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The ATLAS neck pain trial

Submission date
14/02/2012

Recruitment status
No longer recruiting

Registration date
14/02/2012

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Musculoskeletal Diseases

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

Plain English Summary

Background and study aims
Chronic neck pain is a common condition in the adult population. As well as being painful and disabling it is associated with significant costs to the individual, their families, the NHS and society in general. The best treatment for uncomplicated neck pain has not been determined and therefore further research is required in order to compare the various approaches available. Patients commonly choose to take Alexander Technique lessons and undergo acupuncture but current evidence of their effectiveness is limited and, whilst promising, is too uncertain for routine referral by GPs.

The purpose of this study is to determine how effective Alexander Technique lessons and acupuncture are for neck pain, when used as an addition to standard GP care. We will look at how these two interventions compare with normal GP care and compare with each other. We will also look at how the costs of the two interventions compare.

Who can participate?
Patients aged 18 or over who have had neck pain for at least 3 months.

What does the study involve?
Eligible patients will be randomly allocated to one of three groups: the first group will be offered 20 free Alexander Technique lessons on a one-to-one basis, which are expected to be completed within a 5-month period, plus continue with normal GP care; the second group will be offered 12 free sessions of acupuncture, which are expected to be completed within a 5-month period, plus continue with normal GP care; and the third group will continue to receive normal GP care.

Patients will be asked to complete a questionnaire at the start of the study and complete three further questionnaires at 3, 6 and 12 months later. These should only take about 20-25 minutes each to complete.

Text messaging (optional)
We would like to collect information on the intensity of neck pain by text. Patients willing to take part in this part of the study will be required to text only a single figure (based on a simple scale) back to us. Patients who agree to receive and send text messages will be contacted on their mobile telephone fortnightly during the initial 6 months and monthly thereafter for a

further 6 months (about 20 texts over 12 months). Costs incurred by sending a text message will be reimbursed.

In-depth interviews (optional)
A small number of people who take part in the main study will be invited to take part in two interviews with a member of the research team.

What are the possible benefits and risks of participating?
Whichever treatment is received it is hoped that patients neck pain will improve. However, this cannot be guaranteed. The information obtained in this study will help us gain knowledge about treatments for neck pain. The risk of side effects from Alexander Technique lessons and acupuncture is low.

Very rarely acupuncture can cause an unwanted health problem. Sometimes people feel a pricking sensation when the needle is inserted. When the needle is withdrawn, it may cause minor bleeding (a few drops) or a slight bruise. Some people feel tired after treatments, while others feel energised. Rarely people may feel sick or faint during treatment. Rare other events that have been associated with acupuncture include dizziness, sweating, vomiting, bruising, numbness at the site of needling, stiffness, headache or migraine, sleeplessness, aggravation of existing symptoms, drowsiness or tiredness after treatment (which might be a concern if patients are driving home), diarrhoea, and emotional reactions, such as anxiety and panic. Treatment reactions can be a sign that the acupuncture is working.

During Alexander Technique lessons people very occasionally have passing dizziness, but this will be noticed and the teacher will provide support. Similarly, tiredness may very occasionally begin 12 hours or more after a lesson or muscle aches be experienced (similar to those post exercise). These experiences rarely pose a health risk.

Where is the study run from?
The study is being run from the York Trials Unit, a registered clinical trials unit, and the Complementary Medicine Research Group at The University of York.

When is study starting and how long is it expected to run for?
The study started in October 2011 and will run for 36 months.

Who is funding the study?
Arthritis Research UK is funding the study and it is supported by the National Institute for Health Research.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11467

Study information

Scientific Title
The ATLAS Neck Pain Trial: Alexander Technique Lessons or Acupuncture Sessions (ATLAS) versus usual GP care for patients with chronic neck pain: a randomised controlled trial to evaluate effectiveness, cost effectiveness, acceptability and safety.

Acronym
ATLAS

Study hypothesis
Chronic neck pain is a common condition in the adult population. As well as being painful and disabling it is associated with significant costs to the individual, their families, the NHS, and society in general due to reduced productivity and social engagement. While patients with chronic neck pain commonly self refer to acupuncture and Alexander Technique lessons, evidence from scientific literature, while promising, is too uncertain for GPs to refer patients routinely to these interventions. This study is designed to provide evidence on the effectiveness, costeffectiveness, acceptability and safety of both acupuncture and Alexander Technique as options for referral of patients with chronic neck pain in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West Research Ethics Committee, 06/12/2011 ref: 11/YH/0402

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Musculoskeletal Disease

Interventions
We aim to recruit 500 participants from GP practices across North England, and will randomly allocate them on a ratio of 1:1:1 to acupuncture and usual GP care, Alexander Technique lessons and usual GP care, and usual GP care alone. Participants allocated to acupuncture will be offered twelve, 50 minute, sessions of acupuncture, and participants allocated to Alexander Technique will be offered twenty, 30 minute, Alexander Technique lessons. We will establish if there are clinical benefits, such as pain reduction, associated with both interventions at 3 and 6 months, and if so, whether these are sustained at 12 months. We will also conduct health economic analyses and assess whether acupuncture and Alexander Technique are cost effective.

We will also ascertain participants attitudes towards the interventions and their experience; and the impact of the interventions on their self efficacy, stress management, quality of life, self care and lifestyle. The results will be of value to patients, practitioners and NHS policy makers in making decisions about the role of acupuncture and Alexander Technique in the management of chronic neck pain in primary care. The duration of the study is three years.

Three groups:
1. Acupuncture, 12 50-minute sessions (600 minutes);
2. Alexander technique lessons, 20 20-minute lessons (600 minutes)
3. Usual GP care, Patients will remain under the care of their GP and will receive usual NHS treatments.

Intervention Type
Other

Phase
Phase III

Primary outcome measure

Northwick Park Neck Pain Questionnaire measured at baseline, 3, 6 and 12 months

Secondary outcome measures
1. Adverse events and beneficial effects measured at 3, 6 and 12 months
2. Chronic Pain Self-efficacy Scale measured at baseline, 6 and 12 months
3. EQ-5D measured at baseline, 6 and 12 months
4. General Flow Index measured at baseline, 6 and 12 months
5. Incorporation of practitoner advice measured at 6 and 12 months
6. Pain intensity by text message measured fornightly for the first 6 months and monthly thereafter until the 12 months' endpoint
7. Perceived Stress Scale measured baseline, 6 and 12 months
8. Preferences, expectations and beliefs about the interventions measured at baseline
9. Short Form (SF)-12v2 measured at baseline, 6 and 12 months

Overall study start date
01/02/2012

Overall study end date
31/03/2013

Eligibility

Participant inclusion criteria
1. Patients aged 18 and over who have consulted their GP with chronic neck pain and are being managed in primary care
2. Patients who have had neck pain for at least 3 months, and have a 28% minimum cut-off score on the Northwick Park Questionnaire (NPQ)
3. Male and female participants
4. Lower Age Limit 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Participant exclusion criteria
1. Serious underlying pathology, prior cervical spine surgery, history of psychosis, rheumatoid arthritis, ankylosing spondylitis, osteoporosis, haemophilia, cancer, HIV or hepatitis, or with alcohol or drug dependency currently or in the last 12 months
2. Actively pursuing compensation or with pending litigation, or currently (or in the previous 24

months)
3. Receiving acupuncture or Alexander lessons, participation in a clinical trial in the previous year if there is potential confounding or the burden for the patient appears to be too great
4. Unable to speak or who find it difficult to communicate in English
5. Patients who are pregnant at baseline (participants who become pregnant after entry in to the trial will remain in the trial and continue to receive the intervention).

Recruitment start date
01/02/2012

Recruitment end date
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
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Sponsor type
University/education

Website

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ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK) ref: 19702

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	10/07/2013		Yes	No
Results article	results	03/11/2015		Yes	No