

An Exploratory Pilot Study to Design and Assess the Credibility of a Sham Kinesiology Treatment

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Key Words

Sham treatment · Kinesiology · Pilot study · Chiropractic

Summary

Introduction: Kinesiology is a complementary therapy assessing subtle change in manual muscle testing results to select individualised treatments. We report the exploratory 2-stage development and pilot of a sham kinesiology treatment for use in a clinical trial to evaluate the specific effects of this intervention. **Aims:** 1. To design, pilot and assess the credibility of a sham kinesiology treatment in a kinesiology-aware population. 2. To pilot the sham kinesiology in a cross-over study of sham versus real kinesiology, and to make an exploratory assessment of its credibility in a kinesiology-naïve population. **Methods:** 1. 10 kinesiology-aware volunteers received a specially designed sham treatment weekly for 5 weeks which was subject to a credibility assessment. 2. 10 kinesiology-naïve patients with low back pain were randomised to receive 4 real and 4 sham treatments in a cross-over design; the treatments were subject to a credibility assessment. **Results:** 100% of participants found the sham protocol a credible treatment as measured by the credibility questionnaire. 100% of patients having real treatment first did not recognise that the second set of treatments were sham. Small numbers precluded the use of formal statistical tests. **Conclusion:** In this small sample it appeared feasible to deliver an apparently credible sham kinesiology treatment. This feasibility study has allowed us to develop a sham treatment for use in a larger prospective clinical trial of kinesiology in patients with low back pain.

Schlüsselwörter

Scheinbehandlung · Kinesiologie · Pilotstudie · Chiropraktik

Zusammenfassung

Einleitung: Kinesiologie ist ein komplementärmedizinisches Therapieverfahren, bei dem aufgrund kleiner Abweichungen im manuellen Muskeltest die individuelle Behandlung bestimmt wird. Wir berichten 1. über die Entwicklung einer kinesiologischen Scheinbehandlung und 2. ihre probeweise Anwendung als Grundlage für einen späteren Einsatz in randomisierten kontrollierten Studien. **Ziele:** 1. Entwickeln, Testen und Beurteilen der Glaubwürdigkeit einer Sham-Kinesiologie in einer Kinesiologie-erfahrenen Stichprobe. 2. Probeanwendung der Sham-Kinesiologie in einem Cross-over-Design mit Sham- und echter Kinesiologie sowie exploratische Erhebung der Glaubwürdigkeit von Schein- versus wirklicher Kinesiologie bei Kinesiologie-unerfahrenen Patienten. **Methode:** 1. 10 Kinesiologie-erfahrenen Freiwillige erhielten 5 Wochen lang eine eigens entwickelte Scheinbehandlung und schätzten ihre Glaubwürdigkeit ein. 2. 10 Kinesiologie-unerfahrenen Patienten mit Rückenschmerzen wurden im Cross-over-Design randomisiert jeweils 4 echten und 4 Sham-Kinesiologiebehandlungen zugewiesen und schätzten die Glaubwürdigkeit der Behandlung ein. **Ergebnisse:** Der Glaubwürdigkeitsfragebogen ergab, dass 100% der Teilnehmer die Scheinbehandlung überzeugend fand. 100% der Patienten, die zuerst die echte Behandlung erhielten, erkannten nicht, dass die zweite Behandlung eine Scheinbehandlung war. Aufgrund der kleinen Stichproben waren formale statistische Tests nicht möglich. **Schlussfolgerung:** In dieser kleinen Stichprobe schien es möglich, eine glaubwürdige Sham-Kinesiologiebehandlung durchzuführen. Es ist vorgesehen, diese Scheinbehandlung in einer größeren prospektiven klinischen Kinesiologiestudie mit Patienten mit Rückenschmerzen einzusetzen.

Introduction

Applied kinesiology (AK), initially developed by George Goodheart in the 1960's is a chiropractic speciality utilising manual muscle testing to assess change in neuromuscular function in response to physical, chemical or mental stimuli. The history, development and detailed processes of AK are described elsewhere [1]. In the 1970's John Thie developed a simple offshoot of AK for lay people called Touch for Health Kinesiology (TFH). Numerous variations of this simplified method were developed, some of which utilise a light muscle test as a yes/no answer system (strong response = yes, weak response = no) and derive their therapeutic interventions from a variety of energetic healing theories. These systems became known collectively as 'specialised' or 'energy' kinesiology.

In our review of the kinesiology literature [2] we concluded that there was insufficient evidence for us to ascertain if kinesiology had any specific therapeutic effect for any condition. However, anecdotal evidence suggests that kinesiology is a clinically helpful therapy and we wanted to understand if this system was of any specific clinical value. We proposed that kinesiology should be evaluated as a 'package' of treatment with a controlled and rigorous but pragmatic approach rather than an attempt to dissect its specific components. We suspected that a substantial proportion of the clinical effect produced by kinesiology could be non-specific. This could be identified by using a carefully constructed and credible sham treatment. Despite the challenges within similar types of manual interventions such as acupuncture [3] in designing and validating appropriate sham treatments, we reasoned that a carefully constructed sham treatment designed to be minimally effective but credible would be an appropriate strategic approach to this area. It would blind patients to group allocation reducing patient bias and allow us to assess its relative contribution of the specific treatment strategies within kinesiology. We also plan to compare real and sham kinesiology with a delayed treatment group to estimate the clinical effect

of being recruited to such a study and regression to the mean in this population.

The aim of this study was therefore to develop a sham treatment that was both practical for practitioners to use and credible to patients. A credible but ineffective sham treatment is essential to control for the potentially therapeutic effects of touch in randomised controlled trials of manual therapies [4]. However, developing sham interventions for manual therapies including osteopathy and chiropractic [5, 6] is difficult.

The aim of this study was two-fold: 1. To design a sham kinesiology protocol credible to kinesiology-aware patients and comfortable for the practitioner to perform convincingly. 2. To pilot the sham versus real kinesiology treatment on a kinesiology-naïve back pain population in an exploratory assessment of its credibility in a single-blind cross-over design.

Methods

Ethical approval was granted by South West Surrey Local Regional Ethics Committee (Ethics number 04/Q1909/22) and the study was carried out in Surrey, UK.

The objectives of stage 1 were to develop a sham protocol by consensus among kinesiologists and to assess the credibility of the sham treatment using a credibility questionnaire among volunteers who had previously experienced kinesiology treatment. These volunteers were told that they would be receiving different types of kinesiology and would be asked for their opinion about the treatments.

The aim of stage 2 was an exploratory assessment of the credibility of the sham versus real kinesiology in a kinesiology-naïve local low back pain population in a pilot single-blind cross-over study. The main object was to develop a preliminary understanding of whether it would be feasible and practical to take this model of sham versus real kinesiology into a larger randomised controlled study.

Stage 1. Development of the Sham Protocol

A panel of three professional kinesiologists with the same training and with greater than 5 years of clinical experience in a particular branch of kinesiology called Professional Kinesiology Practice (PKP) agreed by consensus that the sham treatment chosen from existing practice should meet the following criteria: i) it is used clinically in many branches of kinesiology and therefore has potential as a sham to investigate most

Table 1. Panel-selected changes to the Thie protocol

Option	Diagnostic protocol	Application of corrective measures
A	Standard 14 muscle assessment with correction point location	Corrective therapy ^a applied at the <i>end</i> of the protocol using <i>standard</i> technique. No re-checking muscles.
B	Standard 14 muscle assessment with correction point location	Corrective therapy applied <i>during</i> the diagnostic protocol with <i>non-standard</i> technique. Non-standard ^b re-check.
C	Standard 14 muscle assessment and correction point location	Corrective therapy points applied at the <i>end</i> of the protocol using <i>non-standard</i> technique. No re-check.
D	Standard 14 muscle assessment with correction point location	Corrective therapy applied <i>during</i> the diagnostic protocol with <i>standard</i> technique at <i>non-local</i> points. Non-standard re-check.

^aCorrective therapies = kinesiology reflex points.

^bNon-standard re-check = non-isolated test.

Table 2. Credibility rating of treatment scale [15]*Pre-treatment questions*

- How confident do you feel that this treatment can alleviate your complaint?
- How logical does this treatment seem to you?

Post-treatment questions

- How confident would you be in recommending this treatment to a friend who suffered from the same complaint?
- How successful do you think this treatment would be in alleviating other complaints?

Table 3. Stage 2. Inclusion and exclusion criteria*Inclusion*

18–65 years

Chronic or recurrent non-specific low-back pain (lower ribs to gluteal folds)

Previous episode of pain at least 3 months previously (constitutes a recurrent problem)

Current pain for the last 3 weeks (excludes short-lived occurrence)

Roland Morris Disability Scale score of ≥ 4 (constitutes a clinical problem)*Exclusion*

Under 18, over 65 years (serious spinal pathology more likely)

Currently undergoing other treatment for back pain other than analgesics (other treatment may have carry-over effect)

Previous kinesiology (naïvety required as a sham treatment is involved)

Serious spinal pathology or systemic illness (outside scope of study)

Psychosis or alcohol abuse (completion of forms, safety of practitioner)

Disability of limbs, inability to lie on or get on and off an examination couch (for purpose of muscle testing).

Weigh more than 15 stone (95.25 kg) (safety limit of examination table)

Litigation pending due to back pain or receiving disability allowance due to back pain (potential treatment resistance until monies received or stopped)

Previous spinal operation or waiting for same (outcome likely to be different)

kinesiology types; ii) the protocol is not condition-specific; iii) possibilities exist for altering the treatment to avoid what is considered therapeutic in kinesiology; iv) it can be convincingly performed by practitioners.

The ‘Thie 14 muscle balance’ [7] was selected as the optimal method for the sham treatment. This protocol is based on AK principles and comprises contraction tests of 14 postural muscles said to be related to the 14 main acupuncture meridians and their corresponding organs of the body. Muscles found to be ‘unlocking’ against tester pressure are purported (within kinesiology) to be strengthened by utilising reflex points on the body or head in specific ways on particular areas.

The panel discussed changes to the protocol that from kinesiology theory should not have a clinical benefit. It was considered important that the sham protocol looked as similar as possible to the traditional method [8] and was easy for a practitioner to perform. The proposed changes included separating the assessment and correction phase, non-standard correction technique, non-local correction points and non-standard result checking. Due to practitioner and volunteer time restraints, the panel agreed four combinations of changes for the practitioner to pilot for ease of use and ability to stay in patient equipoise (table 1).

Both touch and talking may have an effect on outcome [9–14] but whilst PKP cannot be performed without the use of touch, the consensus was to

Table 4. Summary of percentage of the groups scoring either very or slightly confident, logical and successful

Credibility question	Treatment allocation	First treatment, %	Second treatment, %
Confident to alleviate complaint	A-B real-sham	60	80
	B-A sham-real	50	100
Logical treatment	A-B real-sham	80	80
	B-A sham-real	100	75
Confident to recommend	A-B real-sham	80	80
	B-A sham-real	75	75
Successful for other complaints	A-B real-sham	80	80
	B-A sham-real	100	100

use polite conversation *only* in the sham treatment avoiding any conversation thought to be therapeutic within the PKP system. Allowed topics would include the weather, current affairs, sport, traffic, TV and fashion. Topics of conversation relating to relationship issues, work-related stress, the impact of the problem on personal achievement etc. would not be permitted within the sham protocol.

The 14 muscles would be tested in the usual manner of isolation which would be familiar to patients who previously had received kinesiology treatment. ‘Corrections’ to a practitioner determined un-lock could be applied directly after a muscle test (options B and D) or left until all the muscles had been assessed (options A and C). Traditionally, kinesiology body reflex corrections (known as neurolymphatic points) involve firm rotary digital pressure for approximately 10 s on specific areas; the sham would utilise light digital touch for 3–4 s on either the traditional (A, B, C) or non-local positions (D) instead; non-local being 2 inches above, below or to the side of the traditional position. The traditional method for kinesiology head reflex corrections (known as neurovascular points) is light digital holding on specific points for up to 5 min; the sham utilised gentle tapping on the traditional or non-local positions for 10 s instead. At the conclusion of the ‘correction’ the practitioner could either re-test the muscle in a slightly different position (un-isolated and involving recruiting muscles) in order for it to appear that a correction had taken place, i.e. the muscle appears stronger (B and D) or not re-test at all (A and C).

Real PKP treatment has a range of approximately 500 manual, psychological and other techniques with patients usually receiving 40–60 min treatment per visit. Each real treatment would be individualised from the full range of procedures whereas the sham treatment would be the same each time and not individualised. The sham treatment would resemble a real assessment and correction protocol although being simpler and utilising techniques assumed not to be corrective or therapeutic in general kinesiology theory. To allow for the potentially shorter treatment time, the standard examination and 14 muscle protocol would be performed more slowly.

Stage 1. Assessment of Credibility in Kinesiology-Aware Volunteers

Credibility of the sham treatment was assessed with the well-validated Borkovec and Nau [15] questionnaire which has been used extensively in previous acupuncture studies [16] (table 2). We were aware that a newer version of this questionnaire had been developed but it had not been validated in this context when this pilot project was initiated. We now plan to further use this new instrument in our next study to evaluate the credibility of the sham treatment [17].

The study was conducted in a single-handed private practice in Surrey, UK. An invitation to participate was sent to all patients on the practitioner’s list in which the treatment was described as a specially designed, similar but shorter general kinesiology treatment. The single practitioner (SH) providing the sham treatment was the same practitioner who had

Fig. 1. Flow chart of initial feasibility and credibility study (Rx = treatment).

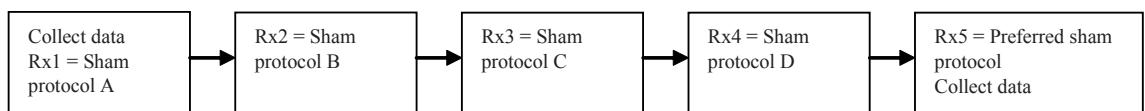


Fig. 2. Flow Chart of the cross-over study.

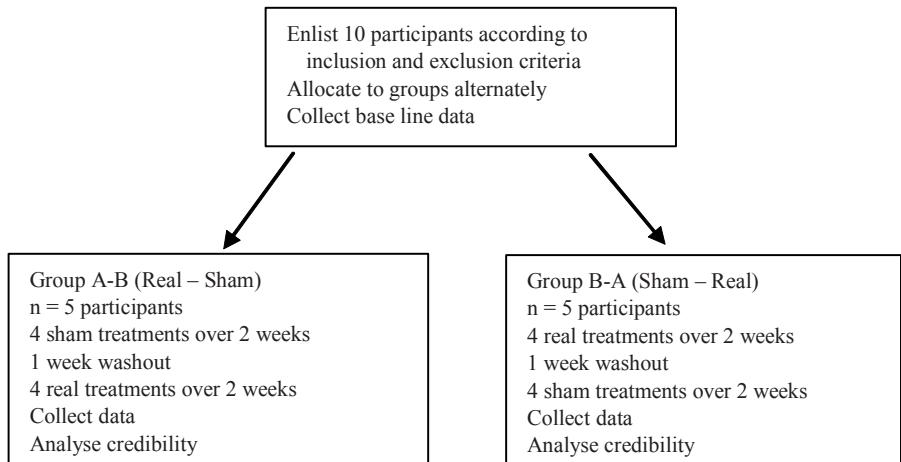
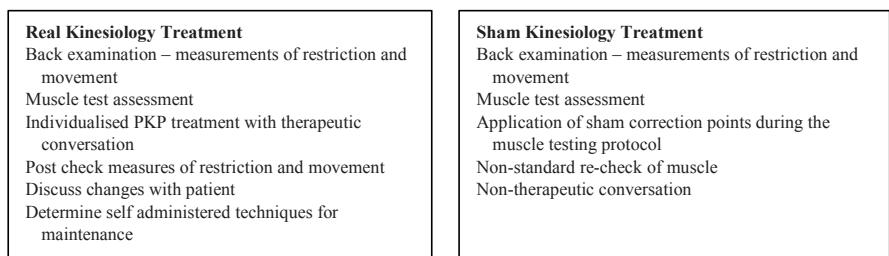


Fig. 3. Overview of treatment protocols.



treated the patients before they entered the study. Patients were told that they would be asked for their opinions about the short-form kinesiology treatment via the use of a questionnaire. The first 10 people who replied to the invitation to participate and could attend all the sessions were entered into the study. Patients were included if they had previously attended the kinesiology clinic for any condition, i.e. they were familiar with real kinesiology, and could attend all 5 sessions. Patients were excluded if they could not attend all 5 sessions. By chance all the participants were female. Informed written consent was obtained prior to the intervention. Patients completed the credibility questionnaire after having read the information leaflet but before the start of treatment and again at the end of the treatments. The process of the treatment protocol is shown in figure 1. The sole practitioner performed sham option A on each patient during week 1, option B on week 2 etc. until all options had been performed. The practitioner noted the timing of each option, the ability to stay in patient centred equipoise and the ease of remembering the protocol changes, discussing with the panel after each option. For the final session the practitioner performed their preferred option to confirm their choice.

Stage 2. Recruitment of Kinesiology-Naïve Patients

Adverts for a kinesiology for back pain study were placed in the local press. Applicants were initially screened by the practitioner's secretary for the inclusion and exclusion criteria (table 3) by telephone and if eligible were sent an information pack containing the patient information sheet and an appointment to come to the clinic at least 7 days later at a time

convenient to them to sign the consent form. 10 participants were entered into the study which took place at the researcher's private practice in Surrey, UK.

Stage 2. Study Protocol

Participants took part in the study for 5 weeks (fig. 2). After reading the patient information leaflet and giving informed written consent, each person received 2 treatments per week for 4 weeks of real or sham kinesiology, crossing over after 2 weeks with a washout-period of 1 week between types of treatment. Treatment protocols are described in figure 3. Eligible participants were allocated to group by the practitioner's secretary by simple alternate allocation in the order in which they had telephoned, which was not necessarily the order in which they presented at the clinic for the consent meeting; the first participant receiving real treatment then sham (treatment A then treatment B) and the second participant receiving sham treatment then real (treatment B then treatment A). The secretary booked all the subsequent treatment visits at times to suit the patients. The practitioner was unaware of group allocation until the first treatment for each patient and due to the patients' own choice of consent meeting and treatment times, group allocation was not initially predictable.

The primary outcome measure was the Credibility Questionnaire [15]. As a further credibility check, at the end of each treatment type, patients were asked if they thought their treatment was real or sham. Percentage comparisons were used as small numbers precluded the use of formal statistical tests (table 4).

Table 5. Patient response to question ‘did you have real or sham treatment?’ asked after each set of treatments.

Patient ID	First set of treatment	Patient guess	Summary	Second set of treatment	Patient guess	Summary
1	real	real	correct	sham	real	incorrect
3	real	real	correct	sham	real	incorrect
5	real	sham	incorrect	sham	real	incorrect
7	real	sham	incorrect	sham	real	incorrect
9	real	real	correct	sham	real	incorrect
Correct / incorrect, %		60 / 40			0 / 100	
2	sham	real	incorrect	real	real	correct
4	sham	sham	correct	real	real	correct
8	sham	real	incorrect	real	real	correct
10	sham	real	incorrect	real	real	correct
Correct / incorrect, %		25 / 75			100 / 0	

Results

Practitioner Assessment of the Sham Protocol

Option B (use of non-standard corrective procedure) was the preferred sham treatment; the routine was familiar, treatment time controllable and the non-standard corrective technique easily remembered. Options A and C were discarded as difficult to time appropriately, and the position of non-local points proved challenging to administer in option D due to the position of some traditional points. Non-therapeutic conversation was difficult with the volunteers due to the prior clinical relationship with the practitioner. It was postulated that this would be less problematic with new patients.

Credibility Assessment in Kinesiology-Aware Volunteers

Credibility questions 1 and 2 (asked before treatment) identified that 100% of patients felt confident about the treatment and 90% thought it was logical. Questions 3 and 4 (asked after treatment) identified that 100% of patients were confident in recommending the treatment and 90% felt the treatment would be successful for other complaints. Due to lack of variation in answers, no further statistics were computed.

Recruitment of Kinesiology-Naïve Patients

21 patients called about the study and were telephone-screened for the inclusion criteria. 3 cancelled their appointments before the consent meeting, 1 did not turn up for the consent meeting and attempts to contact them were unsuccessful and 7 were excluded as not meeting the inclusion criteria. 1 patient dropped out after consent but before the start of treatment leaving 9 patients (3 female and 6 male, mean age 51.6 years) who completed the study.

Credibility Questionnaire

Overall, there was no difference in credibility scores suggesting similar credibility between both treatment types in this

small sample: both groups had a higher percentage score for very or slightly confident in the treatment at the start of the second set of treatments whether they had a real or sham intervention. The percentage of both groups for very or slightly confident to recommend the treatment and very or slightly confident in alleviating other complaints were identical for both sets of treatment (table 4).

Patient Guess – Real or Sham?

For the first set of treatments, 40% of patients having real treatment first (group AB), guessed incorrectly thinking the treatment was a sham, whereas 75% of patients having sham first (group BA) guessed incorrectly thinking the treatment was real. For the second set of treatments, 100% of patients who had real treatment first also thought that the sham was real. 100% of patients having sham first guessed correctly that the real treatment was real (table 5).

Discussion

The sham kinesiology used in this small exploratory study appeared both feasible and credible and with practice was easy to perform whilst the practitioner remained in equipoise. To our knowledge, this is the first attempt to develop and evaluate a sham kinesiology procedure. We recognise that this exploratory study was carried out in a very small sample, but it has allowed us to develop the basis of a sham versus real kinesiology approach that can now be employed in a larger and more rigorous randomised controlled trial.

Kinesiology assumes that the specific treatment protocols employed are active, however the mechanisms involved are unclear. Clearly we cannot be certain whether the sham kinesiology protocol we designed was inactive due to the many non-specific factors that influence response to treatment in both

conventional and complementary medicine. However, we designed the sham protocol with the intent that the intervention would be minimally effective in relation to kinesiology theory. It appears, in this small sample, that it is feasible to deliver an apparently clinically credible sham kinesiology treatment. Although the sample size was small and therefore no statistical results could be computed, further work with a larger sample size is required and planned. The sole aim of this exploratory study was fulfilled, i.e. a sham treatment was designed and is apparently equally credible to real kinesiology treatment in both a kinesiology-aware and kinesiology-naïve population. Phase 1 was designed to identify a suitable sham treatment and utilised patients known to the sole practitioner who conducted this study. They were self-selected and unblind to kinesiology; it is possible that their prior relationship with the sole practitioner may have biased the outcomes they recorded. It is also possible that in stage 2, patients were treated differently depending on their treatment group although there is no evidence to suggest this argument.

Based on these findings, we propose that the sham intervention may be a credible and viable approach that will allow us

to explore the specific effects of kinesiology in the context of a randomised controlled trial. A clinical trial assessing the overall effectiveness of kinesiology as a 'package' of treatment is now underway. This will be based on a 3-arm design to assess real kinesiology treatment versus sham kinesiology treatment and a waiting list control (who will eventually receive kinesiology treatment) among patients with low back pain. We plan to evaluate the credibility of these interventions as well as the clinical effect of kinesiology in this population of patients in pain. This preliminary feasibility study has allowed us to develop our research strategy in a thoughtful and rigorous manner.

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