# A Randomized Controlled Trial of Community-Delivered Heated Hatha Yoga for Moderate-to-Severe Depression

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## Abstract

**Objective:** To evaluate feasibility, acceptability, and preliminary efficacy of heated yoga to treat moderate-to-severe depression.

**Design:** An 8-week randomized controlled trial (RCT) of heated yoga versus waitlist control was conducted from March 2017 to August 2019.

**Methods:** Participants in the yoga condition were asked to attend heated yoga classes at 2 community heated yoga studios at least twice weekly. We assessed acceptability and feasibility using exit interview and attendance data, respectively. The primary intervention efficacy outcome variable was change in the Inventory of Depressive Symptomatology—Clinician Rated (IDS-CR) score from baseline to post-intervention (week 8).

**Results:** We randomized 80 participants and included 65 (mean [±SD] age 32.7 [±11.7] years; 81.5% female) in the analyses (yoga n = 33, waitlist n = 32). The mean IDS-CR score at baseline was 35.6 (±7.9) for the full sample, 36.9 (±8.8) for yoga participants, and 34.4 (±6.7) for waitlist participants. Participants attended an average of 10.3 (±7.1) total classes over the 8-week intervention period. Yoga participants had a significantly greater pre- to post-intervention reduction in IDS-CR scores than waitlist participants (Cohen $d = 1.04$, $P < .001$). More yoga participants (59.3%; n = 16) than waitlist participants (6.3%; n = 2) evidenced larger treatment responses (IDS-CR ≥ 50% decrease in symptoms). Participants rated the heated yoga and its aftereffects positively in exit interviews.

**Conclusions:** Approximately 1 heated yoga session per week (mean of 10.3 classes over 8 weeks) was associated with significantly greater reduction in depression symptoms than a waitlist control. Participants rated heated yoga positively. Taken together, results suggest feasibility, acceptability, and preliminary efficacy for patients with depression and warrant further research using active control conditions.

**Trial Registration:** ClinicalTrials.gov identifier: NCT02607514

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According to the World Health Organization (WHO), depression is the leading cause of disability worldwide.[1] Even though increasing numbers of people are receiving treatments for depression, there are still unacceptable levels of morbidity and mortality.[2] Approximately one-third of patients respond to their initial trial of an antidepressant medication[3]; however, difficult-to-tolerate side effects are common, such as weight gain, sexual dysfunction, sleep disturbances, apathy, fatigue, and cognitive impairment.[4] For the significant population of individuals who do not respond to, have access to, or tolerate standard antidepressant medications and/or behavioral health interventions, treatment approaches are urgently needed.

There have been numerous randomized controlled trials (RCTs) of non-heated yoga as a treatment for individuals with depression with mostly positive findings, but none pivotal.[5–9] Yet, RCTs of heated yoga are sorely lacking, despite the fact that whole body hyperthermia (WBH) has promise as a treatment for depression[10] and the combination of yoga and heat could have synergistic effects. Previous studies have found that elevating body temperature (hyperthermia) demonstrates antidepressant effects. There is 1 double-blind RCT of WBH for depression conducted

## Clinical Points

- There is very little research on heated yoga for the treatment of depression, and treatment options for depression are sorely lacking; we therefore conducted a randomized controlled trial of heated yoga for depression.
- Heated yoga appears to be associated with a reduction in depressive symptoms over an 8-week period when compared to a waitlist control intervention.
- Heated yoga at a frequency of approximately 1 class per week could be a viable treatment option for medicated and unmedicated patients with moderate-to-severe depression.

in 30 medication-free participants who were randomized to a single session of WBH (temperature = 101.3°F) vs a plausible sham. The WBH group demonstrated reduced depression scores compared to the sham, sustained for 6 weeks post-treatment.[10] Another RCT investigated repeated WBH for mild depression showed a reduction in depressive symptoms.[11] We previously conducted an open-label study of heated yoga that identified improvements in moderate-to-severe depressive symptoms over 8 weeks.[12] There is 1 RCT of heated yoga by La Rocque and colleagues[13] for mild-to-moderate depression, which found that heated yoga outperformed a waitlist control but not an active exercise comparator in a group of women with mild-to-moderate depression. We are building upon the results of this study by including all genders, a larger sample, and individuals with moderate-to-severe depression.

In view of the above, the combination of yoga and heat may ultimately prove superior to non-heated yoga or WBH alone to treat depression. We aimed to explore whether heated yoga reduces moderate-to-severe depressive symptoms in a mixed gender sample, which would extend the findings of La Rocque and colleagues into a more severely depressed population.[14] We hypothesized that the combination of yoga and heat would be feasible and acceptable and improve depressive symptoms more than a waitlist control in individuals with moderate-to-severe symptoms of depression.

# METHODS

## Protocol and Design

This study (ClinicalTrials.gov: NCT02607514) was approved by the Mass General Brigham institutional review board (IRB). All subjects signed an IRB-approved informed consent statement. We followed the CLARIFY[15] and CONSORT[16] guidelines in reporting our study design, results, and other relevant information (see Supplementary Appendices 1 and 2, respectively). We randomized 80 subjects to 8 weeks of ≥ 2 weekly heated yoga classes ("yoga") vs a waitlist control ("waitlist") arm. The study statistician completed randomization by creating a random permuted block design in blocks of 2 and 4. The randomization schedule was kept in a locked file, and randomization status was kept from all blinded assessors. Unblinded study coordinators assigned participants to intervention using the randomization sequence. Eligible participants attended a baseline visit, followed by assessment visits every other week over the 8-week study period. At the assessment visits, study staff measured vital signs, administered clinician- and self-rated assessments, and monitored for adverse events. Clinician assessors were blinded to randomization arm ("yoga" vs "waitlist"). If a participant terminated early, they were asked to complete an exit evaluation.

## Participants

Subjects were recruited through advertisements and local referrals in the greater Boston metropolitan area. The study was advertised through online sources (eg, Facebook advertisements, hospital study recruitment website) and physical sources (eg, posters on public transportation). Recruitment began on March 2, 2017, and ended on August 5, 2019. Participants completed assessment visits at the Depression Clinical & Research Program (DCRP) at Massachusetts General Hospital and completed heated yoga sessions at 2 community heated yoga studios in the Boston area.

## Inclusion Criteria

Inclusion criteria were as follows: (1) aged between 18–60 years; (2) English language proficiency; (3) ability to provide informed consent; (4) depressive symptom severity (score ≥ 23 on the clinician-rated Inventory of Depressive Symptomatology scale (IDS-CR)[17]; (5) willingness to maintain current medication and exercise regimen over the course of the study; (6) willingness to attend at least 2 heated yoga sessions a week for 8 weeks; (7) willingness to adhere to hydration requirements; and (8) willingness to use birth control if of child-bearing potential.

## Exclusion Criteria

Exclusion criteria were as follows: (1) pregnant or planning to become pregnant during the study; (2) psychiatric hospitalization or active suicidal intent in the past 12 months, determined by the Columbia-Suicide Severity Rating Scale[18]; (3) diagnosed with any neurologic disorder(s) that would impact participation; (4) history of bipolar disorder, psychotic disorder, eating disorder, or substance use disorder with less than 12 months of remission prior to screening; (5) any medical conditions that would affect participant safety (eg, unstable/contraindicated cardiac risk factors or heat intolerance); (6) antidepressant medication initiated within 8 weeks or a dose change within 4 weeks prior to screening; (7) current individual or group psychotherapy established for < 3

months; (8) prescription or over-the-counter stimulants or lithium use (due to dehydration); (9) antipsychotic medication (due to thermoregulatory interference); (10) a positive urine toxicology screen; (11) any medical conditions that could be causal for depressive symptoms (epilepsy or hypothyroidism); and (12) attended > 6 hours of yoga or another mind-body practice (tai chi, meditation) within 6 months prior to screening.

## Rationale for Sample Selection

At the time of study development, heated yoga had not been tested in an RCT for depression. As such, we included those with moderate-to-severe depression (depressed enough to observe changes with the intervention). Given the lack of prior studies testing the intervention as either an augmentation or monotherapy for depression, we included participants both on and off treatment with stable antidepressants. In lieu of an upper limit on depressive symptoms, we included patients without active suicidal plan or intent for the past year.

## Medical Clearance Procedures

A physical examination was conducted by a study physician prior to randomization, and vital signs were measured. A blood draw was performed for routine safety laboratory tests, and an electrocardiogram was administered to assess cardiac health.

## Intervention

The study intervention, Bikram yoga, is a standardized form of heated yoga practiced in a 105°F room (referred to as "heated yoga").[19] Classes involve a vigorous 90-minute, sequenced series of 26 hatha yoga postures and 2 breathing exercises (see Supplementary Appendix 3 and Nyer et al[12] for a list of postures). Each 90-minute session is bookended by 2 breathing exercises, totaling 10 minutes. The intervention was conducted in 2 community heated yoga studios in the Boston area. Yoga instructors were Original Hot Yoga certified. The instruction method was based on verbal guidance. Participants were prescribed at least 2 classes per week for 8 weeks with no upper limit on the number of classes and could interchangeably use either studio. Prior to starting yoga, each participant completed a 50-minute preparatory session with the principal investigator (PI) or designee on strategies to adapt to exercising in a heated environment (eg, hydration, when to eat a meal, what to wear, how to breathe) and to promote consistent attendance (eg, explore any barriers to participation, worries or concerns, questions). Participants also received brief 10-minute biweekly phone calls from the PI or designee to provide support, answer questions, and address concerns. To assess fidelity to the yoga protocol, our yoga research liaison (J.K.), a senior Original Heated Yoga instructor, dropped in on at least 10% of classes offered to participants.

## Waitlist Control Condition

The waitlist control condition ("waitlist") consisted of the same assessment schedule as the yoga group. Participants in either group (yoga and waitlist) receiving preexisting treatment prior to enrollment (ie, psychotherapy or medication) were asked to maintain stable treatment throughout the duration of the study (exclusion criteria 6 and 7). The waitlist group was asked to access only these pre-established treatments during their waitlist period and not to add additional treatments, yoga practice, or exercise. All members of the waitlist group were offered the yoga intervention after the 8-week waitlist period. Waitlist participants completed another baseline assessment at the end of their 8-week waitlist period to gather data prior to the open-label extension portion of the study. Results from the open-label extension portion for the waitlist group will be reported elsewhere.

## Measures

**Screening.**

Clinical Information: Psychiatric History Form[20]: adapted from the Structured Clinical Interview for *DSM-IV* Axis I Disorders, Research Version, Non-Patient Edition (SCID-I/NP) (SCID) used to gather demographics, age at onset of depressive illness, psychiatric history, concurrent treatment, and treatment history.

Mini-Neuropsychiatric Interview, v7.0.0 (MINI)[21]: clinician-administered structured diagnostic interview was used to evaluate the presence of major depressive disorder (MDD) and other Axis I psychiatric disorders based on *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition[22] (*DSM-5*) criteria.

Columbia-Suicide Severity Rating Scale18: Clinician-administered assessment of recent and lifetime suicidal ideation and behavior.

**Primary outcome.** The Inventory of Depressive Symptomatology—Clinician Rated (IDS-CR),[17] a well-validated clinician-rated scale that assesses severity of depressive symptoms, was the primary outcome measure. A clinician blinded to randomization arm administered the IDS-CR at baseline and weeks 1, 3, 5, and 8.

**Secondary outcomes.** We assessed secondary outcome measures using computerized surveys for self-report measured at baseline and weeks 1, 3, 5, and 8, except for the HDRS, which was measured only at baseline and week 8.

Hamilton Depression Rating Scale (HDRS)[23,24]: A well-validated clinician-rated measure of depression.

Spielberger State-Trait Anxiety Inventory (STAI)[25]: A self-report measure that distinguishes between state and trait anxiety.

Medical Outcomes Study 36-Item Short Form Survey (SF-36)[26]: A self-report scale that assesses bodily pain, general health perception, vitality, social functioning, physical and emotional impediments to role functioning, and mental health.

Table 1.
**Sample Characteristics at Baseline**

| | Full sample (N = 65) | Yoga (n = 33) | Waitlist (n = 32) |
|---|---|---|---|
| **Demographics** | | | |
| **Race, % (n)** | | | |
| White | 69.23 (45) | 72.73 (24) | 65.63 (21) |
| Black | 12.31 (8) | 12.12 (4) | 12.5 (4) |
| Asian | 6.15 (4) | 6.06 (2) | 6.25 (2) |
| Multiple | 9.23 (6) | 9.09 (3) | 9.38 (3) |
| Unknown | 3.08 (2) | 0 (0) | 6.25 (2) |
| Hispanic | 10.77 (7) | 6.06 (2) | 15.63 (5) |
| **Gender, % (n) female** | 81.54 (53) | 75.76 (25) | 87.5 (28) |
| **Age, y, mean (SD)** | 32.71 (11.7) | 32.3 (11.65) | 33.12 (11.93) |
| **Education, % (n)** | | | |
| Less than college degree | 13.85 (9) | 15.15 (5) | 12.5 (4) |
| College degree or more | 86.15 (56) | 84.85 (28) | 87.5 (28) |
| **Annual income, USD, mean (SD)** | 65,325 (62,181.80) | 60,654 (34,946.75) | 69,242 (78,518.24) |
| **Marital status, % (n)** | | | |
| Never married | 67.69 (44) | 66.67 (22) | 68.75 (22) |
| Ever married or living with partner | 32.31 (21) | 33.33 (11) | 31.25 (10) |
| **Parental status, % (n) parent** | 21.54 (14) | 18.18 (6) | 25 (8) |
| **Treatment engagement** | | | |
| **Antidepressants, % (n) using** | 43.08 (28) | 51.52 (17) | 34.38 (11) |
| **Psychotherapy, % (n) engaged** | 50.77 (33) | 54.55 (18) | 46.88 (15) |
| **Baseline severity, mean (SD)** | | | |
| **IDS-CR** | 35.63 (7.87) | 36.86 (8.80) | 34.38 (6.68) |
| **HDRS-17** | 21.51 (4.80) | 22.21 (5.42) | 20.78 (4.02) |

Abbreviations: HDRS-17 = Hamilton Depression Rating Scale-17 item, IDS = Inventory of Depressive Symptomatology—Clinician Rated.

Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF)[27]: A self-report measure of satisfaction and enjoyment.

Exercise Induced Feeling Inventory (EIFI)[28]: A self-report measure that assesses feeling states associated with physical activity: positive engagement, revitalization, tranquility, and physical exhaustion.

Perceived Stress Scale (PSS)[29]: A self-report measure of perceived level of stress.

**Acceptability and feasibility measures.**

Attendance (feasibility): Attendance data were tracked via HIPAA-compliant transfer from each studio's database. Some participants attended class without signing in and were not logged into the studios' database. Post-study participation, subjects were contacted to confirm accuracy of attendance data. Discrepancies were resolved by accepting participant self-report.

Likert-scale/exit interview (acceptability): We adapted a clinician-administered exit interview from Hopkins et al.[30] Likert-scale questions pertaining to acceptability were included in this report (1 = lowest; 10 = highest):

1. How much did you enjoy the yoga itself (ie, doing the yoga)?
2. How much did you enjoy the aftereffects of the yoga?
3. How reasonable did you find the time commitment to be?

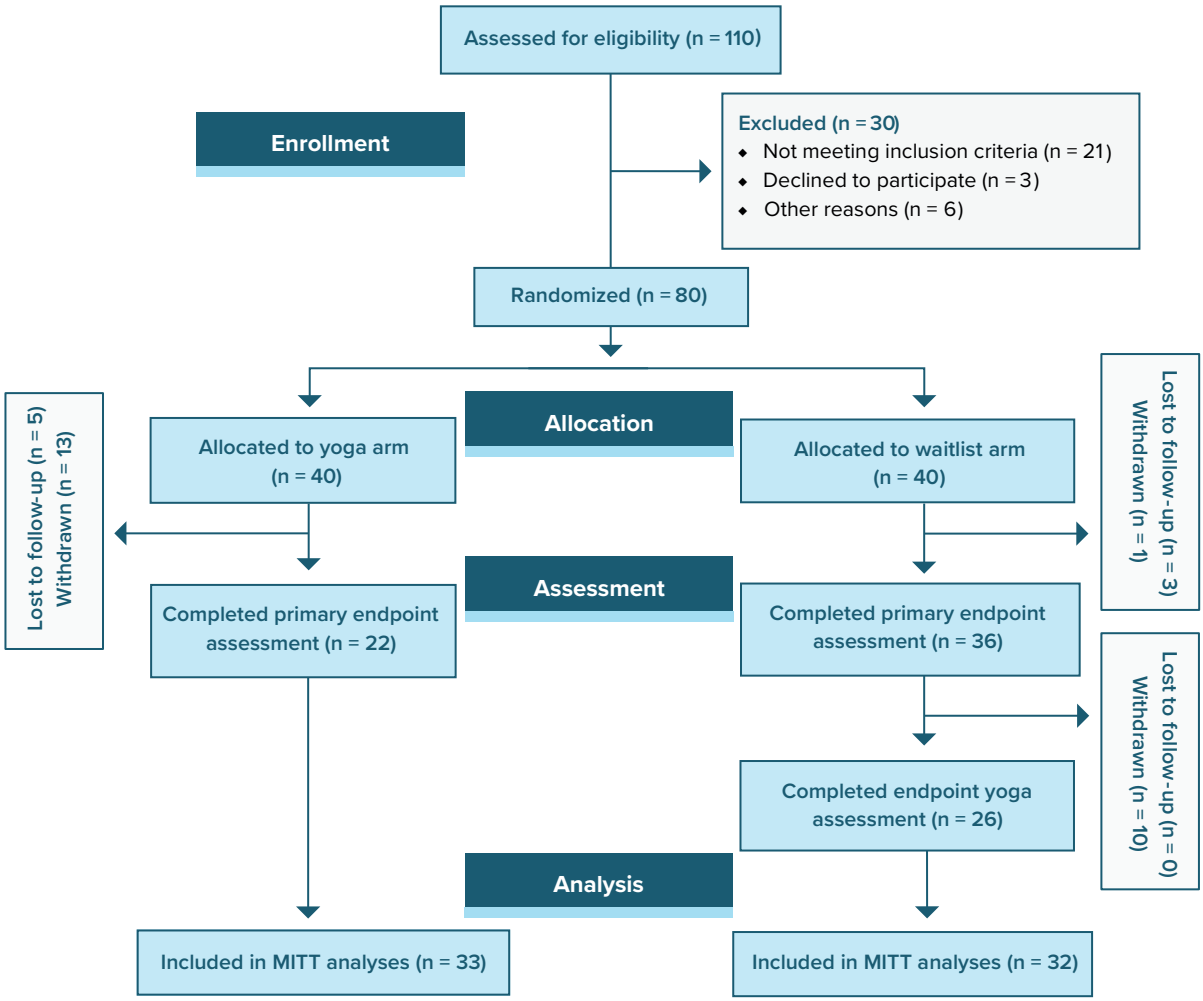
## Statistical Analysis

Analyses only included participants who completed at least 1 assessment following their initial baseline visit; yoga participants were only included if they completed at least 1 heated yoga class and subsequent assessment. *T* tests and $\chi^2$ tests were used to describe between-arm differences.

Univariate logistic regression models to examine completion of clinical assessments and self-report measures were used to identify factors related to missing data. To describe the feasibility of the treatment, we calculated the average number of yoga classes attended and the percentage of participants achieving the minimum prescribed dose (≥ 12 classes). For variables with extreme skew (4 subscales of the SF-36 and 2 subscales of the EIFI), we created binary variables (cut points/percentages specified in Table 2).

To test whether randomization arm (yoga vs waitlist) was related to primary and secondary outcomes, we fitted 1 repeated measures model per outcome of interest. As the primary outcome was specified a priori (IDS-CR score at week 8), we did not correct for multiple testing. In these models, the primary outcome was the dependent variable, and the predictors were arm (yoga vs waitlist), time (baseline, week 2, week 4, week 6, week 8), and the time × arm interaction effect. Difference between the yoga and

**Figure 1.**
**Participant Flow Through the Study**




Abbreviation: MITT = modified intent-to-treat.

waitlist arms on the week 8 IDS-CR was assessed using an independent *t* test. Linear mixed model analysis was conducted in R 4.1.0 using the "lmer" function.

Yoga attendance was examined as both a continuous (0–16 classes attended) and binary (≥ 75% of classes attended vs < 75%) variable as a determinant of week 8 IDS-CR.

**Sample size and power estimation.** The study was powered conservatively based on an 80% (n = 64) completion rate. Effect sizes for the degree of change in IDS-CR (primary outcome) were estimated for the yoga vs waitlist Cohen *d* (effect size for *t* test). A power analysis found that with an evaluable sample of 64 (32 per arm), a 2-tailed *t* test with an α level of 0.05 will yield a statistical power of 79% to detect a large effect size of 0.70 and 50% to detect a moderate effect size (0.50).

## RESULTS

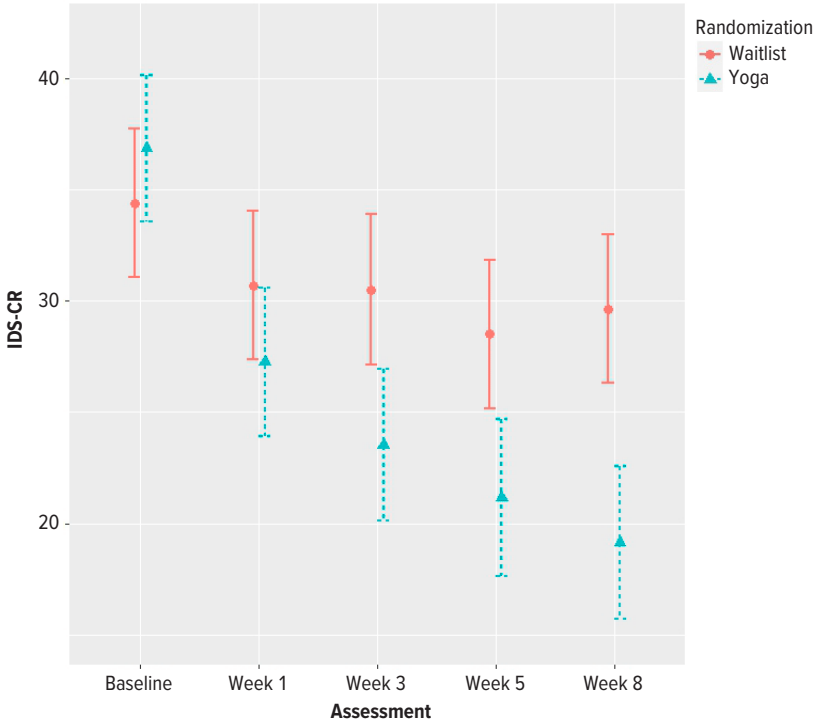
### Sample Description

Eighty participants were randomized; 65 (81%) participants (yoga, n = 33; waitlist, n = 32) were included in the analyses. Participants in the yoga vs waitlist group did not differ on demographic, other concurrent psychiatric treatment, or baseline severity factors (Table 1). At baseline, our sample displayed moderate-to-severe depressive symptom severity, as measured by the IDS-CR (mean = 35.6, SD = 7.9) and HDRS-17 (mean = 21.5, SD = 4.8).

Forty-eight subjects (74%; 22 yoga, 36 waitlist) completed the study (see Figure 1, CONSORT). Fewer participants completed self-report secondary outcome measures (n = 21 and 30, respectively). Randomized

Figure 2.

**Decreases in Depressive Symptom Severity Over the 8-Week Study Period**




Abbreviation: IDS-CR = Inventory of Depressive Symptoms, Clinician-Rated.

arm assignment, demographics, depression treatment engagement factors (Table 1), and baseline IDS-CR scores did not predict data inclusion/availability, ie, whether participants were included in the analyses and completed the clinician-rated primary outcome assessment at the week 8 endpoint (n = 58) versus those who did not (n = 22; all *P*s ≥ .08). Participants with higher HDRS-17 scores at baseline were less likely to be included in analyses and/or complete end of treatment clinician assessment (OR = 0.88 [95% CI = 0.78 to 0.99], *P* = .04). For completing self-report measures, randomization arm, gender, and baseline HDRS-17 scores emerged as significant predictors of data inclusion/availability, with yoga participants (OR = 0.37 [0.14 to 0.97], *P* = .04), non-female participants (OR = 0.24 [0.07 to 0.79], *P* = .02), and participants with higher baseline HDRS-17 scores (OR = 0.90 [0.80 to 0.996], *P* = .04) less likely to be included in the sample and complete self-report end of treatment measures.

## Feasibility and Acceptability of the Heated Yoga Treatment

**Feasibility: attendance outcomes.** Yoga participants who were included in the analyses (n = 65) attended 10.3 ± 7.1 classes (range: 1–30) over the 8-week study period. Thirty-six percent (n = 12) of participants attended 12 classes or more (ie, 75% of the prescribed dose of at least 16 classes, which was twice weekly for 8 weeks).

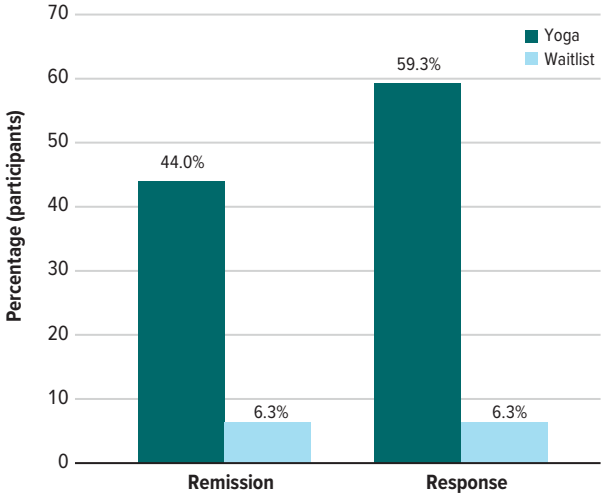
**Acceptability: Likert scale/exit interview results.** The results for the yoga arm (n = 27) on the 1–10 Likert scale items for the acceptability interview are as follows: (1) "How much did you enjoy the yoga itself?": mean (SD) = 7.17 (2.28); (2) "How much did you enjoy the aftereffects of the yoga?": mean (SD) = 8.33 (1.74); and (3) "How reasonable did you find the time commitment to be?": mean (SD) = 6.90 (2.38).

## Adverse Events

Among participants in the yoga arm, there were 3 mild adverse events (AEs) (headache, back pain, and knee pain) and 4 moderate AEs (chills/nausea, dizziness/vertigo, and back pain) designated as probably related to the intervention. Only 1 AE (gagging) was related to the intervention and classified as mild. No serious adverse events (SAEs) were reported. Additionally, there were 1 mild AE (headache), 5 moderate AEs (fatigue, headaches, soreness/pain, cough, panic attack, tennis elbow), and 1 severe AE (emergency room visit presenting with gastritis) designated as probably unrelated to the intervention. There were also 8 mild AEs, 5 moderate AEs, and 4 severe AEs unrelated to the intervention.

Figure 3.

**Remission (IDS-CR Score <14) and Response (IDS-CR ≥ %50 Decrease in Symptoms) Rates by Arm**




Abbreviation: IDS-CR = Inventory of Depressive Symptoms, Clinician-Rated.

Among participants in the waitlist arm, there were 27 reported AEs during the waitlist period prior to being offered the yoga intervention, from 18 individual participants (the results of the waitlist group's yoga period will be reported elsewhere). Of these reported AEs, 11 were mild, 13 were moderate, and 3 were severe. The mild AEs generally consisted of fatigue, upper respiratory infection (URI), soreness/pain, swelling, and planned medical procedures. The moderate AEs consisted of gastrointestinal distress, headaches, soreness/pain, fatigue, vomiting, strep throat, emergency room visit, planned surgery, and URIs. The severe AEs were lower back pain, fatigue, and neck pain. No serious adverse events (SAEs) were reported. Only 1 moderate AE (knee pain) was designated as probably related to the intervention. One moderate AE (strep throat) and 1 severe AE (fatigue) were designated as probably unrelated to the intervention. All other AEs were unrelated to the intervention.

## Primary Outcome: IDS-CR Scores at Week 8 Endpoint

At the week 8 endpoint, yoga participants had significantly lower scores on the IDS-CR than waitlist participants (Cohen $d = 1.04$, $P < .001$). IDS-CR scores declined in general (time effect: $b = -2.61$, $P < .001$), but at a faster rate among the yoga participants than the waitlist participants (time × arm effect: $b = -3.09$, $P < .001$), as illustrated in Figure 2, which shows the least square means estimated by the repeated measures model. Sensitivity analyses were conducted to test whether the time × arm interaction differed based on whether participants were taking antidepressants, indicating that antidepressant use status did not influence the effect of randomization status on depressive symptoms (IDS-CR) over time (time × arm × antidepressant use: $b = 0.99$, $P = .31$). Although not significant, there was a trend between number of yoga classes and lower IDS-CR scores at the week 8 endpoint when controlling for baseline IDS-CR ($b = -0.42$, $P = .09$). When attendance was examined as a binary variable (> 75% of yoga sessions attended vs < 75% of classes attended), a nonsignificant result was observed ($b = -2.58$, $P = .39$).

## Remission and Response Rates

Overall, in the yoga arm, 59.3% (n = 16) of participants responded to treatment (IDS-CR ≥ %50 decrease in symptoms), whereas only 6.3% (n = 2) in the waitlist arm were responders. Moreover, 44% (n = 12) in the yoga arm remitted (IDS-C score < 14) compared to 6.3% (n = 2) in the waitlist arm (see Figure 3).

## Secondary Outcomes

Week 8 endpoint arm differences on secondary outcomes are presented in Table 2. Due to skew, we dichotomized scores for 4 subscales on the SF-36 (physical functioning, role limitations due to physical health, role limitations due to emotional problems, pain) and 2 subscales on the EIFI (positive engagement, revitalization). Cut points and percentage of participants in the dichotomized arm are presented in Table 2. Significant effects in the expected direction (yoga participants reporting better functioning) were found for the STAI (trait and state), HDRS-17, some subscales of the SF-36, the Q-LES-Q, some subscales of the EIFI, and the PSS; no effects in the unexpected direction were found. In sensitivity analyses, we included gender as a covariate, as gender was related to survey nonresponse. This model did not converge for 3 secondary outcome measures due to low cell counts over time: SF-36 physical functioning, SF-36 pain, and EIFI revitalization. For the remaining secondary outcomes measures, including gender as a covariate did not meaningfully impact conclusions.

# DISCUSSION

Heated yoga for moderate-to-severe depression proved a feasible and acceptable intervention in this population. The primary hypothesis was confirmed: participants who received heated yoga displayed significantly greater improvements in depressive symptoms over the 8-week study when compared to a waitlist control. Reduction in depressive symptoms was observed in participants who received approximately 50% of the prescribed dose, suggesting that heated yoga sessions less than twice a week could be beneficial. This is consistent with previous studies of yoga for depression, which have found that approximately 1–2 classes per week are effective for reducing symptoms of depression.[5–9]

Table 2.

## Between-Arm Differences at End of Treatment (EOT)

| | Yoga (n = 21–27) | Waitlist (n = 30–32) | EOT between-arm difference | | | | |
|---|---|---|---|---|---|---|---|
| | | | *b*[a] | [95% CI] | *P* | Cohen *d* | Pooled SD |
| **Treatment completion, % (n)** | 82.0 (27) | 100.0 (32) | | | | | |
| **Primary outcome** | | | | | | | |
| **IDS-CR, mean (SD)** | 17.93 (12.70) | 29.63 (9.58) | 9.63 | [3.96 to 15.29] | <.001 | −1.04 | 11.25 |
| **Secondary outcomes** | | | | | | | |
| **STAI—State, mean (SD)** | 40.69 (10.74) | 48.43 (9.66) | 6.56 | [1.04 to 12.08] | .021 | −0.76 | 10.22 |
| **STAI—Trait, mean (SD)** | 46.70 (11.80) | 54.1 (8.25) | 6.42 | [1.10 to 11.75] | .019 | −0.73 | 10.18 |
| **HDRS-17, mean (SD)** | 11.04 (7.79) | 15.97 (5.29) | 4.31 | [0.90 to 7.71] | .014 | −0.74 | 6.66 |
| **SF-36** | | | | | | | |
| Physical functioning, % (n) experienced some limitations | 47.62 (10) | 53.33 (16) | 0.14[b] | [−0.89 to 1.16] | .794 | | |
| Role limitations due to physical health, % (n) with some problems | 85 (17) | 86.21 (25) | 0.01[b] | [−1.31 to 1.32] | .993 | | |
| Role limitations due to emotional problems, % (n) with score > 0 | 76.19 (16) | 43.33 (13) | −1.21[b] | [−2.29 to −0.13] | .029 | | |
| Energy/fatigue, mean (SD) | 40.5 (20.83) | 20.33 (13.77) | −20.34 | [−29.7 to −11.0] | <.0001 | 1.14 | 17.66 |
| Emotional well-being, mean (SD) | 56.2 (21.38) | 43.6 (14.22) | −11.15 | [−20.7 to −1.65] | .022 | 0.69 | 18.16 |
| Social functioning, mean (SD) | 70.83 (25.41) | 50.42 (21.14) | −18.60 | [−31.0 to −6.23] | .004 | 0.87 | 23.38 |
| Pain, % (n) with score > 80 | 57.14 (12) | 36.67 (11) | −0.44[b] | [−1.46 to 0.57] | .393 | | |
| General health, mean (SD) | 61.67 (23.15) | 53.5 (18.72) | −7.82 | [−18.3 to 2.69] | .142 | 0.39 | 21.05 |
| **Q-LES-Q-SF, mean (SD)** | 51.33 (7.90) | 41.34 (8.24) | −8.23 | [−12.8 to −3.69] | .001 | 1.24 | 8.07 |
| **EIFI** | | | | | | | |
| Positive engagement, % (n) with score > 0 | 95.24 (20) | 73.33 (22) | −2.33[b] | [−4.96 to 0.30] | .083 | | |
| Revitalization, % (n) with score > 0 | 85.71 (18) | 43.33 (13) | −2.05[b] | [−3.43 to −0.67] | .004 | | |
| Tranquility, mean (SD) | 6.29 (2.43) | 4.13 (2.50) | −1.82 | [−3.20 to −0.44] | .011 | 0.87 | 2.47 |
| Physical exhaustion, mean (SD) | 5.19 (3.43) | 7.7 (3.20) | 2.40 | [0.66 to 4.14] | .008 | −0.76 | 3.32 |
| **PSS, mean (SD)** | 17.42 (8.22) | 22.33 (5.84) | 4.43 | [0.66 to 8.20] | .022 | −0.69 | 7.13 |

[a]Planned comparison between heated yoga and waitlist at EOT based on this model: dependent variable = arm (heated yoga vs waitlist) + time (baseline, week 2, week 4, week 6, week 8) + time × arm.
[b]Binary outcome modeled using GENMOD procedure with logit link function.
Abbreviations: EIFI = Exercise-Induced Feeling Inventory, HDRS-17 = Hamilton Depression Rating Scale-17 item, IDS-CR = Inventory of Depressive Symptomatology—Clinician Rated, PSS = Perceived Stress Scale, Q-LES-Q-SF = Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form, SF-36 = 36-Item Short Form Survey (Medical Outcomes), STAI = State-Trait Anxiety Inventory.

This rigorous intervention shows that 90 minutes of high temperatures, strenuous physical movements, high humidity, and profuse sweating was well tolerated and safe. The AEs observed in this study were similar to those reported in a non-heated yoga for depression study[32] and a heated yoga for depression study,[14] in that musculoskeletal pain was the most commonly reported AE and resolved over the study course. Responses to the acceptability questionnaire were all positive, with enjoyment rated the most positively, followed by liking the intervention and then time commitment.

Despite lower than prescribed attendance (~1.25 classes per week), the intervention was still associated with reductions in depression symptoms. Thirty-six percent of participants attended 75% (at least 12 classes), our a priori feasibility goal. Our dropout rate was higher than the 20% previously reported in a meta-analysis of exercise-based interventions for individuals with depression,[33] which may be due to the rigorous nature of the intervention. We also found that subjects with higher depressive severity (HDRS) at baseline were less likely to qualify for the analyses and complete follow up assessments. La Rocque and colleagues (2021)[14] also found that lower pretreatment depression was significantly associated with lower posttreatment depression and that responders had significantly lower pretreatment depression compared to nonresponders. This is consistent with the literature showing that more severe depression makes exercise adherence more difficult.[33]

Our findings suggest that individuals with depression can benefit from heated yoga with a relatively low practice frequency of about 1 class per week (mean of 10.3 total classes over 8 weeks). This finding is bolstered from those of La Rocque and colleagues (2021),[13] who found a similar reduction in depressive symptoms with approximately 1.5 classes per week (mean 12.80 classes in total over 8 weeks). One dosing study has been conducted in non-heated yoga for depression, in which 2 and 3 classes of 90-minute Iyengar yoga per week both reduced symptoms of depression; however, the 3 doses per week had a greater percentage of participants in remission at the end of study.[31] In

sum, it appears that there is a dosage effect from yoga, heated or non-heated, but that one can still benefit from lower doses of heated yoga with consistent practice.

Our study validates and extends the findings of a previous RCT of heated yoga in mild-to-moderate depression in women, which included an active exercise condition and a waitlist control.[14] The effect size found in our study was large (Cohen $d = 1.04$) for the primary outcome measure, IDS-CR. La Rocque and colleagues' study also reported a very large effect size (2.03).[14] These effect sizes reported in the treatment of depression with heated yoga are greater than those observed in a meta-analysis of effect sizes for antidepressant medications, which ranged from 0.3 to 0.4.[34] These results are also consistent with the findings from our open-label study[12] with the same intervention and patient population, which had no control group and a smaller sample size.

The only prior RCT of heated yoga[14] did not find a significant effect between frequency of class attendance and antidepressant effect. While we did not observe a statistically significant relationship between class frequency and antidepressant effect, we did find a trend. We observed a relationship between higher class attendance and greater antidepressant response in our prior open-label trial of heated yoga for depression. It is possible that our study was underpowered to detect a relationship between dose and outcome.

There have been numerous RCTs of non-heated yoga as a treatment for individuals with depression with mostly positive findings, but none pivotal.[5–9] There have been no known studies comparing heated or non-heated yoga to standard therapy such as cognitive-behavioral therapy (CBT) or antidepressant medications, or large-scale multisite trials. In a non-heated waitlist-controlled yoga study for depression in depressed women with a similar, moderate-to-severe range of depression symptoms, the yoga group demonstrated a reduction in depressive symptoms compared to the waitlist control group with approximately 1.6 classes per week over 12 weeks.[7]

### Strengths and Weaknesses

Strengths of the study include the randomized, controlled design and the use of blinded outcome assessors on gold-standard clinician-administered measures. The sample included more minority participants (30.8% non-white) than is commonly seen in the yoga literature.[35] The intervention was community delivered, which increases the ecological validity of the study.

Limitations included lack of an active comparator. The sample of participants we obtained was primarily female (81.5% women) and educated (86.2% college educated). Due to the physical rigor and heat of the intervention, it may not be generalizable to populations with greater medical complexity.

Future research is needed to compare heated to non-heated yoga for depression to explore whether heat has benefits over and above that of yoga for the treatment of depression, especially given the promising evidence for whole body hyperthermia as a treatment for MDD.[10] We did not measure treatment resistance in the current study, which would have been interesting to explore given our 2 case reports documenting heated yoga's success in treatment-resistant cases.[36,37] We do not know if the findings from this study are generalizable to a severe, treatment-resistant depression sample, or those with mild depression, or depression with other medical or psychiatric comorbidities. Additionally, we are not sure if these results will hold when compared against an active comparator.

## CONCLUSION

Our results indicate that heated yoga is effective for reducing symptoms of moderate-to-severe depression when compared to a waitlist control. The treatment was enjoyed by participants despite the heat and rigorous nature of the intervention. Heated yoga was associated with reductions in depression symptoms, even though on average, participants attended fewer than the prescribed at least twice weekly classes. Perhaps a frequency closer to once per week would be a feasible dose for a follow-up larger-scale study, including using active controls and comparing heated yoga to non-heated yoga.

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**Supplementary Material:** Available at Psychiatrist.com.

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The Journal of Clinical Psychiatry

# Supplementary Material

**Article Title:** A Randomized Controlled Trial of Community-Delivered Heated Hatha Yoga for Moderate-to-Severe Depression

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## LIST OF SUPPLEMENTARY MATERIAL FOR THE ARTICLE

1. **Appendix 1** CLARIFY Guidelines
2. **Appendix 2** CONSORT Checklist
3. **Appendix 3** Heated Yoga Series

## DISCLAIMER

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

## Supplementary Appendices

Supplementary Appendix 1. CLARIFY Guidelines

| No | Item | Response |
|---|---|---|
| 1a. | Include the word "yoga" in the publication title. | Completed, see title |
| 2a. | Describe why the specific population was included in the study. | Completed, see page 10 |
| 3a. | Describe the type of yoga practices included (eg, postures/asana, breathing/pranayama, meditation, relaxation). | Completed, see page 10 and Appendix 3 |
| 3b. | Describe the duration of yoga practices within the yoga session (eg, 20 min postures, 10 min breathing). | Completed, see page 10 |
| 4a. | Describe the qualifications of the yoga instructor(s). | Completed, see page 10 |
| 5a. | Describe the teaching approach including: visual demonstration, verbal guidance and/or hands on assistance. | Completed, see page 10 |
| 6a. | Describe the duration of each yoga session (in minutes). | Completed, see page 10 |
| 6b. | Describe the duration of the yoga intervention (ie, over 8 weeks). | Completed, see page 10 |
| 6c. | Describe the frequency of yoga sessions (eg, twice weekly). | Completed, see page 10 |
| 6d. | Describe the no of yoga sessions. | Completed, see page 17 |
| 7a. | Describe the duration and frequency of home practice (if any) | N/A. Did not include home practice. |
| 7b. | Report whether yoga was available to participants during the follow- up period (if relevant), and list any recommendations made for home practice dose. | N/A. This paper doesn't report on follow up period. |
| 7c. | Describe if and how adherence to home practice was measured. | N/A. Did not include home practice. |
| 8a. | Describe any changes to the yoga protocol during the study. | N/A. No changes to yoga protocol. |
| 8b. | Describe the rationale for changes to the yoga protocol during the study. | N/A. No changes to yoga protocol. |
| 9a. | Describe if and how class/session attendance was measured. | Completed, see page 13 |
| 9b. | Describe any strategies used to promote practice adherence. | Completed, see page 11 |
| 10a. | Describe the assessment of protocol fidelity. | Completed, see page 11 |
| 10b. | Describe the reasons for deviation from study plan. | N/A. No deviations. |
| 10c. | Describe any differences between proposed programme and actual programme delivery. | N/A. No differences. |
| 10d. | Describe when protocol was modified. | N/A. No modifications. |

Supplementary Appendix 2. CONSORT Checklist

| Section/Topic | Item No | Checklist item | Page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 4 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 6 |
| | 2b | Specific objectives or hypotheses | 7 |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 8 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A |
| Participants | 4a | Eligibility criteria for participants | 9 |
| | 4b | Settings and locations where the data were collected | 8-9 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 10-11 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 11-13 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A |
| Sample size | 7a | How sample size was determined | 15 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 8 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 8 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 8 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 8 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 8 |
| | 11b | If relevant, description of the similarity of interventions | N/A |

| | | | |
|---|---|---|---|
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 14-15 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 14-15 |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Figure 1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 8 |
| | 14b | Why the trial ended or was stopped | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Table 1, Figure 1 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Table 2 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Table 2 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A |
| **Discussion** | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 23 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | 23 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 20-24 |
| **Other information** | | | |
| Registration | 23 | Registration number and name of trial registry | 4 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | N/A |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 1-2 |

Supplementary Appendix 3. Heated Yoga Series.

| | *Sanskrit Posture Name* | *English Posture Name* |
|---|---|---|
| | **Standing Postures** | |
| 1 | Pranayama | Standing deep breathing |
| 2 | Ardha-Chandrasana and Pada-Hastasana | Half moon pose and hands to feet |
| 3 | Utkatasana | Awkward |
| 4 | Garurasana | Eagle |
| 5 | Dandayamana-Janushirasana | Standing head to knee |
| 6 | Dandayamana-Dhanurasana | Standing bow pulling |
| 7 | Tuladandasana | Balancing stick |
| 8 | Dandayamana-Bibhaktapada-Paschimotthanasana | Standing separate leg stretching |
| 9 | Trikanasana | Triangle |
| 10 | Dandayamana-Bibhaktapada-Janushirasana | Standing separate leg head to knee |
| 11 | Tadasana | Tree |
| 12 | Padangustasana | Toe stand |
| | **Floor Postures** | |
| 13 | Savasana | Dead body |
| 14 | Pavanamuktasana | Wind removing |
| 15 | Yoga Sit-Up | Yoga sit-up |
| 16 | Bhujangasana | Cobra |
| 17 | Salabhasana | Locust |
| 18 | Poorna-Salabhasana | Full locust |
| 19 | Dhanurasana | Bow |
| 20 | Supta-Vajrasana | Fixed firm |
| 21 | Ardha-Kurmasana | Half tortoise |
| 22 | Ustrasana | Camel |
| 23 | Sasangasana | Rabbit |
| 24 | Janushirasana with Paschimotthanasana | Head to knee |
| 25 | Ardha-Matsyendrasana | Spine twisting |
| 26 | Khapalbhati | Blowing in firm |