(102)** | | | |
| Reduced fasting insulin | | | | | | **(90) (NS)** |
| Reduced OGT maximum/AIT | | **(99,100)** | | | | |
| Fasting glycated hemoglobin | | | | | | |
| Reduced | **(83,97,98)** | **(100)** | | | **(101) (84) (NS)** | |
| No change | | | | | | (90) |
| Blood lipid profiles | | | | | | |
| Total cholesterol | | | | | | |
| Reduced | **(109)** | **(68,88,100)** | **(102)** | **(104,106,111,112)** | **(84)** | **(79) (90) (NS)** |
| Unchanged | | | | | | |
| Triglycerides | | | | | | |
| Reduced | **(109)** | **(88,100)** | | | | **(79) (90) (NS)** |
| Unchanged | | | | (106,112) | (84) | |
| Low density lipoprotein (LDL) | | | | | | |
| Reduced | **(109)** | **(88)** | | **(104,106,111,112)** | **(84)** | **(79) (90) (NS)** |
| High density lipoprotein (HDL) | | | | | | |
| Increased | **(109)** | **(68,88)** | | | **(84)** | |
| Unchanged | | | | (106,112) | | (79,90) |
| Reduced very LDL | **(109)** | **(88)** | | | | |
| Reduced cholesterol/HDL ratio | | | | | **(84)** | |
| Reduced LDL/HDL ratio | | **(88)** | | | | **(79)** |
| Anthropometric measures | | | | | | |
| BMI | | | | | | |
| Reduced | | | | **(111)** | | |
| Unchanged | | (99,100)[¥] | | | | |
| Body weight | | | | | | |
| Reduced | **(92,93)** | | **(102)**+ | **(104)**[¶] **(106)** [¶¶]**(112)** | | **(79)** |
| Unchanged | | (99,100)[¥] | | | | |
| Body composition | | | | | | |
| Reduced waist, hip circumference/ratio | | **(100)** | | | | |
| ↓% body fat, ↑% lean mass | | | | **(112)** | | |
| Blood Pressure | | | | | | |
| Reduced systolic and/ or diastolic pressure | **(83)** | **(68,94)** | | **(106)**[¶¶] | | **(90)** |
| No change in systolic or diastolic pressure | | | | | (84) | |

**Table 3.** *Continued*

| Findings, by clinical measure | Study design | | | | | |
|---|---|---|---|---|---|---|
| | Uncontrolled clinical trials | | Non-randomized controlled clinical trials | | Randomized clinical trials | |
| | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions |
| Systolic blood pressure | | | | | | |
| Reduced | **(83)** | **(68,94)** | | **(106)**¶¶ | | **(90)**†† |
| Unchanged | | | | | (84) | |
| Diastolic blood pressure | | | | | | |
| Reduced | **(83)** | **(68,94)** | | **(106)**¶¶ | | **(90)** |
| Unchanged | | | | | (84) | |

Studies demonstrating beneficial effects are in boldface.
*Described only as reduced plasma glucose.
+No statistics given; reduction greater than that with diet alone but similar to yoga + diet.
†In Ss with DM 2 ($n = 33$) ¥Baseline BMI average 22–23.
¶In overweight Ss.
¶¶Data presented only for intervention group.
†† $p = 0.08$ ($n = 6$ in yoga-based intervention).

usual care, exercise and/or dietary interventions (Tables 2 and 3). Although findings varied among studies, all documented significant changes in at least two measures of dyslipidemia. The most consistently and frequently reported improvements included reductions in total cholesterol and LDL (Table 3). Data from a third RCT of American seniors at risk for CVD also suggested improvement in several lipid indices following a yoga-based intervention. However, changes did not reach statistical significance, likely due to small sample sizes ($n = 6$ in the yoga-based intervention group) (90).

Controlled studies ranged in length from 3 (102,112) to 12 months (79,104,106,113) and included investigations of both diabetic (84,100,102,109) and other at risk populations (68,79,88,90,104,106,112,113). Among those studies demonstrating significant changes in specific lipid indices, completion of yoga-based interventions were associated with a 5.7–25.2% decrease in total cholesterol, 8.0–23.7% reduction in triglycerides, a 5.1–26.0% reduction in LDL, a 14.5–17.7% decrease in VLDL and a 4.2–33.3% increase in HDL, with the observed magnitude of the effects differing by population and design (Table 5).

Again, published data from both uncontrolled and controlled studies suggest that the practice of yoga may have a positive influence on blood lipid profiles. However, most of the studies have methodological or other limitations that hinder interpretation of findings. These include absence of comparison groups or conditions (68,88,100,109), low power due to small sample sizes (68), stratified analyses (68,90,102,109, 112) or other factors (84), lack of evidence for blinded outcome assessment [all but one study (90)], potential selection bias (88,111,113), differential loss to follow-up (89,106), lack of randomization (102,104,106,112,113) or information on the randomization process (79), multiple interventions (68,79,88–90,100,105), inadequate description of populations (89,102) or of the sampling or treatment allocation process (89). Other methodological concerns include unclear statistical analyses (68,109,111), possible uncontrolled confounding factors (88,100,109,111) and lack of adequate point estimates (68,88,104,111), intergroup comparisons (106,107) or adjustment for multiple comparisons (68,84,88,90,100,102, 109,111).

### *Anthropometric Measures*

Ten published clinical trials in four countries examined the effects of yoga on anthropometric indices of CVD risk in populations that included adults with Type 2 diabetes (Table 3). All utilized interventions incorporating active yoga asanas. Three of the four uncontrolled clinical trials (92,93,100) and all five non-randomized controlled studies identified reported declines in body weight (102,104,106, 112,113), reductions in waist/hip ratio (100), and/or improvements in body composition (113) following yoga-based interventions ranging from 40 days (100) to 12 months (104,106, 113). Similarly, a 12 month RCT in Indian men with CAD (79) demonstrated improvement in body weight relative to usual care (79). Results reporting improvement in anthropometric characteristics included investigations targeting adults with diabetes (92,93,100,102), as well as those with CAD (79,104, 106,113) and/or other chronic conditions (112). Of these, completion of yoga-based programs was associated with a 3.5–8.2% reduction in body weight (Table 4). Only two studies reported no change in body weight (99,100), likely in part reflecting the participants' low BMI values at baseline.

Limitations include lack of control groups (92,93,99,100), reduced power due to low number of subjects (93) or other factors (102,112), possible selection bias (79,93,102,105,111), uncontrolled confounding (92,99,100,111) or floor effects (99,100), lack of appropriate statistical analyses or presentation (92,99,104,111), multiple comparisons (92,102,111), inadequate description of analytic methods (92,93,99,111), population (92,93,100,102), intervention (93), treatment allocation (89), or sample selection process (93,100,102,112),

**Table 4.** Observed percent change with yoga in selected metabolic and anthropometric measures among adults with diabetes and/or other chronic disorders*

| Findings, by clinical measure and study population | Uncontrolled clinical trials | Non-randomized controlled clinical trials | Randomized clinical trials |
|---|---|---|---|
| Measures of insulin resistance | | | |
| Reduced fasting glucose | | | |
| Adults with diabetes/hyperglycemia | 9.1–33.4% (83,88,91,94–100) | 23.4–34.4% (102) | 6.9% (101)†† |
| Adults with hypertension/CVD or other chronic condition** | 6.1–6.2% (68,88) | | |
| Reduced post-prandial glucose | | | |
| Adults with diabetes | 23.9–32.8% (65,83,92–94,97) | | |
| Reduced glucose (tolerance test) | | | |
| Adults with diabetes | | | |
| 1 h post-load | 10.1–32% (94–96) | | |
| 2 h post-load | 15.8–19.2% (94–96) | | |
| Area under the curve (AUC) | 16.5–29.5% (99,100) | | |
| Reduced fasting insulin | | | |
| Adults at risk for CVD | | | 19.2% (90) |
| Reduced fasting glycated hemoglobin | | | |
| Adults with diabetes | 13.3–27.3% (83,97,98,100) | | 3.3–15.5% (84,101) |
| Blood lipid profiles | | | |
| Reduced total cholesterol | | | |
| Adults with diabetes | 5.9–7.2% (100,109) | 8.3–19.9% (102) | |
| Adults with hypertension/CVD or other chronic condition** | 5.7†-7.5% (68,88) | 8.7–25.2% (104,106,112) | 5.8–21% (79,90) |
| Reduced triglycerides | | | |
| Adults with diabetes | 8.9–11.9% (100,109) | | |
| Adults with/at risk for hypertension/CVD or other chronic condition** | 8.0%-12.4† (68,88) | 8.3% (111) | 14.1–23.7% (79,90) |
| Reduced low density lipoprotein (LDL) | | | |
| Adults with diabetes | 7.5% (109) | | |
| Adults with hypertension/CVD or other chronic condition** | 5.1%† (88) | 13.7–26.0% (104,106,111,112) | 6.8–24.4% (79,90) |
| Reduced very LDL (VLDL) | | | |
| Adults with diabetes | 14.5% (109) | | |
| Adults with DM, HT, or other chronic condition** | 17.7%† (88) | | |
| Increased high density lipoprotein | | | |
| Adults with diabetes | 4.2% (109) | | |
| Adults with/at risk for hypertension/CVD or other chronic condition** | 3.5†-5.7% (68,88) | 33.3% (111) | |
| Anthropometric markers | | | |
| Reduced body weight | | | |
| Adults with diabetes | 8.2% (93) | 3.5% (102) | |
| Adults with hypertension/CVD** | | 3.4–5.0% (106,112) | 7.8% (79) |
| Blood pressure | | | |
| Reduced diastolic BP | | | |
| Adults with diabetes | 6.7–12.9% (83,94) | | |
| Adults with or at risk for CVD** | 15.8% (68) | 5.8% (106) | 9.3% (90) |
| Reduced systolic BP | | | |
| Adults with diabetes | 11.1–11.3% (83,94) | | |
| Adults with or at risk for CVD** | 13.9% (68) | 3.9% (106) | 4.4% (90) |

**Table 4.** *Continued*

| Findings, by clinical measure and study population | Uncontrolled clinical trials | Non-randomized controlled clinical trials | Randomized clinical trials |
|---|---|---|---|
| Reduced baseline heart rate | | | |
| Adults with diabetes | 10.2% (83) | | |
| Adults with hypertension/CVD** | | 5.7% (106) | |

CVD, Cardiovascular disease
*Including studies reporting improvement in these indices; studies not reporting point estimates or presenting insufficient data to allow reliable calculation of point estimates were excluded.
**Including adults with diabetes mellitus †Ss with cholesterol $\geq$200 mg dl$^{-1}$ ($n = 43$) (88).
††18.9% mean difference relative to controls (101).

loss to follow-up (89,93) and multiple interventions (79,89,99,100,105). Among controlled studies, additional limitations included failure to compare control and intervention groups (106,107) and lack of randomization (102,104,112,113) or description of randomization methods (79). Blinded outcome assessment was not detailed in any of the 10 studies.

### *Blood Pressure*

We identified seven eligible studies that assessed the effects of yoga-based interventions on blood pressure. Six of these studies reported significant improvement in both systolic and diastolic blood pressure as compared to baseline values (68,83,94,106,112), or to controls receiving enhanced usual care (90). One study, a small British RCT of poorly controlled insulin-treated diabetic adults, showed no change in blood pressure despite significant improvement in other indices of CVD risk (Table 3) (84). Research reporting positive results included three uncontrolled trials targeting Indian adults with diabetes (83,94) or hypertension (68), one NRCT in US adults with CAD (106), one NRCT of German community-dwelling adults (112) and one RCT in US seniors (90). Interventions ranged from 40 days (83) to 1 year (90,106) in duration, and all incorporated active asanas. Reductions in systolic and diastolic blood pressures varied from 3.9 to 13.9% and 5.8 to 15.8%, respectively, depending on design and population (Table 4).

However, the potential biases and limitations characterizing most of these studies again hinder interpretation of findings. These include absence of comparison groups (68,83,94), small sample sizes (68,83,94), reduced power due to stratified analyses (68,90) or other factors (84), possible selection bias or confounding by lifestyle or other factors (83,94), absence of detailed information regarding the population (83), statistical methods (68,83,94,111) or subject selection process (83,112), potential uncontrolled variation in exposure to the intervention (94) or loss to follow-up (94). Only one reported blinding of outcome assessment (90), and most studies used yoga in combination with other interventions (68,89,90,106,112), making it difficult to isolate an effect specific to yoga. Other methodological limitations are lack of randomization (106,111) and inadequacies in statistical analyses or presentation, including lack of appropriate point estimates (68,94,111), adjustment for multiple comparisons (68,83,84,90,94,111) and appropriate comparisons between (106) or within (68) groups.

## Influence of Yoga on Other Indices

Eligible data suggest that yoga-based interventions may also have beneficial effects on coagulation profiles and oxidative stress, sympathetic activation and lung function in adults with DM 2, although investigations including diabetic populations are few. For example, recent uncontrolled trials targeting Indian adults with uncomplicated diabetes mellitus (97) or hypertension (68) reported significant reductions in malonyldialdehyde (MDA), an estimate of lipid oxidative damage, following a 40 day yoga training course (97) and a 12 week yoga lifestyle intervention (68). These findings suggest a decrease in oxidative damage with yoga. Data from a non-randomized controlled study of German adults (including an unspecified number with diabetes) suggest that yoga may also improve coagulation profiles. Compared to relative to community controls matched on age, gender and baseline fibrinogen levels, participants who completed a 3 month residential Kriya yoga program showed a significant decline in fibrinogen among participants ($n = 76$ subjects, including 38 controls) (111). These findings are consistent with those of uncontrolled (114–116) and controlled studies (117,118) in healthy adults (114–116,118) and in adults with other related chronic disorders (115,117). Recently, reviewed by Innes *et al.* (82), these reports showed significant improvement in measures of oxidative damage (115–118) and coagulopathy (114) following yoga-based interventions ranging from 10 weeks (118) to 5 months (116). Procoagulant changes and damage due to oxidative stress are thought to mediate many of the atherosclerotic and thrombotic changes associated with IRS (119–123) and to play a central role in the pathogenesis and progression of diabetes (18) and CVD (119–121,123).

Although many investigations have examined the effect of yoga on markers of sympathetic/parasympathetic activation and cardiovagal function (82), our search identified only four that included adults with diabetes, including two uncontrolled studies (68,83) and two NRCTs (106,112); only one of them specifically targeted patients with DM 2 (83) (Table 2). Relative to baseline (68,83,106) or to controls receiving no intervention (112), participants who completed a yoga program showed significant reductions in heart rate (83,106) and

**Table 5.** Clinical trials investigating the effects of yoga and yoga-based programs on specific clinical outcomes, stratified by study design and intervention (yoga, including yoga-based meditation, alone versus in combination with other interventions)

| Findings, by outcome | Study design | | | | | |
|---|---|---|---|---|---|---|
| | Uncontrolled clinical trials | | Non-randomized controlled trials | | Randomized controlled trials | |
| | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions | Yoga alone | Multiple interventions |
| Clinical outcomes | | | | | | |
| Reduced need for medication | | | | | | |
| Hypertension/CAD | | **(68)** | | **(104)** | | |
| Diabetes | **(65,83,92,93)** | **(99) (68)** | | | **(84,101)** | |
| Studies targeting adults with CVD | | | | | | |
| Reduced revascularization procedures related complications | | | | **(112)** | | **(79)** |
| Reduction in anginal episodes | | | | **(112)** | | **(79)** |
| Reduced carotid intimal media thickness | | | | | | **(90)** |
| Reduced progression of CAD | | | | **(104)** | | **(79)** |
| Increased regression of CAD | | | | **(104)** | | **(79)** |
| Reduced number of serious coronary events | | | | **(112)** | | |
| Reduced number of hospitalizations | | | | **(104)** | | |

Studies reporting beneficial effects are in boldface. CAD, coronary artery disease; CVD, cardiovascular disease.

catecholamine levels (68,112). In agreement with these findings, results from over 35 in other populations, including healthy and hypertensive adults, suggest that yoga promotes a reduction in sympathetic activation, enhancement of cardio vagal function and a shift in autonomic nervous system balance from primarily sympathetic to parasympathetic (82). Documented changes have included significant reductions in respiratory and heart rate, in cortisol concentrations, catecholamine levels, and renin activity, in skin conductance, and in cardiovascular response to stress, as well as significant increases in heart rate variability and baroreflex sensitivity (82).

Impaired lung function is both an important complication (23,24) and a significant predictor (25) of type 2 diabetes, and has been inversely associated with insulin resistance (23) and glycemic exposure (24,124). Recent research in adults with DM 2 suggests that yoga may improve pulmonary function in this population (98). In an uncontrolled (pre–post) study of 24 Indian adults with an established diagnosis of DM 2, participants demonstrated significant increases in forced expiratory volume, forced vital capacity, peak expiratory flow rate and maximum voluntary ventilation following completion of a 40 day yoga program (98). Other research using healthy adults have yielded similar findings (125–129), although only one of them included controls (128).

While limited, available data support a possible beneficial influence of yoga on oxidative stress and coagulation profiles, sympathetic activation and pulmonary function in adults with DM 2. Limitations of existing research include lack of appropriate comparison groups (68,97,98,106), small sample sizes (68,97,98), possible selection bias or uncontrolled confounding by lifestyle and other factors (97,111), lack of randomization (111), inadequate information regarding the population (97,98), subject selection (97,98,112), or analytic methods (68,97,98,111), multiple interventions (68,101,111), and problems with data analysis or presentation (68,97, 98,111). In addition, blinding of outcome assessment was not well-reported in any identified studies.

## Influence of Yoga on Clinical Outcomes

Several studies in Indian (68,79,89,92,99), European (84,101) and American populations (90) have suggested that yoga may also improve specific clinical outcomes in patients with type 2 diabetes and other IRS-related chronic conditions. Twelve eligible studies evaluated the influence of yoga and yoga-based interventions on medication use and cardiovascular outcomes, including six uncontrolled trials, two non-randomized controlled studies and four RCTs (Table 5). In uncontrolled studies of Indian adults with hypertension (68) and/or diabetes (65,68,83,92,93,99), completion of a simple (65,83,92,93) or comprehensive yoga program (68,99) was associated with a reduced need for medication relative to baseline. In agreement with these findings, controlled studies of adults with diabetes (84,101) and/or CAD (89) showed a decline in medication requirements among those enrolled in a yoga-based intervention compared to controls receiving usual care (101), usual care plus intensive education and exercise (84), or usual care plus a diet and exercise program (89). Controlled studies in Indian (79) and American (90,113) populations also suggest that yoga may help reduce complications and improve the prognosis of those with frank or underlying disease. For example, in an RCT of Indian men with CAD, those enrolled in a 12 month comprehensive yoga program showed retardation of coronary atherosclerosis, increased regression and reduced progression of vascular lesions, and reduced anginal episodes

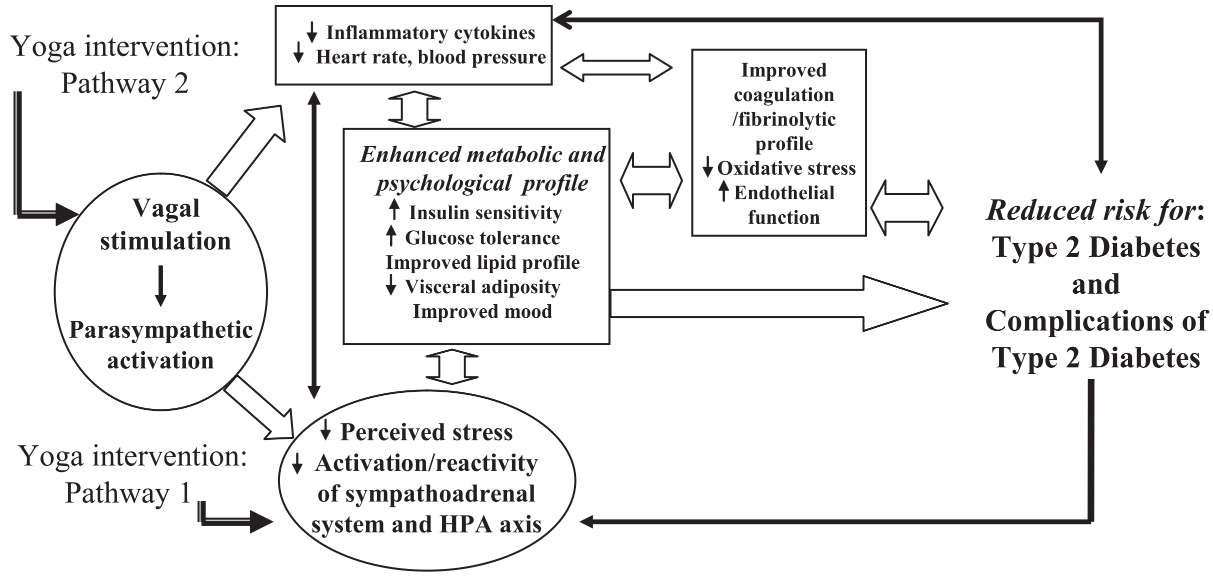


**Figure 1.** Hypothesized pathways by which yoga intervention may reduce risk for Type 2 Diabetes mellitus (DM 2) and for complications related to DM 2.

relative to usual care controls (79). Two other non-randomized controlled studies of CAD patients in India (89) and the United States (113) yielded similar results (Table 5). In an RCT in American seniors, participants completing a 12 month comprehensive yoga-based program demonstrated a decline in carotid intimal media thickness, an indicator of carotid atherosclerosis, relative to those receiving usual care or a comprehensive medical, diet and exercise intervention (90). The reduction was inversely correlated with adherence to the yoga program, suggesting a direct relation between practice of this program and atherosclerotic change.

Although promising, several of these studies have methodological and other limitations, including absence of control groups (65,68,83,92,93,99), small sample sizes (65,68,93, 101), lack of randomization (89,113), loss of participants at follow-up (89), possible uncontrolled confounding factors (92,99,101), unclear statistical analyses (65,68,83,92) or absence of intergroup comparisons (101), lack of adjustment for multiple comparisons (68,90,92) and multiple interventions (68,79,83,89,90,99,101,113). Several lacked adequate descriptions of the study population (83,89,92,93), sample selection process (83,93), intervention (65,93,101), treatment allocation (89) or statistical methods (68,92,99,101). Only one study presented information of blinding with outcome assessment (90). In addition, reporting bias may have resulted in omission of negative findings, possibly inflating the apparent positive effect of yoga on clinical outcomes.

## Yoga, Psychosocial Risk Factors for Diabetes and CVD, and Possible Underlying Mechanisms

While methodological and other limitations preclude drawing firm conclusions, the published research reviewed above nonetheless offer evidence that yoga may improve risk profiles and clinical outcomes in adults with type 2 diabetes. In addition, although studies that specifically target diabetic populations are lacking, investigations in healthy adults (66,130–134) and in other chronically ill populations (135–142) suggest that yoga therapy may reduce psychosocial risk factors for the development and progression of diabetes as well. Yoga has been reported to decrease perceived stress (134,143,144) and reactivity to stressors (133), enhance stress-related coping (137,138), reduce symptoms of depression (130,132,136,140,142,145) and anxiety (66,88,130,132,135, 137,138,141), decrease anger, tension and fatigue (130,135), enhance psychological well-being (66,68,88,94,130–133, 137,138), and reduce sleep disturbance (134,139).

Mechanisms underlying the beneficial effects of yoga practice on diabetes-related risk profiles are not yet well understood. However, the observed changes may occur via at least two major pathways. First, by reducing the activation and reactivity of the sympathoadrenal system and the hypothalamic pituitary adrenal (HPA) axis and promoting feelings of well-being, yoga may alleviate the effects of stress and foster multiple positive downstream effects on neuroendocrine status, metabolic function and related systemic inflammatory responses (Fig. 1, Pathway 1) (74,146,147). Second, by directly stimulating the vagus nerve, yoga may enhance parasympathetic activity and lead to positive changes in cardiovagal function, in mood and energy state, and in related neuroendocrine, metabolic and inflammatory responses (Fig. 1, Pathway 2) (74,146,147). In addition, yoga may both indirectly (by encouraging healthy lifestyle changes) and directly lead to weight loss and reduced visceral adiposity. Weight loss itself lowers risk for DM 2 and CVD complications (148,149).

In addition to physiologic improvements, yoga may provide a positive source of social support, a factor strongly associated with reduced risk for CVD (34,58), and may aid in improving health-related attitudes and lifestyle choices, in part by enhancing psychological well-being (34), and in this way also play an important role in diabetes management and prevention of cardiovascular complications (34).

## Summary and Conclusions

In summary, a growing number of studies suggest that yoga may improve indices of risk in adults with type 2 diabetes, including glucose tolerance and insulin sensitivity, lipid profiles, anthropometric characteristics and blood pressure. Limited data also indicate that yoga may reduce oxidative damage, improve coagulation profiles and pulmonary function, and decrease sympathetic activation in adults with diabetes and related chronic disorders. Yoga may also be useful in reducing medication requirements in patients with diabetes and could help prevent and manage cardiovascular complications in this population.

However, despite the apparent therapeutic promise of yoga for diabetes management, rigorous, systematic studies regarding the effects of yoga on physiological, anthropometric and psychological profiles in adults with diabetes are few, and those in western populations are even fewer. Over 85% of published clinical trials (1970–2006) investigating the therapeutic applications and psychophysiological effects of yoga practice in diabetic populations have been conducted in India, where yoga forms a central part of long-standing spiritual and cultural traditions. Interpretation of existing studies is limited by small sample sizes, selection bias, lack of appropriate control groups, failure to adjust for baseline anthropometric characteristics, lifestyle factors, and other potential confounders, exposure to multiple interventions, and other methodological limitations. In addition, considerable variation in design, duration, intensity and delivery methods of yoga-based interventions renders comparison across studies problematic. Publication bias may also contribute to the selective reporting of positive results (150), particularly in non-Western countries, where yoga is more widely accepted and more likely to be incorporated into medical care. While existing RCTs have produced results consistent overall with those of non-randomized and uncontrolled studies, suggesting that the positive findings of these latter studies do not simply reflect poor study design, clearly, additional high-quality RCTs are warranted. Specifically, rigorous studies are needed to clarify the effects of specific yoga therapies on measures of DM 2 risk and related clinical outcomes, especially in American and other Western populations that remain under-represented in existing research.

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## Original Article

# Utilization of 3-month Yoga Program for Adults at High Risk for Type 2 Diabetes: A Pilot Study

**Kyeongra Yang[1], Lisa M. Bernardo[1], Susan M. Sereika[1], Molly B. Conroy[2], Judy Balk[2] and Lora E. Burke[1]**

[1]School of Nursing and [2]School of Medicine, University of Pittsburgh, Pittsburgh, PA, USA

Various modes of physical activity, combined with dieting, have been widely recommended to prevent or delay type 2 diabetes. Among these, yoga holds promise for reducing risk factors for type 2 diabetes by promoting weight loss, improving glucose levels and reducing blood pressure and lipid levels. This pilot study aimed to assess the feasibility of implementing a 12-week yoga program among adults at high risk for type 2 diabetes. Twenty-three adults (19 Whites and 4 non-Whites) were randomly assigned to the yoga intervention group or the educational group. The yoga group participated in a 3-month yoga intervention with sessions twice per week and the educational group received general health educational materials every 2 weeks. All participants completed questionnaires and had blood tests at baseline and at the end of 3 months. Effect sizes were reported to summarize the efficacy of the intervention. All participants assigned to the yoga intervention completed the yoga program without complication and expressed high satisfaction with the program (99.2%). Their yoga session attendance ranged from 58.3 to 100%. Compared with the education group, the yoga group experienced improvements in weight, blood pressure, insulin, triglycerides and exercise self-efficacy indicated by small to large effect sizes. This preliminary study indicates that a yoga program would be a possible risk reduction option for adults at high risk for type 2 diabetes. In addition, yoga holds promise as an approach to reducing cardiometabolic risk factors and increasing exercise self-efficacy for this group.

**Keywords:** exercise self-efficacy – high risk – type 2 diabetes – yoga

## Introduction

Type 2 diabetes affects more than 21 million Americans (1), and the death rate from diabetes has increased 45% since 1987 (2). One important regimen for people with diabetes and for those at risk for developing diabetes is engagement in appropriate physical activity. The beneficial effects of physical activity typically include reductions in glucose level, body weight, blood pressure (BP) and cholesterol (3–6). As a particular form of physical activity, yoga programs using various physical postures have been shown to benefit individuals with a wide range of health conditions including hypertension (7) and diabetes (8). Yoga appears to be especially effective in reducing BP, glucose and cholesterol (7–11). For example, yoga practice was effective in lowering BP in healthy people (9), people with hypertension (7,8) and people with metabolic syndrome (11). Adults with chronic diseases including hypertension, coronary artery disease and diabetes had significantly lower glucose and cholesterol levels after short-term, intensive yoga practice (3–4 h per day for 8 days) (8). Yoga also improved exercise tolerance by significantly reducing exercise-induced cardiovascular changes (e.g. heart rate and BP) (12).

For reprints and all correspondence: Kyeongra Yang, School of Nursing, University of Pittsburgh, 415 Victoria Building, 3500 Victoria Street, Pittsburgh, PA 15261, USA. Tel: +1-412-624-6943; Fax: +1-412-383-7293; E-mail: yangk@pitt.edu

Deep relaxation, a unique part of a yoga program, relaxes the sympathetic nervous system (13) and helps with physiological stress reduction (14,15). Physiological stress itself is related to metabolic disease, including diabetes.

The practice of yoga generally includes meditation, relaxation, breathing exercises and various physical postures (16). Between 1997 and 2007, the number of yoga practitioners significantly increased in the USA (17). The 2007 National Health Interview Survey (17) showed that 6.1% of US adults practiced yoga in the months immediately prior to the survey in 2007, compared with 3.7% in 1997 and 5% in 2002 (18). In addition, adults participating in a yoga intervention found that yoga was easily learned and performed (19). Once learned, yoga can be practiced at any time on an individual basis, thus reducing common barriers to physical activity such as time conflicts and poor weather.

Self-efficacy, the degree of confidence one has in the ability to perform a behavior, is regarded as one of the primary factors that is influential in achieving behavior change (20,21). Research suggests that yoga participation and mastery could improve the degree of exercise self-efficacy and perhaps lead to long-term adherence to physical activity and its attendant benefits (22). In Oleshansky's 2004 study of American adults aged 29–40 years (22), hatha yoga practitioners showed higher levels of self-efficacy for physical activity, including yoga, than non-practitioners.In spite of its growing acceptability and known positive effects on physiological variables, yoga has not been widely adopted as part of a regimen to prevent type 2 diabetes. It is not clear, therefore, whether individuals at risk for type 2 diabetes might benefit from the regular practice of yoga. The purposes of this study were to assess the feasibility of implementing a 12-week yoga program among adults at high risk for type 2 diabetes, to begin examining whether yoga improves cardiometabolic risk factors (i.e. BP, lipid and blood glucose levels, and body weight), and to examine the effect of yoga on exercise self-efficacy.

## Methods

### Design and Setting

This study used a two-group, randomized and controlled trial design. After Human Subjects Committee's approval was obtained, participants were recruited via automated voice mail messages that were delivered to university employees, flyers posted in hospital outpatient waiting rooms and advertisements in local newspapers. To be eligible, participants had to be between 45 and 65 years of age, non-exercisers (no more than 30 min twice per week) for the previous 12 months, had a family history of type 2 diabetes (first- or second-degree relative), and at least one of the following cardiometabolic risk factors: impaired fasting glucose (FPG >110 but <125 mg/dl); prehypertension (systolic BP/diastolic BP: 120–139/80–89 mmHg); overweight/obese [body mass index (BMI) >25 but <45 kg/m$^2$]; or abnormal level of cholesterol (total cholesterol >200 mg/dl). Persons who were pregnant, those who had used any drug to reduce their blood cholesterol level, BP or glucose, or those who had a physical disability that would limit their ability to practice yoga were excluded from the study. After respondents to recruitment announcements were screened by telephone for eligibility (age, exercise status, family history of diabetes, willingness to be randomized, pregnancy status, medication history and physical limitations), we confirmed their eligibility with additional screening tests for glucose, BP, cholesterol level and BMI at the Montefiore University Hospital Clinical and Translational Research Center (MUH-CTRC). To avoid any disappointment with group assignment, we fully informed individuals of the randomization process when they first contacted the Project Office for the initial telephone screening. A copy of the consent form was sent for their review prior to their screening visit to the MUH-CTRC. We reviewed the study details described in the consent form with them in person and responded to their questions before they signed the consent form. Twenty-three participants (19 Whites and 4 non-Whites) were randomly assigned to a yoga intervention group or a control group (Fig. 1).

### Intervention (or Experimental Procedure)

Participants in both the intervention group and control group were asked to maintain their current activity levels during the intervention. The intervention group participated in a 3-month Vinyasa style yoga intervention program developed and led by a certified yoga instructor who is a PhD certified nurse. Vinyasa yoga is an evolving form of hatha yoga, so both yoga styles share the same basic elements, but Vinyasa is more fitness-based than traditional hatha yoga. This Vinyasa style yoga program included various physical postures (*Asanas*) such as sun-salutations, standing poses, seated/kneeling poses and counterposes. Each movement was combined with various breathing patterns of inhalation and exhalation (*Pranayamas*). All postures were modified to meet the participants' needs and to assure safety. For example, tree pose, a one-leg balance pose, was performed using a chair or wall for support when a participant had difficulty with balance. Each 1-h session of the yoga program began with a warm-up (5–7 min) and ended with a relaxation period (10 min). To facilitate and guide home practice, participants were given an audio recording (CD) of the yoga instructions recorded by the yoga instructor. Group sessions were held twice per week, with 2–3 days between sessions. Participants were expected to practice

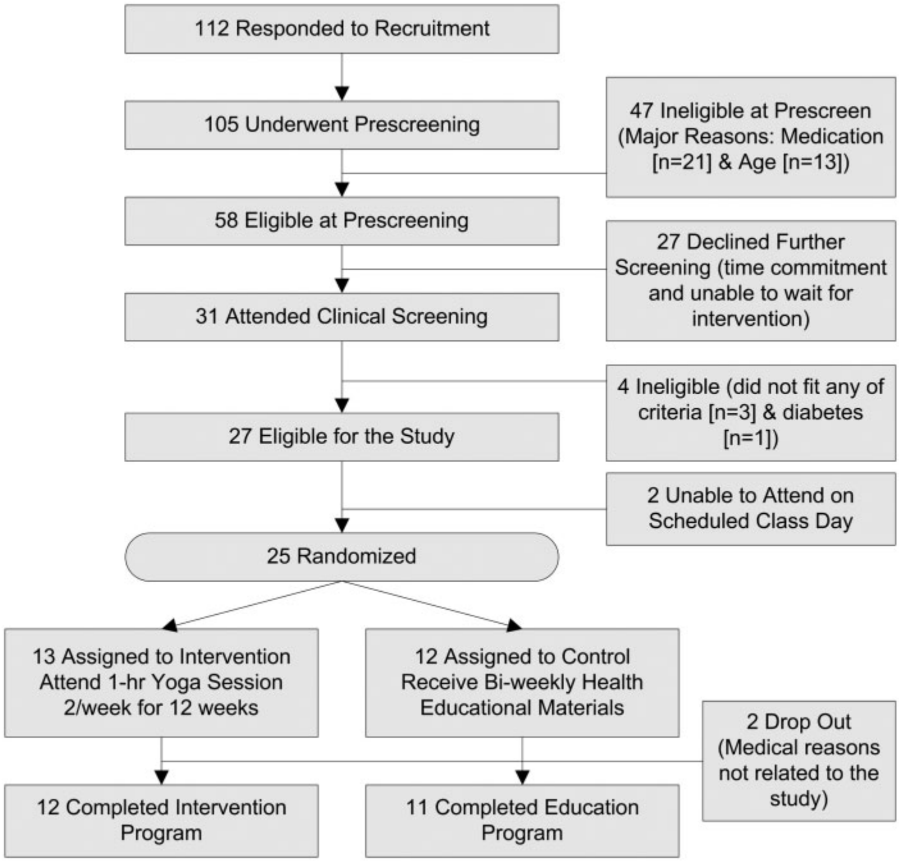


**Figure 1.** Screening and enrollment flow chart.

**Table 1.** Yoga sequencing

- Warm-up (5–7 min)
  - Standing, seated or supine; includes all movements of the spine
- Sun-salutations (10–12 min)
  - Full or modified, depending on the participant's needs
- Standing poses (12–15 min; poses are held for 3–4 breaths)
  - Two-legged balances (warrior series, triangle series)
  - One-legged balances
- Seated/kneeling poses and counter-poses (12–15 min; poses are held for 2–3 breaths)
  - Spinal extension
  - Hip-opener
  - Spinal rotation; Spinal flexion
- Relaxation (10 min) using deep relaxation pose

yoga at home and record the number of minutes they engaged in yoga per day, but there was no certain amount or frequency required. The components of our intervention using Vinyasa style yoga are detailed in Table 1. Participants in the control group received general health-education materials mailed to their home every 2 weeks for 3 months, including content pertaining to risk factors associated with type 2 diabetes and the prevention of diabetes that included tips for healthy eating out, cardiovascular risk factors (hypertension and high cholesterol), consuming a balanced diet and engaging in physical activity. During the 3-month measurement, we discussed health-education content and responded to their questions and interpreted this to be a confirmation that they had reviewed the materials.

## Measures

### *Clinical Measures*

BP, blood glucose, insulin, lipid levels [cholesterol; high-density lipoprotein (HDL); low-density lipoprotein (LDL); triglycerides] and body weight were obtained at baseline and at the end of 3 months. The blood test required a 12-h fast (no food or drink, except water and medications); ~20 ml of blood was obtained via a venipuncture in the arm with the individual in an upright position and after at least 5 min in a resting state. We measured weight (in kilograms) after an overnight fast with the participant dressed in light clothing and without shoes using the Tanita bioelectrical impedance scale (Tanita Corporation of America, Inc., Illinois, USA), and height (in meters) on a wall-mounted stadiometer. We calculated BMI using the equation of weight (kg)/height $(m)^2$. All physical measurements were done at MUH-CTRC by their staff members who were blinded to group assignment. During the measurements, we were available to answer any questions and participants were asked not to discuss their program with MUH-CTRC staff. Participants in both groups were asked to describe their demographic and co-morbidity profile at baseline and complete questionnaires on exercise self-efficacy at baseline and at the end of 3 months. Those in the yoga group were asked to complete questionnaires on treatment expectation, program satisfaction and exercise log during or after the yoga program.

*Medical History and Sociodemographic Information*

The Demographic Questionnaire and Brief Co-Morbidity Questionnaire, developed by the Center for Research in Chronic Disorders (CRCD) at the University of Pittsburgh School of Nursing, were used to collect data on age, marital status, race, educational level, employment status, income, living arrangements, religion, health insurance and co-morbidity at baseline.

Exercise self-efficacy (20,23) was measured by the Exercise Self-Efficacy Scale at baseline and at the end of 3 months. Exercise self-efficacy is the degree of confidence one has in his or her ability to engage in exercise in the face of competing day-to-day conditions (20). The Scale was developed by researchers at Stanford University to measure one's confidence in his or her ability to perform exercise routines regularly under various circumstances. It measures self-efficacy belief rather than outcome expectancy. The questionnaire consists of 18 items, each related to a different routine. The answers range from zero ('Cannot Do') to 100 ('Certainly Can Do') and are summed to yield a single total score. Higher scores on the scale indicate greater perceived self-efficacy to participate in physical activity. Cronbach's alpha for this scale was 0.95.

During the intervention (after Session 1, Session 8 and Session 16), treatment expectation was measured by the Treatment Credibility and Expectancy Questionnaire (24), which assesses perceived logic of and confidence in a treatment, willingness to recommend the treatment to a friend, and belief in the likelihood that the treatment will help their condition. Sum of the first three items (9-point Likert-type scale) gives the credibility score and the fourth item (10-point scale, 0–100%) provides the expectancy score. Higher scores indicate greater perceived treatment credibility and expectancy. The treatment credibility score had a high internal consistency coefficient (Cronbach's $\alpha = 0.86$) in a study using cognitive-behavioral treatment for adults with panic disorder (25).

Acceptability of the yoga intervention was evaluated at the end of the yoga intervention by the Yoga Program Satisfaction Questionnaire. The questionnaire consists of five semi-structured questions related to participant satisfaction with the yoga program and feelings about the yoga program. In addition, each participant logged the average number of minutes he or she engaged in yoga practice per day in an Exercise Log. These self-reports provided a check on how much the participants were practicing yoga during the 3-month intervention period. Individuals were instructed to record daily to avoid recall bias.

**Statistical Analysis**

Data were analyzed using SPSS (version 15.0, SPSS, Inc., Chicago, IL, USA), with significance set at 0.05 for two-sided hypothesis testing. Demographic characteristics for each treatment group were described as means and standard deviations for continuous variables, and frequency counts and percentages for categorical variables. To examine the effect of yoga on the major outcome variables compared to the education group, the Mann–Whitney U-test was used to compare their mean differences between baseline and 3 months. Correlations (Spearman's rho) between attendance rate and outcomes were reported. Due to the small sample size in this pilot study, effect sizes (using Cohen's $d$ comparing mean changes from 3 months to baseline between treatment groups) were also calculated to show magnitude and direction of the effect of the yoga intervention relative to the control condition for outcome variables. According to conventional definitions of effect size from a behavior science perspective (26), values of Cohen's $d$ on the order of 0.20, 0.50 and 0.80 represent small, medium and large effects sizes, respectively. The sample size for this pilot study was determined considering the feasibility of recruiting and retaining study participants rather than to have sufficient statistical power to formally test hypotheses.

## Results

All 23 participants finished the program and completed baseline and 3-month visits for the assessments and also completed the questionnaires. Table 2 summarizes demographic characteristics of study participants. Ninety-one percent of the sample was female and 17.4% was minority. Their mean age was 51.7 years (SD = 4.9), and their mean years of completed education was 18.0 (SD = 4.1). The mean BMI was $29.79 \pm 5.24\,\mathrm{kg/m^2}$ [$28.2 \pm 3.7$ in the yoga group versus $31.5 \pm 6.2$ in the education group ($P = 0.139$)]. The average number of self-reported co-morbidities was 5.9 (SD = 3.6) with the most common co-morbidities reported being headache and depression. One-third of participants ($n = 7$, 30.4%) had pre-hypertension and the majority ($n = 20$, 87%) of them had abnormal cholesterol levels. All 12 participants completed the yoga program without complication; attendance ranged from 58.3 to 100% for the yoga sessions (mean ± SD 81.3 ± 14.9%). There was no significant relationship between attendance and amount of yoga practiced during the 3 months (mean ± SD 416.67 ± 492.52 min; range 0–1370 min).

Table 3 summarizes post-intervention changes in the major outcome variables. Compared to the education group, the yoga group revealed a pattern of improvements in weight (effect size $d = -0.53$), systolic BP (effect size $d = -0.62$), diastolic BP ($d = -0.35$), insulin ($d = -0.34$), total cholesterol ($d = -0.22$), triglycerides ($d = -0.91$) and exercise self-efficacy ($d = 0.80$). However, effect sizes for fasting glucose level ($d = -0.20$), LDL ($d = -0.10$) and HDL ($d = 0.24$) reflected small or no changes. Based on data from the Treatment Credibility and Expectancy Questionnaire, participants experienced increased confidence over time in recommending the yoga program to their friends at high risk for type 2 diabetes. There was a pattern for a positive relationship between attendance rate and perceived expectancy (Spearman's rho = 0.548, $P = 0.065$) for the yoga program, but no relationship was observed between attendance rate and perceived credibility (Spearman's rho = 0.206, $P = 0.520$). There were significant correlations between attendance rate and systolic BP (Spearman's rho = 0.651, $P = 0.022$). Participants in the yoga group indicated on the Yoga Program Satisfaction Questionnaire that they were highly satisfied with the program (mean ± SD 99.2 ± 2.9%; range 90–100%). They liked a slow and gentle yoga approach without peer pressure and reported that they gained strength, flexibility and balance through their yoga practice.

**Table 2.** Demographic information ($N = 23$)

| | *n* (%) | Mean ± SD |
|---|---|---|
| Age (years) | | 51.7 ± 4.9 |
| Gender | | |
| Male | 2 (8.7) | |
| Female | 21 (91.3) | |
| Race | | |
| White | 19 (82.6) | |
| Black | 2 (8.7) | |
| Hispanic | 1 (4.3) | |
| Native American | 1 (4.3) | |
| Level of education (years) | | 18.0 ± 4.1 |
| Sedentary lifestyle | 23 (100) | |
| Family history of diabetes | 23 (100) | |
| Impaired fasting glucose | 2 (8.7) | |
| Pre-hypertension | 7 (30.4) | |
| Overweight/obese (BMI ≥30 kg/m$^2$) | 20 (87) | |
| Abnormal cholesterol levels | 20 (87) | |
| Number of co-morbidities | | 5.9 ± 3.6 |

## Discussion and Conclusion

This pilot study assessed the feasibility of implementing a yoga program among adults at high risk for type 2 diabetes. The preliminary study results indicate that this yoga program is feasible and acceptable to this population. Participants in the yoga group showed increased confidence over time in recommending the yoga program to their friends who are at high risk for type 2 diabetes and expressed high satisfaction with the program. Even though we did not use strategies to enhance adherence and retention for this pilot study, all participants completed the yoga program with an average attendance rate of 81.3%. Consistent with prior research (27,28), individuals in the intervention group considered group interaction and support and the no-cost nature of our intervention to be worth the time commitment involved in attending the sessions.

As participants were asked not to change their exercise level by initiating any new form of exercise during this study, we limited our recommendations for physical activity to emphasizing the importance of being active in day-to-day life. Therefore, we do not have information on how yoga practice helps with adoption and maintenance of other physical activities. However, this pilot study helped us to understand the relationship between

**Table 3.** Post-intervention changes in the major outcomes ($N = 22$)

| | Yoga ($n = 12$) | | | Education ($n = 10$) | | | *z* | *P*-value | Effect size |
|---|---|---|---|---|---|---|---|---|---|
| | Baseline Mean (SD) | 3 months Mean (SD) | Change | Baseline Mean (SD) | 3 months Mean (SD) | Change | | | |
| Weight (Ib) | 175.5 (30.0) | 174.7 (29.8) | −0.79 | 188.4 (28.8) | 189.4 (29.4) | 1.02 | −1.385 | 0.166 | −0.53 |
| BP (mmHg) | | | | | | | | | |
| Systolic | 119.3 (14.3) | 114.1 (7.7) | −5.17 | 115.7 (15.9) | 119.3 (13.9) | 3.60 | −1.519 | 0.129 | −0.62 |
| Diastolic | 68.7 (8.3) | 69.3 (9.0) | 0.58 | 68.9 (9.5) | 72.6 (7.5) | 3.70 | −0.925 | 0.355 | −0.35 |
| Fasting glucose level | 90.1 (11.5) | 92.8 (11.7) | 2.75 | 91.2 (13.9) | 95.8 (10.8) | 4.60 | −0.396 | 0.692 | −0.20 |
| Insulin | 10.5 (5.8) | 8.1 (5.7) | −2.42 | 9.8 (5.3) | 9.9 (7.4) | 0.01 | −0.799 | 0.424 | −0.34 |
| Lipid panel | | | | | | | | | |
| Total cholesterol | 209.8 (33.6) | 193.3 (32.1) | −16.50 | 198.8 (46.5) | 187.6 (34.1) | −11.20 | −0.726 | 0.468 | −0.22 |
| Triglycerides | 120.5 (41.3) | 109.0 (46.6) | −11.50 | 98.3 (48.1) | 114.3 (47.9) | 16.00 | −1.914 | 0.056 | −0.91 |
| LDL-C | 130.3 (35.2) | 117.8 (33.9) | −12.41 | 126.1 (46.8) | 116.0 (32.2) | −10.10 | −0.132 | 0.895 | −0.10 |
| HDL-C | 60.3 (10.1) | 56.6 (12.8) | −3.75 | 57.0 (15.3) | 51.4 (11.8) | −5.60 | −0.298 | 0.766 | 0.24 |
| Exercise self-efficacy | 43.9 (23.2) | 57.9 (23.0) | 13.97 | 52.5 (30.5) | 49.2 (23.7) | −3.33 | −1.583 | 0.114 | 0.80 |

Change is from baseline to 3 months. One participant in the education group was excluded from data analysis because she was on special diet for weight loss.

self-efficacy and practicing yoga. Individuals who practiced yoga showed a pattern of improvement in exercise self-efficacy, a strong and consistent predictor of adherence to multiple health-related behavior changes such as diet (29), physical activity (22) and smoking (30). Therefore, we could hypothesize that if yoga could help enhance exercise self-efficacy, yoga practice may directly or indirectly change health-related behaviors such as adopting healthy exercise habits. Changed behaviors would influence physiological and psychological responses related to cardiometabolic risk factors and vice versa. Additional research would be necessary to determine how self-efficacy might be further enhanced with yoga practice as part of future development of interventions to promote exercise self-efficacy and to examine how yoga practice eventually leads to increased adoption of physical activity among adults at high risk for type 2 diabetes.

Compared with the education group, after the 3-month intervention, the yoga group experienced improvement in cardiometabolic risk factors. Small to large effect sizes were found in the between-group changes in cardiovascular risk factors such as weight, BP, insulin and triglycerides. Due to its small sample size, this pilot study did not duplicate the statistically significant results reported from previous studies (7–11); however, this study will allow for the estimation of sample size in planning the next intervention study considering the targeted hypothesis testing of immediate and long-term treatment effects of yoga on cardiovascular risk factors. While the small sample limits the generalizability of our findings, the randomized, controlled trial design helps to better understand the benefits of the intervention program, because such a design permits allocation of participants that minimizes any bias from known and unknown determinants of outcome. Also, even though all physical measurements were done by MUH-CTRC staff members who were blinded to group assignment, we acknowledge a possibility of having exaggerated estimates of treatment effect due to participants' awareness of their control group assignment (31).

In summary, the results of this pilot study suggest that a yoga program could potentially be a risk reduction option for adults at high risk for type 2 diabetes. Anecdotal comments by study participants revealed that they perceived improvement in their strength, flexibility and balance after practicing yoga. We recommend that future studies involving yoga obtain objective measures of strength, flexibility and/or balance. Moreover, additional research with a larger sample and a longer follow-up for diabetes development is warranted to further evaluate the beneficial effects of yoga practice in this population.

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**Review**

# Yoga Practice for the Management of Type II Diabetes Mellitus in Adults: A systematic review

**Badr Aljasir[1], Maggie Bryson[1] and Bandar Al-shehri[2]**

[1]University of Ottawa, Ottawa and [2]University of Toronto, Toronto, Ontario, Canada

The effect of practicing yoga for the management of type II Diabetes was assessed in this systematic review through searching related electronic databases and the grey literature to the end of May 2007 using Ovid. All randomized controlled clinical trials (RCTs) comparing yoga practice with other type of intervention or with regular practice or both, were included regardless of language or type of publication. Each study was assessed for quality by two independent reviewers. Mean difference was used for summarizing the effect of each study outcomes with 95% confidence intervals. Pooling of the studies did not take place due to the wide clinical variation between the studies. Publication bias was assessed by statistical methods. Five trials with 363 participants met the inclusion criteria with medium to high risk of bias and different intervention characteristics. The studies' results show improvement in outcomes among patients with diabetes type II. These improvements were mainly among short term or immediate diabetes outcomes and not all were statistically significant. The results were inconclusive and not significant for the long-term outcomes. No adverse effects were reported in any of the included studies. Short-term benefits for patients with diabetes may be achieved from practicing yoga. Further research is needed in this area. Factors like quality of the trials and other methodological issues should be improved by large randomized control trials with allocation concealment to assess the effectiveness of yoga on diabetes type II. A definitive recommendation for physicians to encourage their patients to practice yoga cannot be reached at present.

**Keywords:** adult – systematic review – type II diabetes – yoga

## Background

Interest in and use of complementary and alternative medicine has recently expanded in many countries around the world. Population-based studies in countries in the developed world, such as Australia, Scotland, UK, Taiwan, Singapore and the United States of America (USA), report that one-half to two-thirds of adults use complementary therapies (1–5).

Conventional medicine for individuals with diabetes has been geared toward regulating blood glucose with a combination of dietary modification, insulin and/or oral agents, maintaining ideal body weight, exercising regularly and self-monitoring blood sugar. Good glucose control can, however, be difficult for many people with diabetes, because these conventional treatment plans require changes to behavior and lifestyle (6). Due to the chronic course of the disease, the debilitation of complications and threat of death, as well as the complexities of treatment plans, people with diabetes often work proactively to manage their condition, optimize their health and alleviate complications through the use of complementary therapies (6–9).

Because of the potential threat to quality of life and the chronic nature of diabetes many people turn to complementary therapies seeking help to control the disease. That they do so is not unexpected since many people

For reprints and all correspondence: Badr Aljasir, Suite 708, 700 Sussex drive, K1N1K4, Ottawa, Canada. Tel: 0016138626262; Fax: 0016136805762; E-mail: draljasir@yahoo.com

with chronic diseases utilize complementary therapies (10–12).

Yoga is an old, traditional, Indian psychological, physical and spiritual exercise regimen that has been studied for several decades for its role in the management of several chronic diseases including hypertension, asthma, obesity, neuromuscular diseases and psychiatric illnesses (13–19).

Additionally yoga has been studied for controlling both the symptoms and the complications associated with diabetes mellitus type II (20–33). The results from these studies suggested a statistically significant role for yoga in controlling diabetes. Furthermore, yoga practice showed a significant improvement for those diabetic patients with pre-existing complications (34). These findings suggest that diabetics may benefit from yoga's ability to improve their quality of life.

There are several hypotheses for the biological mechanisms that link the benefits of yoga to diabetes management (24). One hypothesis points to the role of stress and relaxation (35–37), while others suggest that the non-invasive nature of yoga provides excellent support and few side effects to the patients already taking medication for the disease. These hypotheses, however, have a limited generalizability as the studies they reference have small sample sizes, different types of outcome and methodological issues. These limitations should be taken into consideration before evidence based conclusions can be drawn (16).

The American Diabetes Association Position Statement (38) recommends that the use of adjuvant therapies be based on evidence from clinical research and presently there is no comprehensive, systematic review in the existing literature that addresses the effectiveness of yoga practice in diabetes mellitus management. A review such as this is urgently needed as type II diabetes is fast becoming one of the leading disabling diseases worldwide (39). In addition this review will help family physicians and endocrinologists in answering the queries of type II diabetic patients with regard to the effect of yoga practice on their medical condition.

## Objective

To assess the effectiveness of practicing yoga for the management of type II diabetes mellitus in the existing literature.

## Inclusion Criteria

All randomized or quasi-randomized clinical trials comparing the practice of yoga with any other type of intervention in adults with type II diabetes were included regardless of language or type of publication. Special attention was afforded to quasi-randomized trials, as they carry a greater potential for bias.

All patients 18 years of age and older with confirmed diagnosis of diabetes mellitus type II by a physician were included. The following criteria for the diabetes diagnosis were considered for the inclusion of the studies: the World Health Organization criteria (40) or the National Diabetes Data Group standards criteria (41).

All types of known yoga practice reported in the literature were included in any comparison with another type of diabetes symptom or complication management strategies (i.e. the usual management care for diabetes or any other kind of complementary or alternative therapy). This review also included all types of comparison studies that involve comparing two or more groups with similar management but were different regarding the practice of yoga. This review also included studies which used Ayurveda as their mode of intervention. Ayurveda is an ancient Asian practice of which yoga is an integral component (42).

Glucose level control, either fasting plasma glucose (FPG) and/or glycolated hemoglobin (HbA1c), was the primary outcome measure identified in the review. Secondary outcomes identified included: change in anti-diabetic medication use (as an indication for diabetes control); development of diabetic complications (including neuropathies, retinopathy, nephropathy and cardiovascular diseases); weight (kg) or body mass index (BMI); lipids profile: total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglycerides; diabetes-related mortality and any adverse effects resulted from yoga practice.

Several electronic and paper-based journal databases and indices were searched to identify studies to qualify for inclusion:

The Cochrane Metabolic and Endocrine Disorders Group: up to May 2007.

The Cochrane Central Register of Controlled Trials (CENTRAL): up to May 2007.

MEDLINE Database (OVID): from 1966; up to the end of May 2007.

EMBASE Database (OVID): from 1980; up to the end of May 2007.

CINAHL Database (OVID): from 1982; up to the end of May 2007.

AMED Database (OVID) from 1982; up to the end of May 2007.

Up to the end of May 2007 trials registrations from (www.controlled-trials.com), Symposium, conference and colloquium proceedings and abstracts were also searched. There were no language restrictions. The research strategy was adapted mainly for Medline with minor modifications for the other databases and it was limited to human subjects only. For the complete search strategy, please see the appendix.

## Hand Search

The related studies and trials to yoga practice and diabetes were reviewed from journals that are not available electronically.

## Other Search Strategies

The list of references for each of the relevant studies was searched.

Experts and authors in the field of diabetes care or yoga were contacted for any studies which were not included at this point.

## Methods of the Review

This review is based on a designed protocol that can be obtained by contacting the main reviewer. The results of the searches and full texts of the included articles can also be provided by contacting the main author.

To identify suitable studies for inclusion, each trial's titles and abstracts were first reviewed. Multiple publications were grouped and evaluated as one review. The reviewing process took in to consideration the presence of adult patients with diabetes mellitus, the usage of yoga practice as the intervention in comparison to any other types of management including usual care and the presence of any of the aforementioned outcome. Full texts of relevant articles were retrieved for further assessment.

## Inclusion Criteria

Adults who are 18 years of age and older with type II diabetes mellitus, diagnosed by a physician based on the criteria specified before, on a medication either oral or insulin injection, both out-patient and in-patients with stable medical condition and able to participate in the intervention.

## Exclusion Criteria

Children below 18 years of age with any other type of diabetes, not diagnosed by a physician, in the critical care unit, not on any medical management for the diabetes either oral tablets or insulin injection, not mentioning a criterion for diagnosis of diabetes that was valid at the time of diagnosis and not having any medical condition that limits the physical activities from conducting the intervention.

A standardized form was developed by the reviewers to assess the quality of each trial. The data extraction form contained information on the following items: general information about the study; characteristics of the study population and participants; intervention and control characteristics and outcomes measured.

Assessing the quality of each of the trials that met the inclusion criteria was conducted independently by the two reviewers (B.A. and M.B.) and disagreement was resolved via further discussion and inter-rater agreement was calculated using the κ-statistic. The quality of each study was assessed based on quality criteria (43) that looked for the following biases:

- Selection bias: randomization and allocation concealment.
- Performance bias: any differences in care provided apart from the intervention.
- Attrition bias: any systematic differences in the withdrawals or loss to follow-up. The studies should be following the concept of intention to treat analysis (ITT) with the full explanation of the withdrawal process.
- Measurement (detection) bias: any kind of bias related to the process of reporting the outcome of the studies.

Each of the aforementioned biases was evaluated in each study and each study was graded as: (43) A (low risk of bias: all of the criteria met); B (moderate risk of bias: one or more criteria partly met) or C (high risk of bias: one or more criteria not met). Sensitivity analysis was conducted using the various levels of study quality.

### *Data Extraction*

The extracted details regarding the relevant studies were done using a data extraction form. This process was conducted for each of the included studies. The data extraction form collected information on the following items: study general information, participant characteristics, intervention characteristics; control characteristics, outcomes characteristics and study characteristics.

### *Data Analysis*

Statistical analysis was conducted using RevMan version 4.2.10., SAS 9.1 and comprehensive meta-analysis. Forest plots have been presented and no subgroup analysis took place. The data were planned to be summarized if they were available and of sufficient similarity and quality. The outcomes measured from each trial in our review were studied according to data-types. Summary statistics (i.e. means, standard deviations, mean difference with 95% confidence intervals) and in cases of data pooling, the weight mean difference (WMD) or standardized mean difference (SMD) were analyzed for continuous outcomes. Dichotomous outcomes were analyzed according to the odds ratios, relative risk (RR) and risk difference (RD) with 95% confidence intervals, and numbers needed to treat (NNT). Statistical heterogeneity, using $I^2$ test (43) and chi-square test, were conducted when there were minimal clinical and methodological differences between the trials.

# Results

## Description of Studies

### *Studies Identified*

A total of 1815 citations were identified. Of these 1799 citations were identified through the electronic search and 16 from other sources. From the initial searches of electronic databases, 1799 citation (51 from the Cochrane Library, 846 from MEDLINE, 860 from EMBASE, 34 from CINAHL and 8 from AMED) were obtained. Total 527 studies were left after removal of the duplications and limited the studies to humans only. The titles and abstracts of these citations were reviewed. This resulted in 22 relevant citations of which the full text was obtained. After the final review of these texts, only three studies were included in this review (Figure 1) (44).

Reviewing the system for information on grey literature, the National Technical Information Service and the British National Bibliography for Report Literature revealed 16 relevant citations. Reviewing the titles and abstracts of these studies resulted in seven studies in which their full text were retrieved and gave a final relevancy of two studies.

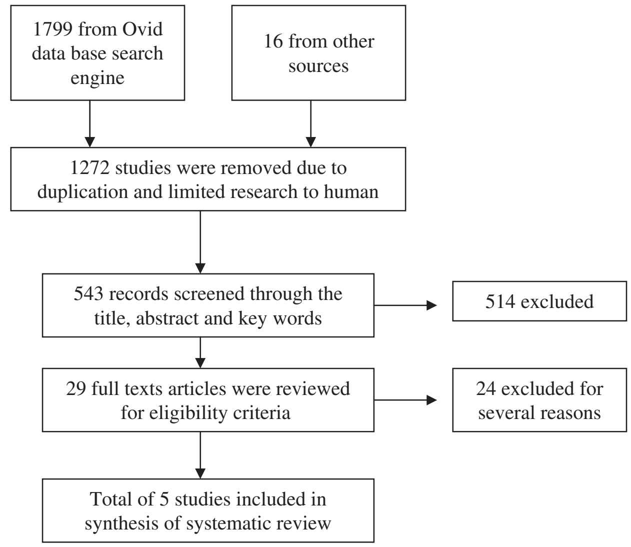


**Figure 1.** Flow through the different phases of systematic review.

### *Excluded Studies*

A total of 24 studies were excluded. Nine studies were pre-post type of studies in which the participants acted as their own control but without a separated control group. Eight studies were reviews or discussion of the role of yoga practice on diabetes but they were not trials. In four of the excluded studies the intervention was not yoga practice or it was not clear that yoga practice was included and finally three of the studies were not exclusive type II diabetic patients. These were the main reasons but some of these studies were excluded for more than one reason. No other outcomes reported from any of the trails if they were not proposed originally in this review (21,27,28,32,35,42,45–62) (Table 1).

### *Studies and Participants*

A total of five studies were included in this review with 10 arms, comparing the intervention of yoga practice alone or combined with other mode of interventions. Five arms (200 participants with the control group in which two arms and 40 participants) received nothing apart from the conventional medical therapy (63,64), one arm and 72 participants received recommendation on unsupervised training at home (65), one arm and 30 participants received herbal, diet and exercise (66) and the last arm with 20 participants reviewed recommendation for diet and walking exercise (20).

A total of 362 participants (200 intervention group and 164 in the control group) were analyzed. The mean age of the participants of the studies ranged from 49.9 years ($\pm$10.98) in the study conducted by Agrawal (65) up to 57.0 years ($\pm$7.3) in the control group of the Monro study (64). In one of the study conducted by Malhotra (20) they did not mention the gender ratio but for the rest of the studies there was 51% male and 49% female participants. The mean study size was 72 patients with a range from 21 to 154 patients. The dropout rate was estimated to be 12.6% of the patients that ranged from (0% to 23%). Only one study lost >10% (65). The mean trial duration was 14 weeks (range from 6 to 24 weeks). These studies were conducted in India and the USA.

### *Exclusion Criteria of the Studies*

In the included studies, the following were used as exclusion criteria for participants: liver disease, pulmonary tuberculosis, malabsorption, thyrotoxicosis, alcoholism, pregnant, nursing women, psychiatric patients, nephropathy, retinopathy (proliferative), coronary artery disease, congestive cardiac failure and any serious medical condition.

### *Interventions*

Yoga practice alone was used in three studies (20,63,64) while it was combined with life style modification only in one study (65). Yoga was accompanied with lifestyle modification, diet and herbal intake in one study (66). All of the participants received training for yoga practice. While it was practiced as group in three studies, those participants in Agte and Elder (63,66) studies were practicing yoga on an individual basis. The range of frequency of each session of yoga practice was different: for example two 20-min sessions per day for one of the trials (66), and three to five 90-min sessions in another (64).

**Table 1.** Characteristics of the excluded studies

| Study | Reason for exclusion |
|---|---|
| Malhotra *et al.* (21) | Trial Design: pre-post trial with no control group. |
| Kaplan-Mayer (27) | Trial Design: a review regarding yoga effects on health population: general population including those with chronic diseases. |
| Khalsa (28) | Trial Design: a review not a trial on yoga effect on several diseases including diabetes and other diseases. |
| Singh *et al.* (32) | Trial Design: pre-post trial with no control group. |
| Surwit and Schneider (35) | Trial Design: pre-post trial with no control group.<br>Intervention: relaxation practice without specification of yoga. |
| Mamtani and Mamtani (42) | Trial Design: a review of ayurveda (herbal treatment) population: the cardiovascular health in general and those with chronic diseases like diabetes and hypertension. |
| Doyle (45) | Trial Design: a review of yoga effect on diabetes but it was not a trail. |
| Ernst (46) | Trial Design: a mini review of relaxation techniques that was not a trail. |
| Head (47) | Trial Design: not a trail but a review of the effect of yoga and several other interventions on peripheral neuropathy. |
| Hensrud (48) | Trial Design: a review not a trial.<br>Intervention: diet with comprehensive lifestyle therapies, involving diet, exercise, and behavioral modification. |
| Irace *et al.* (49) | Intervention: different types of exercises not including yoga. |
| Jam *et al.* (50) | Trial Design: pre-post trial with no control group.<br>Outcome: oral glucose tolerance test (OGTT) |
| Bijiani *et al.* (51) | Trial Design: pre-post trial with no control group. |
| Kathleen (52) | Trail Design: a review of the effect of alternative therapies in peripheral neuropathy. |
| Kerr *et al.* (53) | Population: both type I and type II diabetes patients. |
| Christiansen *et al.* (54) | Trial Design: pre-post trial with no control group.<br>Intervention: a group of alternative medicine that did not include yoga. |
| Lane *et al.* (55) | Intervention: relaxation training that did not mention the usage of yoga. |
| DiPietro *et al.* (56) | Population: the participants were not diabetics.<br>Outcome: oral glucose tolerance test (OGTT). |
| Mc Ginnis *et al.* (57) | Intervention: biofeedback-assisted relaxation with mention of the usage of yoga. |
| Naruka *et al.* (58) | Trial Design: pre-post trial with no control group. |
| Singh *et al.* (59) | Trial Design: pre-post trial with no control group. |
| Diaz-Nieto *et al.* (60) | Trial Design: pre-post trial with no control group.<br>Intervention: usage of different interventions that not clear to include yoga in all of them. |
| Tsujiuchi *et al.* (61) | Intervention: it used alternative medicine interventions that did not include yoga. |
| Vanelli *et al.* (62) | Population: type I diabetic patients and younger that 18 years. |

### *Outcome Measures*

Primary outcome measures included in this review included FPG which was reported in four studies; and HA1c that was reported in three studies. Secondary outcomes included BMI; lipid profiles; and diabetes complications (nerve conduction) (20). None of the studies reported any adverse events.

### *Methodological Quality of Included Studies*

The κ-score statistic was calculated to assess the agreement between the two assessors (B.A.) and (M.B.) by using SAS 9.1 software. A value of 0.6 was calculated which indicated moderate agreement (67). After discussion a final agreement was reached for all of the studies. Risk of bias was apportioned on an alphabetic score value: B (medium risk of bias) was given to two studies (64,66) while the remaining three studies were considered having a score of C (high risk of bias) (20,63,65).

### *Publication Bias*

We did not pool outcomes due to the clinical and methodological heterogeneity; however we felt it was important to estimate the magnitude of publication bias using statistical approaches. The bias coefficient from weighted regression was not significant for fasting blood glucose (Egger's test $P = 0.247$) while the calculated fail-safe N was 67. HA1c (Egger's test $P = 0.176$) was not significant and the fail-safe N of the might-be-missed studies to bring the effect to the null was 2. For the secondary outcomes, the bias coefficient for the cholesterol estimation was Egger's test = 0.148, while the calculated fail-safe N was 47. The coefficient for HDL was Egger's test = 0.146 and the fail safe N was 85, the triglyceride was insignificant as well with (Egger's test = 0.362) and fail-safe N of 26. We could not apply the statistical procedure for the remainder of the outcomes due to the low number of the studies included.

## Outcomes

After assessing the characteristics and quality of each trial included in this review, a pooled estimate using meta-analysis was not calculated. This was mainly attributable to the high level of heterogeneity between the characteristics of studies including the specific interventions particularly the method and frequencies in conducting the intervention. Other variations existed between groups in inclusion of participants and the inconsistency in reporting outcomes between the different trials. Another important consideration is the low quality of the included studies (two of medium risk of bias and three of high risk of bias) might result in a biased overall summarization of the results (20, 63–66) (Figure 2).

### Primary Outcomes

*Fasting Plasma Glucose*

Four studies provided results on FPG. These four studies provided favorable results for the intervention in lowering FPG. The mean differences ranged from –28.8 to –41.1 in lowering the plasma glucose between the intervention and control groups, and they were all significant in three studies (63–65), however the difference in the Elder study was –3.6 and it was not significant (66).

*Glycolated Hemoglobin*

Three of the included studies reported the value of HbA1c (64–66). The mean differences indicated that the intervention lowered the level of the HbA1c. However, the results were only statistically significant in the one study (64).

### Secondary Outcomes

*Lipid Profile*

Three of the included trials reported an effect on lowering cholesterol level (63–66). The mean differences for the effect ranged from –9.1 to –35.9 which were significant in all of the trials except one (66). These trials reported outcomes additionally for HDL suggesting that yoga had a positive effect in increasing the level of HDL. The mean difference magnitude was 8.49 and 10.0 and they were both statistically significant (63,65). The Elder trial reported opposite effect in increasing HDL by a mean difference magnitude of –1.30 and a 95% CI of (–5.32, 2.72) (66). However, these trials were consistent in their reporting of the beneficial effect yoga has on triglyceride levels in which all of them reported negative mean differences ranging from –8.00 to –31.01. Only two of the trials reported the effect of yoga on LDL (65,66), one showed a lowering effect while the other evidenced a harmful effect by increasing the LDL, however this effect was not significant.

*Weight and Body Mass Index*

The study conducted by Agrawal reported a minimal drop in the mean difference of the weight of –0.17 which was not statistically significant (65). The Elder study found a two-BMI unit (66).

*Diabetes-Related Complication*

The only effect of yoga practice on diabetes complications identified was improvement in the nerve conduction velocity by Malhotra (20). They reported an improvement in nerve conduction velocity in both arms in the yoga group, but the change was not statistically significant.

## Discussion

This review addressed the effect of yoga practice on patients with type II diabetes. Despite an extensive review of the literature via different methods, we could only include five trials that compared those practicing yoga alone or with other co-interventions to a control group. To find high-quality trials (RCTs), we excluded a large number of pre-post trials, and unfortunately the included studies were not of high quality.

Yoga practice varied in type and duration between trials; while it was only for 40 days in Malhotra study, it increased to six months in the Elder trial (20,66). Among those studies who reported the details of the yoga practice, the mean time of yoga practice was 300 min per week (approximately 45 min per day).

The trials we reviewed suggested a general beneficial effect of yoga on diabetic patients. These effects were most prominent in FPG levels and lipid profiles. The results were significant in the majority of the trials. Certain long-term parameter, such as HbA1c was reported to improve slightly with the practice of yoga. However this did not increase statistically significant levels in two of the three trials in which it was reported. Other outcomes showed a favorable but not significant effect in reducing BMI units and body weight. Only one study tested the effect of yoga on diabetic-related complications (nerve conduction velocity) that showed no significant improvement from the control group.

The results suggest favorable effects of yoga on the short-term parameters related to diabetes but not necessarily for the long-term outcomes. This might be attributable to the short duration of the trials which were not able to detect a long-term effect and to the low power

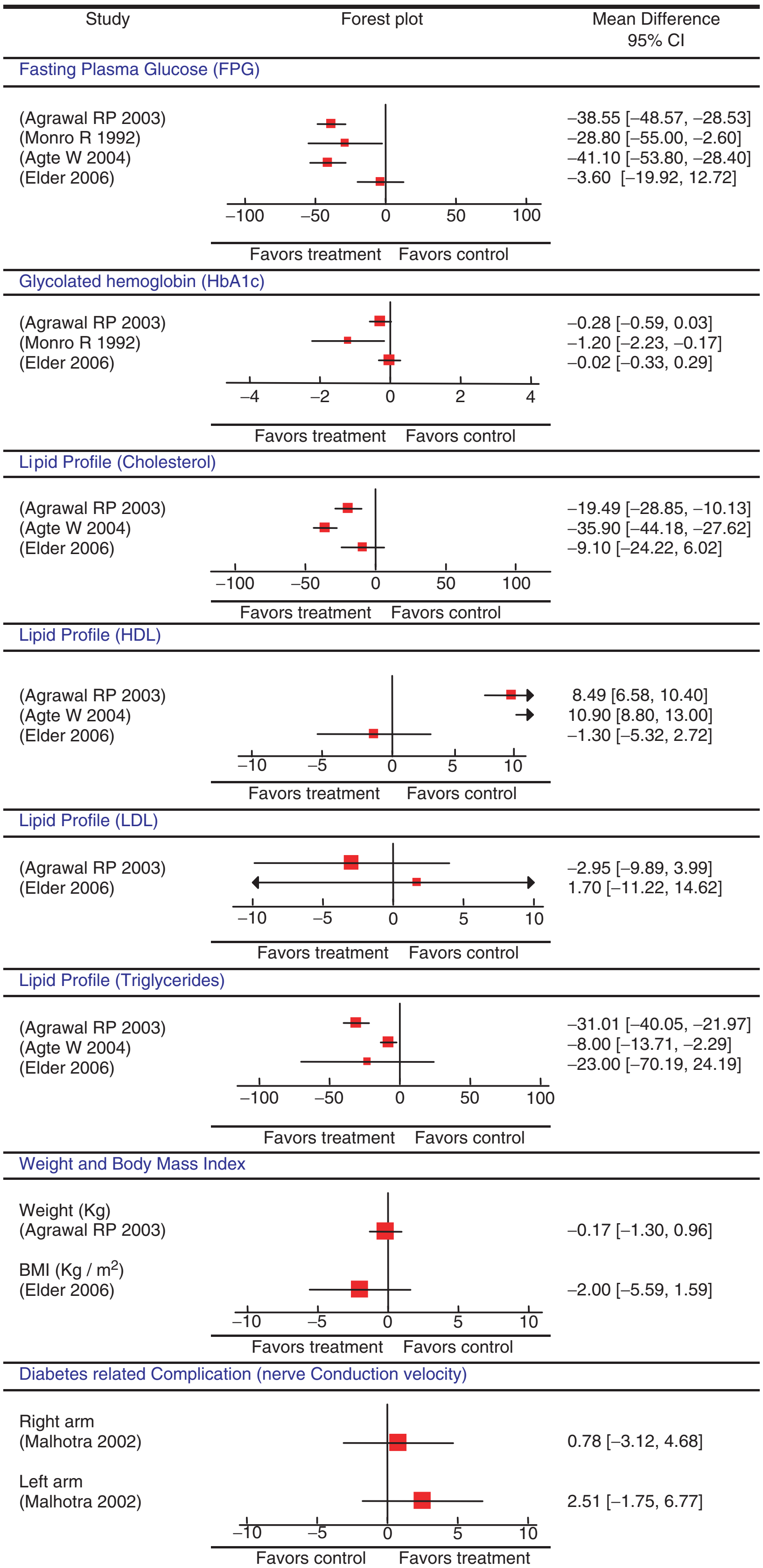


**Figure 2.** Forest plots of the primary and secondary outcomes of the included studies.

of each trial due to a small number of participants. Also, these long-term parameters require consistency in practicing yoga which raises the issue of non-adherence of the patients practicing yoga as they were scheduled to do so.

The rest of the proposed outcomes were not able to be retrieved, mainly those related to long-term complication and mortality. The reasons could be the result of the eligibility criteria of the trials since they excluded any patient with poor health status or having any kind of complication and the short period of the trials.

The results of the sensitivity analysis showed mixed results: for the primary outcomes there were no changes in the effect produced by yoga, and for the secondary outcomes the effect was null with the exclusion of high risk trials.

In this review, pooling the results from the different studies would not be of a scientific value due to the clinical heterogeneity between the studies and the risk of bias due to low quality of the studies. The low quality of included studies could be resulted from methodological deficiencies, from inappropriate reporting, or both. Methodological deficiencies such as allocation concealment, randomization, selection bias, statistical analysis, usage of multiple interventions and adjustment for confounders were noticed with varying degrees among included studies.

Publication bias assessed for the different outcomes reported by the trials to assess if there were any evidence suggesting a bias that would lead to publication of specific trials and not the other. The bias coefficient from weighted regression was not significant for all of the included studies and the number of studies of negative results that would bring the effect of yoga practice on the primary outcome, FPG and HBA1c to the null were 67 and 2. While it is unlikely that we were not able to include any of the 67 studies for the FPG, not including any of the two studies to bring the effect of yoga on HbA1c to the null is possible.

In summary, yoga showed favorable outcomes among patients with diabetes type II. These improvements were mainly among short term or immediate diabetes outcomes and not all of the improvements were statistically significant. Factors like the study quality and intervention characteristics should be taken into consideration.

## Conclusions

None of the included trials report any side effects for yoga practice. Short-term benefits for patients with diabetes might be achieved from practicing yoga. Further analysis of practice details and frequency are needed. The trials in our review had methodological quality considerations, and the trials' reported benefits have not been confirmed by large trials of high-quality. A definitive recommendation for physicians to encourage their patients to practice yoga cannot be reached at the present.

The important recommendation that can be drawn from this systematic review is the need for well-designed large randomized clinical trials to assess the effectiveness of yoga on diabetes type II. These trials should concentrate on the methodological quality and the specification of the characteristics of yoga practice. These trials should avoid including different interventions in the same arm which may cause confounding effects on the relationship between yoga and diabetes. If researchers want to include other types of co-interventions in the trial they should take into consideration methodological issues such as sample size and study power and to include subgroup analysis. Studying the long-term impact of yoga and its side effects is needed and likely stipulates standardized monitoring and reporting. Trials are recommended to follow CONSORT statement in reporting.

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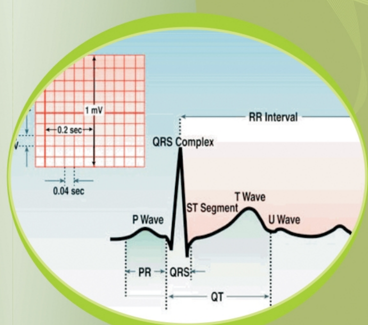


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