

Alexander technique and supervised physiotherapy exercises in back pain

Submission date 17/08/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/02/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Back pain is a common problem, which affects most people at some point in their lives. Back pain is said to be chronic when a sufferer experiences episodes which last for at least three months. Many people who suffer from chronic back pain are prone to repeated episodes (recurrent back pain), which can have a big impact on their lives. The Alexander technique teaches people how to avoid movements that cause unnecessary tension in their daily lives by increasing self-awareness and “unlearning” bad habits (such as bad posture). The Alexander technique is taught by a qualified teacher who uses gentle hand contact and verbal instruction to guide movement. This helps patients to become aware of, and to avoid, harmful muscle movements which can be applied to daily actions such as sitting or standing. For people with chronic back pain, the Alexander technique is often used in combination with physiotherapy. This means that for patients who experience and improvement of their back pain, it is unclear what has caused this. The aim of this study is to compare the effectiveness of the Alexander technique, physiotherapy exercise classes or both together in relieving chronic back pain.

Who can participate?

Adults who suffer from recurrent back pain, who have been experiencing a current episode for more than three weeks.

What does the study involve?

Participants are randomly allocated into one of four groups to receive a treatment for 6 months. The first group receives normal care only, the second group receives 10 Alexander technique lessons, the third group receives 10 physiotherapy exercise classes, and the fourth group receives both Alexander technique lessons and exercise classes. Participants in all groups are asked to complete questionnaires regarding pain and how well they are functioning after three months and after six months.

What are the possible benefits and risks of participating?

A possible benefit of participating is that participants may experience relief from their back pain. There are no risks of participating in the study.

Where is the study run from?
Aldermoor Health Centre (UK)

When is the study starting and how long is it expected to run for?
September 2011 to September 2013

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Gillian O'Reilly
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Contact information

Type(s)
Scientific

Contact name
Dr Gillian O'Reilly

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10790

Study information

Scientific Title
Alexander technique and Supervised Physiotherapy Exercises in back pain (ASPEN): a randomised controlled trial

Acronym
ASPEN

Study objectives

The study will compare the Alexander technique (AT) with an optimal set of conventional exercises based on the best evidence and will assess if AT has additive benefits to exercise that are likely to work through different mechanisms. This study will also allow a significantly improved estimate of the 'dose-response' relationship for AT. We currently only have information on the effect of 6 and 24 lessons (6 provides half the benefit of 24 lessons). We propose investigating the effect of weekly AT over 10 lessons where the steepest rate of improvement is likely. In terms of mechanisms and markers of change our study will assess whether trunk muscle strength, back flexibility, patterns of muscle use and recovery of deep postural muscle function are related to both intervention and outcome. This should both clarify key processes and potentially allow better monitoring and targeting of treatment in the future. This application is for a feasibility study prior to the main trial to assess recruitment methods and rates, the feasibility of the mechanistic and outcome measurement, referral rates in each group, group contamination, and allow a preliminary exploration of the relationship between intervention, mechanistic measures and outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central - Southampton A, 18/07/2011, ref: 11/SC/162

Study design

Feasibility parallel-group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Group A: Normal care

Group B: Course of lessons in the Alexander Technique, 10 weekly lessons

Group C: Course of supervised physiotherapy exercises, 10 weekly lessons

Group D: Combined group

Follow Up Length for all groups : 3 and 6 months.

Intervention Type

Behavioural

Primary outcome measure

Severity of back pain; Timepoint(s): Roland Morris Disability Questionnaire

Secondary outcome measures

1. Secondary measures for back pain
 - 1.1. Pain and disability (Von Korff scale)
 - 1.2. Deyo 'Troublesomeness' scale
 - 1.3. Overall improvement (Health transition 28)
2. Fear of activity - the short version of Tampa Scale for Kinesiophobia (TSK) scale
3. Modified Enablement scale 12
4. We will also measure quality of life (EQ5D) and NHS resource use. Health service resource use will be quantified using data collected from the general practitioner (GP) notes after one year's follow-up - the number of visits to the surgery, who was consulted (i.e. the practice nurse or GP), the name, dose and duration of any drugs prescribed, and all referrals (and who the patient was referred to plus the number of times they were seen). Resource use will be valued using market prices where possible and other published sources, such as NHS reference costs. In addition, patients will be asked if they have self referred to anyone for back pain (e.g. chiropractor, physiotherapist) the number of times they were seen and how much they paid per visit. The main emphasis of this study is not an economic analysis: however, for any pragmatic effectiveness trial to follow this trial then this data will be useful for a modelling exercise to help justify the trial groups.

Overall study start date

01/09/2011

Completion date

01/09/2013

Eligibility

Key inclusion criteria

1. Age 18-65
2. Experiencing a current episode of back pain with Roland Morris score of 4 or more today and either
 - 2.1. Has previously consulted their general practitioner (GP) with back pain or
 - 2.2. Is currently consulting their GP with back pain
3. Currently has back pain that has lasted for 3 weeks or more (does not have to be constant pain but must be at least 14 days out of 21 in pain)
4. No previous experience (several lessons or practicing) of AT
5. No clinical indicators of serious spinal pathology (past history of cancer with renewed episode of back pain, osteoporosis)
6. No current nerve root pain (sciatic pain below knee). Nerve root pain above knee is ok
7. No previous spinal surgery
8. Torsional range +/- 10 degrees
9. No history of psychosis or major alcohol abuse
10. Able to walk 100 meters

- 11. Not pregnant
- 12. Not pending litigation
- 13. Not terminally ill
- 14. No unexplained fever; Target Gender: Male & Female; Upper Age Limit 65 no age limit or unit specified ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria

- 1. Previous experience of AT
- 2. The over 65s (serious spinal pathology more likely)
- 3. Clinical indicators of serious spinal pathology
- 4. Previous spinal surgery (outcome may be very different, and groups too small to analyse)
- 5. History of psychosis or major alcohol abuse (difficulty completing outcomes)
- 6. Perceived inability to walk 100 metres (exercise difficult)
- 7. Pregnancy
- 8. Pending litigation

Date of first enrolment

01/09/2011

Date of final enrolment

01/09/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Aldermoor Health Centre

Aldermoor Surgery
Aldermoor Close
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SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation Programme (EME)

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	01/10/2014		Yes	No