Published in final edited form as:

Contemp Clin Trials. 2014 July ; 38(2): 321–332. doi:10.1016/j.cct.2014.06.003.

Testing the efficacy of Yoga as a Complementary Therapy for Smoking Cessation: Design and Methods of the *BreathEasy* trial

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Abstract

Smokers trying to quit encounter many challenges including nicotine withdrawal symptoms, cigarette craving, increased stress and negative mood and concern regarding weight gain. These phenomena make it difficult to successfully quit smoking. Studies in non-smoking populations show that yoga reduces stress and negative mood and improves weight control. By increasing mindfulness we anticipate that yoga may also improve smokers' ability to cope with the negative symptoms associated with quitting. Yoga may also improve cognitive deliberation which is needed to make effective choices and avoid smoking in tempting situations.

The *BreathEasy* study is a rigorous, randomized controlled clinical trial examining the efficacy of Iyengar yoga as a complementary therapy to cognitive-behavioral therapy for smoking cessation. All participants are given an 8-week program of smoking cessation classes, and are randomized to either twice weekly yoga (Yoga) or twice-weekly health and wellness classes which serve as a control for contact and participant burden (CTL).

Assessments are conducted at baseline, 8 weeks, 3, 6, and 12 months follow up. The primary outcome is prolonged abstinence using an intention-to-treat approach. Multiple internal and external audits using blind data collection are employed to ensure treatment fidelity and reliability of study results. To understand why yoga may be more effective than CTL, we will examine mechanisms of action (i.e., mediators) underlying intervention efficacy. We will examine maintenance of yoga practice and smoking status at each follow up. Focus groups and interviews will be used to enrich our understanding of the relationship of yoga practice and smoking abstinence.

Keywords

Yoga; Smoking Cessation; Wellness

1. Introduction

Cigarette smoking is the leading preventable cause of morbidity and mortality in the U.S. [5]. Despite the importance of quitting, smokers encounter a number of substantial barriers when they try to quit including nicotine addiction and its associated withdrawal symptoms,

cigarette craving, increases in stress and negative affect [1–3] and concern regarding post-cessation weight gain [6–7]. Each of these factors has been shown to be associated with shorter time to relapse among recent quitters [8–9]. Therefore, developing interventions that effectively address these barriers to successful and sustained cessation is vital if we are to significantly reduce the prevalence of smoking.

Exercise was initially suggested as a potential aid for smoking cessation because of its ability to minimize weight gain associated with quitting smoking [10–11]. A number of studies have indicated that aerobic exercise (e.g., walking, cycling) also produces significant, acute improvements in positive affect and reductions in negative affect, cigarette craving and nicotine withdrawal symptoms [12–16]. Thus, exercise may offer significant benefits for smokers who are attempting to quit, both by directly addressing their fear of weight gain and attenuating the physiological and affective symptoms commonly associated with nicotine withdrawal [17–18]. Yoga is an alternative to standard aerobic exercise (e.g., walking, cycling) and may have potential as a complementary treatment for smoking. Yoga contains two components shown to enhance affect and stress reduction: *asanas* (yoga postures) and *pranayama* (breathing exercises) [19,20]. While yoga is associated with health benefits similar to standard exercise, yoga practice also aims to create a calm state of mind through a combination of physical postures, breathing techniques, and directed meditative/mindfulness focus [21–22]. Mindfulness has been defined as intentionally paying attention to present-moment experiences (physical sensations, perceptions, affective states, thoughts and imagery) in a non-judgmental way [23]. Increase in mindfulness has been associated with reductions in perceived stress, psychological distress and cognitive reactivity [24–25].

Yoga offers benefits similar to aerobic exercise that has shown to be effective in previous smoking cessation studies [10,11]. In addition, by increasing mindfulness [4], yoga may offer additional advantage for smoking cessation. This focus may reduce symptoms of nicotine withdrawal, improve the smoker's ability to cope with negative symptoms associated with quitting smoking, and/or improve cognitive deliberation needed to make effective choices to avoid smoking in tempting situations [4, 26–27]. Moreover, the association of yoga with increased mindfulness [4], stress reduction and improved affect is likely to have special relevance for smokers who are trying to quit [19, 26–27]. Yoga has also been shown to improve weight control and body composition [28–33]. Therefore, yoga may be helpful to those quitting smoking because it may reduce both actual weight gain and concerns regarding post-cessation weight gain. By addressing barriers such as stress, cravings, and weight concerns, yoga may prove to be an effective complementary therapy for smoking cessation.

2. Methods

2.1. Study design

The *BreathEasy* study is designed to test the efficacy of *Iyengar* yoga as a complementary therapy for smoking cessation using a randomized, controlled 2-group study design. *Iyengar* yoga was chosen because of its emphasis on postural alignment, including the use of props which facilitate learning and injury avoidance. Adult smokers (n=300) are randomly assigned to either; 1) Yoga, or 2) a comparison condition that controls for contact time and

participant burden (CTL) by providing a general health and wellness program. All participants are provided (separately by treatment group assignment) with the same cognitive-behavioral smoking cessation counseling (SCC) during the 8-week supervised program. Yoga participants are also given a 12-week maintenance program to facilitate continued yoga practice after the supervised yoga program has concluded. CTL participants are provided with materials by mail to match for contact during this transition period (program weeks 9–20). Smoking abstinence will be measured at the end of treatment (week 8) and at 3, 6 and 12 months follow-up. We will also test theoretically posited mediators of intervention efficacy (e.g., perceived stress, cognitive/perceptual changes), and explore the relationship between maintenance of yoga practice during the post-treatment period and smoking status.

2.2. Ethical and safety oversight

All study procedures and materials including advertisements, consent forms and procedures are reviewed and approved by the Miriam Hospital Clinical Research Review Board (IRB registration #0000482). The Miriam Hospital IRB conducts periodic audits of all studies to ensure that informed consent is appropriately administered and documented, and that study procedures relevant to participant confidentiality are followed. The study Data Safety Monitoring Board (DSMB) is comprised of 6 individuals from outside our Center (CBPM) not otherwise affiliated with this study. The DSMB membership includes researchers, clinicians, a biostatistician, and physician. The DSMB meets twice yearly to review reports of recruitment, attrition, consent process and adverse events. A report to the DSMB is sent by the study Data Manager, and reports generated by this meeting are sent annually to NCCAM by the DSMB chair.

2.3. Research goals and hypotheses

The primary aim of this study is to test the efficacy of *Iyengar* yoga as a complementary therapy for smoking cessation in a rigorously designed two-arm clinical trial. The primary outcome variable is prolonged abstinence at 6-month follow-up. We hypothesize that participants given the smoking cessation counseling (SCC) plus yoga intervention will show a significantly higher prolonged abstinence rate at follow-up compared to those given SCC plus the contact-control. We will also examine the relationship of continued yoga practice after the 8-week treatment program and smoking status at follow up.

Secondary aims of the study are to explore the mechanism(s) of action (i.e., mediators) underlying the efficacy of yoga for smoking cessation. Posited variables include mediators of initial cessation at end of treatment, and mediators of longer-term outcomes. This comparison is important for understanding why Yoga may be more efficacious than CTL and how it may act on different behavioral and cognitive mechanisms. We hypothesize that the following variables will be shown to mediate the effect of treatment assignment on smoking outcomes at end of treatment and between end of treatment and follow-up: withdrawal symptom severity, self-efficacy, affect, perceived stress, and cognitive/perceptual changes (e.g., attention/mindfulness).

We will also examine the relationship between baseline variables (e.g., age, gender, motivation, nicotine dependence), process variables (e.g., program attendance), and maintenance of yoga practice through the 12-month follow-up period, and examine whether these variables predict smoking status at follow-up. We will calculate the cost-effectiveness of treatment. Qualitative focus groups at end-of-treatment and interviews at six months follow up will be conducted to enrich our understanding of the relationship of yoga practice and the maintenance of smoking abstinence.

2.4. Sample size and power calculations

Sample size estimates for the primary aim are calculated as follows. In our previous RCT that tested traditional aerobic exercise versus a wellness control, the abstinence rate for those in the control condition was 5.4% [10]. The current study uses a similar control group, but we will take a more conservative approach and assume an estimate for smoking cessation in the CTL group to be approximately 10% greater, such that we estimate cessation at month 6 will be 6% among controls (CTL). The estimates of effect size for the Yoga arm are based on our feasibility trial [34–35]. At the 6-month assessment the intention-to-treat (ITT) abstinence rate among yoga participants was 18.8%. We will also take a conservative approach with this treatment arm, in which we assume our quit rate in the current study may be 15% smaller after we impute positive smoking status for all Yoga arm participants for whom data on smoking status is missing. We thus estimate abstinence rates at the month 6 assessment, among those in the yoga arm will be 16%. A power analysis for the primary aim indicated a need for a sample size of 300 participants, or 150 per group, for a two-sided alpha of 0.05 and 80% power to detect differences in the ITT cessation rate (missing=smoking). This hypothesized difference (16% vs. 6%) represents a standardized proportional difference using Cohen's metric of $h=.33$, an effect intermediate between a small and a moderate effect size based on guidelines suggested by Cohen [36].

2.5. Statistical Power for Secondary and Mediation Analyses

In general, secondary analyses that use the complete sample ($N=300$), will have similar power to that for the primary analyses, that is 80% power for a two-sided test at the $\alpha = .05$ level to detect standardized deviation differences of 0.33. With respect to power for the mediation analyses we are primarily concerned with the indirect effect from the independent variable (IV) to the mediator (M) to the outcome or dependent variable (DV). For a single mediator model, which we will also explore in addition to the more complex multiple mediator model, our sample size ($N=300$) has 80% or greater power under several conditions of values for the paths a (IV to M), b (M to DV) and the resulting indirect effect axb . A goal of this study is to determine the effect sizes for any significant mediated paths and using a Structural Equation Modeling (SEM) approach will enhance this effort. The statistical approach chosen by the investigators is particularly robust in order to assure the rigorosity of the conclusions drawn from the data.

3. Study Procedures

3.1. Recruitment and screening

Recruitment methods include placing advertisements on local radio stations and websites, and posting flyers and brochures at physician's offices and commercial locations (e.g., convenience stores, grocery stores). Advertisements invite individuals to a smoking cessation research program. These ads also explain that participants will be given help to quit smoking by smoking cessation specialists and will also be given either a health & wellness program or a yoga program. Interested persons calling about the study are screened for eligibility by the study research assistants (RAs). Callers are excluded if they are pregnant, have a body mass index over 40, smoke less than 5 cigarettes per day, are currently enrolled in a quit-smoking program or are using medications to quit smoking, or have a medical condition that would make participation in yoga difficult or potentially hazardous. Medical conditions that exclude participation include cardiovascular disease (e.g., heart failure, ischemia), current cancer, chronic obstructive pulmonary disease requiring supplemental oxygen, and uncontrolled hypertension. Individuals are excluded if they have participated in yoga, tai chi or Qi Gong classes in the past year. Written physician consent is required for individuals over age 65, or who have peripheral vascular disease, a cancer diagnosis in the past 5 years, COPD not requiring supplemental oxygen, medically controlled hypertension, hyperthyroidism, asthma or diabetes. Individuals are also ineligible if they cannot obtain physician clearance when required.

Unlike our previous trials [34–35], individuals are not excluded if they engage in other forms of physical activity that are not similar to yoga, or smoke marijuana. Those using illegal substances other than marijuana are excluded. Callers are also screened to ensure safe participation in physical activity by answering a variety of questions regarding their current and recent health history including questions from the PAR-Q [37].

3.2. Informed consent, enrollment and randomization

Individuals who screen eligible are scheduled for an in-person group orientation session in which the study RA presents the details of the study, reviews what is required of participants and administers informed consent. At orientation participants are told that CBT for smoking cessation is an effective, well established therapy for smoking cessation, but we do not know whether the addition of a yoga or a wellness program will enhance the effectiveness of CBT, and this question is what the study is testing.

After providing written consent and completing baseline assessments, participants are scheduled for a second visit (randomization visit). At the randomization visit participants report their current smoking status, physical activity (7-day Physical Activity Recall) and provide a breath sample for Carbon Monoxide (CO) analysis. CO is used as an indicator of recent smoking (see section 4.1). Immediately following these assessments, participants are randomized to either the Yoga or CTL group and given their weekly class calendar. The randomization scheme generated by the study statistician uses a permuted block randomization procedure, with small, random sized blocks. Randomization is stratified based on gender and level of nicotine dependence (FTND score, see below). If individuals

enroll in the same cohort with family members, friends, co-workers, and/or roommates, these individuals are yoked for randomization to reduce the likelihood of contamination across intervention conditions. Group assignment to either the Yoga or CTL group is calculated by computer program and delivered to the study RA on the day of the randomization visit.

3.3. Data collection and blinding

Study data are collected at initial eligibility screening, study enrollment (baseline), weekly during the 8-week treatment program, and at follow ups conducted at end of treatment (week 8), 3, 6, and 12 months (see table 1). Individuals are scheduled for their follow up visit by the study RAs. Survey packets are sent to the participants one week before each scheduled follow up visit. Participants are asked to bring the completed surveys to the follow up visit to reduce the amount of time they would have to spend if they completed all surveys at the visit. RAs who are blind to the treatment assignment collect and review the survey packets for completeness. Self-reports of no smoking for >7 days are verified by the RA verbally to ensure these data are still current. The RA then collects two tubes of saliva from each participant reporting smoking abstinence. A second blind RA interviews each participant in a private room to complete the 7-day PAR interview. Since randomization occurs after completion of baseline assessments, all assessments at screening and baseline are blind to randomization assignment. Practical logistics prevent blinding for weekly assessments conducted during the program (See CO/Interview form described below). Blinding is also not possible for qualitative data collected at focus groups and interviews, since these interview guides have questions tailored specifically asking about participant experiences in the Yoga or Wellness classes. Assessments conducted at the end of treatment and all follow up assessments are conducted by RAs who are blind to the participant's randomization condition.

4. Covariates and outcome measures

4.1. Smoking outcome measures

During the 8-week treatment program participants are asked each week about their current smoking, cigarette craving, and use of quit smoking medications. Self-reported abstinence is verified weekly by exhaled carbon monoxide (CO). A CO reading of < 10ppm is considered an indicator of smoking abstinence for the previous 12–24 hours [38]. Self-report of seven days of non-smoking (7 day point-prevalence abstinence: 7PPA) and the date of the last cigarette smoked is assessed weekly throughout treatment, at the end of treatment (Week 8) and at all follow ups. The primary outcome variable is prolonged abstinence which is abstinence following a grace period starting two weeks post-quit-date [38]. Collected data will also allow us to document a range of smoking behaviors from rate and brand changes to initial 24-hour quit attempts, 7PPA, prolonged abstinence, and relapse events. Self-reported abstinence at all follow up assessments is verified with saliva cotinine. Cotinine provides a more rigorous indication of smoking abstinence than CO. Values below 15 mg/ml are indicative of no smoking for the previous seven days [39]. Individuals whose saliva sample exceeds the 15 mg/ml cutoff value are counted as smokers. A chart of the study measures is presented in Table 1.

4.2. Smoking-related covariates

Measures of smoking include smoking history, current smoking, nicotine dependence, withdrawal symptoms, motivation, confidence, and social support for quitting, perceived risk from smoking, temptations to smoke in various situations, and locus of control. The smoking history questionnaire consists of 25 items asking about the participant's smoking history including age started smoking, current smoking rate, previous quit attempts and use of medications, and presence of any smoking-rules at home. Nicotine dependence is assessed using the Fagerstrom Test for Nicotine Dependence (FTND) [40]. Symptoms associated with nicotine withdrawal during previous quit attempts are assessed using the Withdrawal Symptoms Questionnaire [41], which was developed from the DSM-IV description of nicotine withdrawal symptoms [42]. Motivation to quit smoking is assessed at baseline and all follow-up assessments using two measures; the stages of change measure [43], and a single Readiness to Quit item that uses a 10-point scale from "not at all ready" to "extremely ready". This has shown strong correlations with other measures of motivation and has good ability to predict quitting smoking [34]. At baseline, participants also indicate their degree of confidence in their ability to quit smoking in the next 3 months using a 10-point scale from "not at all confident" to "extremely confident". Temptation to smoke under a variety of circumstances is measured using the short form 9-item Smoking Situations Temptations (SST) scale [44]. The SST has three sub-scales assessing temptations related to habit, negative affect, and social situations.

Perceived risk related to smoking is measured through 7 items developed in previous studies [45] that ask participants to rate their chances of getting smoking related illnesses (lung cancer, other lung diseases, heart disease), their risk compared to other smokers, and the degree to which they worry about their health because of smoking. We use the 7-item Smoking Situations Questionnaire (SSQ) developed by Weekley and colleagues [46] to assess the degree to which individuals are motivated to smoke in order to control their weight. Social support for quitting smoking is assessed using the SFQ [47]. The SFQ contains six items that are summed to comprise two subscales measuring the degree of support for quitting smoking from family and friends, and three additional questions concerning the number of current smokers and successful quitters among the participant's family and friends, and the participant's expectations regarding how supportive, or unsupportive these individuals would be of the participant's efforts to quit smoking. An 11-item smoking locus of control instrument [48] measures the degree to which the participant has an internal locus of control (believes ability to quit smoking due to factors he/she can control) versus an external locus of control (believes ability to quit smoking is related to factors not within his/her control, such as destiny or the responsibility or interest of others). This scale contains four factors representing the following types of locus of control for smoking that measure the perceived influence of (1) Self, (2) Chance, (3) Significant Others and (4) Powerful Others on smoking outcomes.

At each meeting of the SCC during the 8-week treatment program, current smoking behaviors are recorded by the study RA on a CO/Interview form. This form includes questions determining 7PPA (i.e., "have you smoked, even a puff, in the past 7 days"), 24-hour quit attempts, use of quit smoking medications (including type and dosage), adverse

events, any medical signs and symptoms (to check for adverse events), and for those in the yoga group any yoga practice in the past week outside of the program's classes.

4.3. Other covariates

Demographic information including age, gender, ethnicity, marital status, education, and menopausal status are collected using an 11-item survey. Height and weight are measured at study enrollment. Several other measures are used to assess likely mediators or moderators of treatment outcome. These include anxiety assessed using the 20-item State-Trait Anxiety Inventory (STAIT) [49], depressive symptoms measured using the 10-item Centers for Epidemiological Studies Depression Scale (CESD) [50], and current affect measured using the 20-item Positive and Negative Affect Questionnaire (PANAS) [51]. Because yoga may influence smoking decisions through improved mindfulness, the 15-item Five Facet Mindfulness Questionnaire (FFMQ) [52] is used to assess the mediating effect of mindfulness. Since impulsiveness may influence smoking outcomes [52] we assess impulsiveness using the 30-item Barratt Impulsiveness Scale [54]. Global (rather than smoking-specific) social support is measured using the 12-item ISEL [55]. We assess participants' outcome expectations regarding yoga practice using a 20-item scale we adapted from the Exercise Outcome Expectations questionnaire [56]. We also ask six investigator-developed questions at baseline regarding the practice of yoga and what participants think yoga is about.

4.4. Physical activity and health-related measures

The Physical Activity Readiness Questionnaire (PAR-Q) [37] is used at initial screening to determine eligibility to participate in exercise. At baseline and each follow up, participation in physical activity is assessed using the interviewer-administered 7-day Physical Activity Recall (PAR) [57]. In our pilot work some participants reported yoga during the PAR and counted it as physical activity [35]. Other participants only revealed their yoga practice when probed specifically for this information. Therefore, for this study, a single item specific to yoga practice is added to the PAR given to all study participants. To maintain blinding during the PAR assessment, this item is asked only after the standard PAR interview is completed. Stage of change for physical activity is measured using the 5-item instrument developed by Marcus and colleagues [58]. Each month during months 3–12 participants are asked to complete logs of their activities. Logs are mailed each month to participants with a self-addressed stamped envelope for returning the log. Participants are advised to record their activities on a daily basis to avoid recall bias at the end of the month. Those randomized to the Wellness (CTL) arm are asked to complete a daily log of health behaviors (servings of fruits & vegetables, water consumed, hours slept). Those in the Yoga arm are asked to complete a daily log of yoga practice (minutes and location of practice) through month 12 of the study.

The frequency of respiratory symptoms is measured using the 8-item self-report American Thoracic Society Questionnaire (ATSQ) [59]. Participants are asked to indicate the degree to which they experience limitations in their ability to engage in normal daily living activities using the SF-8 [60].

4.5. Process measures

Program attendance is recorded for each session (smoking, wellness, yoga) during all eight weeks of the treatment program. At week eight, participants complete a group cohesion survey to indicate how connected they felt to their fellow participants within their randomization arm. Participants also complete consumer satisfaction and leader evaluations to indicate their degree of satisfaction with their group leader (smoking and either wellness or yoga) as well as the program overall.

4.6. Quality control and assurance

All data are collected on case report forms (CRFs) which are signed and dated by the staff member collecting the data. Data are entered into a Microsoft Access database and study processes (class scheduling, reminder calls, follow up sessions, etc) are tracked through an electronic Access database tracking system. All (100%) primary outcome data and 20% of all other quantitative data are audited by study RAs supervised by the Data Manager to ensure accuracy of data entry. Attendance sign-in sheets are used to log participant attendance at each SCC, Yoga and/or Wellness sessions. Each session is audio-taped and 20% of the tapes are audited quarterly by an off-site investigator. This audit includes an examination of the consent, randomization, weekly session attendance documentation process, and the Physical Activity Recall (PAR). PAR recordings are rated using a form modified from the Cooper Institute. This is done to ensure that all PAR's are administered via the protocol and that the interviewers are reliable in conducting of the PAR. For audits of SCC sessions, checklists have been developed following contents of the treatment manual. These checklists are used to quantify the delivery of key theoretical and behavioral concepts each week. Auditors also rate the smoking cessation counselor on variables such as enthusiasm, supportiveness, use of problem solving skills, and knowledge, and rate the group process on variables including cohesiveness, and equity in the group in terms of individual speaking time. Quarterly meetings are held to review the results of quality control assessments and to provide corrective feedback as needed. These methods have been used in other large scale randomized smoking cessation trials [61].

Summary data audit reports are reviewed with study staff and reconciled in the participant file as well as the electronic tracking system. All study documentation, including CRFs, consent forms, DSMB reports and process measures are audited annually by an independent auditing firm on behalf of the National Center for Complementary and Alternative Medicine (NCCAM). This audit includes an examination of the consent, randomization, and weekly session attendance documentation process as well as all data and CRFs. This annual audit concludes with a report by the auditing agency to NCCAM regarding adherence to the NCCAM-approved study protocol.

4.8. Qualitative research

The qualitative methods are designed to increase our understanding of the possible mediating factors and synergistic effects of yoga and smoking cessation. Prior research suggests that particular theoretically-based variables may relate to efficacy in the yoga intervention, and mediate intervention efficacy [4, 19, 20, 21–23]. Those posited variables form our key areas of qualitative inquiry: withdrawal symptom severity and withdrawal-

related experiences, effects of yoga on affect and stress level, and cognitive or perceptual changes as a result of practicing *asanas*, *pranayama* or meditation exercises. We are also interested in whether and how participants develop a long term yoga practice and if they do, whether they attribute that to maintaining their smoking cessation.

We are exploring these variables in focus groups, conducted with participants immediately after the 8 weeks of active smoking cessation classes, and in semi-structured interviews conducted 6 months later. Our qualitative design includes both the yoga and the wellness control participants. This comparison is important for understanding the relative efficacy of the interventions and for understanding if and why yoga may (or may not) be more efficacious than our wellness control. The addition of focus groups with wellness control participants, however, requires that questions about how yoga affects the smoking cessation experience have parallel questions about how wellness affects the experience of quitting smoking. Therefore, yoga focus groups assess participants' experiences with yoga and seek to understand which experiences interact with their quitting experience, while parallel wellness control focus groups examine whether the wellness classes impact the smoking cessation experience. The semi-structured interviews conducted at six months post-treatment are conducted with a sub-sample of participants with equal numbers who are quit at 6 months and smoking at 6 months. These interviews inquire into yoga practice (or wellness behaviors) during the post-treatment period and participants' perceptions about their relationship to smoking status. Ultimately we want to understand if SCC+Yoga act on different behavioral, cognitive and phenomenological mechanisms compared to SCC+ a control (wellness).

Analyses will explore differences between yoga participants who stayed abstinent from nicotine and those who were unable to quit or who started smoking again after the intervention. We are conducting focus groups and interviews with participants in the first five cohorts, and if saturation has not been reached on key areas of inquiry after 5 cohorts, qualitative data will be collected from up to 4 subsequent cohorts. Detailed coding and a thematic analysis will be conducted; NVivo 10 qualitative software will be used to manage the data and its analysis.

5. Interventions

5.1. Smoking cessation counseling (SCC)

The SCC intervention consists of a group-based 8-week program using cognitive-behavioral therapy (CBT) techniques and delivered separately to each randomization arm. CBT is derived from Social Cognitive Theory, which posits that behavior, environmental and personal factors interact with each other and are mutually influential [62]. Smoking cessation programs using CBT have been shown to be effective with both men and women smokers [63]. CBT-based programs teach smokers to recognize specific environmental events ("*triggers*") that precede smoking so that they can then employ behavioral and cognitive strategies to cope with these triggers. Strategies include avoiding triggers, altering the situation (e.g., drinking juice instead of coffee), or engaging in an alternative behavior (e.g., taking a short walk). The content of the SCC intervention is similar to CBT-based smoking cessation programs used in our previous trials [10,11,13].

Participants in this trial attend one hour of SCC per week. The SCC sessions are scheduled to immediately follow or precede the first Wellness or Yoga class of each week, such that participants only need to travel to our facilities twice weekly to attend all classes. All SCC sessions are led by a PhD-level psychologist with experience in conducting smoking cessation groups. Treatment is delivered through use of a program manual to ensure consistent delivery of program content between groups and across study cohorts. Audiotapes of the sessions are reviewed for quality control (see above). This quality control includes a Co-Investigator reviewing 20% of randomly selected audio recordings on a quarterly basis. Quality control is completed on these sessions to ensure protocol delivery is consistent between smoking group leaders. The audio recordings are reviewed, scored and provided to the staff with any additional feedback. Program topics include preparing for quit day (set to occur on week 3 of the program), self-monitoring, getting social support, physiological addiction and coping, psychological addiction/breaking learned habits, relapse prevention, including planning for high-risk situations, coping with slips and changing one's thoughts; problem solving, time management, and techniques to avoid weight gain while quitting smoking. Participants who miss a session are mailed relevant materials immediately following the session. This program was used in our prior study [34]. Participants are not provided with nicotine replacement therapy (NRT) or other smoking cessation medications, but are allowed to use them in conjunction with the program. The content of the SCC program is altered slightly for the yoga arm of the study. These alterations are limited to the inclusion of specific mention of using breathing and other exercises learned in the yoga class to reinforce the use of these practices as methods for coping with stress and cigarette cravings. For example, when discussing self-monitoring: "Your yoga classes will also build your self-awareness and your skills in self-observation, which will help with self-monitoring your smoking."

5.2. Iyengar yoga intervention

Iyengar Yoga is a method of Hatha Yoga developed over the past 75 years and originally developed by B.K.S. Iyengar. The *Iyengar* approach emphasizes postural alignment, the use of props (blankets, blocks, straps) to facilitate learning and sometimes recommends specific sequences of postures as therapeutic for specific health conditions or injuries. The *Iyengar* methodology involves precise use of language, demonstration, and observation teaching specific points of action in posture, individual correction and adjustment of the students. Students learn to individualize their practice, and are guided in self observation and reflection. As they develop more awareness of their physical body, they also observe the effect of their practice on their state of mind. Yoga props are used to modify postures (*asanas*) to meet the needs of specific students. This allows for a deeper understanding of the pose, longer holds, and the avoidance of injury. Sequencing, a safe and systematic progression of poses, is another important aspect of *Iyengar* Yoga. The sequence of poses in a typical class is devised to build understanding from pose to pose, class to class and year to year. *Iyengar* Yoga emphasizes the standing postures to develop strength, flexibility, confidence and stamina. Alignment and breath awareness are used as tools to keep the mind in focus on the present activity; hence, the goal is for practice to become like "meditation in action". Although not used in this study, over time *Iyengar* students advance to more complex poses including back bends and inversions.

For this study, yoga classes are conducted twice weekly for eight consecutive weeks by certified *Iyengar* yoga instructors who have over 15 years experience. In collaboration with the research team, the yoga instructors select a pattern of *asanas* that are appropriate for beginners and teach them consistently during each class. Each class consists of five minutes of breathing exercises and seated meditation, followed by 45 minutes of dynamically linked *asanas*. Classes conclude with ten minutes of closing postures (similar to the "cooling down" period following aerobic exercise) and a final seated meditation. A yoga manual is developed to ensure consistent delivery of program content across study cohorts. Weekly handouts are also provided with photos of the *asanas* used during the current week's practice to encourage home practice (Table 2). Participants who miss a session are mailed relevant materials immediately following the session.

To encourage continued yoga practice after the end of the 8 week smoking treatment program participants are given vouchers to pay for 1 class per week during weeks 9–20 so that they can continue practicing yoga at local yoga studios. An initial overview of studios is introduced in week 6 but there is no further involvement from research staff after the end of the smoking treatment program. Participants complete and mail in a monthly log to report their yoga practice.

5.3. Health & wellness contact-control (CTL)

Health & Wellness classes take place twice weekly for 1-hour each. Classes consist of either videos or lectures regarding a variety of health topics (e.g., cancer screenings, sleep hygiene) followed by a discussion guided by the study wellness counselor or other health care professional (e.g., nurse, sleep expert). Each class includes distribution of written materials relevant to the session topic. See Table 3 for a complete listing of topics and content. Participants who miss a session are mailed relevant materials immediately following the session. This protocol has been used successfully in previous studies [10,11]. The purpose of the Health & Wellness group is to control for contact time with the study staff and reduce the risk of differential attrition between groups. Upon completion of the 8-week smoking treatment program, participants are sent health and wellness materials weekly for the maintenance period (weeks 9–20). Participants complete and mail in a monthly log to report their health behaviors (servings of fruits & vegetables, water consumed, hours slept).

6. Subject payments

To encourage adherence to the treatment protocol, participants are compensated \$10 for each week that they attend at least 2 of the 3 scheduled classes (two yoga or wellness sessions plus one smoking cessation session). Individuals who are able to attend the focus groups at week 8 are compensated \$50 for their time. Follow up assessments are compensated as \$30, \$50 and \$50 for the 3, 6, and 12-month follow ups, respectively. Individuals selected for interviews at month 6 are compensated \$30. To encourage compliance with returning monthly logs that track yoga practice (Yoga) or health behaviors (CTL) each month that individuals return logs, they are entered into a drawing for \$100.

7. Planned analyses

Although randomization should equalize group characteristics, preliminary analyses will examine comparability of participants in the Yoga and wellness groups at baseline on demographic, smoking history, psychosocial and behavioral characteristics using Chi-Square tests for categorical variables or analysis of variance (ANOVA) for continuous variables. We will examine the distributional properties of continuously-scaled variables to determine if normalizing transformations should be applied before conducting further analyses. If group differences are found for any variables, we will evaluate them and statistically control them in outcome analyses. As the study progresses, and before conducting the final outcome analyses, we will explore the relationship of several key variables that may impact smoking outcome, such as participant attendance and use of quit smoking medications during the study. If there are group differences on these variables and/or there are relationships of these variables to smoking outcomes, we will include them as covariates in our primary outcome analysis.

Analyses of primary outcome data will not be conducted until the conclusion of the study to avoid any bias or contamination of the study process. Consistent with the primary study aim, we will conduct a logistic regression analysis that will compare the rate of prolonged abstinence at 6 months follow-up between the Yoga vs. CTL conditions. For this analysis we will use the intention-to-treat principle, in which participants with missing data are counted as smokers, to calculate treatment effects. Prolonged smoking abstinence will be measured as a dichotomous outcome variable, measured by self-report of no smoking for the past 7 days each week following the designated quit week (allowing a 2-week grace period) and at each follow-up interval, with biochemical verification of abstinence (CO and saliva cotinine). Variables not balanced by randomization will be controlled for in the analysis.

Secondary analyses will include the examination of potential mediators of the treatment effect. Specifically, we will examine whether the effect of Yoga is mediated by several variables including self-efficacy, withdrawal symptoms, affect, perceived stress, and cognitive/perceptual changes (attention/ mindfulness). There are many approaches to mediation analysis [64], and we will implement a Structural Equation Modeling (SEM) approach using Mplus Version 7 for these analyses [65]. Mplus accommodates the evaluation of complex multivariate models of mediation (multiple mediators with multiple variable indicators) across time, and the use, and statistical evaluation, of the parameter estimates of continuous mediators to predict categorical outcomes. We will also evaluate a series of nested models to explore how the modeling process changes as the effect paths of specific mediators are removed from the overall model.

Cost-effectiveness analyses will compare the relative costs per unit of comparably defined benefit. Decision analytic cost-effectiveness models can be used to examine cost-effectiveness ratios from various perspectives including society at large, healthcare organizations, and individuals. The cost-effectiveness analysis for this study will consist of 3 phases. First, we will refine and run new decision analytic models examining the best strategies for delivering smoking interventions and combining them with the follow-up treatment protocols of the study design. Treatment strategies will be based on a comparison

of the Yoga + SCC arm compared with SCC alone. The model will incorporate consideration of readiness to quit smoking, nicotine dependence and age at baseline as well as dose of treatment received (number of sessions attended). Information related to cost (e.g., cost of training counselors, materials, time spent by yoga instructors and counselors in intervention delivery), will be collected prospectively. Finally, we will integrate clinical trial and cost data into the decision analytic cost-effectiveness models. These analyses will allow us to calculate incremental cost-effectiveness ratios for each arm in terms of additional cost per additional smoker quit. We will also be able to examine ratios for subgroups based on readiness to quit smoking, nicotine dependence, age at baseline. We will estimate the effect of dose of treatment delivered on incremental cost-effectiveness ratios as a function of received treatment dose.

Additionally, we will examine the relationship between maintenance of yoga practice and smoking status at follow-up assessments. We will use the intention-to-treat principle, assuming that participants missing at follow-up are smokers and not practicing yoga (non-maintainers), in separate logistic analyses at each follow-up. We will also create a grouping variable that represents those participants who have maintained their yoga practice through the final assessment versus those who have not and enter it as the grouping variable of interest in a longitudinal analysis to examine its relationship to smoking status across time (3, 6 & 12 months) using the generalized estimating equations (GEE) approach of Zeger and Liang [66].

Finally, we will examine the effect of treatment assignment on: achievement of other smoking-related outcome variables, such as a 24-hour quit, 7-day PPA, time to first slip/relapse, number of 24-hour quit attempts, and total days abstinent. Analyses will fall into 3 types (multiple logistic regression, ANOVA, or analysis of covariance (ANCOVA), and survival analysis), depending on the type of dependent variable. We will employ multiple logistic regressions with appropriate covariates to analyze the effects of treatment on variables with categorical outcomes, such as 24-hour quit and 7PPA. ANOVA or ANCOVA analyses that will use baseline values as covariates (where appropriate) will be used to examine the effects of treatment on continuously-scaled variables, such as the number of 24-hour quit attempts and total days abstinent. Survival analyses, using a proportional hazards regression approach, will be used to investigate the effects of treatment on time to first slip/relapse.

8. Implementation and Timeline

Because yoga practice, and to a large extent smoking therapy, rely upon building new knowledge and skills progressively over time, participants are recruited in consecutive cohorts who progress through the program together. We anticipate approximately 12-14 cohorts of 20–26 participants each to reach our planned recruitment goal of 300 participants. Funding for this study began in July 2012 and was provided through a grant from NCCAM to Dr. Bock (1R01AT006948). Recruitment for the first cohort started in September 2012.

9. Summary

This is the first randomized controlled trial (RCT) to study yoga as a complementary treatment for smoking cessation. This study design pairs both yoga and control conditions with smoking cessation counseling based in cognitive-behavioral therapy, a well-tested, effective intervention for tobacco cessation [63]. By providing a high quality, intensive therapy for smoking cessation, this study should provide a stringent test of the relative efficacy of yoga compared to a condition that controls for contact time and attention. This study builds on our previous work [10,11] demonstrating that aerobic exercise such as cycling and walking was an effective addition to smoking cessation treatment. The yoga intervention provides the active components of the aerobic exercise shown to be effective in our previous studies [10,11], plus additional features specific to yoga that may further improve smoking cessation outcomes. In particular, yoga may offer both behavioral and psychological benefits that may be especially valuable for smokers who are attempting to quit [26–27]. Yoga may increase self-efficacy for smoking cessation, reduce stress and withdrawal symptoms and enhance mindfulness, which would in turn, help support and sustain successful quit attempts. This study examines these features using a rigorous RCT design to provide clear information about the foundational basis of the effects of yoga in this population. The results may provide a valuable blueprint for wider implementation of yoga programs as a complementary treatment for smoking cessation, and offer more evidence-based options for individuals who are attempting to quit smoking.

As with all trials, some limitations should be noted. The SCC portion of the program is intensive as it comprises eight, hour-long visits over two months. In addition, the control condition is an active program involving equal contact time with the yoga program. Therefore abstinence rates may be higher in both groups in this trial than would be the case for less intensive programs, and thus may reduce the potential effect size for yoga relative to the Health & Wellness control. In addition, this is not a “real world” comparison in that smoking cessation programs are not typically paired with a Health & Wellness program. A more real world comparison may have been to not offer any supplemental classes for controls. However, in designing this study we rejected that option in order to avoid any bias resulting from unequal subject burden and attention that would result from the latter design. It can also be argued that using medications to aid smoking cessation is the current standard of care [63], and at a minimum, NRT should have been provided (or its use required) by this trial. We considered this, however we were concerned that if yoga produces a small positive effect on cessation, it could be effectively washed out by the introduction of medications, which typically produce a doubling of effect size [63]. To detect this effect above and beyond the impact of medications would require a very large sample size that we were unable to accommodate. It is also worth considering that individuals seeking a therapy such as yoga to aid them in smoking cessation may be more inclined than others to avoid the use of medications, although there are currently no data to support or refute this. Similarly, many individuals cannot use or choose not to use quit-smoking medications due to cost and contraindications [67], and it seems worth investigating yoga as an option for those who cannot or choose not to use quit-smoking medications.

Despite minor limitations, this study is an important pragmatic step in the field of yoga and smoking research. This rigorous trial uses a mixed methods approach to test the efficacy of yoga for smoking cessation. This methodology gives the opportunity to validate the existing knowledge about yoga and also helps to explore new themes, which will form the basis of future mindfulness and yoga research. This study explores the potential of yoga to improve smoking cessation through any of three mechanisms: 1) reduction of post-cessation weight gain and/or concern about weight gain; 2) reducing stress-responsiveness that often leads to relapse; and 3) improving attention and deliberative planning by providing mindfulness training as part of yoga practice. This last feature should, in turn, improve the participant's ability to use coping skills taught in CBT smoking cessation therapy. The key behavioral and psychological mediators identified in this trial can be used to develop and streamline future studies to test the effect of yoga on other addictions.

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Table 1**Measures and Schedule**

	Baseline	Weekly (1–8)	Week 8	Months 3, 6, 12 Follow-up
Smoking Outcomes				
Current smoking	s, x	x	x	x
CO Interview: current smoking, CO, adverse events		x		
Saliva cotinine			x	x ^{6m,12m}
Smoking Covariates				
Smoking History	x			
Fagerstrom Nicotine Dependence (FTND)	x		x	x
Withdrawal symptoms, medication use	x	x	x	x
Readiness, confidence, stage of change	x		x	x
Smoking Situations Temptations (SST), Smoking Risk	x			
Smoking for Weight Control (SSQ)	x		x	x
Social Support for Quitting (family / friends)	x			
Smoking locus of control (LOC)	x		x	
Other Covariates				
Demographics	x			
Height, Weight, BMI	x			
Affect & Anxiety: Stait, CESD-10, PANAS	x		x	x
Five Facet Mindfulness Questionnaire (FFMQ-15)	x		x	x
Barratt Impulsiveness Scale (BIS)	x		x	x
Interpersonal Support Evaluation (ISEL)	x			
Outcome Expectations for Yoga	x			
Yoga Expectations	x			
Physical Activity and Health				
PAR-Q	S			
7-day PAR & Stages of Change	x		x	x
Yoga Logs (yoga arm)			x	M ^{1–12}
Heath behavior Logs (wellness arm)				M ^{1–12}
ATSQ and SF-8 health status questionnaire	x		x	x
Current health status and health history	S			
Process Measures and Program Evaluation				
Program attendance (weeks 1–8)		x		
Group Cohesion Survey			x	
Group leader evaluations (SCC, Yoga, CTL)			x	
Focus groups		x		
Interviews				x ^{6m}
Quality Control				

	Baseline	Weekly (1–8)	Week 8	Month s 3, 6, 12 Follow -up
Audit 20% of SCC class tapes				Quarterly
Data Safety Management Board				Quarterly
External independent audit				Annually
IRB review				Annually
IRB audit of consent documents				Periodic

S = Screening; M = monthly during months 1-12; x^{6m} = at six months only; x^{6m,12m} = at six and 12 months only

Table 2**Yoga Program Homework: Tip Sheets, Practice Cards, Readings**

Session	Yoga Homework: Tip Sheets, Practice Cards with demonstration photos, and Readings
Randomization visit	<ul style="list-style-type: none"> • Ready Set Yoga • Directions to the Studio
Week 1	<ul style="list-style-type: none"> • What is Iyengar Yoga and What are Iyengar Props? • Practice card with body scan relaxation • Index of Poses • Helpful tips for a yoga home practice • General Guidelines for a healthy yoga practice • How to use yoga practice sheets
Week 2	<ul style="list-style-type: none"> • Top Ten Reasons to Try Yoga • Practice card with body scan relaxation • 20 Minute Practice for Anxiety
Week 3	<ul style="list-style-type: none"> • Tips for a Great Yoga Practice 1 • Practice card with Breathing Break: Observing the • Breath
Week 4	<ul style="list-style-type: none"> • Yoga Myths Debunked 1 • Practice card with Breathing Break: Observing the Breath • Yoga For Stress Relief by Barbara Benagh
Week 5	<ul style="list-style-type: none"> • Tips for a Great Yoga Practice 2 • Practice card with Breathing Break: • Normal Inhalation, Lengthened Exhalation • 20 Minute Energizing Practice
Week 6	<ul style="list-style-type: none"> • Yoga Myths Debunked 2 • Attending Yoga Studios and Completing Yoga Homework • Practice card with Breathing Break: • Lengthened Inhalation, Normal Exhalation • Review visit to studios homework
Week 7	<ul style="list-style-type: none"> • Yoga For Every "Body" (Types of Yoga) from Yoga Journal • Practice card with Breathing Break: • Lengthened Inhalation and Exhalation • Review visit to studios homework
Week 8	<ul style="list-style-type: none"> • Overcoming Obstacles and Barriers in Your Yoga Practice • Practice card with Breathing Break: • Lengthened Inhalation and Exhalation • 40 Minute Energizing Practice

Session	Yoga Homework: Tip Sheets, Practice Cards with demonstration photos, and Readings
Weeks 9-20	<ul style="list-style-type: none">• 40 Minute Practice for Anxiety
	<ul style="list-style-type: none">• Yoga Maintenance Newsletter & Vouchers

Table 3**Wellness Program Weekly Topics and Content**

	In-person topics	Content
Week 1	Disease prevention	nurse lecture, handouts
Week 2	Stress management	lecture, handouts, stress ball
Week 3	Fruits & vegetables	video, handouts, resource book
Week 4	Emotional well being	lecture, handouts
Week 5	Cancer screenings	MD presentation, handouts
Week 6	Healthy eating	Lecture, handouts, in-class tasting
Week 7	Heart health	nurse lecture, handouts
Week 8	Sound sleep	sleep expert lecture, sleep log, video
Maintenance Period (weeks 9-20) Mailed Information Topics		
Week 9	Barriers and physical activity	Handouts
Week 10	Healthy back	Handouts
Week 11	Humor and health	Handouts
Week 12	Vitamins	Handouts
Week 13	Allergies	Handouts
Week 14	Seat belt safety	Handouts
Week 15	Sun safety	Handouts
Week 16	Environment & food safety	Handouts
Week 17	Preventing colds	Handouts
Week 18	Dental health	Handouts
Week 19	Headaches	Handouts
Week 20	Healthy eating during holidays	Handouts