

A randomized preference trial of cognitive-behavioral therapy and yoga for the treatment of worry in anxious older adults

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ABSTRACT

Background: Worry is a common problem among older adults. Cognitive-behavioral therapy is the most studied nonpharmacological intervention and it has demonstrated efficacy in reducing late-life worry and anxiety. Although the evidence-base is smaller, yoga has been shown to reduce anxiety and stress. However, little is known about the relative effectiveness of these two nonpharmacological interventions. Further, the impact of patient preference on outcomes is unknown.

Purpose: The purpose to this study is to compare the effectiveness of cognitive-behavioral therapy (CBT) with yoga for improving late-life worry, anxiety, and sleep. We will also examine the effects of preference and selection on outcomes, adherence, and attrition.

Methods: We are conducting a two-stage randomized preference trial comparing CBT and yoga for the reduction of worry in a sample of anxious older adults. Five hundred participants will be randomized to either the preference trial (participants choose the intervention; N = 250) or to the randomized trial (participants are randomized to one of the two interventions; N = 250) with equal probability. CBT consists of 10 telephone-based sessions with an accompanying workbook. Yoga consists of 10 weeks of group yoga classes (twice a week) that is modified for use with older adults.

Conclusions: The study design is based on feedback from anxious older adults who wanted more non-pharmacological options for intervention as well as more input into the intervention they receive. It is the first head-to-head comparison of CBT and yoga for reducing late-life worry and anxiety. It will also provide information about how intervention preference affects outcomes.

Trial registration: ClinicalTrials.gov NCT02968238.

1. Introduction

Worry is a cognitive component of anxiety and has been defined as “a chain of thoughts and images, negatively affect laden and relatively uncontrollable” (p. 10) [1]. It has been conceptualized as a coping strategy to reduce the experience of anxiety [2]. Excessive and uncontrollable worry is the cardinal feature of Generalized Anxiety Disorder (GAD) [3] and is common among older adults. Golden and colleagues found that among older adults, 37% report experiencing excessive worry and 20% report excessive and uncontrollable worry within the past month [4]. Further, GAD is one of the most prevalent anxiety disorders in older adults [5], with prevalence rates as high as 7.3% [6]. Excessive worry, independent of GAD diagnosis, is associated

with greater distress [7], poor quality of life [4], increased prevalence of depression [4], and poor health outcomes including increased risk of myocardial infarct [8] and fatal coronary heart disease [9].

Medications and psychotherapy are the primary treatments for worry associated with GAD. Benzodiazepines and selective serotonin reuptake inhibitors (SSRIs) are the primary pharmacological treatments. However, both classes of medications are associated with serious adverse effects for older adults, including increased risk of falls and fractures [10], impairment in cognitive functioning [11,12], and risk of abuse and dependence [13]. Perhaps more importantly, older adults prefer psychotherapy over pharmacotherapy for the treatment of anxiety and worry [14]. Older adults report prior negative experiences with medications and fears of addiction, which can lead to an aversion

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of medications [15]. Moreover, worried, anxious older adults frequently do not want to add another medication to their potentially extensive list. Because worry and anxiety are associated with increased sensitivity to bodily sensations, some refuse medications due to perceived side effects.

Alternatives for the treatment of late-life worry are needed. CBT is the most efficacious nonpharmacological treatment for worry [16] and has the strongest evidence base for treating late-life worry [17]. In our prior work, we demonstrated that CBT is superior to supportive therapy in reducing worry, depressive symptoms and sleep problems in rural older adults, and most improvements were maintained up to 1 year after completing treatment [18–20]. Participants who received CBT demonstrated a clinically meaningful decline in worry symptoms. Further, satisfaction with treatment was high and attrition was low.

Yoga is another approach that may reduce late-life anxiety. Yoga is an ancient tradition that dates back thousands of years and was introduced in the United States in the late 1800's [21]. Yoga reduces anxiety among patients diagnosed with GAD [22], and a recent review found that over 70% of studies reported a significant decrease in anxiety and stress symptoms when a yoga intervention was implemented [23]. Older adults described the following as benefits of yoga practice: improved overall physical function and capacity (83%), reduced stress/anxiety and enhanced calmness (83%), and enriched sleep quality (21%) [24]. One recent RCT found that older yoga participants improved more than both chair exercise and control group participants in anxiety, depression, well-being, general self-efficacy, and self-efficacy for daily living [25]. Further, adherence to yoga interventions is high, and the interventions are generally easy to practice and maintain [23]. Despite these findings, there have been no comparative effectiveness studies of CBT and yoga for reducing worry and anxiety and improving sleep in worried older adults.

2. Overview and specific aims

This manuscript describes a two-stage randomized preference trial [26] comparing CBT and yoga for the treatment of worry in a sample of anxious older adults (See Fig. 1). Five hundred participants will be randomized to either the preference trial (participants choose the intervention; N = 250) or to the randomized trial (participants are randomized to one of the two interventions; N = 250) with equal probability. This study design allows for the calculation of traditional intervention effects (differences in outcomes between participants randomized to either CBT or yoga), selection effects [expected difference in outcomes between those who would choose intervention A (if allowed to do so) and those who would choose intervention B (if allowed to do so)], and preference effects (differences in outcomes between participants who received their preferred intervention and those who did not). The primary aim of this study is to compare the effects of two interventions, CBT and yoga, on worry in older (≥ 60 years) adults. The secondary aims of this study are to compare the effects of these interventions on anxiety and sleep. The exploratory aims of this study are: 1) to determine participant preference for CBT or yoga; 2) examine participant preference effects on worry, anxiety, sleep, adherence to intervention, and attrition rates; and 3) examine selection effects on worry, anxiety, sleep, adherence to intervention, and attrition rates. See Fig. 1.

3. Study design/methods

3.1. Ethics

This study adheres to the guidelines of the Declaration of Helsinki. It has been approved by Institutional Review Board at Wake Forest School of Medicine.

3.2. Settings

Participants will be recruited through clinics affiliated with an academic medical center and from the community. Clinics participating in the study will include a clinic that provides primary and preventive care to a low-income population; academic and community-based family medicine clinics; a geriatrics clinic; and gynecology clinics. Clinics may use different strategies for referring individuals to the study: administration of an anxiety screening measure by clinic staff with automatic referral of positive screens; mailings to clinic patients; and direct physician referral of patients to the study. Study flyers and brochures will be distributed at local YMCAs, senior centers, senior housing establishments, and restaurants and stores with community boards. Advertisements will be placed in local newspapers, magazines, a newsletter sent to almost 10,000 community-dwelling adults aged ≥ 60 years who are interested in research studies, and church bulletins.

3.3. Participants

Inclusion criteria include age 60 years and older and a baseline score ≥ 26 on the Penn State Worry Questionnaire-Abbreviated (PSWQ-A). Older adults may experience anxiety differently than younger adults [27], and traditional diagnostic classifications do not reflect these differences [28,29]. This results in many older adults with symptomatic worry not meeting criteria for DSM diagnoses. Thus, we are targeting people with clinically significant worry for study inclusion rather than relying on a clinical diagnosis. A score of ≥ 26 on the PSWQ-A represents moderate and severe levels of worry. A score of 26 is 1 standard deviation below the mean in our previous study of late-life GAD [18]; approximately 75% of the sample scored a 26 or higher. Further, participants with a baseline score ≥ 26 on the PSWQ-A had more than double the reduction in PSWQ-A score (-10.45 vs. -4.55) than those with a score of 25 or lower. Finally, Stanley and colleagues [30] found that older adults who scored < 26 on the PSWQ-A showed little improvement on measures of worry, anxiety, and depression after intervention with CBT.

Exclusion criteria include currently receiving psychotherapy, currently practicing yoga, current active alcohol/substance abuse, dementia, global cognitive impairment based on the Telephone Interview for Cognitive Status-modified (TICS-m) [31], current psychotic symptoms, active suicidal ideation with plan and intent, change in psychotropic medications within the last month, and hearing loss that would prevent participation in telephone or class sessions.

3.4. Screening procedures and randomization

Individuals will undergo an initial screening to determine potential eligibility and then provide informed consent either by telephone or in person, depending upon participant preference. Participants will then complete the baseline assessment measures prior to randomization. Once eligibility is determined, randomization will occur. Randomization into the preference and random trials will be stratified by psychotropic medication use to ensure balance and appropriate representation of psychotropic medication users between the intervention groups. Participants who receive CBT will be randomized to one of two study coaches.

3.5. Assessment instruments and procedures

Assessments will be conducted at Week 0 (baseline), Week 11 (post-intervention), and Week 37 (6 month follow up). Additionally, there will be an abbreviated assessment at Week 6 (mid-intervention) that includes the primary and secondary outcomes only. Most measures are self-report, with the exception of the Cornell Medical Services Index and medication use. See Table 1 for a description and data collection schedule for measures.

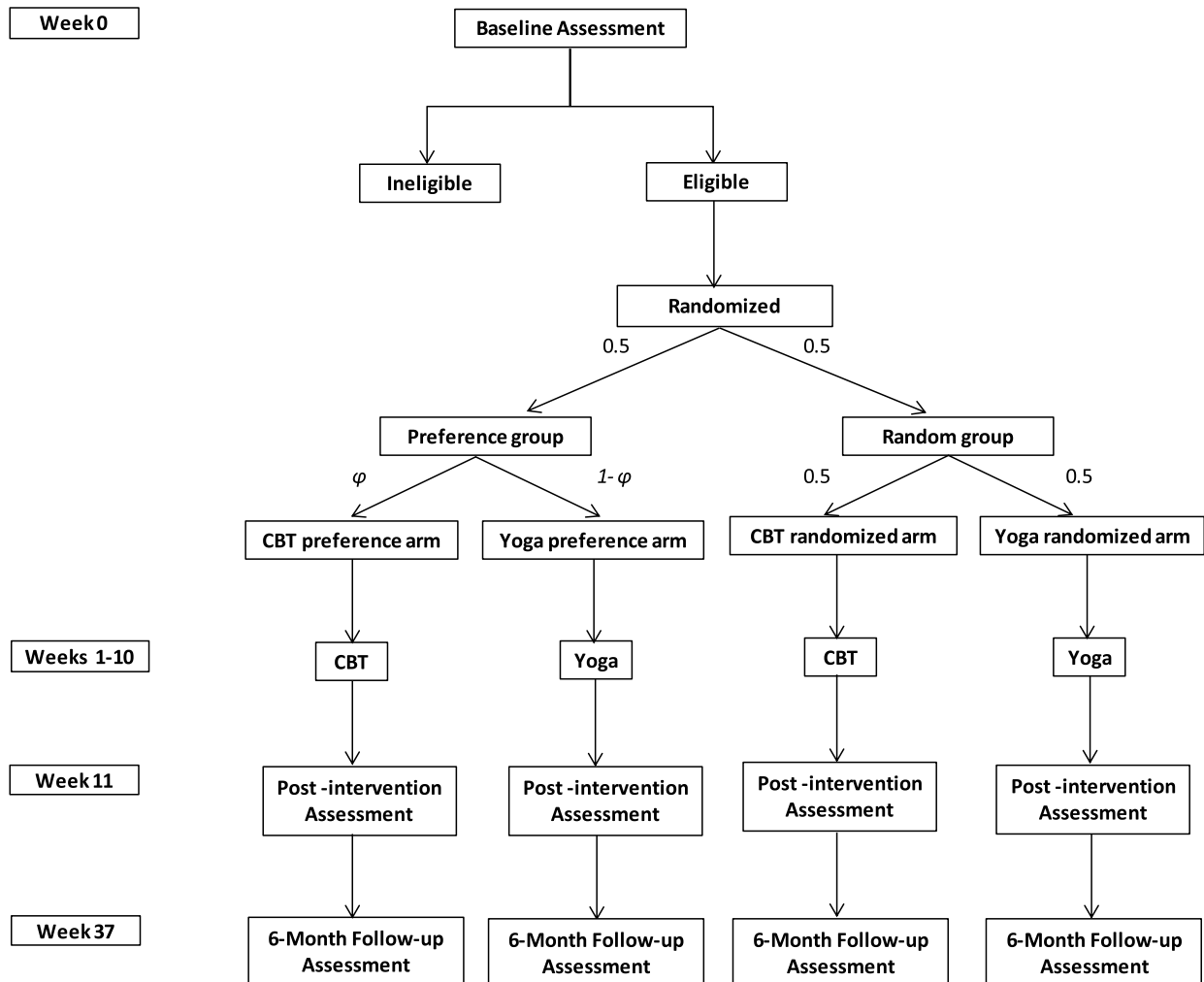


Fig. 1. Randomization and assessment schedule.
CBT = Cognitive-behavioral therapy.

3.6. Interventions

3.6.1. Cognitive-behavioral therapy (CBT)

CBT will consist of 10 individual weekly psychotherapy sessions with a study coach and an accompanying workbook. We have used this intervention in two previous randomized controlled trials (RCT) (R01 MH083664 & K23MH065281, Brenes PI). The 10-chapter workbook focuses on techniques that have demonstrated efficacy in treating adults with GAD [32,33] and older adults with GAD [18,34–37]. Chapter 1 describes the intervention and presents a cognitive behavioral model of anxiety. Chapters 2 through 9 each address a specific anxiety management technique or a specific problem that may be comorbid with anxiety, and include relaxation, cognitive restructuring and use of coping statements, problem solving, worry control, behavioral activation, exposure therapy, sleep, and pain. Chapter 10 focuses on relapse prevention. Chapters are approximately 5–10 pages long and written in lay terms. They are presented in a large font, and key points are highlighted and reiterated simply to aid readers in fully understanding the content. Each chapter contains multiple examples of specific situations that an older adult might experience. Chapters are also focused on relevant problems for older adults, such as sleep and pain. Each chapter is followed by a homework exercise to practice the technique described in that chapter. A completed example is provided, followed

by blank copies to be completed by the participant. The homework is used to encourage the application of the techniques to daily life.

Weekly telephone sessions with the study coach will last 45–50 min. To ensure privacy, every participant will be asked if he/she needs to reschedule the appointment due to a lack of privacy. All sessions will start with a review of homework and any problems or stressors participants have encountered within the context of the homework. The coach and the participant will discuss whether anxiety coping skills were used and how effective they were. If so, use of the coping techniques will be reinforced. If the worry was not adequately managed, coping skills will be reviewed and ways to incorporate or improve their use will be identified. The study coach will then review the chapter and the exercise with the participant. The participant will be encouraged to ask questions about the reading materials and discuss any difficulties he/she may have experienced when implementing the technique.

3.6.2. Yoga

Yoga will consist of 20, 75-min group gentle yoga classes held twice weekly using a modified version of an intervention protocol that we have developed and used in 3 previous trials [38–40]. Participants who are randomized to participate in yoga will take classes separately from those who chose to participate in the yoga classes. For both groups, participants will be asked to practice breathing exercises and poses for

Table 1
Description and timing of study measures.

	Week 0	Week 6	Week 11	Week 37	Description
Primary Outcome Measure					
Penn State Worry Questionnaire-Abbreviated (PSWQ-A) [61,62]	X	X	X	X	8-item measure of frequency/intensity of worry; most commonly used worry measure. Strong psychometrics [61,63]; responsive to treatment [18]. Used in our previous studies [18,35].
Secondary Outcome Measures					
PROMIS Anxiety [64]	X	X	X	X	Included in PROMIS 29 (described below).
Insomnia Sleep Index [65]	X	X	X	X	7-item self-report measure of type and severity of insomnia symptoms
Additional Outcome Measures					
PROMIS 29 [66]	X		X	X	29-item self-report measure with 4 items each for the following: physical function, anxiety, depression, fatigue, sleep, social function, pain interference; 1 item for average pain intensity. Physical and social function domains assess current function; items for other domains reference past 7 days.
PROMIS Depression [64]	X		X	X	Included in PROMIS 29 (described above).
PROMIS Physical Function [67–69]	X		X	X	Self-report measure of current capability for physical activities. Will use only 4 unique items (not already in the PROMIS-29).
GAD-7 [70]	X		X	X	Self-report measure of DSM-IV GAD symptoms. Validated for use in general population [71] and primary care [70]. Strong psychometrics [70,71].
Demographic and Health-Related Information					
Demographics and health	X				Self-report age, education (years), gender, race, income. Self-rated health (0–100).
Charlson Comorbidity Index [72]	X		X	X	Creates weighted index to account for number/seriousness of comorbidities.
Medical Services Utilization/Medication Use Cornell Services Index [72]	X		X	X	Structured interview; assesses services used; aggregated into outpatient psychiatric or psychological services, outpatient medical services, professional support services, and intensive services.
Medication use [73]	X		X	X	Participant provides name/dosage of all prescription medications in past month.
Process Measures					
Expectancy Rating Scale [74]	X (after 1st session for CBT group)				Assesses beliefs in how logical the treatment seems, confidence in undergoing treatment/recommending to others, and expectations for success. Used in anxiety treatment studies with older adults [34,36,75].
Client Satisfaction Questionnaire [76]			X		Assesses satisfaction with treatment. Adequate reliability with older adults [77].
Working Alliance Inventory, Client and Therapist [78]			X		Assesses therapist-patient working alliance. Strong psychometrics [79]. For CBT group only.
Intervention adherence			X		The percentage of completed sessions (max = 10 CBT; max = 20 yoga).
Other Measures					
Patient treatment preferences	X				Preferred treatment/strength of preference. For preference trial only.

15 min at least 5 days per week and record their length of home practice on a tracking form. Participants will enter the yoga classes on a rolling basis rather than waiting until a particular group session begins to mirror “real life.” Class size will be capped at 10 participants so that the instructor can provide adequate attention to each participant. Classes will be offered at different times of day at several locations in the community (e.g., agencies that serve older adults, churches).

In the yoga classes, teachers will emphasize the following yoga practice principles for use with older adults including: do no harm, create a safe environment, meet people where they are, emphasize feeling over form, emphasize fluidity, use skillful language (encourage and invite rather than direct and demand), be a guardian of safety, and teach people rather than poses or conditions [41]. Participants will be told that they should not practice any pose that causes or exacerbates pain. The following additional principles will be followed: (1) It will be made clear to study participants that yoga is not a religious or religious-based program. (2) Classes will not include any designated time for participants to interact verbally or socially, to minimize any “support group” feeling to the classes. We anticipate, though, that unstructured interaction among participants will take place before and after yoga classes, and to some extent, during them. This potential for social interaction is one reason for keeping participants randomized to yoga in the randomized trial separate from those who selected yoga in the preference trial as interaction among these participants could bias the selection and preference estimates.

A review of the current literature was used to determine which elements of yoga should be included [42]. This review included a consensus statement from highly experienced yoga teachers using the Delphi method on yoga components that should be included for addressing anxiety [43]. Yoga classes will begin more actively (to match the state of mind of someone who is anxious) and then gradually slow

down, ending the practice with soothing/calming postures and meditation to facilitate relaxation [44]. The yoga intervention also intentionally *excluded* the following components as recommended by the consensus statement for components essential to avoid when instructing yoga to reduce anxiety: holding one’s breath after inhalation or rapid breathing techniques; meditation practices without a specific focus (e.g., emptiness or inner silence); yoga done in heated, crowded, or enclosed spaces; and techniques and practices that emphasize ability, accomplishment or competition, or require difficult and complex instructions [43].

Study yoga classes are based on the philosophy that yoga instructors working with older adults should “recognize the importance of adapting the practice to senior bodies, minds, and spirits” and are not affiliated with a specific yoga style [41]. The specific class sequences are adapted from the *Relax into Yoga* program, created by yoga therapists Carson and Krucoff and presented in their book: *Relax into Yoga for Seniors*. [45] All postures and practices presented in this program are designed to comply with essential safety considerations important for older adult practitioners with common health challenges including heart disease, osteoporosis, arthritis, and hypertension. Each 75-min class incorporates breathing practices (*pranayama*) for centering and relaxation, mindfulness meditation, and gentle postures (*asana*) to improve strength, flexibility, balance and endurance. A typical class will follow this format: (1) *Centering and Breathing (10 min)* (done either lying down or seated in the chair); (2) *Posture Practice (50 min) to include a warm-up with a range of motion sequence, chair seated poses, standing poses, prone poses, and supine poses (all gentle and modified as needed)*; and (3) *Meditation/Relaxation (15 min)* either lying down or seated in a chair.

3.6.3. Interventionist training and supervision

Training of CBT coaches will include use of the intervention manual, didactic presentations, readings, role-plays, and two closely supervised training cases. The competency and adherence of coaches in delivering CBT-T will be evaluated with a measure developed and used in prior research [36,37]. Competency and adherence are each rated on a 9-point Likert scale ranging from 0 (none/no adherence) to 8 (excellent/optimal adherence). Coaches who fail to demonstrate good competency (mean competency score < 6) will receive additional training and exposure to role-play exercises until competency is demonstrated. In addition, coaches must achieve good adherence (mean adherence score \geq 6) across the sessions before contacting any potential participants. If any coach fails to achieve this level, the PI will determine if there are specific components across sessions that are routinely omitted or implemented incorrectly and will retrain the coach in the identified intervention components. The PI will meet with the coaches weekly to discuss cases, review adherence and competence ratings, and answer any questions regarding the administration of the protocol. Any areas of nonadherence will be reviewed with the coaches.

Proper training by a skilled and qualified yoga teacher is essential for the safe and effective use of yoga [42,46,47]. Consistent with consensus recommendations reported for use of yoga for anxiety, we will require that all study yoga teachers will have: (1) at least 200 h of yoga training; and (2) at least one year of yoga teaching experience (preferably some experience with older adults). We will not require that yoga teachers have prior yoga for mental health training [43]. Training will entail two full days with the study investigators and the yoga consultant (Krucoff) who has expertise in modifying yoga for older adults. The training will focus on the study-specific intervention in great detail and provide opportunities for each instructor to practice teaching and receive feedback from the study consultant and yoga instructor colleagues.

3.6.4. Intervention fidelity

CBT Fidelity: To ensure intervention integrity, all weekly participant telephone calls will be recorded; 10% of these sessions will be randomly selected to be coded by a therapist with expertise in CBT. The sessions will be evaluated against the steps outlined in each telephone call protocol using an existing measure of adherence and competence [36,37]. This measure assesses both the competence and adherence of the coach in the delivery of the specific intervention skills (e.g., progressive muscle relaxation, problem solving, etc.) as well as an overall rating of competence and adherence. Data from this measure suggest high internal consistency ($\alpha = .91-.94$) and greater variability in ratings attributed to clinicians (29%) than raters (9%), suggesting good reliability of the instruments (personal communication, Dr. Stanley). The coach may also undergo retraining if mean adherence scores are not good (operationalized as < 6 on adherence rating).

Yoga Fidelity: We have developed a intervention fidelity plan to ensure that the yoga intervention is delivered as intended [42]. Recommended strategies regarding intervention design, training interventionists, delivery of intervention, and receipt of intervention will be implemented as recommended by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium [48,49] and other investigators [50,51]. Each yoga teacher will receive a two-day training session and demonstrate his/her knowledge of content; complete a checklist for each session; record number of sessions and their length; videotape each yoga class (with the focus on the teacher, not the participants); and report any deviations from the planned protocol. We will also randomly select 10% of the videotaped yoga classes to be reviewed by a yoga instructor/researcher. Yoga teachers will meet bi-monthly with one of the Co-PIs to discuss their experiences and facilitate consistency among sessions.

3.7. Safety monitoring

To ensure participant safety, we have excluded potential participants who have problems in need of attention that cannot be provided during the course of this study, including active alcohol or substance abuse, cognitive impairment, psychotic symptoms, or active suicidal ideation (with intent and plan). Care was taken to design a yoga program that is tailored to the limitations and comorbidities an older adult may experience to minimize risk of injury. If any participant indicates a significant worsening in worry scores (1 standard deviation increase or 5.6 points) [18], the computer software system will automatically generate an e-mail to the co-PIs and the project manager. If there is ever a need for immediate intervention (e.g., active suicidal ideation, active psychotic symptoms, disorientation, active substance abuse), staff will notify the co-PIs. In both cases, the participant may be referred for psychiatric care. As an additional safety precaution, we will ask each participant upon study entry to identify two persons whom we can contact in case of an emergency. Spontaneous as well as ascertained adverse events at each assessment period will be monitored. Further, all study interventionists will receive extensive training in the provision of the intervention (CBT or yoga) and fidelity will be assessed (as described above).

3.8. Statistical analysis

3.8.1. Sample size justification

In this intention-to-treat design, all individuals randomized into this study will be included in the primary analyses. In addition to the intervention effect, the proposed randomized design allows for the estimation of the selection and preference effects. As described below, a contrast within the framework of a constrained mixed model for randomized trials will be used to test the primary null hypothesis of no intervention effect at the post-intervention assessment visit at Week 11. This analysis will be performed in the subset of participants in the randomized trial. The detectable effect size was calculated for the test of equality of PSWQ-A means at the post-intervention assessment visit (Week 11) based on an analysis of covariance (ANCOVA) two-sample T-test. Preliminary data that informed the calculations came from various sources including internal data and published reports of intervention effect sizes from similar studies conducted with change in overall PSWQ-A score as the outcome in aging populations [18,35].

Assuming a two-sided significance level of 5% and a correlation between baseline and follow-up scores of 0.5, we will have at least 90% power to detect intervention effect sizes of 0.25σ in the randomized trial, which corresponds to a PSWQ-A score difference of 1.4 between individuals who were randomized to the CBT and yoga arms (Table 2). Equivalently, because the two randomized groups should have equal means at baseline, the proposed study will have close to 90% power to detect a difference of 1.4 in change from baseline to the post-intervention measure (Week 11). In our prior RCT of late-life GAD [18], the observed correlation estimate between the baseline and follow-up PSWQ-A score measured 16 weeks post-randomization was 0.51, and 0.45 after 12 months of follow-up.

Table 2

Achievable power relative to detectable effect size and longitudinal correlation, with N = 250 individuals randomized into the random trial.

Standardized effect size	Correlation between baseline and follow-up PSWQ-A score					
	0.3	0.35	0.4	0.45	0.5	0.55
0.15	0.42	0.43	0.45	0.47	0.49	0.52
0.20	0.65	0.66	0.68	0.71	0.73	0.76
0.25	0.83	0.85	0.86	0.88	0.90	0.92
0.30	0.94	0.95	0.95	0.96	0.97	0.98
0.35	0.98	0.99	0.99	0.99	0.99	1

Table 3Achievable power for detectable preference and selection effect sizes, with N = 500 individuals assuming an equal preference for treatment ($\varphi = 0.5$).

Preference effect size	Selection effect size							
	0.2	0.25	0.3	0.35	0.4	0.45	0.5	0.55
0.20	(0.71, 0.83)	(0.71, 0.76)	(0.71, 0.68)	(0.71, 0.58)	(0.71, 0.52)	(0.71, 0.62)	(0.71, 0.71)	(0.71, 0.79)
0.25	(0.84, 0.79)	(0.84, 0.69)	(0.84, 0.58)	(0.84, 0.53)	(0.84, 0.65)	(0.84, 0.75)	(0.83, 0.83)	(0.83, 0.90)
0.30	(0.91, 0.75)	(0.91, 0.63)	(0.91, 0.51)	(0.91, 0.62)	(0.91, 0.74)	(0.90, 0.83)	(0.90, 0.90)	(0.90, 0.95)
0.35	(0.94, 0.71)	(0.94, 0.59)	(0.94, 0.55)	(0.94, 0.69)	(0.94, 0.80)	(0.94, 0.88)	(0.94, 0.94)	(0.94, 0.97)
0.40	(0.96, 0.69)	(0.96, 0.55)	(0.96, 0.59)	(0.96, 0.73)	(0.96, 0.84)	(0.96, 0.91)	(0.96, 0.96)	(0.96, 0.98)
0.45	(0.97, 0.68)	(0.97, 0.53)	(0.97, 0.62)	(0.97, 0.75)	(0.97, 0.85)	(0.97, 0.92)	(0.96, 0.96)	(0.96, 0.99)
0.50	(0.97, 0.67)	(0.97, 0.53)	(0.97, 0.62)	(0.97, 0.75)	(0.97, 0.86)	(0.97, 0.93)	(0.97, 0.97)	(0.96, 0.99)
0.55	(0.97, 0.68)	(0.97, 0.54)	(0.97, 0.61)	(0.97, 0.74)	(0.96, 0.85)	(0.96, 0.92)	(0.96, 0.96)	(0.96, 0.98)

Note that power for the preference effect (rows) is listed first in parentheses, followed by the power for the selection effect (columns).

The additional 250 participants in the preference trial provide the data necessary for estimating the selection and preference effects. The estimation of the statistical power to detect these effects assumes a total sample size of 500 individuals (250 in the preference trial and 250 in the randomized trial). The randomized trial contributes in the estimation of these effects through the randomization performed in the first stage (preference vs. randomized trial), and the expected equal distribution of preferences in the two arms of the randomized trial [26]. Power calculations were based on the power estimation approach described by Turner and colleagues [52]. Assuming a two-sided significance level of 5%, we will have 71% and 83% power to detect a selection and a preference effect size of 0.2 standard deviation, assuming the proportion of study participants who prefer CBT to yoga is around 50% (Table 3).

3.8.2. Primary analyses

The primary analysis will follow an “intent to treat” philosophy. Descriptive statistics and data plots will be examined for outliers and the necessity of data transformation. Simple associations between variables will be estimated using Spearman’s rank correlation coefficient. PSWQ-A scores, modeled as the number of items reported by a study participant, tend to be skewed and often are in need of transformation to approximate normality; however, residuals from models on untransformed values often approximate normality after accounting for the baseline observation. Diagnostic methods will be used to check model assumptions. The intervention effect for the primary aim will be estimated by comparing mean PSWQ-A scores between CBT and yoga groups in the randomized group (N = 250, 125 per group) using constrained mixed-model repeated measures analysis of covariance to account for the fact that the multiple measurements (at Weeks 0, 6, and 11) from participants are not independent. For randomized trials, constrained mixed-models can provide more efficient estimates of post-randomization intervention differences when either baseline or post-randomization measures are missing [53].

3.8.3. Secondary analyses

Analyses of the preference and selection effects are considered exploratory. The estimation of the selection and preference effects sizes is based on data collected in both randomized and preference trials. Therefore, these analyses will be based on a sample size of 500 individuals. Unbiased estimates of the selection and preference effect sizes will be based on formulas provided by Walter et al. [26] The preference rate ($\hat{\varphi}$) (see Fig. 1) will be closely monitored since significant deviation from 50% could affect the power to detect the preference and selection effects. The adjusted means and variance-covariance matrix needed to compute these effects and their standard error will be estimated from the fitted model.

Consistency of intervention effects will be explored within the following baseline subgroups: 1) depressive symptoms from PROMIS measure (none or mild vs. moderate or severe), 2) use of psychotropic meds (any vs none), 3) age (60–79 vs 80+), 4) gender (female/male),

and 5) race (White vs. other races).

4. Discussion

The current study is a randomized preference trial of CBT and yoga for the intervention of late-life worry. The design of this study grew out of feedback from participants in our prior study of late-life GAD [18]. Participants indicated that they wanted additional non-pharmacological options for the treatment of anxiety and worry and to have a say in which intervention they received. Little is known about the effects that patient preference has on intervention outcomes. In fact, a preference-based randomized trial has never been used to study intervention, selection, and preference effects on late-life anxiety intervention outcomes. Studies examining the impact of patient preference have been limited to the treatment of depression (with one exception) [54]. There is evidence that preference moderates intervention outcomes [55]; patients who receive their preferred intervention show greater declines in depressive symptoms [56,57] while patients who receive their non-preferred intervention have higher rates of attrition, decreased intervention adherence, and decreased working alliance [58]. Thus, it is important to know the relative efficacy of the two interventions (traditional RCT results) and the effects of patient preference on outcomes, and how preference may affect attrition. The design of the current study allows us to answer these questions.

Further, understanding the effects of patient preference also will give providers more information when presenting treatment options to patients. We anticipate that the information learned about patient preference will be of broad interest particularly since we have had strong interest in the study design by community sites, clinician stakeholders, and patient stakeholders, and study interventionists (CBT therapists, yoga teachers). Our study team is interested to see how intervention selection turns out for those participants randomized to the preference trial. We have discussed in great detail why participants might choose one intervention over the other, but we have no reason to believe that we will have different accrual rates for the intervention groups in the preference trial.

This study is the first head-to-head comparison of CBT and yoga for treating late-life worry. We are aware of only one other study in progress comparing CBT and yoga using an RCT design for adults ≥ 18 years with GAD [59]. CBT and yoga likely reduce worry and anxiety via different mechanisms. CBT focuses on modifying thought processes and changing behaviors that lead to the maintenance of anxiety and worry. Yoga classes have a strong focus on the breath and will also begin with more active postures and move gradually to more calming postures and meditation. The breath/meditation emphasis and the gradual slowing of postures serve to slow down both the physiologic stress response and the speed of thoughts, such that being calm physiologically and mentally is incompatible with worry. While a relaxation exercise is included in the CBT intervention, it is one of many components with the primary CBT focus on modifying thoughts/behaviors. The meditation and mindfulness components of the yoga intervention promote a relaxed

state as a core feature of the intervention.

There are a number of barriers that older adults face in seeking mental health treatment [60]. In addition to practical barriers (e.g., cost, not knowing where to go, lack of transportation), older adults often hold a number of personal beliefs that may interfere with treatment such as the belief that they should not need help, mistrust of mental health providers, and not wanting to talk about private matters with a stranger. Stigma remains a significant barrier, and older adults report embarrassment in talking about their problems as well as concerns about what others would think. The interventions offered in this study were chosen in an attempt to overcome some of these barriers. For instance, the CBT intervention is delivered by telephone, which allows participants to engage in treatment without having to leave their homes. This reduces some of the practical barriers, such as not knowing where to go for treatment, access issues, and lack of transportation. Treatment by telephone may also reduce stigma, as no one will see them enter a mental health clinic. Similarly, yoga may reduce other barriers, such as cost as yoga classes may be cheaper than insurance copays. Yoga may be especially appealing to older adults since it does not have stigma that may be attached to psychological care that could create resistance to treatment of anxiety symptoms. Participants who receive yoga will complete the intervention at local yoga studios, community centers, and senior centers that typically are not associated with mental health treatment provision. Yoga may also reduce the impact of mistrust of mental health providers since the instructors are not mental health providers. Similarly, participants will not be talking about their personal problems within the context of the yoga sessions. Thus, ultimately the availability to choose CBT or yoga has the potential to reduce some barriers to mental health treatment.

Two limitations of this study are the differences in the delivery format and frequency of the interventions. CBT is delivered via telephone (for reasons described above) and is offered once a week. In contrast, yoga is delivered via group sessions and is offered twice a week. Differences in frequency of the interventions are partially mitigated by home practice. Participants who receive CBT are encouraged to practice the techniques by completing daily home exercises for 15–30 min daily (105–210 min/week). Yoga participants are encouraged to practice for 15 min 5 times a week (75 min). Further, CBT is usually provided once a week whereas yoga classes are provided multiple times a week. However, the frequency of these interventions also mimics implementation in the real world. Regarding format, home-based individual intervention versus community-based group intervention will likely affect preference choices. We are gathering data on reasons for intervention choice to determine the impact of this factor on preferences. Despite these limitations, this study has the potential to provide great insight into the relative efficacy of two different non-pharmacological interventions and the impact of preference on outcomes.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.conctc.2018.05.002>.

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