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Background: Clinical practice and randomized trials often have disparate aims, despite involving similar interventions. Attitudes and expectancies of practitioners influence patient outcomes, and there is growing emphasis on optimizing provider– patient relationships. In this study, we evaluated the experiences of licensed massage therapists involved in a randomized controlled clinical trial using qualitative methodology.

Methods: Seven massage therapists who were interventionists in a randomized controlled trial participated in structured interviews approximately 30 minutes in length. Interviews focused on their experiences and perceptions regarding aspects of the clinical trial, as well as recommendations for future trials. Transcribed interviews were analyzed for emergent topics and themes using standard qualitative methods.

Results: Six themes emerged. Therapists discussed 1) promoting the profession of massage therapy through research, 2) mixed views on using standardized protocols, 3) challenges of sham interventions, 4) participant response to the sham intervention, 5) views on scheduling and compensation, and 6) unanticipated benefits of participating in research.

Conclusions: Therapists largely appreciated the opportunity to promote massage through research. They demonstrated insight and understanding of the rationale for a clinical trial adhering to a standard-ized protocol. Evaluating the experiences and ideas of complementary and alternative medicine practitioners provides valuable insight that is relevant for the implementation and design of randomized trials.

KEY WORDS: massage therapist; practitioner perceptions; research design; complementary and alternative medicine; qualitative research

INTRODUCTION

Emerging evidence demonstrates the efficacy of massage in reducing pain, altering lymphocyte production, improving neuromuscular function, increasing attention, and reducing depression and aggression.⁽¹⁻³⁾ In addition to biological and clinical markers that influence healing, growing research suggests that the attitudes, expectancies, and perceptions of health care providers may largely influence patient outcomes.⁽⁴⁾ Providers involved in research may be unfamiliar with the rationale of clinical trial design and procedures, and clinicians may need to be reminded of the purpose during a research trial.⁽⁵⁾

The practitioner–patient relationship is especially important in many complementary and alternative medicine (CAM) approaches, given the emphasis on shared decision-making, empowerment, and patientcenteredness.⁽⁶⁾ Literature consistently supports the importance of perceived clinician expertise, shared mission or goals, and perceived bond or connection between patient and provider for enhancing outcomes.⁽⁴⁾ However, relatively few studies have aimed to elucidate this patient–provider relationship by analyzing perceptions and viewpoints of CAM providers.

Several studies to date have assessed the feedback of acupuncturists who participated in clinical trials, focusing largely on their opinions surrounding the inclusion of a sham control group.⁽⁷⁻⁹⁾ Similar to acupuncture trials, massage interventions are challenging in that control groups are not intuitive or easily standardized. Nonetheless, clinical research often requires a randomized controlled trial (RCT) design that uses a control group.⁽¹⁰⁾ Clinical trials of massage have controlled for nonspecific effects using a light pressure control intervention.⁽¹¹⁻¹⁴⁾ During the light touch control, a therapist places his or her hands on the body for a specified period of time, controlling for the time that clients interact with a therapist, as well as the type of physical contact they receive, without the perceived 'active' motions of massage therapy.

Such control groups have their unique implications for complementary and integrative medicine research. Light touch may raise suspicion with participants as an "obvious sham," complicating and confounding research findings because of patients' expectation bias.⁽¹⁵⁻¹⁷⁾ An expectation bias exists for providers as well, since performing such a treatment may be perceived as being inauthentic. A massage therapist often engages in conversation with the client during a session, so any awkwardness may be communicated to the patient, further confounding expectations and results.

Considering the role of the provider in CAM research, the experiences and perceptions of providers should be considered when designing clinical trials. Qualitative research conducted on structured interviews provides an opportunity to assess such feedback in a systematic manner.⁽¹⁸⁾ Thus, we designed a qualitative study of licensed massage therapists (LMT) who had participated as interventionists in the same randomized controlled trial. The purpose of the current study was twofold: to assess the experiences of LMTs involved in a clinical trial, and to consider the relevance and importance of this information for the design and implementation of future research in CAM.

METHODS

Study Design and Sample

This was a qualitative study based on interviews with LMTs who had participated in a randomized multisite clinical trial.⁽¹⁹⁾ All LMTs in the underlying trial participated in this study. Interview questions were adapted from previous studies of provider perceptions (see Table 1).^(7,9) Interviews lasted approximately 30 minutes, were conducted by a single investigator (TK), and occurred either by phone or in-person. Interviews occurred independently to ensure providers would not be influenced by others' responses. LMTs had no knowledge of underlying study results at the time of the interview. This protocol was approved by the Duke University School of Medicine Institutional Review Board.

Description of the Underlying Trial

The LMTs had participated in a randomized, threearm, multisite clinical trial comparing the effects of a Swedish-style massage to a light touch control and a usual care group for treatment of osteoarthritis of the knee.⁽¹⁹⁾ The standard Swedish full-body massage followed a protocol that specified the body regions and the standard Swedish strokes to be used.⁽¹⁴⁾ The control (light touch) methodology was first developed by Patterson et al.⁽¹¹⁾ Example instructions for the LMT in this condition were: "Both hands are placed on the right shoulder blade. Pressure will be light and consistent for approximately 40 seconds." The control intervention was performed by the same LMTs delivering the massage intervention.

Data Analysis

Interviews were recorded, transcribed, and reviewed for accuracy (TK). The transcripts were independently analyzed by three reviewers (AA, TK, AP) using standardized methods of content analysis.^(20,21) Reviewer comments were analyzed to identify common categories or themes using an iterative process.^(22,23) This process involved independent identification of categories, followed by a discussion of common ideas, then subsequent readings of the transcript that confirmed seven categories: 1) LMT expectations, 2) standard massage, 3) light touch protocol, 4) light touch deception, 5) research logistics issues, 6) future recommendations, and 7) other. Once categories were established, two coders (TK, MD) assigned codes to specific statements in each transcript. Coded items mentioned by a majority of LMTs (4 of 7) were considered themes. Participants (LMTs) were not involved in analysis or interpretation of the data.

RESULTS

Participants

All seven licensed LMTs from the underlying trial participated in this qualitative study. Six were female, and average massage experience was 16 years, ranging from 4 to 25 years. Four LMTs had master's degrees, two had bachelor degrees, and one had some college and military training. One had previous experience working in a research study.

Themes

Six themes emerged from the interview transcripts: 1) promoting massage through research, 2) pros and

TABLE 1. Interview Questions

^{1.} What were your expectations regarding the experience of being a massage therapist for a clinical trial? How were your expectations the same or different than the actual experience?

^{2.} How did you feel about giving a standardized massage session; i.e., following a prescribed protocol?

^{3.} How did it feel to give the light touch (placebo/sham) treatment to your participant?

^{4.} When giving the light touch treatment, how did it feel to not be able to tell your participant about the true nature of the intervention?

^{5.} What recommendations do you have for researchers who are planning future massage studies?

^{6.} What was your motivation or reason for working on a massage research study?

^{7.} What perceptions of the study were shared with you by your colleagues that were not working on the study?

^{8.} Any other comments or suggestions?

cons of a standard massage protocol, 3) challenges of the sham massage, 4) participant response to light touch, 5) logistics (scheduling and compensation) and 6) unforeseen benefits of participating in research.

Theme #1: Promoting massage through research

LMTs reported eagerness to learn about the research process. Three LMTs mentioned burgeoning interest among their peers and colleagues for massage research. Two LMTs expressed the hope that studies could validate massage for insurance reimbursement.

"More and more people are looking at massage as legitimate health care, and when you do that, they always ask you for research." (LMT #4)

Five LMTs said they were open-minded and curious about participating in a research study. "I didn't really expect a lot. It was just kind of like, what is it like? What do I have to learn? How do I have to behave?" (LMT #1) Three LMTs also expressed appreciation for the opportunity to promote massage in a systematic and methodological way.

"The biggest thing was to have an impact on the way potential clients or other medical professionals view our work, so [...] people view massage as a preventative or remedy to their symptoms, rather than just a feel good thing they do occasionally." (LMT #5)

Theme #2: Pros and cons of a standard massage protocol

This theme focused on the protocol used for the Swedish massage intervention. Despite using the same series of techniques and strokes for each massage session, two LMTs noted the massage could still feel individualized. "Even though we're doing the same procedure, same type of massage, same strokes, same protocol, it feels different with each person." (LMT #3) LMT #2 mentioned even incorporating some of the procedure in their private practice.

Three LMTs said implementing a standardized protocol was challenging because it was not consistent with individualized clinical practice. Two LMTs mentioned this was especially difficult when participants were in pain or requested specific areas on which to focus.

"If we feel something under our hands, we are just so used to trying to correct the problem in our own way that we know how, and you just can't do that. You have to follow the protocol." (LMT #3)

However, LMTs acknowledged the importance of adhering to a protocol: "I understood why this is necessary, because you want to compare apples to apples between different therapists." (LMT #6) LMTs found themselves adopting the routine after several sessions. Similarly, participants began knowing what to expect. "I got into a rhythm and got more comfortable, [and] after a while, the clients knew what to expect every time they got on the table." (LMT #4)

Theme #3: Challenges of the "light touch" sham massage

All seven LMTs said the "light touch" control, where LMTs placed their hands on the participant for specified periods of time, had unique challenges.

"It wasn't as relaxing to me as I thought it would be. It ended up being more tension than actually doing real bodywork." (LMT #4)

Two LMTs said it was uncomfortable maintaining an open, honest practitioner-patient relationship while keeping the participant blinded to their randomization. "I ended up feeling like a fraud, like I was telling them it was a massage, but we knew it really wasn't." (LMT #6) Two LMTs mentioned it was important to allow participants to form their own perceptions. Five LMTs shared what they said during the light touch when participants would ask, "What are you doing?" Responses included: "They are trying to determine whether it's actually manipulation of the soft tissue or it's simply touch." (LMT #7) "This is a form of compression." (LMT #2) "This isn't Reiki." (LMT #5) "If you have specific questions, you need to ask the study staff." (LMT #6)

Two LMTs said that clients would confuse the light touch with Reiki, which involves placing the hands on the recipient in various positions.⁽²⁴⁾ The protocol for light touch instructed LMTs not to use any healing intention. Three LMTs said this was challenging. Three LMTs expressed difficulty not using any healing intention in this condition. "That was the hardest piece of being in the study. It kind of asks us not to do one of the fundamental pieces of our work, by having that healing intention and to send good energy to the client." (LMT #7) Despite some discomfort with performing light touch, however, LMT comments reflected understanding the rationale of a control intervention.

Theme #4: Participant response to light touch

Two LMTs reported that clinical trial participants expressed skepticism of the light touch intervention, and three LMTs were surprised that clinical trial participants appreciated this treatment.

"At first I was like, no one is going to go for this, this is going to be a joke. Then some people took it really seriously, which was great." (LMT #2)

Two LMTs mentioned that study participants who enjoyed this intervention had never received a massage. Three LMTs speculated why clinical trial participants appreciated these light touch sessions, with general consensus that it was the time and attention. "Some people actually said it feels wonderful. Some of them, they actually still walk away feeling like it's the best 50–55 minute they've had all day." (LMT #5) Two LMTs further commented that older study participants seemed the most grateful, and it was encouraging to see positive effects. "They are very appreciative, the older people. I think just being touched and cared for, for an hour, it means so much to them." (LMT #3)

Theme #5: Logistics (scheduling and compensation)

The underlying clinical trial compensated LMTs for completed massages and thus not for no-shows. Six LMTs expressed some frustration with this policy.

"When massage therapists are not working, they are not making a living. It's a challenge to look at how we schedule and how much time we keep open for a study and not have clients." (LMT #7)

Three LMTs expressed concern that clinical trial participants were not motivated to show up, since they were not penalized for missed appointments. "They are still getting these freebies, even when they miss one, and I think they should be docked one when they do that." (LMT #2) Two LMTs suggested the research protocol include ways of better incentivizing participants to show up for appointments.

Another LMT proposed that the LMTs schedule appointments themselves rather than adhere to the study protocol, which prohibited LMTs from contacting participants directly. One LMT suggested that LMTs make personalized reminder calls to help increase retention.

Two LMTs offered feedback regarding scheduling of appointment times, requesting that research appointments be grouped back-to-back to prevent traveling multiple times in one day.

Theme #6: Unforeseen benefits of participating in research

Four LMTs mentioned unexpected benefits from participating in a research study.

"One of the most fulfilling things is when participants who have never had a massage before, they are pleasantly surprised at how great they feel physically and some of them also emotionally [...] and how it's changed how they think about massage." (LMT #5)

Two LMTs said they liked being part of a collaborative academic research team that focused foremost on the well-being of the patient. "This is great teamwork. I feel like we are all supporting each other, and I see that everybody on this team is concerned about the population as individuals. It's not just a cut-and-dry experiment. I appreciate that there is a real human element to it." (LMT #1)

DISCUSSION

This study assessed perceptions of LMT providers who had participated in a randomized controlled clinical trial of massage therapy. The themes that emerged from interviews involved lessons learned by the LMTs, their experiences following a set treatment protocol, their perceptions of a sham massage intervention, and logistic feedback regarding scheduling and compensation. Our findings both reflect the results of similar studies⁽⁷⁻⁹⁾ and raise important issues that can be considered when designing future massage studies.

LMTs were exposed to the considerations of a randomized controlled trial, such as the importance of using a prescribed intervention. Although LMTs could not tailor the massage to the individual participant needs as they might in community practice, they understood that a standardized protocol was necessary to ensure internal validity.

The light touch control intervention was met with apprehension. While LMTs understood the theoretical rationale for control interventions, some LMTs felt disingenuous administering light touch when participants were expecting a massage; others assumed participants would believe it was a sham treatment. On the positive side, however, LMTs were pleasantly surprised when participants actually enjoyed the light touch intervention, speculating that participants still appreciated the time, attention, and opportunity to relax and talk. This reflects findings from Patterson et al.⁽¹¹⁾ who found that, at the end of a sham massage, all participants still had positive feedback about their experience.

There were both similarities and differences among our study findings and those of acupuncturist perception studies.⁽⁷⁻⁹⁾ In a 2012 publication, acupuncturists involved in a clinical trial reported that a standardized protocol and sham acupuncture was easier than normal practice, given the treatment required less evaluation of symptoms and used predetermined acupuncture points.⁽⁷⁾ However, LMTs in the current study initially found research protocols to be more difficult than real world practice. This difference between acupuncturists and LMTs perceptions may be attributed to LMTs' sessions involving nonstop hands-on work for the duration of the treatment. On the other hand, one consistency between our results and studies of acupuncturists was that practitioners were pleasantly surprised when patients reported benefit from a sham treatment. This led the interventionists to consider the positive impact of nonspecific effects (e.g., being taken care of, receiving attention, and having the chance to relax).

Future investigators may want to not only consider providers' perceptions at the conclusion of the study, but also monitor feedback throughout the study. McManus et al.⁽⁹⁾ recommended that observation of study providers' interactions and frequent meetings were necessary to maintain quality control. The current study supported this idea, finding that LMTs responded in various ways to participants' questions regarding the light touch control intervention (theme #3). For example, telling the participant that "this is a form of compression" may have different implications than "they are trying to determine if it's manipulation of the soft tissue or simply touch." The former suggests the participant may expect benefit, and the latter contextualizes the treatment as a control group. Future studies may wish to consider standard language for practitioners to describe the control intervention, as well as ongoing assessments that ensure providers are responding to participants in a consistent manner.

Finally, there were concerns that arose only during the qualitative interviews for this study; for example, the research protocol overlooked that LMTs would not be compensated for patient no-shows. Participants, on the other hand, were rescheduled, leaving LMTs to feel patients had no real incentive to attend their appointments. This issue highlights a common oversight in clinical research where participant needs and clinical trial logistics may be prioritized over research staff concerns.

Given the crucial role of the patient–practitioner relationship in behavioral and nonpharmacological interventions,^(4,6,25) we propose the role of patient and practitioner be considered equally important in complementary and integrative medicine trials. Soliciting and analyzing provider feedback may help identify any inconsistencies between the priorities of study participants and interventionists.

We acknowledge several limitations of the current study. Since our inquiry was restricted to seven LMTs, the generalizability of our findings is limited. It would be interesting with a larger sample, for example, to note any differences in perception based on practitioner experience, education level, or previous research experience. Furthermore, a massage intervention cannot be identical provider-to-provider, patient-to-patient, or even between the same provider and patient at different times. This not only introduces bias (performance bias and expectation bias), but it may also limit the generalizability of the perceptions and viewpoints provided here.

There are also strengths of the current study. This is the first time the experiences of LMTs have been systematically assessed after participating in a randomized, controlled trial. Whereas other health care professionals may have more experience with the use of RCTs, all LMTs in this study still recognized the importance of such research. They also identified complexities that arise from a standardized treatment and a control group. Finally, all LMTs from the underlying RCT voluntarily participated in the interviews. Data were collected before knowing the results of the RCT, thus eliminating this as a source of bias.

CONCLUSION

LMTs were largely appreciative for the opportunity to promote the profession of massage therapy through research. They learned the importance of a set protocol, identified the necessity and peculiarities of a sham control group, and raised important logistical issues for future study coordinators. Feedback from research practitioners should be routinely included in ongoing study assessments. Evaluating the experiences of CAM providers participating in clinical trials can provide insight into more effective study design and have important clinical implications.

CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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