ISRCTN76057921 https://doi.org/10.1186/ISRCTN76057921

A pragmatic, single blind randomised controlled pilot study for professional kinesiology practice and back pain with initial feasibility study

Submission date
19/11/2007

Recruitment status
No longer recruiting

Registration date
10/04/2008

Overall study status
Completed

Last Edited
27/11/2012

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Nearly half of all adults in the UK have had back pain at some point in their lives making it a very common and costly problem. The United Kingdom Office for National Statistics report that three and a half million adults suffer with back pain the entire year. Fourteen to fifteen million GP consultations every year in the UK are due to back pain. Back pain costs the UK approximately £10668 million accounting for 13.5% of all incapacity benefits. Whilst there are many types of treatment for back pain, one that helps everyone has not yet been found.
Kinesiology is a relatively new and increasingly popular alternative treatment. It originated in the 1960s in America from a chiropractic technique and became known as Applied Kinesiology. Applied Kinesiology is practiced by some doctors, dentists and chiropractors. Since then many other types of kinesiology have been developed and the practice has spread to over 50 countries. Kinesiopractic®, otherwise known as Professional Kinesiology Practice (PKP) was developed from Applied Kinesiology in the 1980s by a New Zealand medical doctor.
Many people who have tried PKP for back pain say it helped them. Our goal was to do a study to find out if there was any scientific evidence that PKP could help back pain.

Who participated?
The participants in our study were men and women aged between 18 65 who had been diagnosed by their GP with low back pain. We included people who had chronic low back pain (pain that had lasted for at least 3 months or more) but were otherwise well and not taking any medication except for pain killers. In order to compare the treatments properly we had to make sure that everyone in the trial had a similar type of back pain. To do this we excluded some people from our study for example people who had already had surgery for their back pain, were waiting for surgery or had pain in another part of their back e.g. upper back.

What did the study involve?
In order to check eligibility for the trial we asked interested people to call us and answer a few questions about their pack pain over the phone. People who appeared to have the type of back pain we were looking for were then invited to the clinic to complete some questionnaires about their back pain. If the questionnaires confirmed they had the right type of back pain we asked

people to consent to participating and we then made appointments with them to come for kinesiology treatment.
The participants came to the kinesiology centre once a week for 5 weeks to have their kinesiology treatment. They completed some questionnaires each time about how their back pain had been during the previous week which helped us find out if the treatment was helping. Everyone in the study received kinesiology treatment. We wanted to test 2 types of kinesiology for back pain to see which was best. The statistician placed our participants into 3 treatment groups using a process called randomization which is rather like a coin toss. Only the practitioner knew which group each person was in. People received either traditional PKP or another type of kinesiology treatment. The people in the first two groups started their treatment straight away and people in the third group started their treatment a bit later.
Seven weeks after kinesiology treatment had finished, people completed a final set of questionnaires by post to help us find out if there were any lasting improvements.

What were the possible benefits and risks of participating?
The benefits we hoped that everyone would receive from the treatments were less pain, more flexibility, a general feeling of wellness and to be able to do more. There are no serious side effects with kinesiology as it is a very safe treatment and none were reported. Three people in our study felt a bit tired and achy after treatment but this only lasted about 24 hours or less. In complementary medicine these effects are quite common and are thought to indicate that the treatment is helping.

Where was the study run from?
The study took place in a private kinesiology office in Surrey.

When did the study start and how long did it run for?
The trial took place during 2008 2009 and ran for 12 months

Who funded the study?
We didnt receive any funding for the study.

Who was the main contact?
Dr Susan Eardley
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Contact information

Type(s)
Scientific

Contact name
Prof George Lewith

Contact details
University of Southampton
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Null hypothesis:
Kinesiology for back pain, as assessed by a reduction of 2.5 points on the Roland Morris Disability Scale after five weeks of treatment is not different from control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was granted by South West Surrey Local Regional Ethics Committee on the 6th August 2004 (ref: 04/Q1909/22).

Study design
A single blind, single centre, randomised controlled pilot study with initial feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic and recurrent low back pain

Interventions

1. Real kinesiolology: five treatments - once a week for five weeks
2. Sham kinesiology: five treatments - once a week for five weeks
3. Waiting control: six-week wait then re-randomised to either real or sham kinesiology - five treatments, once a week for five weeks

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Back pain disability measured on the Roland Morris Disability Scale, a 24 item tick questionnaire where a score of at least four points indicates a clinical problem suficient to measure change and a reduction of 2.5 after treatment indicates clinical change. Data collected at baseline, end of treatment and follow up.

Secondary outcome measures
1. 36-item short form health survey (SF-36): a global quality of life scale - 11 questions measuring physical function, role limitation, mental health, vitality, pain and general health, measured at baseline, end of treatment and follow up
2. Visual Analogue Scale (VAS) for pain (0 - 10) (0 = no pain, 10 = worst imaginable pain), measured at baseline, end of treatment and follow up
3. Patient Enablement Instrument (a measure of patient enablement): six questions asking how the patient feels about coping with life after the consultation - scored on a four-point scale, measured at end of treatment
4. Consultation and Relational Empathy (CARE) (a measure of empathy): 11 questions scored on a six-point scale - how did the patient feel the practitioner was at making them feel at ease, etc., measured at end of treatment
5. Measure Yourself Medical Outcome Profile (MYMOP) (a patient rating of their chosen symptoms) comprises four items, scored by the patient on a seven point scale. The first two items are for symptoms that the patient decides are most important to them and the other items relate to daily activities and general well-being, measured at baseline, end of treatment and follow up
6. Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) (a measure of beliefs about complementary medicine): 17 questions asking about the patients beliefs about health and treatment, measured at baseline, end of treatment and follow up
7. Credibility/expectancy questionnaire: six questions asking how much the patient believes the treatment will help their condition, measured at end of treatment

Overall study start date
01/09/2007

Completion date
31/01/2009

Eligibility

Key inclusion criteria

1. 18 - 65 years, male and female
2. Chronic or recurrent non-specific low back pain (lower ribs to gluteal folds)
3. Previous episode of pain at least three months previously (constitutes a recurrent problem)
4. Current pain for the last three weeks (excludes short lived occurrence)
5. Roland Morris Disability scale score of greater than or equal to four (constitutes a clinical problem)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Under 18 years or over 65 (serious spinal pathology more likely)
2. Currently undergoing other treatment for back pain other than analgesics (other treatment may have carry-over effect) - six weeks washout required
3. Previous kinesiology (naivety required as a sham treatment is involved)
4. Serious spinal pathology or systemic illness (outside scope of study)
5. Psychosis or alcohol abuse (completion of forms, safety of practitioner)
6. Disability of limbs, inability to lie on or get on and off an examination couch (for purpose of muscle testing)
7. Weigh more than 15 stone (safety limit of examination table)
8. Litigation pending due to back pain or receiving disability allowance due to back pain (potential treatment resistance until monies received or stopped)
9. Previous spinal operation or waiting for same (outcome likely to be different). Facet joint injections are accepted because the spinal anatomy remains the same.

Date of first enrolment
01/09/2007

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
The University of Southampton (UK)

Sponsor details
Aldermoor Health Centre
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Sponsor type
University/education

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ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No