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A randomized controlled dosing study of Iyengar yoga and coherent breathing for the treatment of major depressive disorder: Impact on suicidal ideation and safety findings

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ABSTRACT

Background: Yoga interventions offer promise for the treatment of major depressive disorder (MDD), yet their safety and potential impact on suicidal ideation (SI) have not been well documented. This study evaluated the safety of a randomized controlled dose-finding trial of Iyengar yoga plus coherent breathing for individuals with MDD, as well as the potential effects of the intervention on SI without intent.

Methods: Participants with Beck Depression Inventory-II (BDI-II) scores ≥14 and a diagnosis of MDD (using DSM-IV criteria) were randomized to either a low dose group (LDG) or high dose group (HDG) and received a 12-week manualized intervention. The LDG included two 90-min yoga classes plus three 30-min homework sessions weekly. The HDG offered three 90-min classes plus four 30-min homework sessions weekly.

Results: Thirty-two individuals with MDD were randomized, of which 30 completed the protocol. At screening, SI without intent was endorsed on the BDI-II by 9 participants; after completing the intervention, 8 out of 9 reported resolution of SI. There were 17 adverse events possibly-related and 15 definitely-related to the intervention. The most common protocol-related adverse event was musculoskeletal pain, which resolved over the course of the study.

Conclusions: The Iyengar yoga plus coherent breathing intervention was associated with the resolution of SI in 8 out of 9 participants, with mild side effects that were primarily musculoskeletal in nature. This preliminary evidence suggests that this intervention may reduce SI without intent and be safe for use in those with MDD.

1. Introduction

Major depressive disorder (MDD) is a common, recurrent, often chronic and disabling disorder.[1] Depression is globally responsible for more years lost to disability than any other disease.[2] Up to 40% of individuals with MDD treated with antidepressant medication do not achieve full remission.[3] Moreover, residual symptoms of depression are associated with increased risk of recurrence and relapse.[4] Data from randomized controlled trials (RCTs) indicate that yoga holds promise as an effective intervention for the treatment of depression.[5–8] However, the safety of yoga, including effects on suicidal ideation (SI), have not been well studied in individuals with MDD.

A meta-analysis and review of 12 RCTs ($N = 619$) using yoga for the treatment of depression found that yoga was significantly better than

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usual care, relaxation exercises, and aerobic exercise. However, this same review noted that there were no published reports of safety data from RCTs. In a recent meta-analysis of 92 RCTs across a broad range of conditions, yoga was not associated with increased frequency of intervention-related non-serious or serious adverse events compared to exercise or usual care. However, when compared to non-physical interventions, such as psychological or educational interventions, yoga was associated with increased frequency of intervention related non-serious adverse events; serious adverse events were rare.[5] There is a need for specific safety data for yoga-based interventions in MDD.

There are no known studies evaluating the use of an Iyengar yoga and coherent breathing intervention (yoga intervention) for SI. This manuscript presents a follow-up analysis of an RCT of a 12-week yoga intervention for individuals with MDD. The primary study found that both the low dose group (LDG; 2 x weekly + homework) and high dose group (HDG; 3 x weekly + homework) were associated with decreased Beck Depression Inventory-II (BDI-II) scores consistent with response (50% reduction in BDI-II scores) and remission (BDI-II < 14)[9]. This manuscript has two aims: 1) to evaluate the effects of the intervention on SI without intent in participants with MDD, and 2) to assess the safety of the intervention. Musculoskeletal AEs were anticipated based on previous reports.[10,11]

2. Materials and methods

We present SI data and safety findings from a parent study described in a previous report,[9] conducted October 2013 – September 2015 at the Boston University Medical Center (BUMC), and approved by their Institutional Review Board (IRB). Recruitment was conducted in the community with flyers, newspaper advertisements, and the internet. Baseline data were collected prior to randomization. A rolling admissions design was utilized; participants entered the 12-week intervention to which they were randomized using a permuted block design ($n = 4$). A blinded statistician (with no participant contact) placed group assignments in sealed envelopes, sequentially opened when a participant was randomized.

2.1. Intervention

Participants were randomized to either a LDG or a HDG. The LDG was assigned two 90-min classes and three 30-min homework sessions per week. The HDG was assigned three 90-min classes and four 30-min homework sessions per week.

Homework consisted of 15-min of Iyengar yoga followed by 15-min of coherent breathing. Each 90-min class included approximately 60-min of Iyengar yoga postures, 10-min of transition including deep relaxation, and 20-min of coherent breathing, paced by a chime tone recording on a compact disc. Iyengar yoga emphasizes correct alignment while performing postures. Coherent breathing entails breathing through the nose with equal duration of inhalation and exhalation at a rate of 5 breaths per minute. These practices have been shown to optimize heart rate variability (HRV) and sympatho-vagal balance.[12–14] Further details of this same intervention were previously reported.[9]

2.2. Instructor training and intervention fidelity

All instructors completed an Iyengar Introductory Level II certification exam (≥ 2 years of study), had > 5 years teaching experience, used the intervention manual, received training in coherent breathing, were assessed quarterly by the Principal Investigator (PI) using a protocol compliance fidelity instrument. There were 15 fidelity assessments on 5 instructors that documented fidelity to the assessment categories. Instructors were trained and allowed to modify the sessions to meet the needs of the participants, which included the use of props (e.g., blocks, blankets, and straps). The protocol encouraged instructors to modify the classic postures such that participants could be successful in their attempts while also minimizing injuries.

2.3. Instruments and assessments

The *Structured Clinical Interview for DSM-IV Axis I Disorders (SCID)* was used at screening to confirm the diagnosis of MDD and assess for other Axis I disorders.[15] The *Beck Depression Inventory-II (BDI-II)*, a 21-item, self-rated questionnaire, measured depressive symptoms.[16] Scoring criteria: minimal depression 0–13, mild depression 14–19, moderate depression 20–28, and severe depression 29–63. BDI-II question #9 assessed SI with the following response options: 0) I don't have any thoughts of killing myself; 1) I have thoughts of killing myself, but I would not carry them out; 2) I would like to kill myself; and 3) I would kill myself if I had the chance.

The *Columbia-Suicide Severity Rating Scale (C-SSRS)* is a clinician-administered assessment.[17] At screening, the C-SSRS form was used for two time frames: 1) "lifetime", and 2) "last year" (rather than the standard time frame of "past month"). At weeks 4, 8, and 12, a "since the last visit" time frame was used. The C-SSRS SI section uses the following items: 1) wish to be dead, "Have you wished you were dead or wished you could go to sleep and not wake up?"; 2) non-specific active suicidal thoughts, "Have you actually had any thoughts of killing yourself?"; 3) active suicidal ideation with any method (not plan) without intent to act, "Have you been thinking about how you might do this?"; 4) active suicidal ideation with some intent to act; without specific plan; and 5) active suicidal ideation with specific plan and intent. Affirmative answers to items 4 or 5 during screening were exclusionary.

The *Weekly Safety Form* contained the following questions: 1) "Are you feeling more depressed?"; 2) "Are you feeling suicidal?"; 3) "Mark your level of depression in the last week – response options: none, mild, moderate, severe"; 4) "Have you had any muscle soreness?"; and 5) "Have you had any other adverse events this week? (Adverse events are new or worsening medical problems.) If so, please list them." Participants returned completed Weekly Safety Forms at the beginning of each calendar week of the intervention. As the 12-week intervention could occur over 13 calendar weeks, each participant could complete a maximum of 13 Weekly Safety Forms.

Clinical evaluations by a psychiatrist (PI) at baseline and a psychiatrist (PI) or clinical psychologist at weeks 4, 8, and 12 included a review of Weekly Safety Forms, BDI-II, and C-SSRS. Additional clinical assessments by a psychiatrist or clinical psychologist were triggered by any 4-point increase on BDI-II, worsening depression or suicidality on the Weekly Safety Forms, staff observations of participant distress, or participant reports of distress. The BDI-II was only given during assessment visits, when the participant also had a clinical and safety assessment. Adverse events (AEs) were defined as new or worsening medical problems that increased by at least one level of severity. Severity level of AEs was rated: 1) mild – does not have a major impact on the participant, 2) moderate – causes some minor inconveniences, and 3) severe – causes substantial disruption to the participant. AE relationship to study was rated: 1) definitely-related, 2) possibly-related, and 3) not related. Pre-existing conditions that continued in the pre-existing pattern were not considered AEs. All subjects had depression at baseline, and depression was not reported as an AE unless a patient changed one level of AE severity rating from their pre-existing baseline condition. Severity of AE and relationship to study was determined by the study PI, a board-certified psychiatrist and neurologist.

2.4. Inclusion and exclusion criteria

Participants met the following criteria: 18–55 years of age, current SCID diagnosis of MDD, and at least mild-to-moderate depression based on BDI-II total scores of 14–28 (> 28 indicates severe depression). Comorbid anxiety disorders that would not interfere with study participation were allowed. The following items were exclusionary: treatment