Forschende Komplementärmedizin
Wissenschaft • Praxis • Perspektiven

Original Article · Originalarbeit

Forsch Komplementmed 2013;20:180–188
DOI: 10.1159/000346291

Published online: Juni 20, 2013

Professional Kinesiology Practice for Chronic Low Back Pain: Single-Blind, Randomised Controlled Pilot Study

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Keywords
RCT · Pilot study · Kinesiology · Back pain · Whole systems medicine · Complex intervention

Summary
Background: Chronic low back pain is a highly prevalent condition with no definitive treatment. Professional Kinesiology Practice (PKP) is a little known complementary medicine technique using non-standard muscle testing; no previous effectiveness studies have been performed. **Methods:** This is an exploratory, pragmatic single-blind, 3-arm randomised sham-controlled pilot study with waiting list control (WLC) in private practice UK (2007–2009). 70 participants scoring ≥4 on the Roland and Morris Disability Questionnaire (RMDQ) were randomised to real or sham PKP receiving 1 treatment weekly for 5 weeks or a WLC. WLC's were re-randomised to real or sham after 6 weeks. The main outcome was a change in RMDQ from baseline to end of 5 weeks of real or sham PKP. **Results:** With an effect size of 0.7 real treatment was significantly different to sham (mean difference RMDQ score = –2.9, p = 0.04, 95% CI –5.8 to –0.1). Compared to WLC, real and sham groups had significant RMDQ improvements (real –9.0, p < 0.01, 95% CI –12.1 to –5.8; effect size 2.1; sham –6.1, p < 0.01, 95% CI –9.1 to –3.1; effect size 1.4). Practitioner empathy (CARE) and patient enablement (PEI) did not predict outcome; holistic health beliefs (CAMBI) did, though. The sham treatment appeared credible; patients did not guess treatment allocation. 3 patients reported minor adverse reactions. **Conclusions:** Real treatment was significantly different from sham demonstrating a moderate specific effect of PKP; both were better than WLC indicating a substantial non-specific and contextual treatment effect. A larger definitive study would be appropriate with nested qualitative work to help understand the mechanisms involved in PKP.

Schlüsselwörter
RCT · Pilotstudie · Kinesiologie · Rückenschmerzen · Ganzheitliche Therapiesysteme · Komplexe Intervention

Zusammenfassung
Hintergrund: Chronischer Kreuzschmerz ist eine häufig auftretende Belastung, die nicht endgültig therapiert werden kann. Eine professionelle Anwendung von Kinesiologie («Professional Kinesiology Practice», PKP) ist eine bislang wenig bekannte komplementärmedizinische Technik, die sich des nichtstandardisierten Muskeltests bedient. Zuvor wurden noch keine Effektivitätsstudien durchgeführt. **Methodik:** Bei dieser Untersuchung handelt es sich um eine explorative, pragmatische, einfach verblindete, 3-armige randomisierte Sham-kontrollierte Pilotstudie mit einer Wartelistenkontrollgruppe im hausärztlichen Setting (2007–2009). 70 Teilnehmer mit einem Wert von ≥4 auf dem «Roland and Morris Disability Questionnaire» (RMDQ) wurden jeweils in 2 Gruppen randomisiert, in denen sie jeweils scheinbar und tatsächlich mit PKP behandelt wurden. Die Patienten erhielten 5 Wochen lang 1 Behandlung wöchentlich oder wurden der Wartelistenkontrollgruppe zugeteilt. Die Kontrollgruppe wurde nach 6 Wochen erneut in 2 Gruppen randomisiert, in denen jeweils scheinbar und tatsächlich mit PKP behandelt wurde. Das Hauptresultat war eine Veränderung des RMDQ-Werts von Beginn bis zum Ende der Behandlung nach 5 Wochen. **Ergebnisse:** Die tatsächliche Behandlung unterschied sich mit einer Effektstärke von 0,7 signifikant von der Scheinbehandlung (durchschnittlicher Unterschied des RMDQ-Werts = –2,9; p = 0,04; 95% CI –5,8 bis –0,1). Verglichen mit der Wartelistenkontrollgruppe wiesen die beiden tatsächlich und scheinbar behandelten Patientengruppen signifikante Verbesserungen des RMDQ-Werts auf (Verum: –9,0; p < 0,01; 95% CI –12,1 bis –5,8; Effektstärke 2,1; Sham –6,1; p < 0,01; 95% CI –9,1 bis –3,1: Effektstärke 1,4). Die ärztliche Empathie und die Befähigung der Patienten antizipierten das Resultat nicht; ein umfassendes Gesundheitsverständnis trug jedoch dazu bei. Die Scheinbehandlung erschien glaubwürdig; die Patienten bemerkten die Behandlungsaufteilung nicht. 3 Patienten berichteten über geringfügige unerwünschte Nebenwirkungen. **Schlussfolgerungen:** Die tatsächliche Behandlung unterschied sich signifikant von der Scheinbehandlung, indem sie einen moderaten spezifischen Effekt der PKP zeigte; beide unterschieden sich klar von der Wartelistenkontrollgruppe, insofern ein grundsätzlicher nichtspezifischer und kontextgebundener Behandlungseffekt beobachtet werden konnte. Unter diesen Gesichtspunkten wäre eine größere Abschlussstudie mit verschachtelten qualitativen Ansätzen angemessen, um die bei der PKP wirkenden Mechanismen verständlicher zu machen.

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Introduction

Kinesiology is a multi-model complementary therapy consisting of many branches using different approaches [1, 2]. But all of them utilise non-conventional manual muscle testing as a diagnostic tool. Through the non-standard muscle test, kinesiology aims to assess the need for and to select individualised natural treatments to aid the promotion of health. The detailed diagnostic and therapeutic processes are described in other publications [3–5]. This study examines 1 specific branch of kinesiology known as Professional Kinesiology Practice (PKP) [6]. PKP is a goal-oriented educational process that employs a non-standard muscle test to select manual techniques derived from chiropractic, practices from traditional healing methods and acupuncture theory, lifestyle and dietary advice alongside psychological approaches said to reduce emotional stress and improve coping strategies. The results of the muscle test guide the process; thus there is no standard decision tree.

We chose to investigate the effect of PKP for chronic low back pain as it is a common problem and the most prevalent of musculoskeletal conditions [7, 8] with nearly half of all adults in the UK having experience of back pain [9]. Anecdotal evidence suggests that PKP is a clinically helpful therapy; however our recent systematic literature review concluded that the quality of the literature in this field was very poor and with insufficient evidence to ascertain if kinesiology of any type had a specific therapeutic effect for any condition [10]. Our aim was to conduct a pragmatic feasibility trial to determine if there was any evidence for the clinical effectiveness and efficacy of PKP in chronic low back pain initially as a whole complex system as suggested by the Medical Research Council (MRC) guidelines [11] rather than make an initial attempt to dissect its component efficacy.

We previously developed a sham PKP procedure with professional kinesiologists and assessed and confirmed its credibility to patients and practitioners [12]. The sham comprised a fixed routine of 14 non-standard muscle tests said to relate the major meridians of the acupuncture system with sham correction procedures. We considered that the contribution of the non-specific effects of PKP might be substantial and therefore designed a 3-arm sham-controlled trial to assess the contribution of the specific and non-specific effects of PKP intervention. Our specific research aims were to estimate the effectiveness of PKP for chronic low back pain with the RMDQ and to investigate its non-specific effects, potential predictors of outcome and the credibility of real and sham treatment.

Material and Methods

Participants

Volunteers were included using similar criteria to the UK back pain exercise and manipulation (UK BEAM) trial [13] i.e. aged between 18 and 65 years, diagnosed by their general practitioner (GP) with non-specific low back pain and scoring ≥4 on the well validated RMDQ [14]. The exclusion criteria were: serious spinal pathology or systemic illness, psychosis, litigation pending or in receipt of disability allowances, previous spinal surgery or awaiting surgery, pain radiating below the knee, weighing more than 15 stone and treatments other than analgesics. Patients with previous kinesiology experience were excluded to improve the security of blinding to placebo. Back pain was defined as musculoskeletal pain generally described as being between the lower ribs and inferior gluteal folds and further defined as chronic if patients had had pain at least 3 months previously and pain during the last 3 weeks [15].

Recruitment

Potential volunteers in the community with low back pain who had previously seen their GP about their back but still had pain were recruited via the local press in 1 UK country (articles, adverts, posters). Interested participants completed an initial screening questionnaire by telephone and if appropriate were sent an information pack describing the study design advising them that a proportion of patients would receive a placebo treatment and an appointment to attend the kinesiology clinic 7 days later for further screening. Ethical approval was granted by the South West Surrey Local Research Ethics Committee, number 04/Q1909/22 and the trial was registered (ISRCTN76057921).

Study Design and Procedures

This was a pragmatic, single-blind randomised sham-controlled pilot study to assess the effect of PKP for non-specific chronic low back pain. At screening clinic, eligible patients gave written consent and completed the baseline outcome measures unassisted in a private waiting area. Baseline measures comprised the RMDQ, visual analogue scale (VAS) pain [16], Short Form Health Survey 36 (SF-36) [17], Measure Your Medical Outcome Profile (MYMOP) [18] and the Complementary and Alternative Medicine Beliefs Inventory (CAMBI) [19] (table 1). Volunteers were randomised to treatment group by a research assistant from a stack of coded sealed envelopes which had been pre-pared by the trial statistician and blocked in units of 9 (the size and starting point of the block was unknown at the point of randomisation). Patients were randomised to A) real treatment, B) sham treatment or C) a delayed treatment. Patients in group C were put on a waiting list for 6 weeks and then subsequently re-randomised to the same real or sham treatment. Each patient received 1 treatment per week from the sole practitioner for 5 weeks of real or sham PKP completing outcome measures comprising the MYMOP, VAS pain, Consultation and Relational Empathy (CARE) [20] and the Patient Enablement Instrument (PEI) [21] after each visit in the waiting area. On arriving for treatment 2, patients completed the Credibility and Expectancy Questionnaire [22] which was based on their perceptions of treatment after 1 session. The RMDQ and SF-36 were also completed at last treatment and at 7 weeks follow-up by post along with the VAS pain, MYMOP and CAMBI (table 1). Patients not responding to the follow-up letter were telephoned after 2 weeks and a further follow-up pack sent if necessary. A final telephone call was made after another 2 weeks for non-responders in an attempt to complete the data set.

All the consultations were audio recorded by digital recorder. A sample (10%) was analysed independently prior to un-blinding by S.B. and G.L. to ensure that the consultation content reflected the allocated type of consultation.

Interventions

Participants in group A received full PKP treatment [3] which comprised individualised techniques from the PKP repertoire at each session. Participants in group B received a previously designed and piloted sham treatment [12] which used a polite conversation avoiding topics assumed in PKP to be of therapeutic value such as feelings, problem impact or goal setting. An overview of the real and sham treatment protocols may be found in table 2. All the treatments took place at the private kinesiology clinic during normal working hours and were delivered by the lead author who was the sole practitioner and was not blind to treatment allocation.

Table 1. Time points for outcome measures through the study

Outcome measure	Baseline	T 1	T 2	T 3	T 4	T 5	Follow-up	Waiting period
RMDQ	✓					P	P	
SF-36	✓					P	P	
VAS pain	✓	✓	✓	✓	✓	✓	✓	✓
MYMOP	✓							
MYMOP follow-up		✓	✓	✓	✓	✓	✓	✓
CAMBI	✓					P	P	
Patient enablement instrument		P	P	P	P	P		
Consultation and relational empathy		P	P	P	P	P		
Back pain improvement question?						P		
Guess which treatment?						P		
Credibility of treatment			P					

RMDQ = Roland Morris Disability Questionnaire; SF-36 = Short Form Health Survey 36; VAS = visual analogue scale; MYMOP = Measure Your Medical Outcome Profile; CAMBI = Complementary and Alternative Medicine Beliefs Inventory.

Table 2. Overview of treatment protocols

Real PKP treatment	Sham PKP treatment
Back examination – measurements of restriction and movement	back examination – measurements of restriction and movement
Individualised PKP treatment according to the PKP protocol [3]	non-individualised muscle testing assessment routine according to the previously developed sham protocol [12]
Therapeutic conversation	non-therapeutic conversation
Post-check measures of restriction and movement	application of sham correction points during the assessment protocol
Discuss changes with patient	sham re-check of muscle strength
Determine self-administered techniques for home maintenance	no advice or self-administered techniques given apart from advice to stay active

Table 3. Baseline characteristics by group

Characteristics, mean (SD)	Group A (n = 20)	Group B (n = 21)	Group C (n = 17)
Age	48.83 (10.5)	48.1 (10.6)	44.6 (10.3)
Gender	male = 3 female = 17	male = 7 female = 14	male = 6 female = 11
Back pain duration, years	15.6 (11.9)	11.6 (8.6)	9.2 (6.6)
RMDQ	10.7 (5.0)	11.3 (4.1)	10.4 (5.2)
VAS pain	43.0 (24.6)	51.8 (19.2)	52.2 (20.5)
SF-36 physical scores	35.3 (6.1)	36.1 (4.8)	37.0 (5.3)
SF-36 mental scores	46.0 (8.2)	46.8 (7.9)	42.6 (8.4)
MYMOP 1	3.8 (1.3)	3.9 (0.9)	4.0 (1.1)
MYMOP 2	3.8 (1.3)	3.8 (1.2)	4.0 (1.0)
MYMOP activity	4.3 (1.3)	4.0 (1.2)	4.4 (1.1)
MYMOP well-being	2.7 (1.3)	3.2 (1.2)	3.2 (1.5)
CAMBI nat treatment	33.4 (6.6)	30.3 (7.6)	31.9 (6.5)
CAMBI participation	25.9 (4.4)	27.1 (4.2)	26.2 (3.3)
CAMBI holistic health	34.3 (5.6)	33.3 (6.6)	34.1 (6.1)

RMDQ = Roland Morris Disability Questionnaire; VAS = visual analogue scale; SF-36 = Short Form Health Survey 36; MYMOP = Measure Your Medical Outcome Profile; CAMBI = Complementary and Alternative Medicine Beliefs Inventory.

Sample Size Calculation

There were no previous trials of any kinesiology type on which to base a sample size calculation but we assumed that the PKP effect would be similar to chiropractic or acupuncture and calculated sample size based on the minimum clinically important difference (MCID) of the RMDQ of 2.5 points [23] and a standard deviation of 4 [24]. This gave a total sample size of N = 144 with 80% power and 5% significance allowing for 20% loss to follow-up.

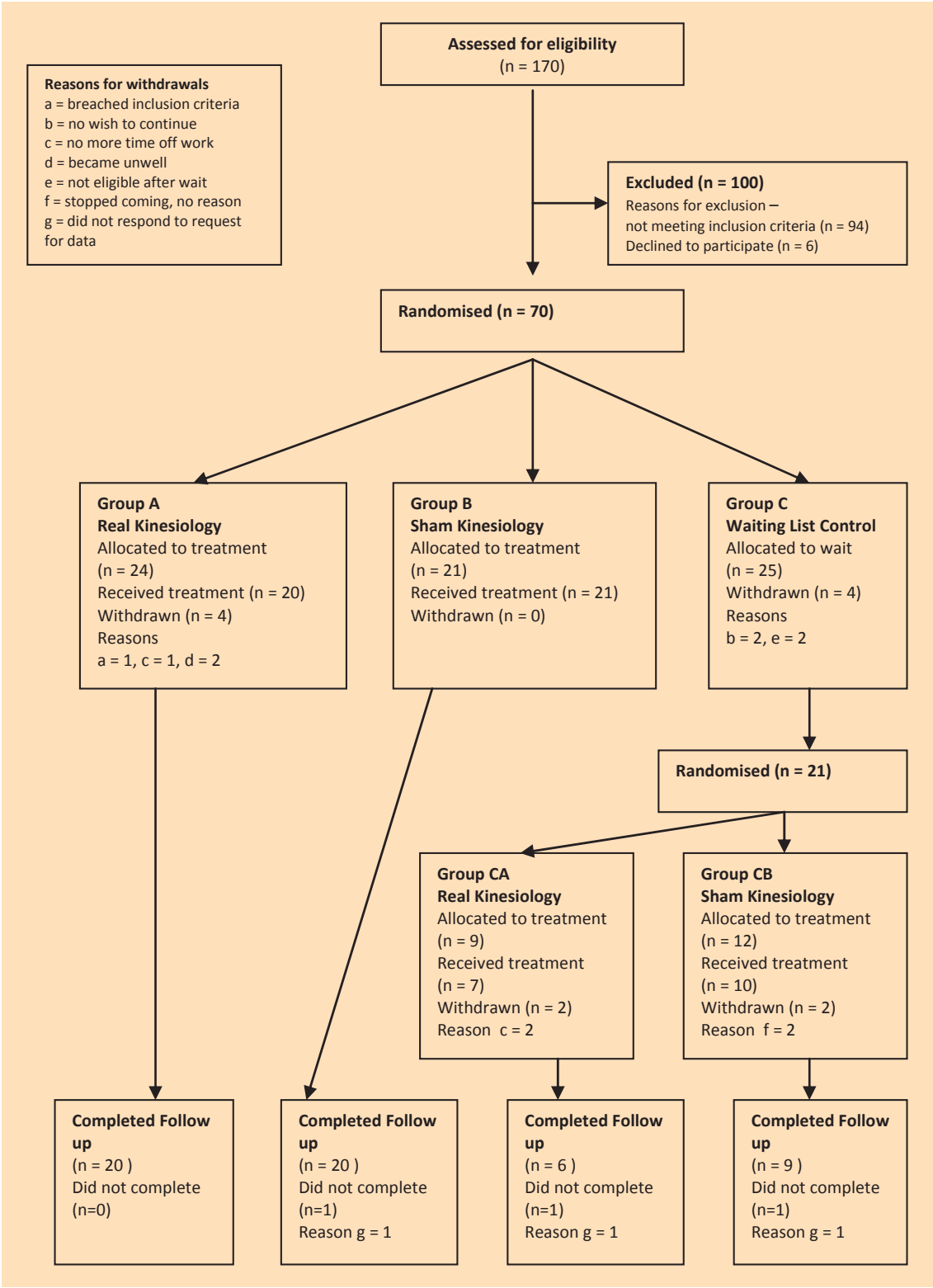

Fig. 1. CONSORT chart flow of participants through the study.

Statistical Analysis

Data was analysed using SPSS version 18. All statistical significances were set at $p < 0.05$. Analysis of covariance (ANCOVA) was used to compare means at week 5 for RMDQ and SF-36 scores for the 3 treatment groups with corresponding adjustments for baseline and demographic variables. Repeated measures analysis was used to compare the trends in weekly scores of VAS pain and MYMOP for the treatment groups over the 5 weeks of treatment. The potential of the CARE, PEI and CAMBI measures to predict the outcomes for the RMDQ was assessed using multiple regression analysis with adjustments for baseline differences and demographic variables. Credibility between the real and sham treatment was compared using a student t-test; frequency of correctness of patient guess for treatment allocation was compared using McNemar's test.

Table 4. Outcome scores at baseline and end of treatment week 5

	Baseline, mean (SD)	End of treatment, mean (SD)	Difference in means (SD)
RMDQ			
Group A	10.7 (5.0)	2.2 (3.5)	–8.3 (5.6)
Group B	11.3 (4.1)	4.9 (4.5)	–6.4 (5.2)
Group C	10.4 (5.2)	10.1 (5.3)	0.0 (4.6)
SF-36 physical scores			
Group A	35.3 (6.2)	40.6 (7.2)	4.3 (7.6)
Group B	36.1 (4.8)	38.3 (5.7)	1.2 (4.2)
Group C	37.0 (5.3)	waiting period	
SF-36 mental scores			
Group A	46.0 (8.2)	43.0 (9.5)	–1.9 (9.2)
Group B	46.9 (7.9)	45.5 (7.2)	–0.2 (9.5)
Group C	42.6 (8.4)	waiting period	
VAS pain			
Group A	43.0 (24.6)	29.0 (22.7)	–14.1 (29.8)
Group B	51.8 (19.2)	36.0 (19.8)	–15.8 (18.1)
Group C	52.2 (20.5)	57.7 (19.2)	3.8 (20.9)
MYMOP 1			
Group A	3.8 (1.3)	2.4 (1.7)	–1.4 (2.1)
Group B	3.9 (0.9)	2.3 (1.0)	–1.6 (1.2)
Group C	4.0 (1.1)	3.0 (1.3)	–1.0 (1.3)
MYMOP 2			
Group A	3.8 (1.3)	1.9 (1.7)	–1.4 (2.1)
Group B	3.8 (1.2)	2.4 (1.1)	–1.6 (1.2)
Group C	4.0 (1.0)	2.7 (1.7)	–1.0 (1.3)
MYMOP activity			
Group A	4.3 (1.3)	2.1 (1.6)	–1.9 (2.3)
Group B	4.0 (1.2)	2.7 (1.2)	–1.4 (1.5)
Group C	4.4 (1.1)	3.3 (1.7)	–1.3 (1.7)
MYMOP well-being			
Group A	2.7 (1.3)	2.0 (1.8)	–0.7 (1.9)
Group B	3.2 (1.2)	2.4 (1.0)	–0.8 (1.7)
Group C	3.2 (1.5)	2.1 (1.4)	–1.1 (1.8)

RMDQ = Roland Morris Disability Questionnaire; SF-36 = Short Form Health Survey 36; VAS = visual analogue scale; MYMOP = Measure Your Medical Outcome Profile.

Results

Participant flow is shown in figure 1. In total 55 patients (79%: 15 males, 40 females) completed both phases of the trial. Recruitment was slow and we were unable to achieve the numbers of patients we desired. Table 3 reports the baseline characteristics of the groups who received treatment and table 4 the outcome scores from baseline to end of treatment. In the ANCOVA of the RMDQ at week 5, baseline RMDQ was a significant covariate and was adjusted for the analyses in addition to age and gender as there were slight differences at baseline in these variables. Duration of back pain was not a significant covariate.

Primary Outcome Measure

ANCOVA of RMDQ at week 5 adjusted for baseline RMDQ showed both real and sham treatments reduced scores by more than the MCID of 2.5 points (table 5). Group A (real) improved significantly more than group B (sham) (mean score difference –2.9, p = 0.04, 95% CI –5.8 to –0.1) with a moderate effect size of 0.7. Group A (real) improved significantly more than group C WLC (mean score difference –9.0, p < 0.01 95% CI to –12.1 to –5.8) with a large effect size of 2.1 (Cohen's d [25] where >0.8 = large, 0.5–0.8 = moderate, 0.2–0.5 = small. Similarly group B (sham) improved significantly more than group C (WLC) (mean score difference –6.1, p = <0.01 95% CI –9.1 to –3.1) with a large effect size of 1.4. Group C RMDQ scores had not worsened over the waiting period; there were no differences in their mean scores from baseline to the end of the waiting period.

Table 5. Mean differences of outcome measures after 5 weeks of treatment adjusted for baseline differences

Groups	Score	Mean difference	SE	Significance	95% CI for differences	
					lower	upper
A vs. B	RMDQ*	–2.9	1.4	0.04	–5.8	–0.1
A vs. C		–9.0	1.6	0.00	–12.1	–5.8
B vs. C		–6.1	1.5	0.00	–9.1	–3.1
A vs. B	SF-36 physical*	3.2	2.2	0.16	–1.4	7.8
A vs. B	SF-36 mental	–2.9	–2.9	0.33	–8.9	3.1
A vs. B	VAS*	–6.4	4.1	0.13	–14.6	1.9
A vs. C		–18.3	4.7	0.00	–27.7	–8.8
B vs. C		–11.9	4.4	0.10	–20.8	–23.0
A vs. B	MYMOP 1*	0.0	0.3	0.99	–0.5	0.5
A vs. C		–0.6	0.3	0.03	–1.2	–0.1
B vs. C		–0.6	0.3	0.03	–1.2	–0.1
A vs. B	MYMOP 2*	–0.4	0.3	0.12	–0.9	0.1
A vs C		–1.1	0.3	0.00	–1.7	–0.5
B vs. C		–0.7	0.3	0.02	–1.2	–0.1
A vs. B	MYMOP a*	–0.6	0.2	0.02	–1.0	–0.1
A vs. C		–0.9	0.3	0.00	–1.4	–0.4
B vs. C		–0.4	0.2	0.15	–0.8	0.1
A vs. B	MYMOP w*	–0.1	0.3	0.77	–0.7	0.5
A vs. C		–0.3	0.3	0.32	–0.9	0.3
B vs. C		–0.2	0.3	0.41	–0.8	0.4

A = real; B = sham; C = waiting control; RMDQ = Roland Morris Disability Questionnaire; SF-36 = Short Form Health Survey 36; VAS = visual analogue scale; MYMOP = Measure Your Medical Outcome Profile.
* = achieved minimum clinically important difference (MCID).

Secondary Outcome Measures

Mean scores of the secondary outcome measures for group A versus group B are reported in table 4. Both treatment groups (A and B) had better mean SF-36 physical scores at end of treatment with the real group attaining the MCID [26]. No significant differences between them were identified (mean score difference = 3.2, p = 0.16, 95% CI –1.4 to 7.8) (table 5). Table 5 also shows the results of the treatment comparisons obtained by repeated measures analysis with adjustments for baseline for the other secondary outcome measures. For group A versus group B the MYMOP activity score was significant (mean score difference = –0.6, p = 0.02, 95% CI –1.0 to –0.1). VAS pain scores for both groups A and B and all 4 MYMOP scores for group A achieved the MCID. Group C (WLC) recorded greater pain after the waiting period (mean = 57.7, standard deviation (SD) = 19.2) than at baseline (mean = 52.2, SD = 20.5).

Predictor Variables and Credibility

There were no significant differences in CARE score between treatment groups identifying that both perceived the practitioner as equally empathic (p = 0.66, 95% CI –0.2 to 5.3). Group A (real) was significantly more enabled as measured by the PEI (2.7, p < 0.01, 95% CI 1.3–4.0). Linear regression analysis of the RMDQ at week 5 adjusted for baseline RMDQ identified that the holistic health beliefs subscale of the CAM-BI predicted outcome ($R^2 = 0.09$, p = 0.02) but the CARE and PEI did not.

Credibility of the Sham Treatment

Table 6 reports the mean scores and significances for the credibility/expectancy questionnaire completed on arrival for treatment 2.

There was no significant difference between groups for the credibility questions and the first of 3 expectancy questions implying initial practitioner equipoise; but the real treatment group showed greater expectancy on the remaining 2 expectancy questions (both p = 0.04). McNemar's tests determined no significant difference between patient guess for treatment allocation at last treatment, week 5 (p = 0.17) indicating that blinding was secure.

Follow-Up and Adverse Events

Both groups maintained their improvements from end of treatment to follow-up at week 12 (real: mean 3.1 (5.5), sham: mean 4.0 (4.7)). ANOVA adjusted for end of treatment differences demonstrated no significant differences in mean RMDQ scores at follow-up between real and sham treatment (differ-

Table 6. Mean scores and significances of the credibility/expectancy questionnaire

Question	Group n = 20/21	Mean (SD)	St Error	95% CI of the difference	Significance A vs. B
Q1. How logical does treatment seem? Scale 0–9	A	5.0 (1.5)	0.3	–1.5 to 0.8	0.50
	B	5.3 (2.0)	0.4		
Q2. Think – how successful in reducing symptoms? Scale 0–9	A	5.9 (1.3)	0.3	–0.4 to 1.4	0.30
	B	5.3 (1.6)	0.3		
Q3. Confident to recommend? Scale 0–9	A	5.9 (1.9)	0.4	–0.5 to 1.9	0.27
	B	5.2 (1.9)	0.4		
Q4. Think – how much improvement by end of treatment? Scale 0–100%	A	54.0 (16.7)	3.7	–6.5 to 23.4	0.26
	B	45.5 (28.6)	6.4		
Q5. Feel – treatment will reduce symptoms? Scale 0–9	A	6.2 (1.3)	3.0	0.1 to 2.5	0.04
	B	4.9 (2.3)	0.5		
Q6. Feel – improvement by end of treatment? Scale 0–100%	A	58.0 (22.4)	5.0	1.2 to 33.8	0.04
	B	40.5 (28.7)	6.3		

Equal variances assumed.

ence = 0.9, p = 0.66, 95% CI 4.48–2.86). Only 3 participants (2 sham, 1 real) reported reactions that could possibly be considered adverse; these comprised mild aching and tiredness after first treatment.

Discussion

The results of the study showed significant improvement in back pain disability after 5 weeks of real and sham treatment which was largely mirrored by most of the secondary outcome measures. Real treatment (A) was significantly better than sham (B) which was better than WLC (C), and both treatment groups achieved the MCID. These differences emerged in a group of patients with long-standing back pain indicating a clinically important effect from PKP. It is not possible to say how much of the sham group improvement was due to the talking or touch or what constitutes specific or non-specific effects within PKP as active components of this therapy have yet to be isolated and determined. It is reported that enhancing motivation, goal-setting and other psychological techniques such as those employed in real PKP improve physical capacity and treatment outcomes in low back pain [27–29]. Within the context of a whole system like PKP the elements of the intervention may have variable component efficacy depending on how they interact in any individual.

The simulation of an active therapy has a non-specific effect probably driven by many factors including treatment context such as patient expectations and emotions, touch and a caring positive practitioner attitude [30]. This is different from WLC which almost certainly measures the natural history of the condition and a comparison with sham allows the separation of these factors. In this study pain and well-being were subjective markers that improved with both treatments and one could assume that they would have got better anyway. However the waiting group showed no improvement and had worsening pain over the same time period. One must conclude that there were non-specific effects from both real and sham treatments specifically as a result of the consultation and treatment process.

Whilst SF-36 physical scores demonstrated improvement at week 5 for groups A and B, SF-36 mental scores were marginally lower and it is possible that volunteers were reacting to the withdrawal of practitioner care and attention although MYMOP well-being scores improved thus contradicting this argument. We postulate that benefits produced by CAM, feelings of control, better coping, self-respect and more choice may not be captured by commonly used outcomes measures like the SF-36 [31]. Qualitative work would be required to explore this concept further.

Whilst neither empathy nor enablement predicted outcome on week 5 RMDQ scores, the holistic health beliefs domain on the CAMBI at baseline did. There is contradictory evidence that attitudes towards and beliefs about CAM predict favourable responses to treatment although the concept of whole person well-being is associated with CAM use [32, 33]. Qualitative work would be necessary to explore this issue more fully.

Comparison with Other Studies

There are no other kinesiology studies with which this can be reasonably compared. Both real and sham PKP demonstrate large effects sizes compared to waiting control (real = 2.1, sham = 1.4). These effect sizes are high in relation other therapies compared to no treatment such as cognitive behavioural therapy (CBT) (0.24), exercise therapy (0.22) [34], acupuncture (0.62) [35] and CBT, exercise, manipulation and rehabilitation (0.5–0.8) [36]. This small feasibility study has produced very significant results compared to current best evidenced-based treatments. This may reflect the skill of the practitioner and may have been due to a particularly responsive group or might be an indication that we have discovered a very powerful intervention for the treatment of chronic low back pain.

Strengths and Limitations

This was the first rigorous study of any type of kinesiology. The inclusion of a WLC to control for natural history, regression to the mean and the non-specific effects of treatment allowed comparisons to be made to both real and sham treatment, thus avoiding some of the criticisms levelled at real versus sham parallel group studies. There were no previous rigorous kinesiology studies on which to estimate likely treatment benefit, so we based the sample size calculation on the assumption that the treatment difference would equal the MCID of 2.5 points on the RMDQ with a SD of 4 as would be used in clinical trials of conventional treatments. These changes in RMDQ represent real and significant clinical benefits for patients [37]. This calculation required 144 patients for the trial. In fact we identified a much greater difference in RMDQ scores between the treatment arms than we predicted. Had we known this a priori and calculated appropriately for the sample size would have been smaller. The fact that stratification for leg pain was not included may have impacted on the results as this factor is recognised to be a predictor of outcome for low back pain [38] and this could be included in future studies. The sham treatment whilst designed to be minimally effective may not necessarily have been so which could introduce bias minimising the real treatment effect.

By necessity the trial was single blind and the sole practitioner (S.E.) delivered all the treatments. However it appeared that participants blinding was successful and secure and the initial credibility was equal for the 2 treatments. It is possible that our findings are not representative of all kinesiology practitioners reflecting the skill of the practitioner rather than the intervention [39]. Future studies should use a number of practitioners.

It is impossible to generalise the results of this PKP study to different types of kinesiology because currently there is insufficient data to ascertain if the mechanisms and clinical effects are the same in the other branches of kinesiology and furthermore different kinesiology practices may approach the treatment of back pain differently.

Conclusions

Real PKP treatment was significantly different from sham PKP treatment demonstrating a significant specific effect for PKP. Both PKP treatments were better than WLC indicating a substantial non-specific and contextual treatment effect. We do not understand the mechanisms underpinning this observation but consider it could be either due to the process of a goal-oriented history taking and interviewing which increased coping skills [40–42] or an actual physical effect from PKP or both. A trial comparing PKP to CBT with a nested qualitative study should allow us to begin to separate out these 2 possible mechanisms.

Acknowledgements

We thank Peter Smith, Professor of Statistics, University of Southampton for randomisation codes, Jane Campbell, research assistant for data entry and Rachel Blake, research assistant for recruitment and data collection. G.L.'s post is funded by the Rufford Maurice Laing Foundation.

Disclosure Statement

There were no conflicts of interest. The trial protocol has been approved by an ethical committee and meets the standards of the Declaration of Helsinki in its revised version of 1975 and its amendments of 1983, 1989 and 1996.

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