

BMJ Open Evaluating a group-based Yoga of Stress Resilience programme: a pragmatic before–after interventional study protocol

Elizabeth Alvarez ,^{1,2} Arielle Sutton,¹ Bria Barton,³ Shailla Vaidya⁴

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¹Health Research Methods, Evidence and Impact, McMaster University, Hamilton, Ontario, Canada

²Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Ontario, Canada

³Ontario Network of Sexual Assault /Domestic Violence Treatment Centres, Women's College Hospital, Toronto, Ontario, Canada

⁴Clairhurst Medical Centre, Toronto, Ontario, Canada

Correspondence to
Dr Elizabeth Alvarez;
alvarez@mcmaster.ca

ABSTRACT

Introduction Rates of mental health illnesses and burnout are increasing internationally. Therapeutic yoga is increasingly used to improve and maintain physical, mental and emotional well-being and general health. This protocol describes a study to evaluate the effectiveness of an existing primary care group-based therapeutic yoga programme, the Yoga of Stress Resilience programme, which combines yoga and psychotherapeutic techniques, in improving mental health and decreasing burnout. Implementation factors will also be evaluated for potential scale-up.

Methods and analysis A pragmatic before–after interventional trial design will be used to study changes in occupational participation and mental health outcomes, including anxiety, depression, burnout, functional impairment, insomnia, perceived stress, loneliness, self-compassion and readiness for change in adults experiencing anxiety and burnout. Repeated measures analysis of variance will be used to determine changes in outcome measures over time. Regression and multivariate analyses will be conducted to examine relationships between participant characteristics and outcomes and among various outcomes. The Reach, Effectiveness, Adoption, Implementation, and Maintenance framework will be used to guide the analyses.

Ethics and dissemination Approval from the Hamilton Integrated Research Ethics Board has been waived: project number 7082 (full review waived). Informed consent will be obtained prior to enrolling any participant into the study. All data will be kept confidential. Peer-reviewed publications and presentations will target researchers and health professionals.

Trial registration number The ClinicalTrials.gov registry (NCT03973216).

INTRODUCTION

Worldwide, mental health illnesses, burnout and other conditions related to stress, are on the rise.¹ Burnout is characterised by emotional depletion or loss of motivation that results from prolonged exposure to chronic emotional and interpersonal stressors on the job.² Women between the ages of 18–49 years old are most commonly diagnosed with burnout; however, men are increasingly

Strengths and limitations of this study

- Multiple mental health outcomes are included to evaluate factors related to anxiety and burnout.
- Implementation factors will be evaluated to support scale-up.
- As a pragmatic study, the intervention is run in real-life conditions, giving healthcare providers applicable findings for practice, and a wider range of participants will be included increasing the external validity of the results.
- The staff and participants are not blinded to the intervention.

being diagnosed with the condition. Depression and anxiety may coexist or follow the occurrence of burnout.¹ Roughly 8% of all Canadian adults are estimated to experience major depression at some point in their lifetime.³ By the age of 40, 1 in 2 Canadians will have had a mental illness.^{4,5}

There is a risk of chronicity as relapse with burnout is common, inevitably impacting daily functioning and quality of life for patients.¹ Burnout also places a high economic cost on the individual, the healthcare system and organisations. A company's cost may rise from absenteeism, sick leave, employee turnover, presenteeism, a decrease in productivity and a higher probability of mistakes.¹ Families may experience the impact of burnout financially, socially, as well as in personal relationships and family activities.⁶ The healthcare system also bears a substantial economic burden as a result of mental health illness; total costs of health service utilisation, lost productivity and health-related quality of life are estimated to be US\$51 billion a year in Canada.^{5,7} Treatment for burnout is often delivered within occupational health but is also sought in rehabilitation, primary care and other healthcare settings such as psychiatry.⁵



In recent decades, therapeutic yoga has become more popularised in the West as a method of increasing or maintaining physical, mental and emotional well-being. Yoga consists of postures, breathing techniques, mindfulness and meditation.⁸ Therapeutic yoga applies teachings and practices of yoga in a therapeutic context.⁹ Mindfulness is defined as a moment-to-moment non-judgemental awareness.¹ Research has found that yoga has produced positive lowering effects on anxiety and depression through improved stress management.^{8 10-12} In one pilot study examining patients with chronic respiratory diseases awaiting lung transplantation, Iyengar yoga practice (characterised by practitioner self-study and a development of awareness through various postures and breathing techniques) was effective at improving breathing, anxiety symptoms, fatigue levels and overall health status.¹³ There is also evidence to suggest that therapeutic yoga-based stress reduction methods reduce visits to primary care physicians and may improve general health.¹⁴

Although holistic yoga interventions have been studied to a somewhat lesser extent, therapeutic mindfulness-based programmes have been implemented and evaluated extensively for their effectiveness in managing psychological well-being.⁶ Mindfulness-based programmes have resulted in improved symptoms of anxiety, depression, stress and other mental health conditions.^{6 15} In reviews that have investigated yoga-based interventions as a whole, similar results were found for domains of health-related quality of life, mental well-being and anxiety related behaviours (eg, fatigue, nervousness, worry and sleep disturbances).^{16 17}

The clinical use and implementation of findings regarding the effectiveness of yoga have been limited due to the methodological limitations of studies. For example, one limitation includes the variations in the types of yoga practice which have been investigated across studies, making it difficult to determine which component of the yoga practice or teacher is responsible for the mood-enhancing effects.¹⁸ Studies are also needed to examine yoga's implications for occupational participation and performance.¹⁶ As the positive effects of yoga have been shown for even minimal frequency in practice, integrating such programmes within a variety of settings may provide further benefits in reducing healthcare utilisation for chronic conditions and comorbid mental health conditions.^{19 20}

Due to the potential for benefits to both the individual and the health system, it is important to: (1) assess the effects of an integrated therapeutic yoga programme in primary care on mental health and well-being and occupational participation in adults dealing with burnout, and (2) identify the necessary implementation considerations to adopt and integrate the programme at a broader health system level. This study will evaluate an already existing programme.

Description of intervention

A primary care group-based therapeutic yoga programme, the Yoga of Stress Resilience programme, was developed by a primary care physician in Toronto, Ontario. The programme combines yoga with psychoeducation and focusses on tools and techniques to better cope with stress. Each class incorporates gentle breath-focussed mindful yoga movement (asana) and breathing techniques (pranayama), to prepare the body for compassion-based (metta) meditation. Each class also includes a discussion related to burnout recovery and stress resilience. The programme was started in 2014 and is run through a medical centre in Toronto. The purposes of the programme are to understand:

- ▶ key concepts of yoga, mindfulness, compassion, acceptance and how these can help with personal transformation, or evaluation of the self through expanding of consciousness.
- ▶ how stress is carried in the body (embodiment of stress) and how stress manifests as anxiety, pain or other symptoms.
- ▶ what happens when stress accumulates in the body, and its effect on performance and health.
- ▶ the role of self-compassion in the response to stress.
- ▶ how to cope with difficult emotions that may contribute to stress.
- ▶ how to deal with difficult people and trying relationships.
- ▶ the importance of connecting with, and caring for ourselves to reduce accumulated stress.
- ▶ how to solidify healthier patterns to build resilience to stress faced in daily life.

Patients are referred by their primary care providers (physician, nurse practitioner and clinical psychologist) through the online site (<https://www.theyogamd.ca/>). Potential patients have a one-on-one visit with the physician leading the therapeutic yoga groups to assess for eligibility into the groups. The programme is covered by the Ontario Health Insurance Plan plus an additional fee to cover non-insured services (yoga, handouts, online programme, Moving Picture Experts Group (MPEG) Audio Layer-3 (MP3s)), which is also provided on a sliding basis dependent on need.

Each weekly session runs for 3 hours and there are nine sessions. Groups are started when there is enough demand, and the groups are about 12 people. A structured format is used in each session, with minor adjustments to the gentle physical postures, which may vary depending on needs of the group (see online supplementary file 1. Introduction and session 1 of programme). Currently, participants fill out multiple scales measuring adverse childhood events (ACE), anxiety, burnout, functional impairment, depression, insomnia, perceived stress, loneliness, self-compassion and readiness for change.

These tests have been administered diagnostically and for treatment at the beginning of the programme, but have not been routinely collected after the intervention.

Therefore, a chart review is not possible and a before–after trial is proposed.

Training of interventionist

The health professional leading the intervention, Dr. Shailla Vaidya, is a licensed family physician with training in psychotherapeutic modalities and yoga and focusses on delivering therapeutic yoga training to help manage stress and emotional difficulties. She is a Certificant of the International Association of Yoga Therapists and a Trained Teacher of Mindful Self-Compassion and Mindful-Based Cognitive Therapy.

Study objectives

1. To study the effectiveness of a physician-led group-based therapeutic yoga programme on anxiety, burn-out and other mental health indicators.
2. To understand the implementation factors surrounding the programme in order to plan for scale-up, including:
 - a. recruitment, retention, attendance in group sessions and missing data.
 - b. resources needed to run the programme, including space, materials and costs.

Primary research question and main study hypothesis

Does a 9-week physician-led group-based therapeutic yoga programme decrease anxiety and improve other mental health outcomes for adults dealing with burnout?

We hypothesise that the programme will improve mental health indicators and decrease absenteeism.

METHODS AND ANALYSIS

Study design

The design for this proposal is a pragmatic before–after interventional study, where participants have data collected at baseline and after an intervention.²¹ Before and after studies are simple to carry out, and are often preferred to observational studies. Though it is difficult to make reliable causal inferences about the programme using this design, it is sometimes preferable to conduct a before and after study before a randomised control trial, which can be expensive, time consuming and may be unethical considering the present population has been identified as high risk.²² In this study, data will be collected at baseline, at 9 weeks (at completion of programme) and at 8 months following baseline to determine sustainability of findings. Data from those not completing the programme will be evaluated to determine characteristics of those completing and those not completing the programme. The study is pragmatic because it is conducted in its natural environment, participants are not randomised, and the research team has very little to no control over events within the programme with few criteria for exclusion.²³ In addition, no restrictions will be placed on concomitant care, as this is more reflective of actual practice. Including a wider range of participants

will allow for increased generalisability of the findings. In addition, needs of the participants are prioritised within their life contexts, for example, missing sessions will be considered in the analysis as opposed to being controlled for in the study. Implementation processes will also be evaluated. These questions are important for health system considerations, especially for scale-up of the intervention. One challenge of pragmatic trials is that they need to be large enough to detect treatment effects given the large variation in the participants.

A randomised controlled trial is not appropriate at this time, as (1) the main purpose is to determine whether an existing intervention is effective and a before–after study is deemed appropriate as a first step in this process.

Implementation factors will be evaluated for the ‘sustainable adoption and implementation of effective, generalisable, evidence-based interventions’ using the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework.^{24 25}

It includes the following five factors:

- ▶ Reach the target population—includes the number and representativeness of individuals participating in the programme.
- ▶ Effectiveness or efficacy—effectiveness includes the impact of the intervention on a variety of outcomes and includes potential harms
- ▶ Adoption by target staff, settings or institutions—includes the setting and people willing to initiate similar programmes.
- ▶ Implementation consistency, costs and adaptations made during delivery—includes a description of fidelity to the elements of the intervention protocol, such as consistency of delivery, costs of the intervention and retention rates.
- ▶ Maintenance of intervention effects in individuals and settings over time—can include institutional factors supporting the continuous running of an intervention/programme and the individual’s lasting effects of the intervention on outcomes.

Patient, public and stakeholder involvement

There are many innovative approaches used by health-care providers to treat a variety of patient conditions. However, practice demands do not often allow for evaluation of these practices or for knowledge dissemination for other providers and health system decision-makers. This protocol was developed in collaboration with and centred around the needs of the healthcare provider to address these gaps in patient care.

Sampling

Consecutive sampling will be used as all patients partaking in the Yoga of Stress Resilience programme will be asked to participate in the study.

Using an online sampling calculator (<http://statulator.com/SampleSize/ss2PM.html#>) for paired differences, including a power of 80%, effect size of 0.5, $p=0.05$, two-sided test, and attrition rate of 20%, our sample size

calculation is 40 participants. Several studies have looked at effect sizes of group-based therapies on anxiety using the Generalized Anxiety Disorder 7-item (GAD-7) scale. Effect sizes ranged from 0.48 to 1.22 but were generally large.^{26–28} For an effect size of 0.4, a sample size of 52 would be needed; for an effect size of 0.8, a sample size of 16 would be needed before accounting for attrition. Therefore, the sample size of 40 seems appropriate.

Recruitment

All patients entering the Yoga of Stress Resilience programme will be asked by the healthcare provider if they would be willing to learn about and possibly participate in the study. If they agree, a research assistant will approach them to enrol in the study and obtain informed consent prior to the first group session (online supplementary file 2. Participant informed consent). If a session has already started, retrospective informed consent will be obtained using the same informed consent form at a subsequent session prior to collecting data for research purposes. Healthcare professionals involved with routine participant care or with the conduct of the programmes will not be directly involved in enrolling participants into the study or obtaining informed consent.

Study setting and participants

This study will be conducted through McMaster University, and the site of the study will be at the Clairhurst Medical Centre, 1466 Bathurst Street, Toronto, Ontario.

As a pragmatic study, all individuals enrolled in the Yoga of Stress Resilience programme are eligible to participate in the study. Due to the nature of the programme, all participants are adults experiencing signs of burnout. Exclusion criterion includes individuals not willing to participate or sign the informed consent form. Individuals who choose not to participate in the study can still take part in the Yoga of Stress Resilience programme.

Data collection

As per usual practice, electronic scales will be used to collect measures on mental health and well-being outcomes. These measures will be sent to participants before the sessions begin using an electronic link. The ACE Scale will be administered only at baseline and in person, as it can be triggering. The ACE Scale includes 10 questions about childhood abuse and exposure to forms of household dysfunction before the age of 18.²⁹ Demographic information will be collected once at the beginning of the study and includes gender, age, marital status, annual family income level, education level, occupation and current work status. Data will be entered into Open Source Clinical Application and Resource (OSCAR), the electronic medical record used at the Clairhurst Medical Centre. Data for this study will be pulled by office staff with patient identifiers removed and a participant identification number (ID) provided. Participant IDs and identifying information will be kept separately in a locked

cabinet at the Clairhurst Medical Centre. Only deidentified information will be used for data analysis.

Participants will also have data collected at 6 months post intervention. Participants will be asked to fill out the mental health scales on-line. A US\$10 gift card for Indigo will be provided for participants who complete the 6-month follow-up data collection. Participants will also be asked about any changes in marital status or work status.

All information will be kept confidential and participant IDs will be used whenever data are used for analysis. Paper documents will be kept in a locked cabinet at the Clairhurst Medical Centre and any electronic information will be kept on password-protected computers. Only research team members will have access to the deidentified data.

Outcome measures

Main outcome measure

The GAD-7 is a validated instrument for the diagnosis and treatment response of anxiety disorders.^{30 31} It comprises seven questions with four answer options, ranging from 'not at all' to 'nearly every day' and scored 0–3 with a total score ranging from 0 to 21.³⁰ Scores of 5–9, 10–14 and 15–21 represent mild, moderate and severe generalised anxiety disorder, respectively. In the primary care setting, the GAD-7 has high diagnostic validity, with a threshold of 10 exhibiting a sensitivity of 89% and specificity of 82% for generalised anxiety disorder.³⁰ Other conditions related to generalised anxiety disorder including panic disorder, social anxiety disorder and post-traumatic stress disorder have also been sensitive to a GAD-7 score of 10.³²

Secondary outcome measures

The scales were selected for addressing a holistic range of mental health indicators that are dealt with in the Yoga of Stress Resilience programme. All of these scales have been validated and used in multiple mental health programmes. *The Patient Health Questionnaire (PHQ-9)* is made up of nine questions and is diagnostic for depression. Importantly, the PHQ-9 has also been found to be sensitive to change for monitoring of treatment outcomes.^{33 34} *The Maslach Burnout Inventory* is a 22-item scale that is divided into three subscales: emotional exhaustion, depersonalisation and reduced personal accomplishment.³⁵ *The Sheehan Disability Scale* is a 3-item scale that assesses functional impairment in three areas: work, social and family.³⁶ *The Insomnia Severity Index*, a 7-item scale, was identified as the most fitting validated scale to identify insomnia symptoms.³⁷ *The Perceived Stress Scale* contains 10 items and is designed to measure the degree to which situations in one's life are appraised as stressful.³⁸ *The DeJong Gierveld 6-item Loneliness Scale* captures both emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network).^{39 40} The short-form *Self-Compassion Scale* includes 12 items and is comparable to the longer, 26 items, scale. The short form includes two items each on

self-kindness, self-judgement, common humanity, isolation, mindfulness (ie, keeping emotions in balance) and overidentified items (ie, obsessing or fixating on things that are wrong).⁴¹ *The Readiness for Change Scale* is based on a 10-point scale, where lower numbers indicate less readiness, and the higher numbers indicate greater readiness for change.⁴²

Although burnout is the primary area of concern for the present study, anxiety was selected as the main outcome measure. This is because the Maslach Burnout Inventory lacks a validated minimal clinically important difference—an important indicator of clinical levels of burnout.^{43 44} The GAD-7 is a well-validated questionnaire with a known minimal clinically important difference.³⁰

Implementation measures

Administrative data will be used for adherence information and for data on costs of running the programme. For example, OSCAR can be used for tracking the number of participants attending each session and physician billing information. Other costs such as office space rental and supplies will be obtained from office staff.

Data analysis

Data will be reviewed for completeness and entered into Excel and/or SPSS by the research assistant. Missing data will be noted in order to evaluate the study instruments themselves and other implementation factors. For any missing data, participants will first be approached to collect the missing data. Patterns in the missing data will be assessed and sensitivity analyses will be performed, if needed. Descriptive statistics will be presented for the participants in the study. Changes within individuals over time will be assessed using repeated measures analysis of variance. Regression and multivariate analyses will be conducted to examine relationships between participant characteristics and outcomes and among various outcomes.

Data and participant monitoring

All team members will meet monthly to discuss study progress and review data quality and monitoring of attendance or any concerns raised by participants or clinicians. Few risks are anticipated for this study. However, there could be anxiety or fatigue caused by participating in the study or in filling out the forms. As a mental health intervention, the clinician leading the sessions will be able to attend to these concerns. If any concerns are noted, the principal investigator will attend to these concerns and may remove the participant from the study, following a discussion with the participant and the team, if this is deemed in the participant's best interests. This study does not require a data and safety monitoring board since there are no drugs or devices being tested and is considered low risk.

Post-trial care

Participants will continue to receive usual care by their primary care providers during and after the trial.

ETHICS AND DISSEMINATION

The study protocol was submitted to the Hamilton Integrated Research Ethics Board (HiREB) and received an ethics waiver because the study is evaluating an existing programme that already collects the noted questionnaires before programme participation. A research assistant will approach potential study participants to explain the nature of the study, their rights as study participants, confidentiality of their data, voluntary entry into the study and their ability to withdraw from the study at any time without consequences to her/his care. If a participant withdraws, no further data on that participant will be collected for the study and data already entered into the study database will be removed until data analysis. Participant characteristics and reasons for non-participation will be kept for implementation considerations. There is minimal risk of entering this study, especially as any concerns in a person's physical or emotional health can be addressed by the physician leading the group sessions. Any questions will be answered, and informed consent will be obtained prior to enrolling any participant into the study. Incentives provided at the 6-month follow-up include a US\$10 Indigo gift card. This amount is not coercive yet shows appreciation for participation. Even though only coded information will be used in the study, decreasing the chances of a privacy breach, in the case of a data breach, the privacy officer will be contacted as soon as the breach is found and McMaster University protocols will be followed. Any key changes will be noted in the final report. If changes impact the conduct of the study, HiREB will be notified and changes will be made based on their recommendations and reported through ClinicalTrials.gov.

Knowledge translation

Peer-reviewed publications and presentations at conferences will target researchers and health professionals. After data analysis is completed, participants will be invited to partake in a knowledge exchange session where findings and interpretations are discussed and further knowledge translation opportunities and feedback on the programme can be elicited.

Timeline and activities

This study will take approximately 24 months. This includes time for recruiting participants, running the programmes, data collection and analysis, and generating knowledge translation activities. It is expected that enough participants can be recruited within a year.

DISCUSSION

The Yoga of Stress Resilience programme will receive support in evaluating their primary care group-based therapeutic yoga intervention to help them determine the effectiveness of this programme in their clinic population and to decide about programme continuation and/or expansion. This intervention has the potential to

improve symptoms of anxiety, burnout and other mental health conditions, which are significant contributors to morbidity and mortality in Canada. Health system benefits may be realised through the identification of implementation and scale-up considerations for the integration of mindfulness principles to improve mental health strategies and promote a healthy workforce in Canada. Knowledge translation initiatives will help with potential scale-up of this intervention along with its implementation factors to improve health systems.

Contributors EA and SV developed the research question and protocol. EA and AS drafted the manuscript. BB provided input into the research design. All authors contributed to the design of the protocol and read and approved the final manuscript.

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Competing interests SV developed and runs the Yoga of Stress Resilience programme.

Patient consent for publication Not required.

Ethics approval Hamilton Integrated Research Ethics Board project number 7082—full review waived.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iD

Elizabeth Alvarez <http://orcid.org/0000-0003-2333-0144>

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