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## Adjunctive yoga versus bibliotherapy for bipolar depression: A pilot randomized controlled trial



Lauren M. Weinstock  $^{a, b, *}$ , Monica K. Broughton  $^b$ , Katherine M. Tezanos  $^c$ , Geoffrey Tremont  $^{a, d}$ , Tom Gillette  $^e$ , Lisa A. Uebelacker  $^{a, b}$ 

- <sup>a</sup> Brown University, Department of Psychiatry and Human Behavior, Box G-BH, Providence, RI 02912, USA
- <sup>b</sup> Butler Hospital, Psychosocial Research Program, 345 Blackstone Boulevard, Providence, RI 02906, USA
- <sup>c</sup> Teachers College, Columbia University, Department of Clinical Psychology, 525 West 120th Street Box 102, New York, NY 10027, USA
- <sup>d</sup> Rhode Island Hospital, Department of Psychiatry, 593 Eddy Street, Providence, RI 02903, USA
- <sup>e</sup> Independent Yoga Consultant, 69 Chestnut Road, North Kingstown, RI 02852, USA

#### ARTICLE INFO

# Article history: Received 19 September 2016 Received in revised form 22 October 2016 Accepted 3 November 2016 Available online 5 November 2016

Keywords:
Bipolar disorder
Depression
Yoga
Adjunctive treatment

#### ABSTRACT

Although yoga has been recommended as a mood management strategy for bipolar disorder (BD), there are no published studies on yoga for the treatment of BD symptoms. The aim of this pilot study was to develop an adjunctive hatha yoga intervention for bipolar depression, and to evaluate its preliminary feasibility, acceptability, and safety in a 10-week randomized controlled trial. Eighteen adults with bipolar I/II depression were recruited and randomized to yoga (n = 10) or self-directed bibliotherapy (n = 8), both delivered as adjuncts to community pharmacotherapy for BD. Yoga participants were invited to attend at least one of two weekly yoga classes for 10 weeks, following a structured yoga manual. Statistical analyses focused on change in depression severity, assessed post-treatment by a blind rater. Participants also completed assessments of mania symptoms, quality of life (QoL), and treatment satisfaction. Although between-groups analysis yielded no significant difference in depression outcomes by condition, within-group analyses of those assigned to yoga revealed medium effects for improvements in depression symptoms (Cohen's d = 0.66) and QoL (Cohen's d = 0.69). Manic symptom severity remained low throughout the yoga program, in contrast to slight increases in the control arm  $(F(1,13) = 7.25, p\ 0.021)$ . Participants attended an average of only  $4.80\ (SD = 5.12)$  yoga classes, yet overall satisfaction with yoga was rated as fairly high and 6 of 10 participants reported practicing yoga at home. We conclude that yoga for bipolar depression merits future research, with a focus on alternative avenues of delivery (e.g., internet) that may not require weekly class attendance.

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#### 1. Introduction

Depression symptom management remains one of the most significant challenges in bipolar disorder (BD). Compared to mania, major depressive episodes in BD are more frequent and considerably longer in length, and are largely responsible for the functional impairment and substantial mortality risk encountered in BD due to suicide (Thase, 2006). Pharmacologic treatment of bipolar

E-mail addresses: Lauren\_Weinstock@brown.edu (L.M. Weinstock), MBroughton@butler.org (M.K. Broughton), kt2604@columbia.edu (K.M. Tezanos), gtremont@lifespan.org (G. Tremont), leegillette@verizon.net (T. Gillette), LUebelacker@butler.org (L.A. Uebelacker).

depression is complicated by generally poor response to mood stabilizing medications, the risk of antidepressant-induced mood switching, and poor rates of medication adherence (Vieta & Valentí, 2013). Although a number of adjunctive psychosocial interventions have shown promise for treating bipolar depression (Miklowitz et al., 2007), such intensive, specialized treatments are not always accessible to patients. Thus, there is a clear need for additional treatment development in this area.

Yoga is an ancient Indian system of philosophy and practice (Desikachar, 1999; Iyengar, 1993). Data suggest that about 5% of US adults practice yoga (Barnes, Powell-Griner, McFann, & Nahin, 2004). In the U.S., most people practice hatha yoga, which includes breathing practices (*pranayama*), physical postures (*asanas*), and forms of meditation (*dhyana*). There are many different styles of hatha yoga; styles range from gentle to physically challenging, and

 $<sup>^{\</sup>ast}$  Corresponding author. Brown University and Butler Hospital, 345 Blackstone Boulevard, Providence, RI 02906, USA.

vary in their use of the above-referenced practices. Yoga often involves the practice of mindfulness (Bishop et al., 2004) of body sensations, breath, thoughts, or feelings while engaging in breathing practices, holding postures, or flowing between postures.

Hatha yoga is gaining increasing acceptance as an adjunctive intervention for many psychiatric disorders (Meyer et al., 2012). Given its growing evidence base as an adjunctive intervention for depression in unipolar samples (Cramer, Lauche, Langhorst, & Dobos, 2013; Uebelacker, Lavretsky, & Tremont, 2016), and the relevance of its putative mechanisms of action for depressive symptom reduction (Uebelacker et al., 2010) – such as decreased rumination, improved sleep and circadian regularity, improved physical health, and reduced inflammation - hatha yoga has frequently been recommended as a symptom management strategy for BD (Meyer et al., 2012; Murray et al., 2011; Shannahoff-Khalsa, 2012). Yet to our knowledge, there have been no published studies on the efficacy of yoga for the reduction of BD symptoms. As a first step toward addressing this gap in the literature, the primary aim of this study was to develop an adjunctive hatha yoga intervention for bipolar depression, and to evaluate its preliminary feasibility, acceptability, and safety in a 10-week randomized controlled trial comparing the adjunctive hatha yoga intervention to a self-directed bibliotherapy control condition.

#### 2. Methods

#### 2.1. Participants

Participants were 18 individuals with bipolar I (n = 16) or bipolar II (n = 2) depression who were recruited through clinician referral and community advertisements. Criteria for inclusion were: (a) 18 years of age or older; (b) diagnosis of lifetime bipolar I or II disorder, as assessed using the Structured Clinical Interview for DSM-IV-TR Axis I disorders (SCID-I; First, Spitzer, Gibbon, & Williams, 2002); (c) at least a moderate level of current depression severity, as evidenced by a score  $\geq$  11 on the Quick Inventory of Depressive Symptoms - Clinician Rating (QIDS-C; Trivedi et al., 2004); (d) at least 4 weeks of stable and ongoing pharmacotherapy for BD with a community medication provider; (e) medical clearance for moderate exercise, as documented in a note from a primary care provider; and (f) sufficient understanding of English in order to participate in study procedures. Exclusion criteria were: (a) current manic episode as determined by the SCID-I; (b) presence of psychotic symptoms within the past 30 days, per SCID-I assessment; (c) suicidal ideation severe enough to warrant inpatient hospitalization; (d) current hazardous substance use, as determined by a score of 10 or greater on the Alcohol Use Disorders Identification Test (AUDIT; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001) and/or 6 or greater (10 or greater if cannabis only) on the Drug Use Disorders Identification Test (DUDIT; Berman, Bergman, Palmstierna, & Schlyter, 2003); (e) pregnancy or plans to become pregnant within the year; and (f) > 8 single sessions of yoga in the past 2 years.

#### 2.2. Assessments

#### 2.2.1. Diagnosis

To assess for the presence of bipolar disorder, the mood disorders and psychosis screener modules of the SCID-I (First et al., 2002) were administered at baseline by trained bachelor's level research assistants. All raters were required to achieve a kappa = 0.80 with expert faculty ratings prior to conducting independent diagnostic assessments. Final diagnostic assessments were based upon consensus, following a review of the SCID-I between the raters and the clinical team.

#### 2.2.2. Symptoms and functioning

The Quick Inventory of Depressive Symptomatology — Clinician Rating (QIDS-C; Trivedi et al., 2004), was administered by trained research assistants to assess severity of depressive symptoms. Total QIDS-C scores range from 0 to 27. Research assistants were required to achieve an intraclass correlation coefficient (ICC) = 0.80 with expert faculty ratings before conducting independent assessments.

Manic symptom severity was monitored using the Altman Self-Rated Mania scale (ASRM; Altman, Hedeker, Peterson, & Davis, 1997), a brief 5-item measure that ranges in score from 0 to 20. Self-reported quality of life was assessed using the 12-item Brief Quality of Life Scale for Bipolar Disorder (Brief QoL.BD; Michalak & Murray, 2010), which ranges in score from 12 to 60 (higher scores indicate greater functioning). The ASRM (Cronbach's alpha = 0.57) and the Brief QoL.BD (Cronbach's alpha = 0.84) demonstrated acceptable internal consistency reliability in the current study in the current study.

#### 2.2.3. Treatment acceptability

Acceptability of study interventions was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson & Zwick, 1982). This questionnaire contains 8 Likert-type items, with total scores ranging from 8 to 32. Higher scores reflect greater satisfaction with treatment. Internal consistency reliability of the CSQ-8 was high in this study (Cronbach's alpha = 0.94). For those randomized to the yoga condition, supplemental open-ended questions were included for the purpose of collecting written qualitative feedback about experiences with yoga. We asked participants about what they found to be helpful, what could be improved, what was not helpful, specific aspects of the yoga program that were particularly useful, and convenience of class location and time. We also asked participants to complete homework cards indicating the amount and type of yoga practice that they did for homework.

#### 2.3. Procedures

All study procedures were approved by the Butler Hospital and Brown University Institutional Review Boards. Prior to the baseline assessment, all participants provided written informed consent to participate. The SCID-I, AUDIT, and DUDIT were administered at baseline to determine eligibility. After this visit, with the participants' written permission, we sent a letter to their primary care provider outlining the study and the possible physical demands of yoga, i.e., stretching and physical activity similar to the level of brisk walking. We asked providers to sign and return a note saying, to the best of their knowledge, participants did not have medical contraindications that would preclude them from safely participating in the classes.

Eligible participants were randomized to 10 weeks of either hatha yoga or a self-directed bibliotherapy condition, both designed to be delivered as adjuncts to ongoing pharmacotherapy provided by community clinicians. Participants were randomly assigned to conditions in a 1:1 ratio, with one stratification variable: baseline depression severity (QIDS-C  $\leq$  15 vs. QIDS-C > 15). Randomization was also blocked, with randomly chosen blocks of size 4 or 6. Those assigned to the yoga condition entered classes on a rolling basis, as yoga was offered continuously throughout the study period.

Outcome assessments, including the QIDS-C (primary outcome), ASRM, and Brief QoL.BD (secondary outcomes), were administered at baseline and again at 10 week follow-up. All follow-up interviews were conducted by research assistants who were blind to condition assignment. The CSQ-8 and qualitative questions were also administered at the 10 week follow-up assessment. All study procedures, including yoga classes, were completed at an

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