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Information without Implementation: A Practical Example for Developing a Best Practice Education Control Group

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Abstract

This paper considers methodology for developing an education only control group and proposes a simple approach to designing rigorous and well-accepted control groups. This approach is demonstrated in a large randomized trial. The Lifestyles trial (n=367) compared three group interventions: 1) cognitive-behavioral treatment (CBT) for osteoarthritis pain, 2) CBT for osteoarthritis pain and insomnia, and 3) education only control (EOC). EOC emulated the interventions excluding hypothesized treatment components and controlling for non-specific treatment effects. Results showed this approach resulted in a control group that was highly

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credible and acceptable to patients. This approach can be an effective and practical guide for developing high quality control groups in trials of behavioral interventions.

Keywords

Control Group; Insomnia; Study Design; Cognitive-Behavioral Therapy

Introduction

Well-designed control groups are essential for scientific evaluation of behavioral interventions, such as cognitive-behavioral therapy. Extraneous factors which may be mistaken for specific treatment effects of behavioral interventions include attention, social support, altered expectations, and changes in patient status not due to the intervention such as regression to the mean or natural history (Borkovec & Sibrava, 2005; Frank, 1961; Lambert & Bergin, 1994; Shapiro, 1971). There is an extensive literature on proper control groups and non-specific effects of participation yielding clinically meaningful benefits (Belanger et al., 2007; Ernst & Resch, 1995; Freedland, 2013; Freedland, Mohr, Davidson, & Schwartz, 2011; Gotzsche, 1994; Hrobjartsson & Gotzsche, 2004; Kienle & Kiene, 1997; Turner, Deyo, Loeser, Von Korff, & Fordyce, 1994). In situations where non-specific effects may contribute to the positive impact of a behavioral intervention, the design features of the control group are essential for obtaining accurate estimates of the efficacy of the treatment intervention being evaluated.

Basic steps in developing a rigorous control group for behavioral interventions include: 1) identifying the active treatment components through which the behavioral intervention influences outcomes, and 2) ensuring that the active treatment and control groups differ as much as possible in the active treatment components, but are as similar as possible otherwise (Safer & Hugo, 2006). While these principles are widely understood, control group design and implementation in behavioral research more often than not fails to put these principles into practice (Baskin, Tierney, Minami, & Wampold, 2003; Critelli & Neumann, 1984; Horvath, 1988; Stevens, Hynan, & Allen, 2000). Commonly used control groups (e.g., wait-list, care as usual, and general education controls) explicitly fail to control for non-specific effects of participation, which may affect patient outcomes and are often poorly accepted by participants, leading to poor subject retention.

Education control groups are commonly used in behavioral interventions. In the case of sleep trials, many previous insomnia intervention studies have employed sleep hygiene information as both a treatment and as a CBT-I comparison control condition (see Stepanski & Wyatt, 2003 for a review). This approach to a control group poses problems, however, due to the fact that there are some behavioral change recommendations included in sleep hygiene materials and that overlap with those in CBT-I. Additionally, sleep hygiene conditions typically do not control for non-specific effects known to be present in group interventions. A few CBT-I studies have attempted to use placebo treatment as a control (see Espie et al., 2012), but these studies have typically been ones that test individual CBT treatments rather than group treatments. The only group CBT-I study we know of that employed a placebo

control group (Rybarczyk et al., 2006) was a stress management intervention offered under the premise that reduction of daytime stress had not been shown to improve insomnia. One drawback to that approach as a control condition was that stress management training could have an impact on daytime functioning and indirectly thus improve sleep.

This paper describes how one research study used control group recommendations to guide the design of a comparison condition in a large randomized trial for insomnia and chronic pain (called Lifestyles) among older persons with osteoarthritis (S.M. McCurry et al., 2014; S. M. McCurry et al., 2011; Vitiello et al., 2013; Von Korff et al., 2012). To summarize the process of designing rigorous and participant-accepted control groups we used the simple phrase *"*Information without Implementation,*"* which means providing educational content and non-specific support to control subjects that corresponds to what is offered in the active intervention arms ("Information"), but excluding the behavioral treatment components that we *a priori* hypothesized were active ingredients of the interventions and that study participants were asked to learn and practice ("Implementation"). This paper describes how a control group intervention designed using this approach achieved favorable patient expectancies and high levels of patient participation and retention. In addition, we discuss factors that could contribute to more widespread use of effective controls in clinical trials of behavioral interventions in the future.

Methods

Design Description

Lifestyles was a double-blind, controlled, cluster-randomized trial with longitudinal assessments of pain, sleep, mood, and function (baseline, 2-month [post-treatment], 9- and 18-month follow-ups). Details of study design, recruitment, and primary pain and sleep outcomes have been published elsewhere (S. M. McCurry et al., 2011; Vitiello et al., 2013; Von Korff et al., 2012). Participants received one of three group interventions: 1) cognitive-behavioral treatment for osteoarthritis pain only (CBT-P), 2) cognitive-behavioral treatment for osteoarthritis pain and insomnia (CBT-PI), and 3) education only control (EOC). Each group consisted of six weekly 90-minute classes conducted by the same two interventionists. During the recruitment process, potential participants were told the study was comparing three treatments that dealt with pain, sleep and activity: one program focused on lifestyle changes, another on relaxation and positive thinking, and a third that combined these approaches. Participants were not informed there was a control group. At the first session, participants were told that they were assigned to one of three treatment conditions that teach participants strategies to help manage osteoarthritis and associated difficulties such as pain and sleep and the purpose of the study was to determine which group might be most effective. Participants were not told how their group differed from any other. Participants received a $50 incentive payment after completing the baseline assessment and attending the first group session. Participants in all groups also received a reminder telephone call from an interventionist one or two days prior to the first class only, and a call for the first unexpected missed class.

Intervention Development

Identifying the active ingredients—The two active treatments (CBT-P, CBT-PI) were designed to test interventions based on biobehavioral models of chronic pain dysfunction (Dworkin, Von Korff, & Le Resche, 1992; Vlaeyen & Linton, 2000) and sleep disturbance (Espie, 2002). Prior to development of the treatment manuals, the pain and insomnia treatment literatures were reviewed and experts in the field were consulted to assist in protocol development. All three groups received copies of The Arthritis Helpbook (Lorig & Fries, 1995) to control for educational content about pain and sleep ("Information") and had comparable social/environmental group experiences. Content in the CBT-P and CBT-PI arms was closely matched for those active ingredients hypothesized based on the treatment literature either to directly produce reductions in pain (activity pacing and goal setting, relaxation instruction, cognitive restructuring) or that are recognized active components in many behavioral interventions (assigned homework, daily monitoring of goals, in-session practice, and problem-solving obstacles to goals). The CBT-PI arm additionally included components designed to impact homeostatic and circadian sleep processes (sleep restriction, stimulus control recommendations). The active components of the CBT-P and CBT-PI interventions all involved participant practice both in and outside of the group sessions ("Implementation"). These active components were broadly categorized into three domain areas (altering activity patterns / attention diversion techniques, changing automatic thoughts, and maintenance) (Table 1). Since the basic pain and sleep education offered in all three treatment arms, and additional educational material offered in the EOC to stimulate group discussion (see below) did not require any additional participant practice, education was not in itself conceptualized as an active treatment component. In addition to classes all participants received a workbook specifically designed for their treatment arm which included educational materials for each session and in the case of CBT-P and CBT-PI homework worksheets, relaxation scripts, and other supporting materials to aid in personal goal setting.

CBT-Pain—The CBT-P arm was based on a previously developed and tested behavioral training program for persons with arthritis pain (F. J. Keefe, Abernethy, & C. Campbell, 2005). Participants were taught strategies for altering activity patterns, attention diversion techniques, relaxation skills, and tools for altering negative pain-related cognitions and emotions. Keefe's training program has been shown to be effective in decreasing pain and disability in older adults with osteoarthritis (OA) knee pain, (F.J. Keefe et al., 1990a; F.J Keefe et al., 1990b) and has also provided the basis for clinical trials showing the efficacy of pain coping skills for treatment of rheumatoid arthritis (Leibing, Pfingsten, Bartmann, Rueger, & Schuessler, 1999; Sinclair, Wallston, Dwyer, Blackburn, & Fuchs, 1998). CBT-P participants developed individualized weekly activity goals and completed daily logs recording their progress following the plan. Both prolonged progressive relaxation techniques and brief "mini-practice" relaxation tools were taught and assigned as homework. In-session planning and between-session monitoring helped to solidify treatment recommendations, and provided a basis for group discussion and problem-solving to overcome any adherence challenges participants experienced with their activity plans and coping skills home practice.

CBT-Pain and Insomnia—The CBT-PI program expanded Keefe's coping skills training program to include well established cognitive-behavior therapy for insomnia active treatment components.(Espie, 2002) Specifically, participants were instructed in the use of sleep hygiene, stimulus control, and sleep restriction techniques that have been shown to be efficacious for treating insomnia in older adults (Morin, 1993; Morin, Colecchi, Stone, Sood, & Brink, 1999) including those with co-morbid medical illness, such as OA (Rybarczyk et al., 2005). In addition to completing activity and relaxation action plans and logs as part of the pain behavioral training, CBT-PI participants received assistance at each group in developing individualized sleep scheduling plans. Sleep efficiency estimates were calculated in session for each participant from the previous week's sleep log, and sleep restriction recommendations were modified (increased or decreased) by group interventionists based upon changes in sleep efficiency over time.

Education Only Control—EOC participants were led in group discussions and personal sharing about educational topics that varied weekly and had face validity for their relevance to living with chronic pain and insomnia. Sample weekly topics included basic education about the causes of OA pain and insomnia, complementary and alternative medical treatments for pain and sleep, and information about pain and sleep prescription medications. Basic information about the topics were provided as a prompt for the group discussions and in cases of components not considered evidence based (e.g., nutrition and sleep), the group leaders would report this so as to not mislead participants. Participants were encouraged to share their personal experiences or thoughts about the topics each week. The emphasis of the sessions was on socialization, establishment of group cohesion, and nondirective information provision.

The EOC group arm explicitly excluded the active ingredients described above that we theorized *a priori* to mediate treatment impact on pain and sleep. For example, although EOC participants received education about the value of maintaining physical activity for reducing OA pain, they received no prescriptive homework assignments from the interventionists, and kept no weekly behavioral logs. Similarly, the EOC group was given information about age-related changes in sleep and primary sleep disorders, but no sleep hygiene education or stimulus control and sleep restriction recommendations. The space provided by the elimination of active treatment components was filled with additional educational materials. We adapted materials from a previously tested control group (Rybarczyk et al., 2005) and included topics that have been shown in previous studies (Teri et al., 2011) to be of general interests to older adults in health promotion programs (e.g., communicating effectively with health care providers). Group leaders were instructed to guide group discussion such that most new information offered on these supplemental topics was provided by fellow group members based on their personal knowledge and experiences.

In combination, these design elements allowed for control of non-specific treatment effects including therapist attention, group social support, treatment duration, basic pain and sleep knowledge acquisition, and therapist quality.

Achieving balance on non-specific effects—In designing the study, treatment fidelity procedures recommended by Lichstein (Lichstein, Redel, & Grieve, 1994) to

standardize treatment dose were followed. All groups met for the same number of sessions, over the same time interval, and all sessions were approximately 90 minutes in duration. All sessions were conducted with both interventionists present. To minimize therapist bias, interventionists were told that the EOC group was an educational comparison condition that included information in a support group format that is widely used and accepted for management of pain and insomnia symptoms in real-world clinical care, but that needed testing in a randomized trial.

Interventionist training and treatment delivery

All sessions of all three treatment arms were facilitated by the same two interventionists. The interventionists were a master's level marriage and family therapist (MS) and a doctoral level psychologist (PsyD). Interventionists received 6 weeks of training by two clinical psychologist co-investigators with substantial expertise and experience in protocol-based cognitive-behavioral interventions for insomnia (SM) and chronic pain (BB). During training interventionists role-played each of the sessions as participants and then role played as the interventionist until they demonstrated proficiency for every session prior to seeing study participants. One of the psychologist co-investigators (SM) observed all six sessions of CBT-P, CBT-PI, and EOC the first time they were delivered to participants, and gave feedback to interventionists immediately after each session. Subsequent sessions were audio recorded and a random sample of recordings (plus any additional recordings that interventionists wanted listened to) were reviewed. Fidelity checklists were used by supervisors to monitor adherence to protocol content, to ensure that there was no contamination of active treatment components into control sessions, and to provide a basis for feedback during weekly group supervision sessions. The supervisor fidelity checklist also included ratings of therapist counseling competence (e.g., reflective listening, participant involvement). Interventionists completed session self-ratings and content checklists to ensure they covered the key topics of each session. Interventionists also highlighted any place they felt they needed review in the weekly supervision meetings with the clinical psychologist co-investigators.

Evaluating Perceived Treatment Credibility

Participation rates—We examined the mean, median, and interquartile range for participation within each arm, and report the results of a non-parametric Kruskall-Wallace test for between-group differences in participation rates. We also examined retention rates between each arm at the 2-month (post-treatment), 9-month, and 18-month follow-up assessments.

Participant Treatment Perception Ratings: We asked trial participants to rate the credibility, acceptability, and perceived effectiveness of their group intervention. Rated items were based on prior work (Morin, 1993) and were: 1) Does this treatment and its rationale make sense to you? 2) How acceptable do you consider this treatment? 3) How suitable is this treatment for improving your quality of life despite having osteoarthritis? 4) How effective do you expect this treatment to be? and 5) How well do you think you will be able to adhere to this treatment program? Ratings were completed at two time points: the end of treatment session 1 (after they had received treatment orientation and rationale relevant to

their treatment group), and again as part of the 2-month post-treatment assessment (rated at that time in the past tense; for example, “Did this treatment and its rationale make sense to you?”). All items were rated on a scale from 1 (low) to 7 (high). We examined the percentage of patients indicating a high positive perception rating (5+ out of 7) across the three treatment arms and report the results of a chi-squared test of between group differences.

Results

Trial Sample

The Lifestyles trial included 367 participants (mean age=73.1 years; 78.5% female) assigned to the three treatment arms (EOC =123, CBT-P = 122, and CBT-PI = 122). Participants did not differ significantly across treatment arms by age, gender, ethnicity, education, or by primary or secondary outcome measures at baseline. There were 39 groups assigned across the three arms, with 14 groups assigned to EOC, 12 groups assigned to CBT-P, and 13 groups assigned to CBT-PI. There was an average of 9.4 participants per group; the largest group had twelve participants and the smallest had five participants (Vitiello et al., 2013; Von Korff et al., 2012).

Participant Session Attendance

The mean number of sessions attended out of six was high for all three treatment arms (CBT-P = 5.12 [SD=1.20]; CBT-PI = 5.34 [SD=1.23]; EOC = 5.39 [SD=1.13]). Given the distribution of the session attendance data, median and interquartile ranges (IQR) for each arm were compared rather than mean values (EOC Mdn=6 [IQR =5-6], CBT-P Mdn=5 [IQR=5-6], CPT-PI Mdn=6 [IQR=5-6]. The chi-square of the Kruskall-Wallis test for between group differences was significant (X^2=9.28, df=2, p = 0.0096).

Participants’ Perceptions

Participants’ pre- and post-intervention perceptions of the credibility, acceptability, and perceived effectiveness of their group intervention are displayed in Table 2. At the end of the first group session participants were asked to rate what they thought of the overall program after it was explained to them, overall the large majority of participants in all three groups gave the high (5+) ratings on all items (EOC high rating range: 70.3-82.0%, CBT-P range: 79.3-89.3%, and CBT-PI range: 70.9-82.2%) (Table 2). Chi-square analyses showed significant between group differences on two items: 1) “How suitable is this treatment for improving your quality of life despite having osteoarthritis?” (p = .03) with higher ratings for the CBT-P (83.5%) and very similar ratings for the EOC (70.3%) and CBT-PI (70.9%) groups, and 2) “How well do you think you will be able to adhere to this treatment program?” (p = .02) with the highest rating for the CBT-P (89.3%), followed by the EOC (82.0%) and the CBT-PI (75.2%) groups. At post-treatment assessment, ratings declined somewhat but generally remained moderate to high for all groups (EOC high rating range: 44.8-69.6%, CBT-P range: 58.8-79.8%, and CBT-PI range: 66.1-83.0%). Chi-square between group analyses showed significant differences for three items: 1) “Did this treatment and its rationale make sense to you? (p = .003) (EOC=63.5%, CBTP=76.3%, CBT-PI=83.0%); 2) How suitable was this treatment for improving your quality of life

despite having osteoarthritis? (p = .006) (EOC=52.6%, CBT-P=69.0%, CBT-PI=71.2%) and 3) How effective do you expect this treatment to be? (p = .004) (EOC=62.0%, CBT-P=58.8%, CBT-PI=69.2%).

Participant Study Retention

Study retention at each follow-up assessment was high for participants in all treatment arms and highest in the EOC condition. Among the 367 participants enrolled, the retention rates at post-intervention follow-up were 97.5% for CBT-P participants, 93.4% for CBT-PI participants, and 99.2% for EOC participants. At nine months, study retention rates were 91.8% for CBT-P participants, 89.3% for CBT-PI participants, and 97.6% for EOC participants. The observed 18-month retention rates were 86%, 83% and 93% for CBT-P, CBT-PI, and EOC respectively. Although retention rates were high for all three treatment arms, the observation that they were actually somewhat higher for the EOC group than the active treatments was not statistically significant ($X^2 = 5.58$, df=2, p=.06).

Fidelity Monitoring

Interventionists completed content checklist ratings at every session to ensure that they stayed adherent to key session components. All group sessions were audio-recorded. Ten percent of these recordings were randomly sampled and reviewed by a supervisor using the fidelity checklist. In addition, full or portions of sessions were reviewed upon request of the interventionists. Checklist ratings and audio-recording reviews provided the foundation for weekly supervision sessions with the interventionists. All group sessions had very high fidelity ratings with ratings of 95% or greater for content and counseling skills and no between-group differences. Any areas not meeting fidelity criteria were corrected at the next session, for example, an educational component missed in one session was reviewed at the next session, thus ensuring all content was covered.

Discussion

In the Lifestyles study, “Information without Implementation” was used to guide the successful design and execution of a control arm that was observed to have favorable perceptions of face validity, group attendance, and long-term study retention. When compared to two active behavioral interventions we observe some differences in attendance and perception between the randomization arms, but these differences are not large suggesting participants in the control group did not reject the idea that the control arm was a viable treatment option. We suggest that the phrase “Information without Implementation” offers a simple tool for remembering and implementing steps in the design of credible and acceptable control groups for behavioral interventions. The essence of this tool involves identifying active ingredients of treatment interventions, and developing a control arm that includes non-specific effects and education in all intervention domains (“Information”), but without including any hypothesized active ingredients participants are asked to learn and practice (“Implementation”).

Drawing on experience from the Lifestyles randomized controlled trial, we found that a control arm developed following this approach was acceptable and credible to participants.

Control arm members' participation in the intervention sessions was high and on par with the active treatment arms; in fact, when comparing attendance data for all three groups, median and interquartile ranges for the EOC and CBT-PI groups were similar and had higher attendance observed than the CBT-P group. We observed differences between the treatment group for treatment suitability and projected ability to adhere to treatment recommendations, with the greatest number of participants in CBT-P giving high ratings (5+), followed by EOC and CBT-PI (Table 2). At post intervention assessment, there were no statistically significant or meaningful differences between groups on the questions regarding treatment acceptance or beliefs about adherence ability. The questions regarding treatment rationale, and suitability showed statistically significant differences between the groups with the greatest proportion of CBT-PI participants giving high ratings, followed by CBT-P and then EOC. There was also a statistically significant between group difference on the question regarding perceptions of effectiveness, with the EOC group having the lowest number of high ratings at follow-up. Between-group differences of early participant perceptions regarding treatment rationale, acceptability or effectiveness were not clinically meaningful nor statistically significant. Although perceptions of the participants assigned to the control arm regarding effectiveness decreased marginally over time, a majority of control arm participants continued to rate it highly. This decrease in perceived effectiveness was not unexpected since many participants in the control arm did not experience improvements in their sleep and pain symptoms. Nevertheless, study retention of EOC participants remained high (in fact, higher than the other two conditions, although not statistically so) throughout the 18-month follow-up, indicating sustained enthusiasm for study participation comparable to that in the other active intervention arms. We found this an encouraging finding because dropout rates are often the highest amongst control groups.

A limitation of the current analysis is that we did not perform statistical tests aimed to formally test equivalency of the treatment groups. Future work should explore what are potential equivalency boundaries for perception, attendance and retention rates that would be regarded as clinically equivalent outcomes and future studies could use these boundaries in formal statistical equivalency tests. An additional limitation of the current study is that we cannot directly compare an "Information without Implementation" control group to a general education, treatment as usual, or waitlist control. Research comparing these two control designs would be needed to draw direct comparison conclusions. However, results do stand in contrast to other studies that utilized wait list or information-only controls and experienced substantially higher participant attrition than seen in Lifestyles. For example, one study examining CBT-I versus a waitlist control in fibromyalgia patients reported only 9 of 11 (81%) usual care control subjects completed post treatment assessment and 7 of 11 (63%) completed 6-month follow-up (Edinger, Wohlgemuth, Krystal, & Rice, 2005).

Another limitation and challenge to comparing different treatments and a control group is making the structure of the groups similar. Although we were able to implement many structural similarities (e.g., number of session, session length, same therapist) we did not do so for other possible variables such as the provision of homework for the control group or the same number of topics per session across arms. For example, given that the pain group had fewer topics than the pain and sleep group, that group was able to spend more time on each particular pain topic. Researchers in future studies will be challenged with similar

decisions regarding balancing methodological equalities against practical implementation of appropriate intervention components.

It should also be noted that there may be circumstances in which a no-treatment or treatment as usual control arm is appropriate. Certainly these designs offer important financial advantages. Researchers may want to consider a treatment as usual control arm when there is a standard practice already in regular use. A no treatment arm may be useful in demonstrating intervention differences from an education only control group, and may be particularly useful when there is high level of uncertainty regarding possible active treatment components which could create the risk of a control group with treatment effects. However, researchers utilizing these types of controls need to be aware that particularly in behavioral research, such approaches typically fail to control for non-specific effects of an intervention so actual active treatment effect sizes may be smaller than they appear when only tested against a no-treatment comparison.

The use of the same interventionists in the current study to run all groups was both a strength and a weakness. Utilizing the same therapists can reduce therapist effects and is more cost efficient. However, it also makes it more difficult to maintain therapist allegiance to the control group, and requires continual monitoring to ensure that there is no spillage of active treatment components over into control group sessions. Despite our best efforts we cannot be certain that therapists did not know the EOC group was an active control group and how that may have impacted how they ran the groups. Given that this study did not employ a fidelity measure regarding this level of potential therapist bias we are limited to the implementation fidelity checklist which did in fact measure how well they adhered to the treatment protocol and checked for possible drift however there may be more subtle forms of therapist bias in this areas we did not assess. This is a common dilemma for trial development, deciding if the same therapist for the different arms will help reduce therapist bias or if the same therapist will reduce therapist effects. This must be considered when developing the trial, subsequent training, and analysis plan. The lack of independent/blinded fidelity ratings on a random subset of taped sessions is also a potential limitation of the study, and future investigators should consider adding this evaluation component if ratings are being used by supervisors as part of ongoing clinical monitoring.

Lastly, as in any study, the sample itself must be considered. We do not know if there is something unique about our study population such as older age, co-morbid osteoarthritis pain and insomnia, or other sample characteristics which may have influenced the acceptability of the provided education only control group. This may be addressed in the future if other studies decide to adopt the suggested control group development methodology with different populations.

Although conceptual guidelines for developing effective control groups in behavioral studies have been described, (Safer & Hugo, 2006) they are rarely implemented. A number of factors likely contribute to this failure. The hypothesized mediating variables through which treatment influences outcomes are not always as well understood or defined as they are for sleep and pain, making it difficult to develop a control group that deliberately removes these active ingredients while retaining nonspecific treatment elements. Rigorous behavioral

control groups are also more expensive to implement than wait-list, care-as-usual, or booklet education conditions. Although this is not a small consideration in an era of shrinking health care and research budgets, the design of the control group is nevertheless essential to the ability of a randomized trial to estimate specific intervention effects and to differentiate them from non-specific effects of attention and favorable expectations of participants. Thus, the challenge and expense involved in designing a good control group simply needs to be faced head-on to the extent possible.

In conclusion, the Lifestyles trial demonstrates the successful development and implementation of a viable education only control condition for a behavioral trial examining chronic pain and insomnia that was both highly credible and acceptable to patients. This comparison condition could serve as a possible control for other trials in these topic areas and certainly there is a history of viable control groups these areas (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Germain et al., 2012; Rybarczyk et al., 2005), but more importantly the concept of “Information without Implementation” may serve as a practical model for control development in other areas. .

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Table 1

Session content and information domain area for each of the study arms.

Session	EOC	CBT-P	CBT-PI
1	• Facts about OA pain and sleep	• Facts about OA pain and sleep • Pain management rationale • Goal setting	• Facts about OA pain and sleep • Pain management rationale • Goal setting • Sleep hygiene • Stimulus control
2	• Medication education for pain and sleep	• Physical activity goal setting • Progressive muscle relaxation training • Goal setting	• Physical activity goal setting • Progressive muscle relaxation training • Goal setting; • Sleep restriction • Development of individualized sleep scheduling plan
3	• Complementary and alternative medical treatments for pain and sleep	• Mood and pleasant activity scheduling • Mini-practice relaxation • Activity and relaxation goal setting	• Mood and pleasant activity scheduling • Mini-practice relaxation • Activity and relaxation goal setting • Sleep diary review and sleep plan modification
4	• Nutrition for health, pain and sleep	• Activity pacing; mini-practice relaxation • Activity and relaxation goal setting	• Activity pacing; mini-practice relaxation • Activity and relaxation goal setting • Sleep diary review and sleep plan modification
5	• Improving memory and communication with healthcare providers	• Automatic thoughts and feelings • Progressive muscle relaxation • Activity and relaxation goal setting	• Automatic thoughts and feelings • Progressive muscle relaxation • Activity and relaxation goal setting • Sleep diary review and sleep plan modification
6	• Topic review and sharing	• Activity and relaxation maintenance plans • Mini-practice relaxation	• Activity and relaxation maintenance plans • Mini-practice relaxation • Sleep diary review and final sleep plan recommendations

Table 2

Percentage of participants within each treatment arm reporting a score of 5 or greater (range 0-7) on the perception scores, at the end of treatment Session 1 and at the 2-Month (Post-Treatment) Assessment.

	Session 1				Post Treatment			
Assessment Question	**EOC n=122**	**CBT-P n=121**	**CBT-PI n=118**	a_p	**EOC n=116**	**CBT-P n=114**	**CBT-PI n=112**	a_p
1. Does this treatment and its rationale make sense to you?[b]	81.2	87.6	82.2	.35	63.5	76.3	83.0	.003
2. How acceptable do you consider this treatment?	80.3	89.3	79.5	.08	69.6	79.8	82.1	.06
3. How suitable is this treatment for improving your quality of life despite having osteoarthritis?	70.3	83.5	70.9	.03	52.6	69.0	71.2	.006
4. How effective do you expect this treatment to be?	80.3	79.3	74.4	.49	44.8	58.8	66.1	.004
5. How well do you think you will be able to adhere to this treatment program?	82.0	89.3	75.2	.02	62.0	58.8	69.6	.22

[a] Between group chi-square test.

[b] Questions presented are for Session 1, verb tense was changed to the past at post treatment assessment.