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-naive 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-naive 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.
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

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

*Corrective therapies = kinesiology reflex points.
*Non-standard re-check = non-isolated test.
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 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
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.

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).
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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