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Original Research Article

Real-World Massage Therapy Produces Meaningful Effectiveness Signal for Primary Care Patients with Chronic Low Back Pain: Results of a Repeated Measures Cohort Study

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Abstract

Objective. While efficacy of massage and other non-pharmacological treatments for chronic low back pain is established, stakeholders have called for pragmatic studies of effectiveness in "real-world" primary health care. The Kentucky Pain Research and Outcomes Study evaluated massage impact on pain, disability, and health-related quality of life for primary care patients with chronic low back pain. We report effectiveness and feasibility results, and make comparisons with established minimal clinically important differences.

Methods. Primary care providers referred eligible patients for 10 massage sessions with community practicing licensed massage therapists. Oswestry Disability Index and SF-36v2 measures obtained at baseline and postintervention at 12 and 24 weeks were analyzed with mixed linear models and Tukey's tests. Additional analyses examined clinically significant improvement and predictive patient characteristics.

Results. Of 104 enrolled patients, 85 and 76 completed 12 and 24 weeks of data collection, respectively. Group means improved at 12 weeks for all outcomes and at 24 weeks for SF-36v2's Physical Component Summary and Bodily Pain Domain. Of those with clinically improved disability at 12 weeks, 75% were still clinically improved at 24 weeks ($P < 0.01$). For SF-36v2 Physical and Mental Component Summaries, 55.4% and 43.4%, respectively, showed clinically meaningful improvement at 12 weeks, 46.1% and 30.3% at 24 weeks. For Bodily Pain Domain, 49.4% were clinically improved at 12 weeks, 40% at 24 weeks. Adults older than age 49 years had better pain and disability outcomes than younger adults.

Conclusions. Results provide a meaningful signal of massage effect for primary care patients with chronic low back pain and call for further research in practice settings using pragmatic designs with control groups.

Key Words. Massage Therapy; Health-Related Outcomes; Primary Care; Practice-Based Research; Pragmatic Research; Complementary Therapies; Rural Population

Introduction

Low back pain is a prevalent health condition that leads all disorders in years lost to disability in the United States [1]. While most patients improve rapidly [2], one-third report persistent back pain [3] and 15% develop chronic low back pain (CLBP) with significant physical limitations [4]. Randomized controlled trials, meta-analyses, and systematic reviews have found clinical massage therapy to have efficacy for CLBP [5–10]. Clinical massage therapy refers to massage applied and practiced by trained massage professionals and delivered within a professional and therapeutic setting to support optimal health and functioning. The most recent and comprehensive low back pain treatment guidelines (2007) recommend massage specifically for CLBP [11,12], noting its "proven benefits" [12]. However, a recent meta-analysis [13] highlights methodological weaknesses in massage research, and CLBP treatment guideline authors [11,12] and others [14] have expressed concern that massage effectiveness has not been evaluated in primary care. For example, massage is rarely integrated into primary care, limiting the potential for interdisciplinary awareness, knowledge, or communication between the fields. In the event that health care providers recommend patients to massage, the likelihood of them knowing the massage therapist or practice-specific patients accessed would be low. The extent to which massage treatments applied in real-world settings replicates those examined in controlled research settings would also be reasonably unknown to health care providers. Research designs reflective of real-world practice situations (of both primary care and massage application) are needed for CLBP stakeholders to understand the extent to which patients will benefit from massage if recommended by their primary care provider (PCP).

This report details outcomes of the Kentucky Pain Research and Outcomes Study (KYPROS). KYPROS was selected by a National Institutes of Health (NIH) funding opportunity specifically designated for pragmatic studies using practice-based research networks (PBRNs) [15]. With a focus on pilot and pragmatic research, the funding opportunity announcement considered applications with control groups as nonresponsive [15]. Thus, this study does not employ a control group. As a pilot and feasibility study, KYPROS was designed and powered to detect and descriptively compare outcomes to established, minimal clinically important differences as a means to determine if real-world massage could produce a meaningful benefit signal for CLBP patients referred by their PCP. A secondary aim of KYPROS was to examine study design feasibility. KYPROS provided participants with cost-free access to 10 massage treatments provided by licensed massage therapists practicing in their community with five or more years of experience. We expected KYPROS participants would be satisfied with massage for their CLBP and report benefit from provided treatment. Our primary aim was to evaluate health-related outcomes of real-world massage for CLBP compared with established minimal clinically important differences for our measures of interest: pain with disability and health-related quality of life.

Methods

The University of Kentucky's Office of Research Integrity provided ethical review and approval (#09-0687-FIV) for KYPROS. Written informed consent was collected from all participants.

Study Design

KYPROS was a repeated measures cohort study (clinicaltrials.gov registration # NCT01147120). It had no comparison group focused on feasibility and outcomes (Figure 1) in urban and rural central Kentucky counties of the Kentucky Ambulatory Network, a large, statewide practice-based research network. Evaluation of outcomes was based on statistically significant change from baseline and recommended methodology [16], applying nonstatistical comparisons of outcomes for achievement of identified clinically meaningful changes. We report patient data from three data collection time points: Visit 1 (V1) at baseline, Visit 2 (V2) at 12 weeks (immediately following course of treatment), and Visit 3 (V3) at 24 weeks (12-week follow-up from course of treatment).

Study Participants

All CLBP patients enrolled in KYPROS were referred by their PCP, which ultimately led to two study participant groups: referring PCPs and CLBP patients.

Referring Primary Care Providers

We randomly selected from Kentucky Ambulatory Network practice locations then serially invited PCPs from 18 practices (14 being group practices) to refer patients into our study. Practice locations included four rural sites (all group practices) and one major academic medical facility. The study team visited each practice to orient the PCPs and staff, including a 20-minute discussion of massage along with risks and benefits. PCPs who consented to participate were asked to: 1) complete and return a point-of-care pocket card for each patient with CLBP they saw in their practice for any reason during their study participation window and 2) refer eligible patients to the study if they thought the study intervention would be of benefit. PCPs were instructed to document their referral on the pocket card, add patient contact information if the patient agreed, and return pocket cards to study personnel weekly. Study personnel contacted patients to explain the study, confirm eligibility, answer questions, and schedule an informed consent/baseline study visit.

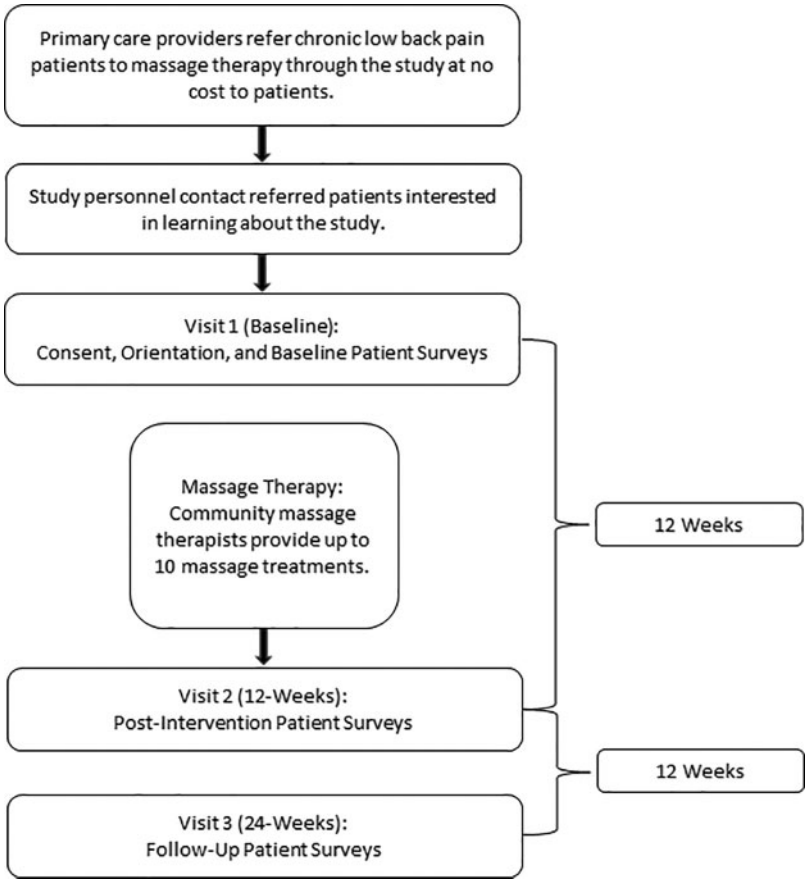

Figure 1 Flow diagram of study activities.

Table 1 Study patient criteria

Inclusion criteria	Exclusion criteria
Currently have chronic low back pain	Pregnant at point of referral
Patient in referring practice for 3+ mo	Current/past history of psychosis
Has visit with participating primary care provider 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+ mo	Course of massage in the past six mo for any reason (spa visits and/or an occasional massage were acceptable)
	Massage contraindications – presence of skin wounds or infections, eczema, active cancer tumor, or advanced kidney disease

Patient Participants

CLBP patients were eligible for referral if having a PCP visit for any reason during their PCP's participation window. CLBP was defined as pain in the lumbar or sacral regions persisting for three months or longer. Table 1 outlines full exclusion/inclusion criteria. Participants received a $25 gift card after each data collection point was completed.

Massage Intervention and Providers

Participants referred and enrolled into the study were each assigned to a KYPROS-affiliated massage therapist. KYPROS protocol stipulated that study massage therapists schedule, develop treatment plans, and apply 10 massage treatments during the 12 weeks between study V1 and V2 for study participants. Study therapists provided treatments at no cost to study participants and

Table 2 Comparison points; clinically meaningful threshold changes for groups and individuals

	Domain	Mean point change threshold for group clinical significance	Point change threshold for individual clinical significance
Oswestry Disability Index (ODI)*	N/A	Change of ≥ 6	Change of ≥ 6
SF-36v2†	Physical Component Summary	Change of ≥ 3	Change of ≥ 3.8
	Mental Component Summary	Change of ≥ 3	Change of ≥ 4.6
	Bodily Pain Domain	Change of ≥ 2	Change of ≥ 5.5

*ODI clinical significance parameters [21,24].
†SF-36v2 clinical significance parameters [19].

were compensated $25 per completed massage session. Details of KYPROS massage therapists are described elsewhere [17], but, briefly, assignment was informed by participant convenience to therapist practice location and distribution. All KYPROS-affiliated massage therapists were licensed in Kentucky, had to have at least five years of professional experience, provide treatment space and supplies, complete study personnel training, and complete and submit treatment documentation forms specific to KYPROS. Study massage therapists scheduled visits, provided treatments in their usual treatment setting, and utilized any massage technique within the purview of their training experience. Techniques included: Swedish massage, active isolated stretching, myofascial techniques, lymphatic drainage, movement, trigger point therapy, neuromuscular therapy, cranialsacral therapy, reflexology, Reiki, acupressure, and positional release. Included techniques represent those typically taught in foundation massage education (i.e., Swedish massage; the United States has no consistent massage training parameters with regards to duration of training or necessary content taught, although efforts to establish such parameters exist among professional organizations), as well as those inconsistently taught in foundation massage education but taught in continuing education (most professional massage certifications and licensures maintain continuing education requirements for renewal) or advanced/specialized training settings (e.g., cranialsacral therapy, lymphatic drainage, Reiki, trigger point).

Measures

Patient Descriptors

Patient descriptors were collected from both PCPs (via pocket cards) and patients (via self-report). Descriptor variables included: PCP reported/perceived health, pain severity, function ability, and pain-related medications (categorized as pain-specific, muscle relaxers, and mood-specific); patient age, gender, race, body mass index (BMI), CLBP duration, education, and means of health care payment. Three medication-related variables were created from PCP-provided medication lists: 1) total number of pain-related medications reported (continuous), 2) dichotomous US Drug Enforcement Administration (DEA) scheduled medications usage (i.e., opioids, benzodiazepines, and Tramadol), and 3) total number of reported scheduled medications (continuous). A dichotomous age variable was created to better consider age-related differences between younger and older study participants. We rounded the average sample age to determine the dichotomous cut-point (50 years), which also happened to neatly divide the sample between the established Baby Boomer and X generations.

Outcomes

Primary outcome measures were the Oswestry Disability Index (ODI) [18] and the Medical Outcomes Study 36-Item Short Form, version 2 (SF-36v2) [19]. The ODI is a frequently used condition-specific measure for pain with disability [20]. Examination of internal consistency yields Cronbach's alphas between 0.71 and 0.87 [21]. Researchers have found that ODI scores of 12 and higher indicate pain with disability in the Japanese population (a country with a higher population age, lower obesity rates, and better population health than the United States) [22] and changes of six points or more are clinically meaningful (group means and for individuals) [21,23]. Sample size was sufficient to detect such change with greater than 90% power. The SF-36v2 is a widely used and validated 36-item patient questionnaire to assess health-related quality of life. It includes eight health domains and yields two summary scales. Dimensions of interest from the SF-36v2 were the Physical Component Summary, the Mental Component Summary, and the Bodily Pain Domain.

Table 2 displays specific point change thresholds showing clinically meaningful improvement for the ODI and SF-36v2 Physical Component Summary, Mental Component Summary, and Bodily Pain Domain when considering group means and individual change scores [19]. Based on V1/V2 and V1/V3 change scores, dichotomous success variables were calculated for each participant to signify whether clinically meaningful change occurred in each of the measures [19,23].

Participant satisfaction and perceived treatment effects can be used to judge whether delivery of the intervention is complete and acceptable [24]; thus they are important

low back pain measure domains [25]. KYPROS measured perceived treatment effects and satisfaction in two ways. At V2 and V3, an 11-point numeric scale was used for the question "How helpful do you believe this therapy was for your chronic low back pain?", with 0 = "not at all helpful" and 10 = "extremely helpful." This variable was treated as continuous. At V2, participants completed a satisfaction survey that used a seven-point Likert scale for the extent to which participants agreed with statements such as "This therapy relieved my pain." Dichotomous positive satisfaction and perceived effectiveness variables were created for each question that combined responses of "strongly agree" and "very strongly agree," as recommended by Ostelo and de Vet [25].

Data Collection, Management, and Analysis

Data were collected at V1, V2, and V3 with paper and pencil surveys either on the University of Kentucky campus or in a neutral, participant-convenient place where relative privacy could be provided (most often a public library). Study data were double-entered by research assistants into and managed using Research Electronic Data Capture (REDCap) [26], a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for data entry, audit trails for tracking data manipulation and export, and automated export procedures. Participants did not interact with REDCap in any way, nor were the completed surveys printed from REDCap.

Statistical analyses used SAS 9.3 (SAS Institute, Cary, NC, USA). Comparisons of baseline variables were made for loss to follow-up status at V2 and V3 using chi-square tests for categorical variables and *t* tests for continuous variables. This study was powered to detect a six-point change in mean ODI, which constitutes meaningful clinical change [21,27]. Our main analyses were completed in two steps. Step 1: Mean changes were examined for each primary outcome (ODI and pertinent SF-36v2 components/domains) using repeated measures (time: V1, V2, V3) mixed linear models and Tukey's post hoc tests. Step 2: Where Step 1 analysis indicated that significant outcomes changes occurred, descriptive analyses examined the extent of clinically significant improvement and exploratory Spearman correlations, chi-square, odds ratio, and logistical regression analyses identified predictive patient characteristics. Large numbers of PCPs (N = 67) and practices (N = 18), relative to number of referred patients (N = 177), obviated the use of practice as a variable in analyses.

Results

Sixty-seven urban and rural (N = 14) PCPs from 18 provider sites (rural = 4) consented to participate in the study, with one to 25 PCPs participating from each site (median = 2). Forty-eight PCPs returned pocket cards for 177 recommendations to massage. Of the recommended 177 CLBP patients, 151 (81%) were interested in being contacted by study personnel. One-hundred four (69%) patients enrolled and completed baseline measures (N = 104).

Sixty percent of participants completed all 10 massage treatments and 75% received at least five treatments. No adverse events were attributed to the study. Three complaints about massage therapists were recorded (personality/belief conflicts): Two participants were reassigned to a different massage therapist, and the third issue was resolved by notifying the massage therapist of patient concerns [17].

Baseline Measures and Attrition

To limit rates of participants lost to follow-up, data collection at V2 and V3 was vigorously pursued for all study participants regardless of the extent to which treatments were accessed. Of the 104 participants, 85 completed V2 (18% attrition) and 76 completed V3 (27% attrition). Baseline measures for study participants are reported in Table 3. Those lost to follow-up at V2 had a higher mean number of PCP-reported pain-related prescriptions (2.9 ± 1.7 vs 2.1 ± 1.4, $P = 0.03$), had a lower mean age (38 years ± 9.9 vs 51.1 years ± 12.7, $P < 0.0001$), and were more likely to be under age 50 years ($\chi^2 = 7.6$); those who reported current smoking behavior were more likely to be lost to follow-up at V2 ($\chi^2 = 5.8$). Study participants lost to follow-up at V3 (includes V2 attrition) had lower mean age (40.4 years ± 11.4 vs 51.8 years ± 12.5, $P < 0.0001$) and were more likely to be younger than age 50 years ($\chi^2 = 8.1$).

Intervention Effectiveness

Step 1 Analysis – Group Means

Mixed model linear regressions were used to examine change in scores across time points for each of the four main outcomes. Significant improvements were demonstrated for the ODI ($F = 22.72$, $P < 0.0001$), SF-36v2 Physical Component Summary (Physical, $F = 19.8$, $P < 0.0001$) and Mental Component Summary ($F = 9.77$, $P = 0.0001$), and SF-36v2 Bodily Pain Domain ($F = 24.4$, $P < 0.0001$). Figure 2 graphs the pattern of mean score improvement from V1 to V2 and subsequent decrement from V2 to V3 for each outcome. Significant improvements in mean scores for all measures were evident from V1 to V2, and significant improvements in disability, functioning, and pain were retained at V3 for the ODI, Physical Component Summary, and Bodily Pain Domain.

Table 4 provides the mean point change scores from V1 to V2, V2 to V3, and V1 to V3, as well as whether reported change is clinically significant according to established guidelines. Clinically meaningful improvements in group mean scores were evident from V1 to V2 for all outcomes and from V1 to V3 for the Physical Component Summary and Bodily Pain Domain of the SF-36v2. Decrements in mean scores were clinically

Table 3 Baseline characteristics for patient participants

Variable	Visit 1 all (N = 104)
Primary care provider reported	
CLBP severity*	
Mean (SD)	6.1 (1.6)
Range	3–9
Overall health†	
Mean (SD)	6.9 (1.7)
Range	2–10
Function†	
Mean (SD)	6.8 (2.1)
Range	2–10
Treatment expectation	
Mean (SD)	7.9 (1.4)
Range	4–10
Primary care provider's specified "pain-related meds"	
Mean No. (SD)	2.2 (1.5)
Range	0–7
Taking scheduled medications, No. (%)	46 (44.2)
Mean No. of scheduled meds (SD)	0.5 (0.7)
Range	0–3
Patient BMI (missing = 9), kg/m^2	
Mean (SD)	31 (7.3)
Range	16.9–55.1
Obese (%)	52 (53.6)
Patient-reported characteristics	
Age, y	
Mean (SD)	48.7 (13.2)
Range	23–82
Younger < 50 y (%)	58 (55.8)
Older ≥ 50+ y (%)	46 (44.2)
Gender, No. (%)	
Female	71 (68.3)
Race, No. (%)	
Nonwhite	10 (9.6)
Ethnicity (missing = 7), No. (%)	
Hispanic	3 (3.1)
Marital status, No. (%)	
Single/divorced/widowed etc.	46 (44.2)
Married/living in partnership	58 (55.8)
Rurality, No. (%)	
Resides in rural county	26 (25.0)
Primary medical payment, No. (%)	
Private insurance	61 (58.7)
Medicare/Medicaid	33 (31.7)
None/self pay	10 (9.6)
Current smoker, No. (%)	
Yes	31 (29.8)
Self-reported health in past year, No. (%)	
Poor/fair	58 (55.8)
Good/excellent	46 (44.2)
Duration of chronic low back pain, No. (%)	
Mean y (SD)	10.6 (9.0)
Range	0.25–40
Expected helpfulness†	
Mean (SD)	7.1 (1.9)
Outcome variables	
Oswestry Disability Index (ODI) score*	
Mean % disabled (SD)	38.0 (16.4)
Range	10–84
SF-36v2†‡	
Physical Component Summary	
Mean (SD)	34.5 (8.5)
Range	16.9–51.8
Mental Component Summary	
Mean (SD)	44.4 (12.7)
Range	15.9–72.3
Bodily Pain Domain	
Mean (SD)	33.4 (6.4)
Range	21.7–51.5

*Higher number indicates worse outcome (0–100 scale).
†Higher number indicates better outcome/higher expectation.
‡Scores are normalized [19].

significant from V2 to V3 for the SF-36v2's Mental Component Summary and Bodily Pain Domain.

Step 2 Analysis – Clinically Meaningful Improvement

Clinically meaningful changes in pain- and health-related quality of life were the outcomes of most interest for the study team. Table 5 displays the proportion of participants who had clinically meaningful improvement from baseline at V2 and V3 for each outcome measure. More than half (54.1%) of participants had clinically improved pain at V2 following the 12-week intervention period, with 42.1% continued to report clinically meaningful change at three months post–intervention application (V3). Of those who had clinically meaningful change on the ODI at V2 (N = 46), 24 (75%) retained clinically meaningful change at V3 ($P < 0.01$). For the SF36v2 Physical and Mental Component Summaries, 55.4% and 43.4% reported clinically meaningful change following the intervention period, with 46.1% and 30.3% reporting clinical improvement at V3. For Bodily Pain, 49.4% and 40% were clinically improved at V2 and V3.

Step 3 Analysis – Factors Moderating Massage Outcomes

Three baseline variables were associated with favorable changes in SF-36v2 Bodily Pain Domain: Specifically, there

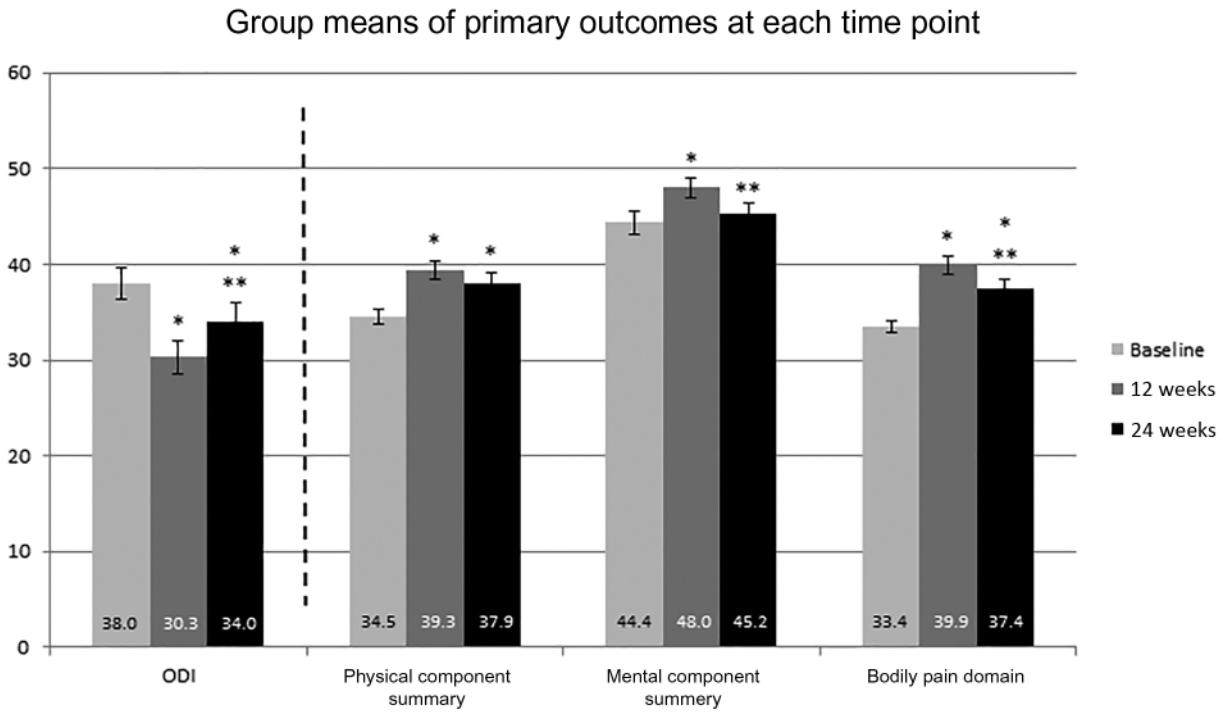

Figure 2 Group means of primary outcomes. ODI = Oswestry Disability Index.
*Compared to Baseline; p ⩽ 0.01
**Compared to 12-weeks; p ⩽ 0.01

Table 4 Mean point change scores for primary outcomes

Outcome variables	Mean point change score V1–V2	Mean point change score V1–V3	Mean point change score V2–V3
Oswestry Disability Index (ODI) Mean (SD)	7.5* (10.6)	4.2 (12.1)	−3.8 (10.9)
SF-36v2[†,‡] Physical Component Summary (missing = 2, TD2), mean (SD)	4.7* (7.0)	3.5* (8.1)	−1.6 (6.4)
Mental Component Summary (missing = 2, TD2), mean (SD)	3.1* (8.7)	0.8 (9.3)	−3.0* (7.6)
Bodily Pain Domain Mean (SD)	6.4* (8.6)	4.1* (8.9)	−2.6* (7.6)

*Determines group mean change is clinical significant improvement (see Table 2).
[†]Higher number indicates better outcome/higher expectation.
[‡]SF-36v2 scores are T-scores with mean = 50 and SD = 10.

was a positive correlation between the measure and PCP's perception of health ($P = 0.04$) but inverse correlations of the measure with PCP perception of pain ($P < 0.01$) and number of pain-related medications ($P = 0.05$). Regression analysis showed that participants age 50 years and older had higher ODI change scores from baseline to 12 weeks (4.6 ± 9.7 vs 10.3 ± 10.8, $P = 0.01$) and ODI change scores increased as number of scheduled medications decreased ($r^2 = 0.07$, $P = 0.02$). The negative influence of the number of scheduled medications on ODI change scores remained when controlling for baseline ODI score, gender, and duration of CLBP (model $P < 0.01$, number of scheduled medications $P < 0.01$). Participants prescribed at least one scheduled medication were 2.46 times more likely to not achieve clinically significant improvement in SF-36v2 physical functional health (95% confidence interval [CI] = 1.01–5.99). The

contribution of scheduled medication status to not achieving clinically significant improvement remained when baseline physical component summary, age, gender, and CLBP duration were included in the regression model ($P = 0.02$).

Regarding V1–V2 change success, odds ratios determined that adults age 50 years and older were 3.75 times more likely than younger counterparts to achieve clinically significant improvement on the ODI (95% CI = 1.5–9.2). Seventy percent of adults age 50 years and older achieved clinically significant improvement compared with 38% of younger adults ($X^2 = 8.6$, $P \leq 0.01$).

Retention of V2 Demonstrated Clinically Meaningful Change at V3. Spearman correlations revealed only one baseline characteristic associated with V3 retention of clinically meaningful change demonstrated at V2. Specifically, nonobese participants had smaller but still clinically meaningful changes at 12 weeks for the ODI retained at 24 weeks. Obese participants had much larger improvement in ODI at 12 weeks but failed to retain this change at 24 weeks (repeated measures mixed linear modeling including time/obesity interaction term; $F = 10.9$, $P < 0.001$).

Table 5 Frequency of individual significant clinical change*

Measure and criterion	V1–V2 (N = 85), No. (%)	V1–V3 (N = 76), No. (%)
Oswestry Disability Index (ODI)		
ODI – point change		
Change of ≥ 6	46 (54.1)	32 (42.1)
SF-36v2		
Physical Component Summary		
Change of ≥ 3.8	46 (55.4)	35 (46.1)
Missing	2	0
Mental Component Summary		
Change of ≥ 4.6	36 (43.4)	23 (30.3)
Missing	2	0
Bodily Pain Domain		
Change of ≥ 5.5	42 (49.4)	30 (40)

*Per outlined clinical significance parameters [19,21,27].

Supportive Descriptive Outcomes

Participant-perceived treatment effects of and satisfaction with massage for CLBP are reported in Tables 6 and 7 for all participants and per success of clinically meaningful change from baseline for the ODI at V2. Table 6 also reports participant-perceived massage helpfulness for CLBP per clinically meaningful ODI change success from baseline to V3. Simple linear regression indicated that those who had clinically meaningful improvement in their ODI from baseline to V2 and V3 perceived massage to be more helpful for their CLBP than did those who did not have clinically meaningful improvement at the respective time point. However, even though fewer participants had clinically meaningful improvement at V3, the mean and standard deviation for perceived massage helpfulness improved from V2 to V3. Created dichotomous variables for treatment satisfaction and perceived effects indicated that a majority of participants were

Table 6 11-point numeric rating for perceived treatment effect at Visit 2 and Visit 3

		Clinically meaningful ODI Improvement at V2				Clinically meaningful ODI improvement at V3		
	V2 All (N = 85)	No (n = 39)	Yes (n = 46)	*P*	V3 all (N = 76)	No (n = 44)	Yes (n = 32)	*P*
Perceived helpfulness of massage for chronic low back pain								
Mean (SD)	6.5 (3.7)	4.9 (3.7)	8.0 (3.0)	<0.0001	7.4 (2.8)	6.4 (3.1)	8.3 (2.3)	0.0027

Table 7 Dichotomous satisfaction and perceived treatment effect variables at Visit 2

	Strongly or very strongly agree, No. (%)	Strongly or very strongly agree at V2 per clinically meaningful ODI improvement at V2		
		No (n = 39)	Yes (n = 46)	*P*
Overall, massage helped my back.	52 (61)	18 (46)	34 (74)	0.009
My low back pain improved because of massage.	50 (59)	16 (41)	34 (74)	0.002
I would want massage again if my back pain returns or gets worse.	63 (74)	24 (62)	39 (85)	0.01
Overall, I am satisfied with the therapy I received.	68 (80)	27 (69)	41 (89)	0.02
This therapy relieved my pain.	46 (54)	14 (36)	32 (70)	0.002

satisfied with and perceived benefit from massage for their CLBP although a higher proportion of participants with clinically meaningful ODI improvement at V2 strongly or very strongly agreed with each measurement statement.

Discussion

Treatment options for CLBP are numerous, with care often discordant with clinical guidelines [28]. While competing demands, patient preferences, and costs influence treatment decisions, clinician perception of whether a treatment works for patients in their practice likely plays a critical role in the selection of treatments [29,30]. Our findings of statistically and clinically meaningful benefit to CLBP after a course of real-world massage therapy suggest the need for further study of massage when recommended by PCPs.

We sought to address concerns that massage is insufficiently studied in primary care and embraced a pragmatic approach [31]. Briefly, PCPs made the decision as to which patients to recommend to massage. Patients were not excluded due to comorbidities. The broad inclusion criteria permitted a wider range of patient characteristics, including age and obesity, that proved to be significant factors. The ability of study massage therapists to develop and apply individualized specific treatment plans informed by their unique training and continuing education experiences enhances confidence that specific massage interventions need not be selected by the PCP but left up to the clinical decision-making of massage therapists. These are marked differences from methods of more controlled studies and are reflective of how a course of massage therapy would typically be applied and accessed in the United States.

Patient-Related Factors Uncovered

Not limiting advanced age allowed for a broad age range (23–82 years) in KYPROS. This contributed to our finding that CLBP patients 50 years of age and older may have a greater probability of receiving clinically meaningful benefit from massage. This is an important finding considering that CLBP prevalence is high in the Baby Boomer cohort (born 1946–1964) [32] and our dichotomous age variable categorized this cohort in our older age category (50+ years).

Another novel methodology aspect of KYPROS permitted inclusion of patients on DEA scheduled medications. While the number of scheduled medications was negatively associated with ODI improvement, the fact that participants were on scheduled medications at all was not associated with the likelihood of clinically meaningful benefit in pain and disability. It may be the quantity of such medications that affects massage benefit rather than whether the patient is simply on scheduled medications. However, we are unsure of the extent to which our study sample is representative of those on scheduled medications for CLBP. First, there were differences in total number of pain-related medications between those who were lost to follow-up or completed V2; those with higher pharmacological burden were less likely to complete data collection at 12 weeks. In addition, patients who were prescribed at least one scheduled medication made up a larger proportion (70%) of those for whom PCPs completed pocket cards but did not refer into the study or specifically recommend massage ($P < 0.01$). Of those who were referred to the study from PCPs and agreed to be contacted, CLBP patients prescribed at least one scheduled medication had a lower proportion of enrollment (63%) than those not reported as being on a scheduled medication (73%; nonsignificant P values). Understanding the extent to which massage is beneficial for those on scheduled medications is important, especially in light of efforts to reduce the use of opioids and other scheduled medications in pain populations [33,34]. Accordingly, targeted methods to recruit and retain more pharmacologically burdened (and specifically, opioid-using) CLBP patients should be incorporated in future studies.

Brief Feasibility Findings

KYPROS incorporated novel design features, the feasibility of which had not been examined previously. Novel design features of note included the use of community practicing massage therapists for intervention delivery and research participants accessing real-world massage as they would in a nonresearch setting. While a single massage therapist was assigned to each participant, all therapist/participant communication and contact were initiated and maintained by study therapists and participants. Research study personnel were not involved with the scheduling or management of treatments accessed or applied. By taking these key elements out of the hands of the researchers, a less controlled and more pragmatic approach was employed. Ultimately, we did not know the extent to which study participants would access and schedule the stipulated 10 massage sessions on their own. We found that 90% of patients initiated at least one massage treatment and 60% received all 10 treatments. The extent to which our CLBP participants accessed and completed the course of massage treatments allowed in this protocol gives us confidence that adequate treatment exposure can be delivered with our study design.

We also found age differences in attrition at V2 and V3, with those younger than age 50 years more likely to drop out of the study. Younger people may have more obligations, making the extra care visits required for massage treatment to address their CLBP harder. This finding is important: low adherence rates in younger patients may make these treatments less advisable from a clinical perspective and from a research perspective; design considerations to support accessibility may be needed for younger patients.

The proportion of completed massage treatments was also considered in regards to feasibility of KYPROS's novel study design. Adherence to protocols of similar massage dosage (10 sessions over 10–12 weeks) for CLBP was considered

as completing eight treatments in prior research, with 88–93% of participants meeting adherence [35]. By comparison, our study found that approximately 78% of those who completed data collection at 12 weeks (N = 85) had accessed at least eight sessions, and so could be considered compliant to treatment utilization. We recognize that our numbers are lower than those of other studies, but KYPROS is the only study to our knowledge in which research study personnel were in no way responsible for intervention scheduling and follow-up. All responsibility for scheduling and access fell to study participants and massage therapists, again reflecting real-world massage access/utilization for most in the United States. To this end, our finding suggests that CLBP patients will access real-world massage treatment if recommended to do so by their PCP, at least under the conditions studied here, in which fee barriers were alleviated.

Limitations and Future Directions

Several limitations of KYPROS could be addressed by a larger, more comprehensive study. As a pilot study developing methods to examine massage in real-world practice, KYPROS made no comparison to usual care. To elucidate the extent to which benefits experienced by KYPROS participants were specifically attributable to massage, a no-treatment control or placebo comparison group is needed [36]. However, changes reported here were sufficient to be clinically meaningful; specifically, psychometric research has determined a six-point change as representing meaningful differences in low back pain with disability for the ODI [21,23,27]. While a 10-point change has been suggested as the minimally clinically important change for the ODI, Ostelo and de Vet also state the 10-point threshold is not set and, depending on aims, "should be used as an indication" [25]. For our pilot and feasibility purposes and considering that many participants not meeting the six-point change threshold in KYPROS still reported treatment satisfaction (69%), pain improvement (41%), pain relief (36%), and the desire to have massage again if the pain were to return or get worse (62%), we are confident in our use of the validated ODI six-point change threshold as indicative of meaningful change in low back pain and disability. Without a control group, we cannot unequivocally determine that massage was efficacious; however, KYPROS results serve as a signal of real-world massage effect for CLBP and further study using our piloted treatment application methods is needed. Finally, this study was conducted exclusively with Kentucky PCPs and patients; attitudes toward and availability of the treatments may differ elsewhere [37]. However, KYPROS results do speak to a region where massage is more novel [38] and not covered by health plans.

Conclusion

KYPROS results provide a meaningful signal of massage effect and call for further research in practice settings employing pragmatic designs with control groups to examine real-world massage effectiveness for primary care patients with CLBP. Our exploratory findings about the role of age, medications, and obesity on clinically meaning benefit and retention of benefit from massage for CLBP patients are promising. Increased study breadth will allow further examination of these variables, including physician perceptions by treatment effects as well as other patient-oriented variables in relation to health outcomes. Ultimately, our results and efforts may move us closer to giving PCPs comprehensive, multiple option strategies for select patient characteristics.

Authors' Contributions

Authors William G. Elder and Niki Munk contributed equally to this work and are co-first authors.

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