R E S E A R C H

The Intersection of Massage Practice and Research: Community Massage Therapists as Research Personnel on an NIH-funded Effectiveness Study

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Introduction: **Few NIH funded studies give community massage therapists the opportunity to become study personnel. A recent NIH/NCCAM-funded study investigating chronic low back pain (CLBP) recruited, trained, and utilized community massage practitioners (CMPs) as study personnel. This study's aim was to determine whether health-related outcomes for CLBP improve when patients are referred from primary care to select CAM modalities including massage therapy (MT). The purpose of this paper is to report the results of the study's three massage practice-driven study objectives which were to: 1) identify challenges and solutions to recruiting and retaining ample CMPs, 2) develop a practice-informed protocol reflecting real-world MT, and 3) determine the extent to which CMPs comply with rigorous research methodology in their clinical practices as study personnel.**

Methods: **Eligible CMPs in urban and rural Kentucky counties were identified through licensure board records, professional organizations, and personal contact opportunities. Interested CMPs completed 6 CE hours of research and Human Subjects Protection training and agreed to comply with a study protocol reflecting MT as practiced. Once trained, study CMPs were matched with study participants to provide and document up to 10 MT sessions per participant.**

Results: **Utilizing prominent MT community members proved invaluable to CMP recruitment and protocol development. CMP recruitment challenges included mixed interest, low number of available rural CMPs, busy clinic schedules, and compensation. Ethics CE credits were offered to encourage CMP interest. A total of 28 Kentucky licensed massage therapists with 5–32 years of experience completed study training. A total of 127 CLBP patients consented to participate (n = 104 for MT). Twenty-five CMPs were assigned CLBP patients and provided 1–10 treatments for 94 study participants. Treatment documentation was provided by CMPs for 97% of treatments provided.**

Conclusions: **When recruitment, retention, and protocol compliance challenges are met, CMPs are valuable study personnel for practice-based research reflecting real-world MT practice.**

KEY WORDS: practice-based research networks; chronic low back pain; licensed massage therapists; methods; clinical trial; real-world massage practice

INTRODUCTION

Large National Institute of Health (NIH)-funded studies are beginning to utilize community massage practitioners (CMP) to deliver therapeutic interventions in research protocols examining massage therapy (MT)[1-3]. With the move away from considering only randomized controlled trials (RCTs) as significantly contributing to an intervention's evidence base in primary care[4-6] and complementary and alternative medicine (CAM)[7-10], more involvement from CMPs is needed for research that examines MT as practiced in the "real world". Effectiveness or pragmatic[11] approaches contrast the efficacy paradigm reflected in RCTs that examine MT in controlled, yet unrealistic, non-real–world settings. This background, previous experience using CMPs[12,13], and the increased relevance for CMPs to deliver MT interventions, motivated researchers with the Department of Family and Community Medicine at the University of Kentucky to develop a novel study design, which included CMPs as study personnel, while examining massage effectiveness on chronic low back pain for primary care patients.

In 2009, the National Center for Complementary and Alternative Medicine (NCCAM) within NIH awarded an R21 to the current study's research team. The R21 award mechanism from NIH is intended to support research that is exploratory or developmental in approach, and which is often within the early and conceptual phases of development and/or examining less accepted or utilized approaches and methods[14]. These studies tend to be pilot and feasibility in nature,

and often provide the foundations for larger scoped and budgeted studies. Meeting these characteristics, the current study was a feasibility study designed to examine less accepted or utilized approaches to a particular condition and provide preliminary data for these approaches. The primary objective of the R21 study was to determine whether health-related outcomes for chronic lower back pain (CLBP) improve when patients are referred from primary care to select CAM modalities (including MT). However, the health-related outcomes of the R21 are not the focus of this article. Rather, the focus of this article is on the above study's demonstration of CMPs as study personnel in the context of a health-related outcomes study for CLBP patients when referred from primary care to MT. Massage therapy administration can vary significantly in real-world settings making it important to examine MT within the massage community in order for applied treatments to reflect real-world practice variability. This formed the basis of CMP inclusion as study personnel.

To our knowledge, ours is the first sizable research study focusing on massage therapy that sought to examine the treatment effectiveness of massage as practiced in the real world. Furthermore, at the time this study was designed, no published methods descriptions existed to inform our approach or strategies to meet these study design objectives. Describing our approach in this regard and some of the lessons learned from our experience is the objective of this contribution and is meant to inform future research that wishes to examine MT as it is practiced and delivered in the massage field. Therefore, this paper focuses on the study's utilization of CMPs as study personnel and has three objectives: 1) identify and discuss challenges and solutions experienced while recruiting and retaining CMP as study personnel, 2) discuss the development of a real-world, practice-informed MT protocol, and 3) report the extent to which CMP study personnel participated in and complied with rigorous research methodology within their clinical practice.

METHODS

Brief Description of the Overall Study

The University of Kentucky's Office of Research Integrity/Internal Review Board reviewed and approved the current study (#09-0687-FIV). All CMP and university study personnel received human subject protection training, and patient and primary care provider (PCP) participants gave written informed consent. Patients were recruited and participated from March 2011 through January 2013.

This study was a two-armed, pragmatic, repeated measures observational trial and feasibility study (Figure 1) in which central Kentucky urban and rural PCPs were invited to participate, allowing their CLBP patients to have free access to a course of selected CAM modalities, including MT. Patients referred by their PCP to the study and who agreed to be contacted were called by university study personnel, invited to participate if they were interested, and informed of study characteristics including the 12-week intervention treatment window and 12-week no intervention follow-up period. Patients referred to the MT arm of the study could receive up to 10 MT treatments over the 12-week intervention treatment window. Primary study outcomes included the Oswestry Disability Index[15,16] and SF-36[17], both validated and reliable methods of measuring disability from back pain and health related quality of life, respectively. Data were collected at three time points during the study: at baseline (Visit 1), after the treatment intervention window (Visit 2), and after the 12-week no intervention follow-up period (Visit 3). Once enrolled and baseline data were collected, patients were matched with a study CMP. Patients were matched to CMPs based on their convenience to CMP practice location, and consideration was given to CMP availability and patient dispersal among study CMPs. Patient contact information was given to the assigned CMP after baseline data were collected, and further communication to schedule MT visits originated from the therapist office.

Rather than utilizing CMPs to deliver only the MT intervention, CMPs were trained as study personnel in order to 1) provide all MT scheduling and treatment communication with patients, 2) train in and demonstrate human subject protection for all study participants, and 3) report data on themselves and study patients gathered in their capacity as a massage therapist in the real world. All MT treatments were documented by CMPs with study forms similar to

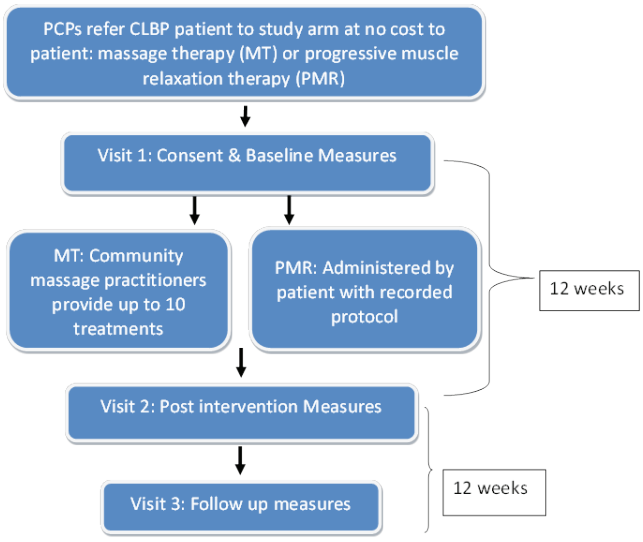

Figure 1. Study design.

typical intake and SOAP-style (Subjective, Objective, Assessment, Plan) documentation procedures which were modified to include specific questions and check boxes related to patient history and treatment modalities utilized. Treatment forms were modeled after those used in previous research with permission[18]. CMPs were issued binders for every patient they were assigned, which included a packet of treatment forms that would serve through intake and up to 10 treatment sessions per patient (see Appendix). All forms in the binder that were completed were finished by study CMPs. Each binder contained a two-page Intake Form which included areas to document patient reported primary complaint and cause of complaint, history, and pain descriptors. An additional four-page form per treatment (40 pages total) were in the binder and included a pain body, check boxes to indicate assessments performed, techniques utilized, and client positioning during each visit. The last page of each treatment day's documentation consisted of free writing space to complete a traditional SOAP note for the treatment. CMPs submitted a scanned or photocopied set of treatment notes to university study personnel at three time points for each client—after the first session, after the fifth session, and after the final session. Original forms were collected by university study personnel after the final treatment session for each study participant. It should be noted that visits to CMPs by study patients did not constitute Visits 1–3 that severed as primary data collection points, as indicated in Figure 1. It should also be noted that the forms completed by CMPs were not considered primary outcome or data collection measures for primary outcomes analysis. Rather, these forms were utilized in an attempt to document as closely as possible each treatment provided to study participants using methods as similar as possible to those used to document treatments in real-world massage practice and that were practical from a research perspective. Secondary data analysis on data collected by study CMPs with the above described forms are planned and will be reported in future manuscripts.

Study CMPs were required to have at least 5 years of documented MT experience, be licensed in the state of Kentucky to practice MT (LMT), and be willing to comply with the research protocol and attend the study personnel training. In order to receive licensure in the state of Kentucky, massage therapists must be 18 years old, have successfully completed at least 600 hours of supervised course instruction in a massage therapy training program approved by the Kentucky Board of Licensure for Massage Therapy (KBLMT), and successfully passed an exam administered by the National Certification Board for Therapeutic Massage and Bodywork or a certifying agency that has been approved by the National Commission for Certifying Agencies, or other examinations approved by the KBLMT[19]. Whether LMTs practiced part- or full-time did not impact their ability to be study personnel. Study CMPs had 5–30 years of massage practice experience and regularly saw 4–30 clients per week. While many of the study's CMPs had undergraduate or professional degrees, none to our knowledge had formal research training outside of the training received through this study's involvement.

Approach to Gathering Reported Information for this Manuscript

The information reported in this manuscript was gathered through the course of the study's development and implementation. The information was documented in team meeting notes and minutes and Excel and Access databases. The interpretation and organization of the information were derived primarily through formal retrospective discussions with study team members and the authors. Descriptive statistics in the form of counts and frequencies were completed using Excel formula functions.

RESULTS

Objective 1: Challenges and Solutions for CMP Recruitment and Retention

Table 1 outlines the various challenges faced by the research team regarding the recruitment and retention of study CMPs. Whenever possible, strategies to lessen the impact of these challenges were utilized to decrease participation barriers. Challenges faced by the study team with regard to CMP recruitment and retention were categorized into four areas: initial contact, inability to participate, unwillingness to participate, and timing issues.

Initial contact - CMP liaison(s)

Making initial contact with and/or approaching CMPs with details about the opportunity were the initial challenge faced by the study. The research team found that one of the most important components in recruitment and retention of CMPs as study personnel were established relationships and partnerships with key CMPs who could serve as liaisons to other CMPs interested in participating. Through previous research activities[12,13], University research personnel had established working and collaborative relationships with a core group of CMPs, two of whom were prominent local leaders in the field—one a Chapter President of the professional organization, American Massage Therapy Association (AMTA-KY), and one the former key administrator for a locally prominent massage therapy school. In addition to utilizing public records from the KBLMT to mail participation invitations to area massage therapists, the liaisons successfully recruited the number of CMPs needed to complete the study. Personal invitations from the known and respected CMP liaisons were the most

Table 1. Community Massage Practitioner (CMP) Recruitment Challenges and Solutions

Challenges	*Solutions*
Initial contact/approach to CMPs with opportunity details.	• Utilizing previous connections with eligible CMPs • Involving prominent CMP community members • Personal invitations from known study personnel, when possible
Inability to participate due to: - Lack of experience - Busyness of practice - Location of practice	• No accommodation could solve lack of experience and busy practices challenges • CMPs had the option to see participants in alternate locations, if needed, due to employer constraints
Unwillingness to participate due to: - Lack of interest - Compensation - Resistance to documentation procedures	• Mass mailings and presentations sought to increase interest in CMP involvement • CMPs compensated $25/treatment • Study training earned 6 CE hours (3 for ethics) for Kentucky massage licensure renewal • Allow supplementary documentation to study forms and ongoing support from CMP liaison
Logistical timing issues that caused long periods of time to pass from initial CMP recruitment to actual participation.	• Refresher information sessions • Status and trajectory updates • CMP recruitment efforts in coordination with other study activity locations

successful strategy, because the personal contact they provided helped to assuage initial concerns and skepticism that could understandably accompany the less successful, unsolicited mail notifications that were initially sent out. Furthermore, these efforts were intended to lend credibility to the motivations of the research team that wished to include the MT field in the research process, rather than to simply use CMPs.

This strategy was particularly helpful because the study scope included urban and rural components, including the beginning edge of Appalachia. Fewer eligible CMPs were available in the rural areas due to lack of experience and/or the less populated market filling practitioner schedules to the point of being too busy to participate. Rural practitioners also tend to practice more in isolation due to the rurality of their environment. CMPs who expressed interests in participating were trained as study personnel before being assigned patient participants. Figure 2 depicts a flowchart of CMPs from state licensure (in 2009) to participation status in the study for both the urban and rural study arms.

Other Challenges and Solutions

The three remaining categories of CMP recruitment and retention challenges faced by the research team were unwillingness to participate, willing but unable to participate, and timing issues. These challenges were identified in the process of recruiting and were addressed, if possible, with the help of the liaison CMPs. Incentives for the CMPs participation consisted of the payment of $25 per treatment for each of the patients they treated, 6 free Continuing Education hours (including 3 for ethics) towards Kentucky licensure renewal for the study and Human Subject protection trainings, and the chance to contribute to the MT knowledge base. These incentives were explained to the CMPs during invitation calls and letters.

The most consistent reasons for unwillingness on the part of CMPs to become study personnel and participate in this research were an overall lack of interest and perceived lack of "adequate" compensation. Kentucky CMPs are compensated at various rates dependent (as throughout the United States) on the environment in which they practice and whether they are hourly or per-treatment paid, earning anywhere from $12 per hour to $100 or more per treatment (the U.S. Bureau of Labor Statistics report median hourly wage at $17.20 per hour[20]). On the other hand, costs paid primarily out of pocket by consumers for massage treatments can range from $25 to $100 or more per treatment, again depending on a variety of circumstances. Budgetary constraints limited the study's ability to pay CMPs based on their usual rate, thereby restraining our ability to reconcile compensation-related deterrents to participation. However, the large pool of therapists to draw from facilitated our success in this area. Some therapists were willing to participate, but were uncertain and/or resistant to the documentation procedures. To aid in documentation procedures, supplementary documentation was allowed, in addition to the study treatment documentation forms, and the study therapist research personnel had ongoing support from key CMP study personnel. Others were willing but could not find time in their schedules to add new clients. Many CMPs are independent contractors and practice in situations where they are paid a percentage of treatment costs or an hourly wage by a managing entity (eg, spa, large clinic, salon). In such situations, CMPs did not have the agency to accept a potentially reduced rate of payment for study participant treatments. In order to allow these therapists to participate, we were able to allow CMPs the option to treat study patients in

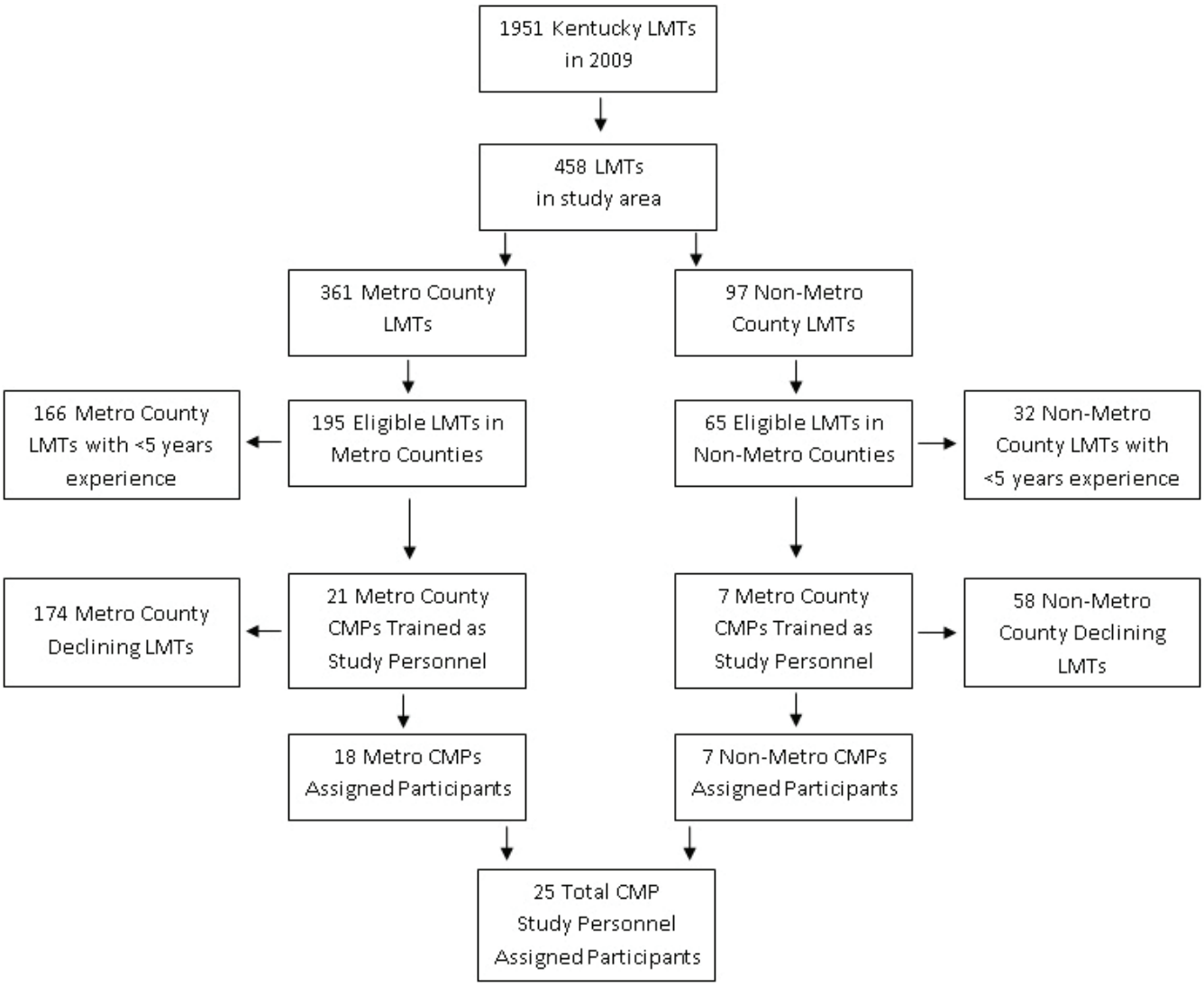

Figure 2. Community massage practitioner (CMP) recruitment flow chart. CMPs were required to be licensed massage therapists (LMTs) in the state of Kentucky.

the patient's home or outside of their usual practice location, if needed.

A final challenge was identified during the course of the study and was related to logistical timing issues. This situation was caused by long periods of time which passed from the initial CMP recruitment period to actual participation. These delays were caused by slower-than-anticipated PCP and patient recruitment to the study. In some cases, interested CMPs were trained five months before assignment to a study patient participant, during which time CMP availability may have changed and/or confidence with study requirements declined. In some instances, CMPs had to withdraw their affiliation with the study because they were no longer able to accommodate participation. Those who remained in the study had this issue resolved through CMP refresher information sessions, and status and trajectory updates that were coordinated with other study activities.

Objective 2: Development of a Real-World, Practice-Informed MT Protocol

When developing the proposal for the current study, only literature pertaining to massage research methodology prior to 2008 was accessible. Table 2 outlines the development of the current study's MT protocol by key study CMP, Katie Stewart. This protocol was informed by the then-current 2008 massage literature, real-world massage practice, and Ms. Stewart's years of clinical experience and mentoring from top professionals in the massage field (in 2008, 10 years).

An aim of this study was to examine MT as practiced in the real world, so numerous effectiveness

Table 2. Development of a Practice- and Research-Informed Massage Therapy (MT) Protocol Reflecting Real-World MT Practice

	Massage Interventions Utilized in Evidence Base prior to 2008[24-27]	*Real-World Practice*	*Current Study's MT Protocol*	
Dosing	*Based on Study Design*	*Based on Client Needs*	*Study Design*	*Adapted for Need*
Session Length	5-30 min/treatment	30-90 min	55-60 minutes	20-30 minutes
Frequency	1-3 times/week	1-2 times/week	1 time/week	2 times/week
Duration	4-16 weeks	3-4 weeks	10 sessions/12 weeks	10 times/12 weeks
Providers				
Type	Lay people, non-descript, nurses, etc.	Certified or Licensed Massage Therapists (LMT)	Urban and Rural Community LMTs	
Experience	Often unreported, 0-7 years	0-25+ years in practice	Minimum 5 years in practice	
Education	Unreported	200-500+ hrs training + CEs	500+ hrs training + CEs	
Environment	Various: hospitals, homes, etc.	Private and group settings	Sole Proprietors or Independent Contractors	
Nomenclature	"Swedish" used as umbrella term with other various confusing descriptions throughout the literature.[24, 27]	Swedish massage as educational foundation – effleurage, petrissage, compression, friction, tapotement. Continuing education adds terminology from modalities such as Trigger Point Therapy, Active Isolated Stretching, Craniosacral therapy, Neuromuscular therapy, Zero Balancing, and a variety of others.	CMPs oriented to the study, documented their treatments based on traditional Swedish nomenclature, and included the nomenclature from modalities learned in their continued trainings/specialties.	
Protocol	Few studies included massage protocol descriptions; i.e., what strokes/techniques were utilized, order and duration of techniques, muscles/ tissues addressed etc.	CMPs, informed by their level of clinical expertise and experience, develop treatment protocols on a per client basis dependent on condition, client history, and desired outcomes. This process is dynamic and evolves throughout any given session or treatment series.	Flexible protocol guidelines allowed for CMP clinical judgment within a structured study outline. Structured Outline: • 10, 60-minute sessions over 12 weeks • initial 5 sessions supine or side-lying • detailed intake • postural assessment • SOAP notes for each treatment Flexible Components • seated massage, if needed • shorter session length, if needed • CMP clinical judgment determined o utilized techniques o treatment progression	
Practitioner Input on Protocol Design	Documentation citing collaboration with massage professionals related to study protocol designs was not identified.	CMPs work in tandem with other health care professionals and continually self-assess and dialogue with clients about treatment effectiveness.	Asking CMP's input on protocol design as they put it into use. "*Did treatment protocol keep you from doing anything today that you feel would have significantly improved the effectiveness of your treatment?* "	
Practitioner Perceptions of Outcomes	In general, outcomes assessment documentation, seeking feedback from study massage personnel was lacking.	CMPs must determine if their modalities are appropriate for the client's health issues. CMPs are often asked how many sessions are needed to "fix" a specific complaint.	CMPs were asked to rate how suitable they felt the patient was for clinical massage. CMPs were asked about how much improvement they expected the patient to achieve in 10 weeks.	

approaches were utilized in order to mirror real-world massage practice. In contrast, efficacy research uses controlled environments and includes strict inclusion and exclusion criteria for study participants. Table 3 features the limited exclusion criteria for the patient participants in this study, which allowed for CLBP patients with complex medical histories and comorbidities to participate. This well reflects the diversity and complexity of real-world massage clients with CLBP. In addition, study patients could participate in conjunction with physician-directed treatment plans that included controlled medications. These more pragmatic participant criteria[11] allowed this study to mirror MT in practice, because massage professionals often face clients experiencing complicated health conditions in conjunction with pharmacological intervention.

In efficacy-focused approaches for MT, treatments are administered in controlled and consistent research settings. This study assigned participants to conveniently located study CMPs and treatments most often occurred within the study CMPs' clinical practices. Appointments and treatment schedules were collaboratively designed and managed by each CMP and patient pairing. This approach imitated MT in practice by allowing for varied treatment settings between patients. In addition, real-world MT clients tend to seek therapy from CMPs that are in relatively convenient locations to them. These clients are also responsible for scheduling and attending their treatments as agreed upon within the therapeutic relationship established between themselves and the massage professional, as were the patient participants in this study.

In addition to the controlled treatment setting in efficacy research, the treatment sessions are usually restricted in number, shorter than real-world sessions, and of limited frequency throughout the duration of the study. This study allowed for a flexible treatment schedule. This included up to 10 MT sessions, the first intake session being 75 minutes to accommodate sufficient intake, and the remainder sessions lasting 50–60 minutes, unless intolerable for the patient. The frequency of therapy was determined through MT clinical judgment in individualized treatment plans, and the 12-week treatment windows could be extended up to two weeks in order to accommodate life events. Real-world MT schedules allow for practitioner clinical judgment to determine frequency and treatment length dependent on the client's needs as informed by condition and availability. Furthermore, effective scheduling often allows for more frequent treatments at the onset, with gradual tapering as work begins to "hold." These real-world scheduling aspects were reflected in this novel study design.

Massage therapy in efficacy research often is restricted to specific or exclusive therapeutic modalities or techniques. Since this is not indicative of the variety of therapy seen in practice, the MT protocol developed in this study allowed CMPs to utilize specialty modality options in which they were trained in addition to basic Swedish massage techniques. These specialties included, but were not limited to trigger point therapy, active isolated stretching, craniosacral therapy, neuromuscular therapy, and Zero Balancing. The only restriction on treatment approach was that CMPs were asked to treat the patients lying supine or on their side for the initial five treatments, unless therapeutic judgment deemed prone or seated treatments more appropriate. This limitation was lifted for the final five treatments, as patient's CLBP conditions were expected to improve. This approach to the developed MT protocol emulated real-world MT in which massage practitioners use their whole skill set of modalities when treating clients with CLBP. While signature or patterns may exist for individual massage practitioners, unique session progressions occur for each treatment, as practitioners responded to the patient's body, condition, and responses throughout the treatment series.

Objective 3: Report CMP Study Personnel Compliance

Being the first study to rely completely on CMPs to schedule, provide, and document study interventions, many unknowns with regard to practitioner

Table 3. Study Patient Inclusion/Exclusion Criteria

Inclusion Criteria	*Exclusion Criteria*
Currently have CLBP	Pregnant at point of referral
Patient in referring practice for 3+ months	Current/past history of psychosis
Has visit with participating PCP during study referral window (visit for any reason)	Presence of nonconsolidated fracture, deep vein thrombosis, or advanced osteoporosis
21+ years old with life expectancy of 6+ months	Course of PMR or CMT in the past 6 months for any reason (spa visits and/or an occasional massage or PMR session were acceptable)
	Presence of skin wounds or infections, eczema, active cancer tumor, or advanced kidney disease

compliance existed. For instance, would CMPs reliably schedule and attend appointments with study participants? Would CMPs complete and submit treatment documentation? Essentially, could CMPs, individuals not specifically trained in research and practitioners from a field with few encompassing clinical practice guidelines, be relied upon to meet the requirements of a research protocol?

The current study trained 28 CMPs as study personnel, 25 of whom were assigned patients (Figure 2). Of the 104 patients referred to the MT arm of the study, 102 were assigned to study CMPs. Of the 102 CMP assigned patients, eight withdrew/dropped from the study before receiving their first treatment. Reasons for three of these withdrawing patients could not be identified, while five discontinued their participation in the study due to life events (eg, house fire, surgery, and unrelated illness). Ninety-four patients remained in the study through at least one massage treatment, and an average of 13 days passed from the time baseline measures were collected for each patient by university study personnel and the time of their first MT treatment (range: 1–46 days). Thirty-three percent of patients who had at least one MT treatment in the study received their initial session within one week of baseline collection, and 69% within two weeks. This illustrates that for a majority of study participants, initial contact from study CMP and schedule accommodations were made relatively quickly. Aspects that hindered prompt initial treatment scheduling included schedule conflicts/compatibility, life events, vacations, holiday seasons and, in a couple of instances, difficulty with patient's returning CMP contact attempts. No reports were made by study participants that CMPs did not attend scheduled appointments or that scheduling reliability issues existed.

Study CMPs were assigned an average of four patients each (range 1–8) through their duration of affiliation with the study and completed an average of 68% (range 0%–100%) of their total potential treatments for assigned patient participants. Figure 3 illustrates the per patient MT treatment utilization for the 104 patients in the study. Of the possible 1,040 MT treatments that could have been provided to PCP referred patients (104 patients referred by PCP to up to 10 treatments each), 73% were utilized and a majority of patients (63%) received all 10 treatments. Study data collection forms were retrieved from CMP study personnel for 97% of the 759 completed MT treatments. In other words, CMPs submitted completed treatment forms for 736 of the 759 provided treatments, demonstrating high reliability in CMPs adherence to research protocol in this regard.

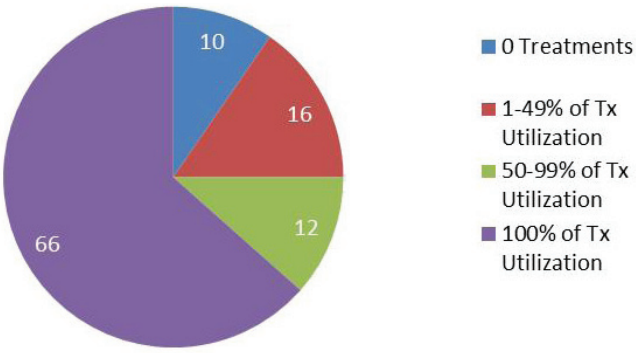

Figure 3. Per patient treatment (Tx) utilization.

DISCUSSION

At the time this study was designed—and to a large extent today—research MT interventions are administered by therapists with few characteristics described other than various experience levels[21]. Descriptions of interventions have included MT performed by non-professionals, or in single or few therapist situations. While massage therapy can be performed by numerous health and therapeutic professionals, few approach such treatments as customarily done by massage professionals, which is why this study's approach of utilizing many CMPs as study personnel is novel.

Although the current study design does not reflect the advances in massage research methodology and evidence base since 2008, the design's novelty is still relevant and significant due to its concurrence with noted advancement and unique aspects. Advances in the field after the design of this study's MT protocol includes the 2011 publication from Cherkin and colleagues[1] which used input from CMPs in many aspects of the design and found no differences in benefits between specific or general massage combined with usual care for CLBP. Additionally, with the creation of the open-access journal, *International Journal of Therapeutic Massage and Bodywork,* and publication of the Dryden and Moyer text *Massage Therapy: Integrating Research and Practice*[22], many more case studies/series, methodology studies, and research studies completed by and with massage professionals have been made generally accessible over the past five years. However, aside from the current study, none to date have examined MT effectiveness when CLBP patients are referred by their PCPs to CMPs who then have essentially full discretion in the MT treatment plan.

Inherent in pragmatic research, variability is expected in treatment approach between treatment/intervention providers. This is especially the case in the current study's design because multiple CMPs were able to develop and provide individualized treatment plans per study participant based on the CMPs unique skill sets and training. These are the very features that represent "real world" in

real-world practice and pragmatic research seeks to examine the effectiveness of interventions within these potentially limiting parameters. These limitations are important considerations when interpreting the outcomes for studies utilizing this type of "real world" research approach, which is outside the scope of this manuscript. Ultimately, while positive results of such research point to the effectiveness of treatment, the results cannot specifically point to what aspect(s) of the treatment provided the effects; that is the purpose of explanatory or controlled research designs. Appropriately, when disseminating the results of this study (currently under review), these limitations will be discussed in full, along with the necessity for these types of research designs. Questions that may come out of and commonly remain after effectiveness/pragmatic research are: "What are the aspects of the treatment that are working or providing the actual effect?," which ultimately leads to, "What is happening in the 'black box' of a treatment?" (the 'black box' being the nebulous intervention, or what happens between the practitioner and patient/client, and is a topic contemplated by many fields[23]). Understanding and measurement of the black box is a challenge that this study began to grapple with by including documentation from CMPs about the provided treatments. In addition to current dissemination efforts of this study's primary outcomes focusing on patient disability and health status, the close work with CMPs in this study and the treatment data collected will lead to additional manuscripts reporting pertinent massage practice aspects in relation to these patient outcomes. It is anticipated that these forthcoming contributions will be a first step in understanding the 'black box' of MT treatment for CLBP, and form a basis for potential CMP informed referral guidelines for PCPs to MT for their CLBP patients.

The reporting of this study's MT protocol to the massage field and others interested in effectiveness research involving MT is important in that few studies examine massage as practiced in the real world. This study's use of CMPs as study personnel was a design strength, in that MT was applied in a setting typical for a real patient/client experience. Furthermore, the cost of MT treatment, a barrier often faced by CLBP patients who may otherwise be open to receiving MT, was alleviated through this study's design. This allowed for MT effectiveness to be studied in a population unhindered by the ability to pay. These features, in addition to the benefits afforded by its use of CMPs as study personnel, make the current study an important model for future effectiveness research reflecting real-world MT. When challenges in recruitment, retention, and protocol design were surmounted, community CMPs proved valuable study personnel for this practice-based, MT effectiveness study for PCP referred patients with CLBP.

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CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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REFERENCES

1. Cherkin DC, Sherman KJ, Kahn J, Wellman R, Cook AJ, Johnson E, et al. A comparison of the effects of 2 types of massage and usual care on chronic low back pain: a randomized, controlled trial. *Ann Intern Med*. 2011;155(1):1–9.
2. Perlman AI, Ali A, Njike VY, Hom D, Davidi A, Gould-Fogerite S, et al. Massage therapy for osteoarthritis of the knee: a randomized dose-finding trial. *PLOSone*. 2012;7(2):e30248.
3. Sherman KJ, Cook AJ, Kahn JR, Hawkes RJ, Wellman RD, Cherkin DC. Dosing study of massage for chronic neck pain: protocol for the dose response evaluation and analysis of massage [DREAM] trial. *BMC Complement Altern Med*. 2012;12:158.
4. Glasgow RE. What types of evidence are most needed to advance behavioral medicine? *Ann Behav Med*. 2008;35(1):19–25.
5. Green LA. Future of family medicine recommendations confirm need for increased research from family physicians. *Ann Fam Med*. 2004;2(3):282–283.
6. Pagoto SL, Lemon SC. Efficacy vs. effectiveness. *JAMA Intern Med*. 2013;173(13):1262–1263.
7. Aickin M. Comparative effectiveness research and CAM. *J Altern Complement Med*. 2010;16(1):1–2.
8. Briggs J. NCCAM Researchblog. 2013. Accessed May 2, 2013. Available from: https://nccam.nih.gov/research/blog/pragmatic
9. Golden I. Beyond randomized controlled trials: evidence in complementary medicine. *eCAM*. 2012;17(1):72–75.
10. Witt CM, Wen-jing H, Lao L, Berman BM. Which research is needed to support clinical decision-making on integrative medicine? Can comparative effectiveness research close the gap? *Chin J Integr Med*. 2012;18(10):723–729.

11. Thorpe KE, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, Altman DG, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *J Clin Epidemiol*. 2009;62(5):464–475.
12. Elder WG, Hustedde C, Rakel D, Joyce J. CAM curriculum activities to enhance professionalism training in medical schools. *Complement Alt Med*. 2008;13(2):127–133.
13. Elder WG, Purdy H, Bentley A. Collecting information about a CAM practitioner's practice: a preliminary report of a self-interview methodology. *Complement Alt Med*. 2005;10(2):147–155.
14. National Institutes of Health (NIH). NIH Exploritory/Development Research Grant Award (R21). 2013 [updated February 14, 2014]. Available from: http://grants.nih.gov/grants/funding/r21.htm
15. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine*. 2000;25(24):3115–3124.
16. Fairbank JC, Pynsent PB. The Oswestry disability index. *Spine.* 2000;25(22):2940–2953.
17. Maruish ME, editor. *User's Manual for the SF-36v2*, 3rd edition. Lincoln, RI: Quality Metric Incorporated; 2011.
18. Cherkin DC, Sherman KJ, Kahn J, Erro JH, Deyo RA, Haneuse SJ, et al. Effectiveness of focused structural massage and relaxation massage for chronic low back pain: protocol for a randomized controlled trial. *Trials*. 2009;10:96.
19. *Laws and Regulations Relating to Licensure as a Massage Therapist*. The Kentucky Board of Licensure for Massage Therapy. Available from: http://www.bmt.ky.gov/Laws%20and%20Regulations/Laws%20and%20Regulations%20Booklet.pdf
20. Bureau of Labor Statistics, U.S. Department of Labor. *Occupational Outlook Handbook, 2014-15 Edition: Massage Therapists*. Accessed March 27, 2014. Available from: http://www.bls.gov/ooh/healthcare/massage-therapists.htm
21. Moyer CA, Dryden T, Shipwright S. Directions and dilemmas in massage therapy research: a workshop report from the 2009 North American Research Conference on Complementary and Integrative Medicine. *IJTMB*. 2009;2(2):15–27.
22. Dryden T, Moyer CA, editors. *Massage Therapy: Integrating Research and Practice*. Champaign, IL: Human Kinetics; 2012.
23. DeJong G, Horn SD, Gassaway JA, Slavin MD, Dijkers MP. Toward a taxonomy of rehabilitation interventions: using an inductive approach to examine the "black box" of rehabilitation. *Arch Phys Med Rehabil*. 2004;85(4):678–686.
24. Ernst E. Massage therapy for low back pain: a systematic review. *J Pain Symptom Manage*. 1999;17(1):65–69.
25. Furlan AD, Brosseau L, Imamura M, Irvin E. Massage for low-back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine*. 2002;27(17):1896–1910.
26. Horowitz S. Evidence-based indications for therapeutic massage. *Altern Complement Ther*. 2007;13(1):30–35.
27. Moyer CA, Rounds J, Hannum JW. A meta-analysis of massage therapy research. *Psychol Bull*. 2004;130(1):3–18.

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