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A randomised factorial trial for patients with recurrent and chronic back pain of GP exercise prescription, the Alexander Technique and massage

Submission date
02/05/2001

Recruitment status
No longer recruiting

Registration date
02/05/2001

Overall study status
Completed

Last Edited
06/01/2010

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0001104

Study information

Scientific Title

Acronym
ATEAM trial

Study objectives
The aims of the trial are to assess the effectiveness and cost effectiveness when compared to normal care of:
1. A longer course (24) of lessons in the Alexander Technique (AT)
2. A an introductory course of lessons
3. GP advice and 'prescription' to take exercise in the free setting
4. A course of massage

A secondary aim is to assess to what extent the effect of AT is specific to learning how to change personal and body use. Patients who have attended their GP within the last 5 years for back pain will be identified from GP computerised databases of 54 practices. Patients with current Rowland low back pain score of 4 or more (i.e. patients with recurrent or chronic back pain) and physically able to exercise will be randomised to one of eight groups defined by two factors:
1. AT factor:
1.1. Introductory AT
1.2. Longer AT
1.3. Massage
1.4. Normal care
2. Exercise prescription factor:
2.1. GP exercise prescription with follow-up
2.2. No prescription

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Primary care

Interventions
Alexander Technique (AT) factor:

1. Normal management (control):
This group provides a realistic comparator, particularly for the economic component of the trial (so that the marginal costs of the intervention groups are realistically assessed). All trial participants will continue to be free to see their GP who will perform investigations, provide treatment - including drug treatments - or refer as they would normally (and this will be documented).

2. Longer course of lessons in the AT and book:
The practical content of each lesson will vary according to the needs and limitations of each participant. What has been taught, the practical procedures used and the participant's progress and difficulties will be recorded on standard sheets. After the first lesson and in the sixth week the Alexander teacher will record how useful they consider AT has been for each subject. Each participant will be encouraged to keep a record of the time outside lessons specifically devoted to AT. Each session will last 30 - 40 min. A standard text describing AT will also be given to each participant at the beginning of the course. The teachers will be included in the trial only if they have undergone a 3 year training at a STAT approved course; are members of STAT; and have at least 3 years post qualification experience. The aim in the longer course of lessons is to provide a much more comprehensive course in line with STATs recommendations for a new pupil. Up to 24 lessons will be provided at the teachers normal place of work: the initial course over 5 months (6 weeks at 2/week, 6 weeks at 1/week, 8 weeks at 1/2weeks) will be followed by two lessons for revision at 7 and 9 months.

3. Introductory course of AT lessons and book:
This group represents a short intervention that has a good chance of being considered by NHS purchasers, and whose costs are in line with the likely costs of interventions from other major trials (e.g. UK BEAM). The aim is to provide an introductory set of lessons (six lessons), and not a comprehensive programme, with material to help understand AT. The first four lessons will be at twice weekly intervals and subsequent lessons weekly. The participant would also be free then to assess their own progress, and choose whether to fund further lessons themselves - as happens in normal practice. (The concern here is that the less affluent participants would be prevented from taking further lessons: what further lessons participants had, and the equity of this approach would therefore be key outcomes when assessing the effectiveness for this group.)

4. Therapeutic massage:
Therapeutic massage is widely used, is credible to patients and therapists. It will provide an attention and touch comparison for non-specific aspects of AT teaching, and is also important to

assess since it may provide benefit in its own right. Patients will receive six sessions in accordance with current normal clinical practice (thus being equivalent to the introductory AT group). As with the introductory course of AT, patients will be free to have further sessions of massage at their own discretion, which mimics what would happen in normal practice. Any further sessions will be documented.

GP Exercise Prescription factor:
Half the patients in each of the AT factor groups will be randomised to an appointment with a GP and follow-up nurse consultations. The GP appointment will be scheduled 6 weeks into the trial to maximise the likely benefit for those groups where exercise and AT are combined. The exercise 'prescription' will use the same format as the feasibility study (see above): the GP will specify the time and frequency of exercise, the date to start on the sheet, and give the sheet to the participant to display in a prominent place around the house. The GP will briefly discuss a list structured points based on previous behavioural literature: the importance of exercise; finding a regular exercise to incorporate into daily life (either walking or equivalent); aiming for a target of 30 min walking 5 times per week according to current national guidelines; and anticipating relapse. Three follow-up appointments with a practice nurse (i.e. four in total) will deal with the same issues as the GP, provide reinforcement and encourage maintenance.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary analysis will be an analysis of covariance for a factorial study at 3 months and 1 year for the principal outcomes between groups (Rowland score; days of back pain).

Secondary outcome measures
Controlling for potentially confounding baseline values and for cluster effects, and transforming data as appropriate. Although we are not expecting interaction between factors we will assess interaction and if significant will report outcomes for groups seperately. This trial will detect large interactions, but if smaller non-significant interactions looked likely they would have to be the subject of further study. If significant and multiple cluster effects are demonstrated a multi-level modelling approach will be used. Secondary analysis will assess the prognostic value of clinical and psychological variables at baseline in predicting outcome at 1 year. The economic evaluation will take the form of a cost-consequence analysis and if appropriate a cost-effectiveness and cost-utility analysis.

Overall study start date
01/12/2001

Completion date
31/05/2006

Eligibility

Key inclusion criteria
1. The entry criteria are similar to the UK BEAM trial to facilitate comparison, except for this trial all patients have chronic or recurrent pain

2. The population will be aged 18 to 65 who presented in primary care with low back pain more than 3 months previously, who currently score 4 or more on the Roland Scale and have had back pain for 3 weeks (ie to exclude short-lived recurrence)
3. Participants will need to be fluent in English and able to read and write (to complete the outcome measures)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
579

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. Current nerve root pain (below knee in dermatomal distribution) or 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. Exercising for 30 min three times a week or above
8. Pregnancy
9. Pending litigation

Date of first enrolment
01/12/2001

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Results article	results	19/08/2008		Yes	No
Other publications	economic evaluation	11/12/2008		Yes	No
Results article	results on patient views	01/04/2010		Yes	No