

A New Educational Film Control for Use in Studies of Active Mind–Body Therapies: Acceptability and Feasibility

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Abstract

Objectives: The study objectives were to ascertain whether a novel educational film class is an acceptable and feasible comparison group for a randomized controlled trial regarding the effects of an active mind–body therapy on cardiovascular disease risk in postmenopausal women.

Methods: Seventy-five (75) participants attended a baseline assessment visit and were randomly assigned to either a yoga group or an educational film (control) group. Both groups attended two 90-minute classes/week for 8 weeks, followed by a second assessment visit. Those not attending the second assessment were classified as dropouts. Over 60 films covering a range of topics relevant to the study population were evaluated; 15 were selected by consensus of at least 2 researchers and 1 layperson. Each film session followed the same format: an informal greeting period, viewing of the film, and a 15-minute postfilm discussion. To determine acceptability and feasibility of the film class, potential between-group differences in dropout and attendance were examined, and participant feedback given during class and on end-of-study questionnaires were evaluated.

Results: The relation between group assignment and dropout was not significant ($\chi^2 [1, N = 75] = 0.14, p = 0.71$). One-way analysis of variance (ANOVA) indicated no significant between-group difference in number of classes attended for the yoga ($X = 13.67 \pm 3.10$) versus film group (13.26 ± 1.97), $F(1,63) = 0.39, p = 0.53$. Participant feedback regarding the film program was positive.

Conclusions: These findings support the feasibility and acceptability of this educational film control. Easy to standardize and tailor to a variety of populations, this film program may offer an attractive alternative to the more traditional educational control.

Introduction

HOW TO DESIGN AN ADEQUATE CONTROL in studies regarding the effects of mind–body therapies on both physical and mental health remains a subject of considerable discussion.^{1,2} Concerns include issues related to recruitment, blinding, differential participant attrition and compliance, and the potentially confounding effects of attention, social interaction, and other nonspecific factors on study outcomes.^{1–3} Incorporation of true placebo controls and blinding of providers and participants to treatment assignment, while easily implemented in pharmaceutical and nutraceutical trials, are challenging and often infeasible in studies of mind–body therapies, especially well-known mind–body therapies such as

yoga. Designing sham interventions for active mind–body therapies that mimic experimental treatment sufficiently to allow blinding of participants and control for nonspecific effects, yet do not operate via similar causal pathways or influence study outcomes, is a daunting, and possibly fruitless, endeavor. While participants can be blinded to study hypotheses, and outcome assessment should be performed by individuals blinded to treatment assignment to reduce bias, choosing an appropriate, acceptable, and feasible comparison condition remains a substantial challenge. Investigators have generally addressed this challenge in one of two primary ways: (1) employing an attention control in an attempt to distinguish the nonspecific effects of treatment; and (2) using an alternative, high-quality active intervention as a comparison condition.

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Among the more common attention controls used in trials of active mind–body therapies involving group interventions are educational programs, discussion groups, and/or regular contacts with staff members.^{4–8} However, these control interventions are not always comparable in time (e.g.,^{5,7}), often do not control for other nonspecific effects of treatment, and may be associated with lower participant satisfaction, greater attrition, and lower compliance.^{1,2} An alternate approach is the use of other credible, high-quality active interventions, such as another mind–body therapy or standard physical exercise as a comparison condition, often in conjunction with a usual-care control. This approach is now increasingly encouraged in the evaluation of mind–body therapies. However, such active control interventions can be problematic, especially in initial efficacy trials, for three reasons: (1) An active, credible intervention is likely to influence study outcomes positively, thus substantially reducing power to detect between-group differences; findings may show no difference even in the face of a powerful experimental group effect, rendering determination of efficacy difficult without large sample sizes (potentially leading to the erroneous conclusion that the experimental treatment is not effective); (2) While justification for use of active control conditions sometimes includes exploration of possible mechanisms of action, such interventions may operate via some, if not all of the same causal pathways as the experimental treatment, further complicating interpretation of findings; and (3) Use of an active intervention with or without a usual care comparison group does not allow control for the nonspecific effects of therapy. Moreover, even in studies that have used either a sham intervention or a credible, high-quality alternative intervention as a comparison condition, differential attrition and adherence, as well as dissatisfaction with treatment assignment, has been reported among controls.²

To address some of these issues, a novel educational film control for use as a comparison group was developed and implemented in a recently completed pilot, randomized controlled trial (RCT) regarding the effects of yoga on cardiovascular disease (CVD) risk in sedentary, overweight postmenopausal women. In this article, the overall study design is outlined, the rationale for choosing a film format is detailed, the methods used to design and implement the film class are described, and the findings are presented regarding feasibility and acceptability of this new film intervention.

Methods and Rationale

Participant recruitment and characteristics

The primary objective of this pilot investigation was to assess the effects of a gentle 8-week yoga program on key indices of CVD risk in overweight, sedentary, but overall healthy postmenopausal women. The study was approved by the University of Virginia Institutional Review Board. Participants were recruited from the community using flyers and local newspaper ads. To enhance credibility and reduce participant bias, the educational film program was presented to potential participants as an informative, engaging, and relaxing alternative to the yoga classes.

Participant eligibility criteria included the following: age range 45–80 years; postmenopausal status (at least 12 months amenorrheic); physically inactive (exercising less than 20 minutes, 3 times per week); and with a body–mass index

(BMI) ≥ 25 , evidence of visceral adiposity (waist circumference ≥ 88 cm), or a first-degree relative with diabetes or essential hypertension. Excluded were women who had practiced yoga within the previous 12 months; were current smokers; had been diagnosed with diabetes, cancer, heart failure, or other serious chronic conditions; or had an orthopedic or neurologic disorder that might prevent them from safely completing an 8-week yoga program. In addition, all participants had to be willing to maintain their current diet, physical activity, and other lifestyle-related practices for the duration of the investigation; reminders to that effect were also given periodically throughout the study. Following provision of written consent, participants underwent a baseline assessment. Upon completion of the 8-week program, participants returned to undergo a follow-up assessment.

Based on sample size calculations, a total of 75 participants were enrolled in three waves from December 2006 through December 2007. The study was powered to meet the primary objective, to determine intergroup differences in specific CVD risk factors related to insulin resistance. As illustrated in Table 1, enrolled participants ranged in age from 45 to 79 years old ($X = 58.8$, standard error = 0.8). All participants were overweight, with BMI averaging 32.0 ± 0.8 kg/m². Over 40% of participants tested in the prediabetic range (fasting blood glucose ≥ 100 mg/dl) at baseline, with an average HbA1c of $5.8 \pm 0.4\%$, and over 30% of participants reported a history of hypertension. Fourteen (14) participants (19%) were from minority populations, 12 of whom were non-Hispanic black.

Outcome assessments

Before and after the treatment period, specific markers of insulin resistance and related physiologic and anthropometric risk factors for CVD were measured; participants also completed well-validated self-report questionnaires measuring specific psychosocial indices of CVD risk, including social support (Duke Social Support Index, abbreviated form⁹). Detailed baseline information was also gathered on medical history, demographic characteristics, and lifestyle factors. A brief questionnaire (the Treatment Expectancy Questionnaire¹⁰) was also administered to all participants to measure expectations of benefit. All assessments were performed by experienced General Clinical Research Center (GCRC) staff and university laboratory personnel blinded to group assignment. All subjects, including those leaving the study prior to completion, were asked to complete a brief, anonymous exit questionnaire. The exit questionnaire included both structured and open-ended questions regarding the participants' experience with the study and investigative staff, and, if applicable, perceived benefits and problems with the intervention, reasons for leaving the study early or not adhering to the study protocol, and other concerns; relevant comments and suggestions were also solicited. Attendance was recorded by the instructor/facilitator at each film and yoga class.

Intervention

Following the baseline assessment, participants were randomly assigned to the yoga ($n = 38$) or the film education (control) ($n = 37$) group using a computer-generated randomization list provided by a statistician not associated with

TABLE 1. PARTICIPANT BASELINE CHARACTERISTICS^a

	Overall (N = 75)		Yoga group (N = 38)		Film group (N = 37)	
	n	%	n	%	n	%
Race/ethnicity						
Non-Hispanic white	60	80.0	29	76.3	31	83.8
Non-Hispanic black	12	16.0	6	15.8	6	16.2
Other	2	2.7	2	5.3	0	0.0
Not reported	1	1.3	1	2.6	0	0.0
Education						
Less than 4 years college	20	26.7	10	26.3	10	27.0
4 or more years college	55	73.3	28	73.7	27	73.0
Employment						
Full time	35	46.7	19	50.0	16	43.2
Part time	17	22.7	6	15.8	11	29.7
Retired/homemaker/unemployed	23	30.7	13	34.2	10	27.0
Marital status						
Married/cohabiting	34	45.3	20	52.6	14	37.8
Divorced/separated/widowed	28	37.3	15	39.5	13	35.1
Single, never married	12	16.0	3	7.9	9	24.3
Not reported	1	1.3	0	0.0	1	2.7
Ever smoked	21	28.0	10	26.3	11	29.7
History of hypertension	23	30.7	14	36.8	9	24.3
Prediabetes (fasting glucose >100 mg/dL)	31	41.3	14	36.8	17	45.9
Age in years (mean ± SE)	58.8 ± 0.8		58.3 ± 1.0		59.2 ± 1.2	
Body mass index (mean ± SE)	32.0 ± 0.8		32.8 ± 1.5		31.1 ± 1.0	

^aNo significant differences between yoga and educational film control groups (*p* > 0.1). SE, standard error.

the study. Each group attended two 90-minute classes a week for 8 weeks. Classes for the two interventions were scheduled at the same times and in similar settings. Class size in both groups was limited to no more than 14 participants. Upon study completion, all participants were given modest compensation for their time and travel expenses. In addition, film group participants were given coupons to attend yoga classes at the local yoga studio where the study yoga instructor taught, as well as all home study materials used by the yoga group. Similarly, yoga group participants were also offered the opportunity to view the educational films after completion of the final assessment.

Yoga program. Subjects in the experimental intervention group attended gentle beginner Iyengar yoga classes specifically designed for this population, and were asked to complete a 30-minute home practice on the days they were not scheduled to attend class. They were provided with a DVD and an illustrated booklet containing two 30-minute yoga routines from which to choose.

Educational film program. Because the staff attention, class time and setting, and social interaction associated with attending yoga classes could potentially influence CVD risk and thus confound any effects observed, the film education program described below was designed to provide comparability with respect to these factors. In developing the film program, more than 60 commercially available documentary and educational (e.g., PBS, Discovery, etc.) films were screened for relevance, accuracy, information content, and likely appeal to the target study population. Each film was screened by a minimum of 2 members of the research team

and 1 layperson not affiliated with the study, and candidate films were selected by consensus. Humorous films or films including footage judged potentially disturbing or unpleasant to view (e.g., graphic footage of surgical procedures) were excluded. A total of 15 films were selected for inclusion in the final program. Films covered a broad range of health topics relevant to overweight, older women, including aging, menopause, diabetes, CVD, and breast cancer risk. The program also provided current information on health-promoting behaviors, mind–body medicine, stress reduction techniques, and other lifestyle-related strategies to manage or prevent heart disease and related chronic conditions, foster healthy aging, and ease the menopausal transition.

Each film session followed a similar format. The class began with an informal meet-and-greet session. After all participants had arrived and settled in their seats, the instructor took attendance, briefly described the film scheduled for that day, turned down the lights, and started the film. Each viewing was followed by a 15-minute discussion of the film, facilitated by the instructor; participants were asked for their thoughts and impressions, and their comments were briefly noted. All participants were encouraged to contribute to the discussion; but no one was pressured to voice an opinion. The facilitator’s role was to keep the conversation moving and to maintain a positive, relaxing environment similar to that experienced by the yoga group participants. Each of the 2 facilitators in this study was a trained clinician, with knowledge of CVD and complementary and alternative medicine.

Rationale

This film attention control was chosen to be developed rather than implementing a more traditional, lecture format

educational control for several reasons: (1) using films would permit us to control not only for staff attention, setting, and social interaction, but also for time without posing an undue burden on controls; in contrast, requiring individuals to attend a 90-minute lecture class more than once per week would likely place an unacceptable burden on controls, and could result in differential dropout among participants assigned to this group (perhaps helping to explain why, in RCTs using an education program as an attention control, education classes are typically offered less frequently than the experimental intervention¹¹⁻¹³); (2) previous studies have indicated that viewing of neutral didactic and/or documentary films has little impact on cardiovascular parameters^{14,15*}; and (3) the film "intervention" could be readily standardized and replicated, and inexpensive to implement.

Analysis

Data analysis was performed using SPSS for Windows, Version 17. Differences between the intervention (yoga) and educational film groups and between dropouts (defined as any participants who did not complete the final assessment) and completers in baseline characteristics were assessed using χ^2 (for categorical variables), Student's independent samples *t* tests (for continuous variables with a normal distribution), or Mann-Whitney *U* tests (for ordinal or continuous variables with evidence of skewing). Acceptability and feasibility of the film control were evaluated as follows: (1) differential attrition was evaluated using χ^2 , (2) yoga versus educational film class attendance was analyzed using a one-way ANOVA, and (3) comments from exit questionnaires were analyzed.

Results

The active intervention and educational film groups did not differ at baseline in demographic characteristics, in lifestyle factors, including physical activity levels and dietary intake, or in anthropometric, metabolic, or psychologic profiles ($p > 0.1$). Participant attrition rates were low, with over 85% (64/75) of participants completing the study. Reasons for dropout included the following: work or other schedule change ($N=4$), work-related emergency ($N=1$), health-related ($N=5$), and long commute in adverse weather conditions ($N=1$). Participants completing the study were similar to those not completing the study in demographic, lifestyle, metabolic, and psychological characteristics ($p > 0.1$). There was no evidence for differential attrition between the yoga (13.2%) and film (16.2%) groups, $\chi^2(1, N=75)=0.14$, $p=0.71$.

Participant attendance at the film classes was good overall, with no difference in the mean number of classes attended by the yoga group ($X=13.7 \pm 3.1$) compared to the film group ($X=13.3 \pm 2.0$), $F(1,62)=0.39$, $p=0.53$. The overall high rates of participant attendance at both the yoga (85%) and the film (83%) classes were particularly encouraging given that there were snowy and icy conditions on

several class days and participants were not given incentives for good attendance.

Participant response to the film program was generally enthusiastic, and film group discussions were lively, with participants often continuing to talk as they left the room. Of the 31 film group participants completing the study, 29 turned in an exit questionnaire. In response to open-ended questions regarding their experiences with the study, 28 (96.6%) of the 29 participants included positive comments about the films they had viewed. Specifically, participants indicated that they found the films interesting and informative and had gained useful new knowledge regarding how to improve their health (77%), that the films had reinforced their own knowledge and beliefs regarding healthy living and/or that the films had been inspiring and enhanced their motivation to make healthy lifestyle changes (40%). In addition, over 50% of subjects ($N=16/29$) cited meeting and interacting with the other group members as a benefit of participating in the study, as did a comparable percentage of yoga group participants (52% of those completing the exit questionnaire; $N=17/31$). Moreover, change in neither social support nor social interaction differed between the 2 groups ($F=0.99$, $p > 0.3$ and $F=0.01$, $p > 0.9$, respectively), offering further evidence that the film intervention program adequately controlled for influence of this potentially confounding factor.

There was no statistically significant difference in the mean treatment expectation scores between the yoga group and the film group (7.5 ± 1.9 versus 6.4 ± 2.6 , $p=0.06$ for expectation of benefit; 6.4 ± 1.6 versus 5.4 ± 2.6 , $p=0.09$ for confidence in expected benefit, based on a 0-10-point numeric rating scale). Additionally, scores were not correlated with change over time in either primary or secondary outcomes of interest.

Discussion

In brief, findings from this study suggest that this educational film control program was both feasible and well-accepted by participants. Recruitment efforts were very successful, with many more potential participants expressing interest than could be enrolled, suggesting that the educational film program was not an obstacle to recruitment. As detailed above, response to the film intervention in this preliminary study was very positive. Discussions among film group participants were lively and comments indicated a high degree of satisfaction with the content and presentation of films shown. Participant retention and adherence were also very good, with film group participants showing no difference from the yoga group participants in either attrition or class attendance. The film classes were designed to provide not only comparable time and setting, but also staff attention and social interaction (in the form of greeting and guided discussion)—factors that may influence the outcome variables and thus are important to consider in studies of mind-body therapies^{2,16}; that change in perceived social support and interaction over time was similar in the yoga and film groups suggests that a structured film program such as this may offer a viable and attractive alternative to the more conventional educational control. Through the use of films, participants can be informed by nationally recognized subject experts on a wide variety of topics in a professional and entertaining way.

*Fang CY. Cardiovascular responses to race-related stressors: The role of hostility and anger. Dissertation Abstracts International: Section B: The Sciences & Engineering, University Microfilms International, 1997.

This film format may thus facilitate delivery of educational material in a manner that may be more engaging and less burdensome than a traditional lecture format, allowing cost-effective implementation of a program that is truly comparable in time, attention, and social interaction to that of the active intervention without compromising recruitment, retention, or adherence. In addition, the film program is easy to standardize and replicate, and can readily be tailored to many different study populations.

Selecting films that hold appeal for the target population appears critical to the success of the educational film control program. While many of the participants reported social factors such as “meeting new people” or “the company of the other women” as among the factors they liked best about the study, all but 1 of the completers cited the film program and/or factors directly related to the film program content (e.g., “I loved the videos! They were most informative.”). Offering both yoga group and film group participants access to the nonassigned intervention may also have aided in recruitment for this RCT as well as enhanced participant satisfaction and retention. For example, during the last film class discussion, 1 participant observed that, while she had initially been disappointed at not being assigned to the yoga group, she had come to feel fortunate that she had been randomized to the film program, because she not only received much valuable information from the film classes, but would then also benefit from attending yoga classes (using study coupons). Many of the other participants who overheard her comment echoed her sentiments. In addition, many participants assigned to the yoga intervention arm expressed interest in viewing the films after completing the study, suggesting again that the control intervention for these studies was perceived positively. While treatment expectation scores averaged marginally higher in the yoga group than in the film group, scores were not correlated with change over time in either primary or secondary risk indices, suggesting that differential expectations of benefit did not significantly influence outcomes in this study.

Limitations

While the findings regarding the acceptability and feasibility of this newly developed attention control are promising, the relatively small size of this study population and the restriction of the investigation to older, overall healthy postmenopausal women limit generalizability to other populations. However, the study included participants from a broad range of ages and occupations, as well as a substantial number of African Americans, suggesting that this control intervention may be attractive to older women from a diverse array of backgrounds. In addition, while the film intervention was presented to prospective participants as an attractive and potentially beneficial program, allocation to treatment could not be concealed in this study, possibly biasing expectations of participants. However, as indicated above, between-group expectancy differences were not significant and were unrelated to outcomes. Finally, no homework practice component was included in this control intervention, precluding controlling for the potential effects of participant effort. A simple homework routine, such as home viewing of short video segments and/or reading

supplementary written materials, could readily be incorporated into this program, likely further strengthening the program’s demonstrated credibility.

Conclusions

Findings from the recently completed RCT regarding the effects of yoga on CVD risk in postmenopausal women suggest that this educational film control was both feasible and well accepted by participants. This program may represent an attractive alternative to the more traditional educational control for several reasons: (1) a structured film program allows control for staff attention, social interaction, and time without posing an undue burden on controls; (2) by using films, participants can be exposed to information on a wide variety of topics, delivered by nationally recognized subject experts in a professional yet entertaining way; and (3) the film control is inexpensive to implement, easy to standardize and replicate, and can be tailored for use in a variety of study populations.

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