Research Article

INDIVIDUALIZED YOGA FOR REDUCING DEPRESSION AND ANXIETY, AND IMPROVING WELL-BEING: A RANDOMIZED CONTROLLED TRIAL

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Background: Depression and anxiety are leading causes of disability worldwide. Current treatments are primarily pharmaceutical and psychological. Questions remain about effectiveness and suitability for different people. Previous research suggests potential benefits of yoga for reducing depression and anxiety. The aim of this study is to investigate the effects of an individualized yoga intervention. Methods: A sample of 101 people with symptoms of depression and/or anxiety participated in a randomized controlled trial comparing a 6-week yoga intervention with waitlist control. Yoga was additional to usual treatment. The control group was offered the yoga following the waitlist period. Measures included Depression Anxiety Stress Scale (DASS-21), Kessler Psychological Distress Scale (K10), Short-Form Health Survey (SF12), Scale of Positive and Negative Experience (SPANE), Flourishing Scale (FS), and Connor-Davidson Resilience Scale (CD-RISC2). Results: There were statistically significant differences between yoga and control groups on reduction of depression scores (-4.30; 95% CI: -7.70,-0.01; P = .01; ES -.44). Differences in reduced anxiety scores were not statistically significant (-1.91; 95% CI: -4.58, 0.76; P = .16). Statistically significant differences in favor of yoga were also found on total DASS (P = .03), K10, SF12 mental health, SPANE, FS, and resilience scores (P < .01 for each). Differences in stress and SF12 physical health scores were not statistically significant. Benefits were maintained at 6-week follow-up. Conclusion: Yoga plus regular care was effective in reducing symptoms of depression compared with regular care alone. Further investigation is warranted regarding potential benefits in anxiety. Individualized yoga may be particularly beneficial in mental health care in the broader community. Depression and Anxiety 00:1-13, 2016. © 2016 Wiley Periodicals, Inc.

Key words: yoga; yoga therapy; mindfulness; mental health; depression; anxiety; well-being; randomized controlled trial; clinical trial

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INTRODUCTION

Globally, more than 350 million people suffer from depression, approximately 4.7% of the world population. Depression is the leading cause of disability worldwide, and is a major contributor to the global burden of disease. Prevalence of anxiety disorders is estimated to be 7.3% of the world population.^[1–3] Many people experience comorbidity of the disorders, symptoms that may be subsyndromal, residual, or undiagnosed,^[4–8] and may also go untreated.^[9, 10]

Current treatments for depression and anxiety include a range of pharmaceutical medications, electroconvulsive therapy, psychological therapies, complementary and lifestyle interventions, and combinations of these.^[10-20] Treatments utilized for depression, anxiety, and their comorbidity, are often similar, including antidepressant medications, cognitive behavior therapy, mindfulness-based therapies, exercise, and relaxation training.^[10,21-25] Questions about efficacy, side effects, placebo effects, cost effectiveness, individual choice, access to services, compliance, ethics and long-term benefits, remain unclear.^[26,27] Some people choose not to seek treatment or be medicated, and others remain depressed despite medications, and there is increasing interest in the potential role of complementary medicine and mind-body lifestyle interventions.^[27-29]

In particular, there is increasing interest in yoga as an intervention for mental health concerns including depression and anxiety. Yoga is popular and appealing for many people, and may be suitable for people with mental health concerns as it includes a broad focus on mind-body or lifestyle intervention, and is viewed as a way to promote both physical and mental health, rather than just a treatment of a mental illness.^[29, 30] Yoga may be used as an adjunct to conventional treatments, and may also have a range of other desirable effects in general health and wellbeing, including musculoskeletal, diabetes, obesity, and cardiovascular.^[31-34] Yoga may be taught individually or in group classes, and tailored to the needs and preferences of different individuals and groups.^[35] When yoga is used to assist people in treatment or recovery from injury, illness, or disability, including mental health concerns, it is often referred to as yoga therapy.[36-39]

Prior research, including several systematic reviews and meta-analyses, suggests potential benefits of yoga in reducing depression and anxiety.^[10, 29, 30, 36, 40–50] A common concern in these reviews is the considerable heterogeneity and lack of detail, rationale, and consistency of approach in the types of yoga interventions between the various studies.^[29, 44] Interventions are generally based on participation in group programs. This study adds to the existing literature by (1) applying consensus-based yoga intervention guidelines, and (2) evaluating the efficacy of individualized application of those guidelines for home practice.^[51] This approach is consistent with clinical yoga therapy practice, as well as classical teachings and practice of yoga, known as the *viniyoga* of yoga, and the more recent development of yoga therapy.^[35, 37, 52, 53]

Yoga is a wholistic multidimensional system of health and wellbeing that focuses on the mind and its functions, with multicomponent mind-body practices, including (1) physical postures and movement; (2) breathing exercises; (3) relaxation; and (4) mindfulness and meditation.^[51] Other aspects of yoga practice include cultivation of positive values, thoughts and attitudes, and lifestyle factors. The multidimensional nature of yoga renders it difficult to standardize interventions for randomized controlled trials, to draw generalizable conclusions of the benefits of yoga, or to evaluate the effectiveness of key components of interventions. Further investigation is warranted. The aim of this study is to test the effectiveness of a 6-week individualized yoga intervention in the reduction of symptoms of depression and/or anxiety, and associated increases in mental health and wellbeing.

METHOD

DESIGN

A two-group randomized controlled trial design compared the mental health outcomes of a 6-week yoga plus treatment-as-usual (TAU) intervention group, with a waitlist plus TAU control group. The control group was offered the yoga intervention following the 6-week waitlist period, which became a single-group crossover comparison of mental health outcomes over the wait period and the yoga intervention. All participants were assessed at baseline, end of intervention, and 6 weeks after completion of the intervention. The study was conducted in accordance with the Declaration of Helsinki, and was approved by the University of Western Sydney, Human Research Ethics Committee (approval number H9529).

PARTICIPANT RECRUITMENT, ELIGIBILITY AND RANDOMIZATION

Participants were recruited through a variety of sources, including referrals from local psychologists and general medical practitioners, mental health service providers, advertisements in local papers, email newsletters, and social media posts. The intervention was provided in five cities in NSW (Sydney, Newcastle, Bowral, Goulburn, and Byron Bay/Mullumbimby). Recruitment was conducted between February 2013 and March 2014. Potential participants were initially assessed for their eligibility via a telephone screening, and then further assessed for eligibility in a face-to-face interview/screening session that included completion of the Depression, Anxiety and Stress Scale - 21 item (DASS-21).^[54] Inclusion and exclusion criteria are summarized in Table 1.

Eligible participants were randomly assigned to either the yoga plus TAU intervention, or the TAU control group. Randomization was conducted by administrative staff independent of the research team, using computer generated randomization of numbered allocation. Randomization allocation was concealed using sealed envelopes. Screening sessions were conducted by four different members of the research team. Participants in the trial had access to suitable psychological support services, and were monitored for any adverse reaction throughout the trial.

| Inclusion criteria | Exclusion criteria |
|---|--|
| Ability to give informed consent. Age 18–65 inclusive. Ability to speak, read and write English. General health and ability to be involved in the yoga program. Medication (including herbal medication, such as St John's Wort) and professional mental health assistance unchanged for 3 months. DASS-21 scores demonstrating at least mild, moderate or severe depression or anxiety (i.e. depression score between 10 and 27; or anxiety | Any serious injury, medical or psychological disorder likely to preclude completion of the trial, including significant cardiovascular, respiratory or endocrine disorders; recent surgery; acute or chronic pain; current psychiatric illness (other than depression or anxiety disorders) or dementia. Frequent alcohol or recreation drug use. Those already undertaking a personal yoga practice, an average of more than once a week, over the past 3 months. |
| score between 8 and 19). | DASS-21 scores in the normal range of depres- sion and anxiety sub- scales, or in the extremely severe range of either |

TABLE 1. Inclusion and exclusion criteria summary

INTERVENTION

Given the heterogeneity of interventions in prior research, the yoga intervention used in this study adhered to objective guidelines established utilizing a Delphi method study for the development of a consensus statement among "experts" in the field.^[51]

subscale.

The yoga intervention given to each participant included four individual 1-hr consultations/lessons over a 6-week period, with a suitably qualified yoga teacher. During these sessions, an individualized yoga practice was developed and taught to the participant, and given for him or her to do at home. The yoga practice conformed to the consensus statement and individualized for each participant according to his or her presenting symptoms, needs, abilities, goals, and circumstances (a classical approach to yoga practice or yoga therapy known as the viniyoga of yoga^[37, 52]). Each individualized yoga practice specified appropriate physical postures and movement; breathing exercises; relaxation; mindfulness and meditation; and other aspects of yoga practice such as cultivation of positive values, thoughts and attitudes, and lifestyle factors. Some components were recommended for reducing both depression and anxiety, some were recommended to include or avoid specifically for depression or anxiety.^[51] Teacher and participant established an agreement on suitable parameters of the voga practice, including time of day, duration, and frequency. Participants were taught their yoga practice during the sessions, and a written copy of the practice, including diagrams and instructions, was taken to assist with doing the practice at home. A summary of key components of each practice was recorded by the teacher. Depending on the participant's feedback and the teacher's observations at each consultation, the yoga practice may have been revised or developed over the course of the four sessions. Actual amount of yoga done, and adherence to the given practice were recorded at each subsequent session. Amount of yoga done included reporting on "How often did you do your yoga practice, since your last session?" and "On average, how many minutes

each day did you do your yoga?" Level of adherence was determined by participants' reporting on "Did you complete the yoga practice the same as it was given to you by the teacher?" Weighted average of "not at all or some parts of it" was categorized as low adherence; "generally similar" was categorized as moderate; and "almost the same or exactly" as high adherence. Encouraging reminders were given to participants by phone call, SMS, or email in weeks when consultation sessions were not conducted. Fifteen qualified yoga teachers provided the yoga sessions. Qualifications of yoga teachers included minimum training and registration requirements for level 2 membership of Yoga Australia (minimum 500 hr teacher training and 5 years teaching experience, equivalent to E-RYT500 of Yoga Alliance in USA). Yoga teachers also had specific training and experience in designing and teaching individualized yoga practices, and training in intervention protocol guidelines utilized in the study.^[51]

CONTROL

Participants allocated to the control group were informed that there was a short wait period of six weeks, prior to commencement of the yoga classes. Upon the completion of the wait period, participants were offered the yoga intervention.

BLINDING

Participants volunteered to receive the yoga instruction, were unaware of study design, and blinded to group allocations. Those allocated to the yoga group commenced the intervention within 1 week of their allocation, and those allocated to the waitlist group were informed that there was a wait period of 6 weeks until availability for commencement of their yoga sessions. Participants were aware that completion of outcome measure self-report scales occurred pre and post intervention. Yoga teachers providing the intervention and supervising participant completion of the outcome scales were blinded to initial group allocations. Data entry and analyses were unblinded.

TREATMENT AS USUAL (TAU)

All participants were asked to continue their current treatment as usual (regular care), including any medications, complementary therapies, counseling, psychotherapy, or other mental health services. Details of adherence to or changes in TAU were collected at each consultation session. Changes in TAU were classified as increase in usual treatment, reduction or discontinuation of usual treatment, or no change in usual treatment.

DATA COLLECTION

Sociodemographic characteristics, recent or current mental health treatments, medical history, recreational drug and alcohol use, and prior yoga experience were collected at baseline.

OUTCOME MEASURES

Six self-report measures were applied at commencement and completion of the yoga training and waitlist periods, and at 6-week followup.

PRIMARY OUTCOME MEASURE-DASS-21

The DASS-21^[54] was used as the primary outcome measure. The DASS-21 is a shorter version of the 42-item DASS, and has been shown to have good reliability and validity properties with clinical populations.^[54-60] Studies have confirmed a factor structure with subscales of depression, anxiety, and stress, which exhibit high convergent validity with other measures of anxiety and depression^[54-56,61] and extensive normative data are available.^[54,59-63] The DASS-21 is well

accepted and recommended as a measure of change in intervention trials. $^{\left[55,64\right] }$

SECONDARY OUTCOME MEASURES

Psychological distress, anxiety, depression, and general physical and mental health, were also measured using the Kessler Psychological Distress Scale (K10),^[65] and the Short-Form 12-Item Health Survey (SF-12v2).^[66] The K10 is one of the most widely used mental health screening instruments in contemporary psychiatry in many countries, including Australia.^[67] The K10 has shown good results for validity and reliability,^[67] and sensitivity to change.^[68] Evidence also suggests that the K10 is not only a measure of psychological distress, but also a short-term measure of anxiety and depression symptoms.^[68] The SF-12 (shorter form of the SF-36) measures functional status and disability related to health concepts and role limitations due to physical and mental health during the past 4 weeks, yielding physical component and mental component summary scales (SF12-PH and SF12-MH, respectively).^[68,69]

Measures of psychological wellbeing were taken using the Scale of Positive and Negative Experience (SPANE) and the Flourishing Scale (FS).^[70] The SPANE scores for positive experience and feelings, negative experience and feelings, and experience balance. The FS (previously called the Psychological Well-being Scale - PWB) consists of eight items and provides a single overall rating of psychological wellbeing in mental health.^[71] Both measures have established psychometric properties.^[70,72–74]

The Connor-Davidson Resilience Scale (CD-RISC 2) is a 2-item measure of resilience, defined as the personal qualities that enable a person to thrive in the face of adversity, and a measure of successful stress-coping ability.^[75] It shows good reliability and validity, and is correlated with other related measures of perceived stress and vulner-ability measures.^[76]

Participants were also asked to complete a Health Activities Questionnaire (HAQ) at each session, including questions about their current exercise, recreation, social activity, additional yoga undertaken, caffeine and alcohol intake, work, and sleep. Adverse events and changes to TAU (including medications, herbs, supplements and other forms of mental health treatments) were also recorded at each session.

The Credibility-Expectancy Questionnaire (CEQ)^[77] relates to two factors of thinking and feeling about treatment outcome expectations, which have been shown to be stable across different populations.^[77] The scale has demonstrated good internal consistency and test–retest reliability. The scale was included in this study as a measure of participant belief in the efficacy of yoga.

STATISTICAL METHODS

Sample size calculations were performed using Glimmpse^[78] and assumed a .65 correlation between baseline and follow-up measures. Power calculations indicated that a sample size of 96 (plus 20% withdrawal) is sufficient to detect a 0.5 SD difference between groups in the primary outcome measures (3.9 points on the depression subscale, and 3.3 points on the anxiety subscale of the converted DASS-21 scores). These changes have been established in prior research as the minimally clinically important effect size.^[79–83] Missing data were imputed using last value carried forward, and analyses were conducted on an *intention to treat* (ITT) basis. A data entry error audit conducted with an independent re-entering of complete data sets from 10% of participants (n = 11) selected at random revealed no significant issues.

Baseline data are summarized for the intervention group and waitlist group separately with Pearson's Chi-square or independent samples *t*tests used to check for any significant baseline differences. Effect of the intervention was tested using between-group analysis of covariance (ANCOVA) where each postintervention outcome was predicted by intervention group, after adjustment for preintervention levels. Results are presented as postintervention means, adjusted mean differences between groups (AMD), with associated 95% confidence intervals (CI) and P-values, and effect sizes calculated as standardized mean differences (SMD) using Cohen's d. P-values of <.05 were taken to indicate statistical significance. Potential influential data were identified using Cook's distance, and the generally accepted rule of thumb of Cook's distance values > 4/n. Where influential data were identified, effect of the intervention was analyzed using the same ANCOVA model after trimming of data where Cook's distance values were > 0.04 (n = 101). Group difference in frequency of changes in TAU was analyzed using Fisher's exact test. Effect of changes in TAU on intervention outcomes was tested using the between-group ANCOVA, including adjustments for changes in TAU. Clinical significance was analyzed using number of people with elevated baseline scores of depression or anxiety (above "normal" DASS range^[54]), who scored within the normal range after intervention.^[84,85] Group differences were analyzed using Person's chi-squared test.

RESULTS

Figure 1 summarizes enrollments, exclusions, and participation in the study. One-hundred forty-four were assessed for eligibility with 107 randomized, and six postrandomization exclusions. One hundred one were included in the primary between-group analyses.

BETWEEN-GROUP BASELINE COMPARISONS

Table 2 summarizes group differences on demographics, clinical and general health information, prior yoga experience, and baseline outcome measures. There were no statistically significant differences between groups on demographics or clinical factors, or baseline outcome measures.

BETWEEN-GROUP POSTINTERVENTION COMPARISONS

Table 3 summarizes results of the effectiveness of the yoga intervention compared to the waitlist control group.

Primary Measures of Depression and Anxiety. There was a statistically significant reduction of DASS depression scores in the yoga group relative to the waitlist group (AMD -4.30; 95% CI: -7.70, -0.01; P = .01; effect size -.44). The reduction of DASS anxiety scores with yoga relative to waitlist was not statistically significant (AMD -1.91; 95% CI: -4.58, 0.76; P = .16). Influential data were observed in changes from pre to post anxiety scores (with Cook's distance values > 0.04). After trimming of these data, group differences on anxiety scores were statistically significant (AMD -2.53; CI: -4.71, -0.35; P = .02; effect size -.40).

Secondary Measures. There were statistically significant differences between groups on total DASS score (P = .03), reduction of psychological distress - K10 (P < .01), improved mental health composite score - SF12-MH (P < .01), positive and negative experiences - SPANE (P < .01 for each), flourishing - FS (P < .01), and resilience - CD-RISC2 (P < .01). The reduction of DASS stress scores with yoga relative to waitlist was



Figure 1. Flow diagram of progression through phases of trial.

not statistically significant (P = .11). There was no significant difference between groups on physical health - SF12-PH (P = .90).

There was no significant differences between groups in frequency of increases in treatment (n = 3/47, 6.4% in yoga group, and 3/53, 5.7% in waitlist group; Fisher's exact test P = 1.00). However, there was a significantly greater frequency of reductions in treatment in the yoga group (n = 6/47, 12.8%) compared to the waitlist group (n = 0/53, 0.0%; Fisher's exact test P < .01). The effect of the yoga intervention compared to wait period remained statistically significant after correcting for changes in TAU (increases, decreases, and no change) in the ANCOVA on postintervention DASS depression scores (AMD -5.47; CI: -8.88, -2.06; P = .02).

When baseline credibility and expectancy scores were accounted for in the covariate analyses, neither factor had any significant effect on outcome measures. All the above findings (except reductions in total DASS scores and increases in resilience scores) were reproduced in a within-group comparison of changes in pre-post scores over the wait period and the yoga intervention period for the control group alone (see Supporting Information).

FOLLOW-UP ANALYSES

Table 4 summarizes results of within-group comparisons of pre, post, and follow-up measures, for participants who completed the yoga intervention to followup (n = 37). At 6-week follow-up, benefits of the yoga intervention continued to show statistically significant improvements on mean depression, anxiety, stress, total DASS (P < .01 for each), psychological distress (K10, P = .03), mental health (SF12-MH, P = .01), and reduction of negative experiences (SPANE-, P = .03). There was no evidence of change from post-yoga to followup on measures of positive experiences (SPANE+, P =.38), flourishing (P = .07), or resilience (P = .16). Differences in measures from baseline (pre-yoga) to follow-up (6 weeks yoga + 6 weeks follow-up) were statistically significant on all measures (P < .01; except physical health (SF12-PH), where P = .04).

AMOUNT OF YOGA (FREQUENCY AND DURATION) AND ADHERENCE

Table 5 summarizes results of frequency, duration, and cumulative amount of yoga practice completed, and

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|---|--------------------------------------|--------|-------------------------------------|----------------------|-----------------|-----------------------|
| | | Sample | $\overline{\mathrm{Yoga}} (n = 47)$ | Waitlist $(n = 54)$ | t-test(df = 99) | Signif.(2- talied) |
| | | n | Mean (SD) | Mean (SD) | | (alloca) |
| Age | | 101 | 39.5 (11.3) | 38.2 (11.2) | 0.57 | .56 |
| | | | n (%) | u (%) | Pearson | Significance |
| | Mala | 00 | 10 6 17 2 | (0 <i>2C</i> / 7 I | chi-square | - |
| Gender | Miale | 707 | 0 (12.0) | (7, 7, 7, 7) | 7./4 | ι. |
| | Female | 81 | 41 (87.2) | 40(74.1) | | ! |
| Education | Secondary school | 19 | 12 (25.5) | 7 (13.0) | 2.6 | .12 |
| | Tertiary-post school | 82 | 35 (74.5) | 47 (87.0) | | |
| Employment | Full-time | 37 | 16 (34.0) | 21(39.6) | 5.01 | .08 |
| | Part-time | 29 | 10 (21.3) | 19(35.8) | | |
| | Not employed | 34 | 21 (44.7) | 13 (24.5) | | |
| Relationship status | Married/de facto | 50 | 24 (52.2) | 26 (48.1) | 1.16 | 69. |
| 4 | Not in a relationship | 50 | 22 (47.8) | 28(51.9) | | |
| | Unknown | 1 | 1 | 1 | | |
| Prior mental illness diagnosis, | | 78 | 37 (78.7) | 41 (75.9) | 0.11 | .74 |
| including depression or anxiety | | | ~ | ~ | | |
| Psychopharmaceutical medications (| anti-depressants. | 35 | 19 (40.4) | 16 (30.2) | 1.15 | .28 |
| anti-psychotic and other medicati | ons for mental illness) | | | | | |
| Currently receiving professional assi | istance for mental health | 40 | 27 (57.4) | 20 (37.7) | 0.24 | .62 |
| Recent voga experience (voga classe | s in past 12 months) | 48 | 24(51.1) | 24 (44.4) | 0.44 | .51 |
| Outcome measure at baseline | , I | | ~ | | | |
| Elevated Depression (DASS Depres | sion ≥ 10) | 82 | 40 (85.1) | 42 (77.8) | 6.36 | .93 |
| Elevated Anxiety (DASS Anxiety ≥ 1 | 8) | 80 | 36 (76.6) | 44 (81.5) | 14.22 | .36 |
| Elevated Depression and Anxiety (D | ASS Depression ≥ 10 and Anxiety | 61 | 29(61.7) | 32 (59.3) | 0.06 | .80 |
| ≥ 8) | | | ~ | | | |
| × | | 101 | Mean (SD) $(n = 47)$ | Mean (SD) $(n = 54)$ | t-test | Significance |
| | | | | | (df = 99) | (2-tailed) |
| Depression-DASS-21 subscale | | | 17.66 (8.92) | 17.81(10.46) | -0.08 | .94 |
| Anxiety-DASS-21 subscale | | | 12.98 (7.38) | 14.65(9.45) | -0.98 | .33 |
| Stress-DASS-21 subscale | | | 21.32 (6.79) | 24.07 (9.25) | -1.68 | .10 |
| DASS-TOTAL | | | 51.96 (18.11) | 56.56 (23.74) | -1.08 | .28 |
| Psychological Distress-K10 | | | 17.38 (6.53) | 15.74(6.33) | 1.28 | .20 |
| Physical Health-SF12 | | | 47.81 (9.16) | 50.37 (7.45) | -1.55 | .13 |
| Mental Health -SF12 | | | 28.35 (5.24) | 29.00 (7.33) | -0.51 | .61 |
| Positive Experiences-SPANE+ | | | 16.49 (3.72) | 17.63(4.04) | -1.47 | .15 |
| Negative Experiences-SPANE- | | | 20.49(3.56) | 19.67(4.54) | 1.00 | .32 |
| Flourishing Scale | | | 37.64 (7.95) | 39.70 (7.68) | -1.33 | .19 |
| Resilience-CD-RISC2 | | | 5.13 (1.54) | 5.11(1.56) | 0.05 | .96 |
| Credibility (CEQ) | | | 28.36 (5.63) | 27.48 (5.40) | 0.79 | .43 |
| Expectancy (CEQ) | | | 13.27 (3.65) | 12.63(4.10) | 0.81 | .42 |

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| | Post yoga + TAU (n = 47) | Post wait-period $+ \text{TAU} (n = 54)$ | | ANCOVA (baseline | adjusted for e levels) | | Effect size ^a |
|-----------------------------|--------------------------------|--|------------------|----------------------|---------------------------|---------|--------------------------|
| Primary outcome measures | Mean (SD) | Mean (SD) | AMD ^a | 95% | CI's | P-value | SMD |
| Depression-DASS-21 subscale | 11.87 (9.22) | 16.26 (10.77) | -4.30 | -7.70 | -0.91 | .01 | 44 |
| Anxiety-DASS-21 subscale | 9.62 (6.97) | 12.56 (9.65) | -1.91 | -4.58 | 0.76 | .16 | 35 |
| Secondary outcome measures | | | | | | | |
| Stress-DASS-21 subscale | 16.55 (7.73) | 20.67 (9.79) | -2.48 | -5.48 | 0.53 | .11 | 47 |
| DASS-TOTAL | 38.04 (20.48) | 49.48 (25.12) | -8.77 | -16.58 | -0.97 | .03 | 50 |
| Psychological Distress-K10 | 11.43 (6.51) | 15.09 (7.47) | -4.58 | -7.01 | -2.14 | <.01 | 52 |
| Physical Health-SF12-PH | 49.37 (8.01) | 51.03 (6.72) | 0.11 | -1.74 | 1.97 | .90 | 22 |
| Mental Health-SF12-MH | 34.06 (7.28) | 29.59 (7.61) | 4.83 | 2.22 | 7.44 | <.01 | .60 |
| Positive Experiences-SPANE+ | 19.70 (4.25) | 18.11 (3.98) | 2.34 | 1.04 | 3.64 | <.01 | .39 |
| Negative Experiences-SPANE- | 17.11 (4.08) | 18.70 (4.28) | -2.08 | -3.45 | -0.70 | <.01 | 38 |
| Flourishing Scale | 42.23 (8.00) | 40.06 (8.11) | 3.81 | 1.71 | 5.90 | <.01 | .27 |
| Resilience-CD-RISC2 | 5.79 (1.40) | 5.07 (1.64) | 0.70 | 0.25 | 1.16 | <.01 | .47 |

TABLE 3. Postintervention mean outcome measures and effect size

AMD, adjusted mean difference (AMD).

^aStandardized mean difference (SMD) using Cohen's d.

level of adherence to the yoga practice given. Yoga practice was done an average of 4.8 days per week during the intervention, for 29.0 min per session, with moderate to high adherence. These amounts of practice and adherence were continued throughout follow-up period.

COMPONENTS OF YOGA PRACTICES

Yoga practices were individually tailored to each individual's perceived needs and abilities. Table 6 summarizes the frequency of components that were included as a main focus in individual practices. Components included as a main focus for the majority of participants (more than 50%) included moving repetition (rather than static holding) of breath-focused gentle postures and sequences, passive relaxation postures, relaxed abdominal breathing, a longer/slower exhalation, meditation practices with a given object of focus (rather than emptiness), and formulation of a personal intention. Other components were also included in each practice, but not necessarily a main focus.

CLINICAL SIGNIFICANCE

For depression, 15 participants (37.5%) in yoga group with elevated baseline DASS depression scores returned to normal range, compared to 7 (16.7%) in control group (RR = 2.25, 95% CI = 1.03, 4.95, P = .04, NNT = 4.8). For anxiety, 13 participants (36.1%) in yoga group with elevated baseline DASS anxiety scores returned to normal range, compared to 11 (25.0%) in control group (RR = 1.44, 95% CI = 0.74, 2.83, P = .28, NNT = 9.0).

ADVERSE EFFECTS

No adverse effects related to the yoga intervention were reported.

DISCUSSION

The aim of this study was to investigate the benefits of a 6-week yoga intervention in the reduction of symptoms of depression and anxiety, and associated increases in mental health and well-being. To our knowledge, this is the first clinical trial that has utilized an individualized intervention approach, based on therapeutic applications of classical yoga teachings and practice.^[35, 37, 52] This is also the first trial to utilize a consensus-based methodology for the development of guidelines for the intervention protocol in yoga for mental health research.^[51]

The overall results suggest that the yoga intervention in addition to regular care was effective in the reduction of symptoms of depression when compared with regular care alone. The benefits remained statistically significant after correcting for changes in usual treatment. The benefit of the yoga intervention for reducing symptoms of anxiety was not statistically significant when compared with controls. However, after trimming of influential outlying data, group differences were statistically significant, and further investigation is warranted.

The yoga intervention was also effective for reduction of psychological distress, improvements in overall mental health, increased frequency of positive experiences and reduced frequency of negative experiences, and increases in measures of flourishing and resilience. The benefit of yoga in reducing stress scores was not statistically significant compared with controls. However, when comparisons were corrected for changes in usual treatment (ANCOVA analyses), the yoga intervention led to statistically significant reduction in stress scores. As stress reduction is considered an important underlying mechanism for symptom reduction, further investigation is warranted.

There was no improvement in the general measure of physical health. This finding suggests the effectiveness of the intervention may be due to its targeted (to reduce

| TABLE 4. Effect of I | ntervention | at 6-week fo | - u) dn-molle | = 37) | | | | | | | | | |
|--|-----------------------------|-----------------------------|-----------------------------|--|----------------|--------------|---------------------|------------------------------|--|--------------|--------------|------------------------|-------------------------|
| | Pre-yoga (Baseline) | Post-yoga | Follow-up | Difference post-yoga to follow-up (6 weeks) | 95% (| 13 | Paired saı (2-tı | nple <i>t</i> test iiled) | Difference baseline to follow-up (12 weeks) | 95% | CI | Paired sa test (2-t | mple <i>t</i> ailed) |
| Primary outcome measures | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) | Lower | Upper | t | Significance | Mean (SD) | Lower | Upper | t 2 | Significance |
| Depression - DASS-21 subscale | 17.24 (9.57) | 11.03 (8.48) | 8.11 (7.90) | -2.92 (5.96) | -4.91 | -0.93 | -2.98 | <0.01 | -9.14 (10.39) | -12.60 | -5.67 | -5.35 | <.01 |
| Anxiety - DASS-21 subscale | 13.03 (7.90) | 9.08 (7.02) | 6.65 (6.26) | -2.43 (5.21) | -4.17 | -0.70 | -2.84 | < 0.01 | -6.38 (7.87) | -9.00 | -3.75 | -4.93 | <.01 |
| Secondary outcome measures | | | | | | | | | | | | | |
| Stress - DASS-21 subscale | 21.35 (6.83) | 16.86 (7.10) | 13.19 (7.42) | -3.68 (7.08) | -6.04 | -1.32 | -3.16 | < 0.01 | -8.16 (9.22) | -11.24 | -5.09 | -5.39 | <.01 |
| DASS - TOTAL | 51.62 (19.16) | 36.97 (18.88) | 27.95 (15.99) | -9.03 (14.23) | -13.77 | -4.28 | -3.86 | <0.01 | -23.68 (24.64) | -31.89 | -15.46 | -5.84 | <.01 |
| Psychological Distress - K10 | 17.49 (7.23) | 11.11 (6.50) | 9.28 (6.17) | -1.82 (4.91) | -3.46 | -0.19 | -2.26 | 0.03 | (8.53) | -11.05 | -5.36 | -5.85 | <.01 |
| Physical Health - SF12 | 48.87 (8.95) | 50.93 (6.74) | 51.38 (7.33) | 0.45(5.13) | -1.26 | 2.16 | 0.54 | 0.60 | 2.51 (7.02) | 0.17 | 4.85 | 2.18 | .04 |
| Mental Health - SF12 | 28.63 (5.49) | 33.85 (7.11) | 36.09 (7.23) | 2.24 (5.26) | 0.48 | 3.99 | 2.59 | 0.01 | 7.46 (7.99) | 4.79 | 10.12 | 5.68 | <.01 |
| Positive Experiences - SPANE+ | 16.46 (3.66) | 20.05 (4.24) | 20.54 (4.66) | 0.49 (3.36) | -0.63 | 1.61 | 0.88 | 0.38 | 4.08 (4.54) | 2.57 | 5.60 | 5.47 | <.01 |
| Negative Experiences - SPANE- | 20.78 (3.35) | 17.05 (3.98) | 15.89 (4.75) | -1.16(3.10) | -2.19 | -0.13 | -2.28 | 0.03 | -4.89 (5.08) | -6.58 | -3.20 | -5.86 | <.01 |
| Flourishing Scale Resilience - CD-RISC2 | 37.62 (8.22) 5.08 (1.52) | 43.05 (6.64) 5.68 (1.40) | 44.50 (7.08) 5.97 (1.74) | 1.45(4.75) 0.30(1.27) | -0.14 -0.13 | 3.03 0.72 | 1.85 1.43 | 0.07 0.16 | 6.88 (7.52) 0.89 (1.45) | 4.37 0.41 | 9.39 1.38 | 5.57 3.75 | <.01 <.01 |
| | | | | | | | | | | | | | |

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| | - | | - | | | |
|---|----------|--------|--------|-------|--------|------------|
| 1. Amounts of yoga practice completed ^a | Mean | SD | 95% | 6 CI | Range | Min-Max |
| Frequency of practice: days per week | | | | | | |
| Yoga intervention $(n = 42^{b})$ | 4.8 | 1.2 | 4.5 | 5.2 | 4.7 | 2.3-7 |
| Follow-up period ($n = 37$) | 4.9 | 1.2 | 4.6 | 5.2 | 4.7 | 2.3-7.0 |
| Duration of practice: minutes of each practice | | | | | | |
| Yoga intervention | 29.0 | 18.6 | 23.3 | 34.8 | 108.3 | 6.7-115.0 |
| Follow-up period | 27.8 | 15.4 | 24.2 | 31.4 | 108.3 | 6.7-115.0 |
| Cumulative weekly practice: total minutes per week | | | | | | |
| Yoga intervention | 147.5 | 121.3 | 109.7 | 185.3 | 674 | 27.5-701.5 |
| Follow-up period | 141.3 | 101.0 | 117.5 | 165.0 | 677.4 | 24.1-701.5 |
| 2. Adherence ^a (to the yoga practice given by teacher) | Low | Mod | lerate | Н | ligh | |
| Yoga intervention | 9.5% (4) | 64.3 9 | % (27) | 26.2 | % (11) | |
| Follow-up period | 9.7% (7) | 61.19 | % (44) | 29.2 | % (21) | |

TABLE 5. Amounts of yoga practice completed ("dosage") and adherence during intervention and follow-up

^aBased on weighted individual means over the 6 weeks.

^bParticipants commenced intervention, but withdrew prior to reporting. No data available.

symptoms of depression and anxiety) rather than general approach, or that physical benefits may take longer to achieve.

Benefits on all measures were maintained or continued to improve at a 6-week follow-up period. Yoga may be effective as an intervention where people can be taught suitable therapeutic self-care practices, which can be maintained without professional assistance. Some participants receiving the yoga intervention also reduced their use of other usual treatments. Reasons for these reductions are unknown, and further investigation is warranted.

Benefits were achieved with an approximate mean frequency of 5 days per week, and duration of 25 to 30 min for each practice, with moderate to high adherence to the yoga practice given by the teachers. This is a practical and achievable amount of yoga for most people. In some cases, benefits may be gained from a lesser amount. Further investigation of effective amounts of yoga practice with differing levels of symptom severity is recommended.

All participants presented with elevated symptoms of depression and/or anxiety (required for eligibility) with mean depression and anxiety scores (DASS subscales) in the moderate range of severity (sample means (SD) were 17.02 (9.92) and 13.29 (8.53), respectively), compared to the general Australian population (14 to 20 for moderate depression, and 10 to 14 for moderate anxiety.^[63] Seventy seven percent (n = 78) of sample participants also reported having a prior diagnosis of a mental health condition. However, mean baseline scores of current psychological distress (K10), which is often used for assessment and referral for psychological treatment by GP's in Australia, were in the "likely to be well and unlikely to have a mental disorder" range (scores of 10 to 19^[6/]; sample mean (SD) was 16.05 (6.65)). This suggests that some participants with elevated symptoms and prior diagnoses may have been experiencing residual symptoms, and many may not have been seeking or referred

for treatment. 31% of participants reported currently receiving professional assistance, and 41% were currently taking psychopharmacological medications.

The trial has demonstrated the effectiveness of the intervention for reducing elevated symptoms or depression and anxiety, improving general mental health, wellbeing, and resilience among a subsyndromal population.

PLAUSIBLE MECHANISMS

Several reviews of possible mechanisms underlying the effects of yoga on mental health outcomes have been published.^[86-93] Proposed theories include neurological, biochemical, and psychological underpinnings. The most commonly proposed mechanisms are related to reduction of stress and allostatic load, balancing of sympathetic (SNS) and parasympathetic (PNS) functions of the autonomic nervous system (ANS), and the downregulation of hypothalamic-pituitary-adrenal (HPA) axis.^[90,94-96] The strongest empirical evidence suggests yoga's capacity to regulate hormones, including a decrease of cortisol and catecholamines (adrenaline and noradrenaline), and increase of serotonin, melatonin, and gamma-aminobutyric-acid (GABA) levels, is a major factor in providing mental health benefits.^[47,86,90,97] Results of the current trial have not shown a statistically significant reduction of stress scores (DASS subscale) associated with the yoga, when compared to the controls.

Psychological perspectives are also proposed. In particular, yoga's focus on body awareness (proprioception and interoception), and visualizations and expectancy of positive emotional states, activates the biochemical selfregulatory systems described above, which in turn increases positive emotions and wellbeing, and decreases negative emotions.^[98, 99] On a neurological level, body awareness has been proposed to correlate with a shift from predominantly medial prefrontal activation, to increased activation of the thalamus, the insular and primary sensory regions, which are also associated with similar positive mental health outcomes.^[89, 100]

Yoga is a complex multidimensional intervention with numerous and varied components, including postures and movements, breath regulation, relaxation, mindfulness and meditation, cultivation of values, visualizations, affirmations, gestures, diet and lifestyle, and relationship or connection with the teacher, with different approaches to each of these and a numerous combinations of them. Yoga may be taught or applied therapeutically for individuals or groups, and adapted for differing needs and abilities.^[35] This renders it difficult to standardize interventions, conduct randomized controlled trials, identify the effectiveness of key components of interventions, or draw generalizable conclusions of the benefits of yoga. To improve the clinical understanding of how yoga might work as a whole, further investigation is required into each of the components of yoga, testing of their specific outcomes, as well as requiring a whole system understanding of the approach.

CLINICAL IMPLICATIONS

Given the general interest and increased popularity and availability of yoga throughout the world, yoga may be both effective and appealing for people with symptoms of depression or anxiety. As a nonpharmaceutical form of intervention, yoga could also be used as a lifestyle adjunct to conventional treatments, which can be modified for people with specific concerns, such as pregnant women, and others who are reluctant to use medications. Finally, yoga may simultaneously have a range of other desirable effects in general health and wellbeing.^[95,101-104] No adverse effects related to the voga intervention were reported in the current trial, and a review of adverse events associated with yoga suggested that yoga "can also be recommended to patients with physical or mental ailments, as long as it is appropriately adapted to their needs and abilities and performed under the guidance of an experienced and medically trained voga teacher."^[105] A personalized yoga practice designed to be done at home, may also be appealing for people with depression or anxiety, if attendance at group yoga classes is unsuitable or difficult to access. However, motivation and adherence to self-care practices for individuals with mental health concerns remains a challenge, and not seen as a panacea for all.

STRENGTHS AND LIMITATIONS OF THE STUDY

In this study, utilization of an individualized intervention approach provides closer adherence to traditional yoga teaching or therapy and practice, which can be evaluated in the context of an underlying psychological and philosophical framework of classical yoga.^[106, f07] Utilization of a census-based methodology for the development of intervention protocol guidelines reduces individual and popular biases in the yoga interventions being studied, and addresses concerns of reviews of prior research.^[29] A sample size of 101 participants from varying geographic and socioeconomic backgrounds provides reasonable generalizability of findings. Effect sizes

TABLE 6. Frequency of components included in participants' practices

| | | N = 47 |
|--|----|--------|
| Components of yoga practice interventions | п | % |
| Postures and movements with a focus on: | | |
| Backward bending | 11 | 23.4 |
| Forward bending | 23 | 48.9 |
| Standing balances | 8 | 17.0 |
| Inverted 1/2 shoulder stand | 4 | 8.5 |
| Moving repetition (rather than static holding) | 40 | 85.1 |
| Breath-focused movements | 47 | 100.0 |
| Gentle postures and sequences | 44 | 93.6 |
| Holding (> 5 breaths) | 17 | 36.2 |
| Resting/restorative | 41 | 87.2 |
| Dynamic sequences (including sun salutations) | 20 | 42.6 |
| Regulation of breathing with a focus on: | | |
| Relaxed abdominal | 38 | 80.9 |
| Longer/slower exhalation | 31 | 66.0 |
| Inhalation | 2 | 4.3 |
| Rapid-forced breathing (kapalabhati or bhastrika) | 4 | 8.5 |
| Alternating nostril | 2 | 4.3 |
| Relaxation with a focus on: | | |
| Passive relaxation postures | 41 | 87.2 |
| Active process (e.g. progressive muscle relaxation) | 21 | 44.7 |
| Guided (recorded) relaxation (including yoga nidra) | 18 | 38.3 |
| Supported inversion (legs up the wall) | 14 | 29.8 |
| Meditation with a focus on: | | |
| Mindfulness meditation technique ^a | 18 | 38.3 |
| With a given object of focus (rather than emptiness) | 34 | 72.3 |
| Other components with a focus on: | | |
| Repetition of a word or phrase (<i>mantra</i>) | 18 | 38.3 |
| Use of sound or chant | 18 | 38.3 |
| Formulation of a personal intention (sankalpa) | 29 | 61.7 |
| Cultivation of values (e.g. gratitude, compassion) | 17 | 36.2 |

Note: Italics highlight components that were included in more than 50% of participants' practices.

^aMindful awareness is also considered an intrinsic component of each component of yoga practice, as well as the specified mindfulness meditation.

found in the current study are consistent with those reported in a meta-analysis of similar studies of complex group–yoga interventions compared with usual care.^[50]

Several study limitations also warrant mention. Although participants in this study met eligibility and were group randomized, it was a volunteer sample interested in and amenable to yoga. Yoga may not be appealing and effective for everyone with mental health concerns. The eligibility process included a single assessment for elevated symptoms of depression and/or anxiety scores on DASS subscales at screening session, which were reassessed for baseline measures at commencement of the yoga intervention. This resulted in some participants being eligible and randomized at screening, but no longer eligible at commencement of the trial. Reconsideration of eligibility, screening, and intake procedures is warranted. Inclusion of an additional assessment of diagnosable depression and anxiety disorders, such as the M.I.N.I. International Neuropsychiatric Interview,^[108] may also be warranted. In addition, the majority of participants (n = 61) presented with comorbidity of elevated scores on both depression and anxiety. The extent to which individualized yoga protocols targeted depression, anxiety, or comorbidity is unclear. Further consideration of the details of interventions specific for each condition and comorbidity is recommended. Study measures were all self-report and generally collected by the yoga teachers providing the intervention, including participant reporting of adherence to the intervention. Inclusion of non self-report measures, including biomarkers and neuroimaging, and independent collection of data are warranted. Strength of the effects of simply doing something in addition to usual care, especially in a self-selecting sample, and the additional connection or personal attention from the teacher are unknown. An active control group, such as walking or exercise, that includes similar amount of personalized interaction with a teacher, is recommended for future research. The majority of participants (80%) were female. Although this is typical of participation in modern yoga classes, findings may not be generalizable to men, and potential gender differences require further investigation. Variability in the "dosage" (frequency and duration), and adherence to voga practices was considerable. Further investigation of minimum and optimal amounts of yoga is recommended. Further investigation of other potential factors that may effect outcomes, such as changes in exercise, attendance at general yoga classes, drug and alcohol consumption, and social engagement, and significant life events, is also recommended.

CONCLUSION

With the high prevalence of depression and anxiety, associated global burden of mental health concerns, limited resources for and access to conventional medical and psychological treatments, there is a need for effective evidence-based strategies to reduce symptoms in nonclinical populations, shorten episode duration, prevent recurrence, and potentially reduce demand on convention treatments. Our study demonstrated the effectiveness of individualized yoga for home practice, and that such interventions may be beneficial in mental health care in the broader community. Appropriate training of yoga teachers in the field of mental health is recommended. Reduction of depression and anxiety is also associated with a range of additional health benefits.

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