UNIVERSITY OF Southampton
School of Medicine

Alexander Technique and **S**upervised **P**hysiotherapy **E**xercises in back pai**N** (ASPEN)

Funder: NIHR EME programme – 09/160/23

Sponsor: University of Southampton

Sponsor's reference number: 7769

REC Ref: 11/SC/162

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2. Background:

2.1. Existing research

The lifetime prevalence of back pain has been estimated at between 59% to 90% and the annual incidence of back pain is approximately 5% of the population[1]. In the UK, 12.5% of all sick days are related to low back disorders (matched only by respiratory illness and mental illness), with very similar figures for other northern European countries[2]. Persistent or major recurrent back pain is one of the commonest chronic problems managed in primary care and has a poor long term prognosis[3].

Physiotherapy exercises

The literature supports the use of a course of supervised physiotherapy exercises tailored to patient expectations and with reinforcement in the management of chronic back pain[4-6]. Systematic reviews support strengthening, stretching and aerobic exercises; exercises tailored to the individual that can also be performed at home; 20 hours of contact time (10 group sessions); and exercise targeting the rehabilitation of deep abdominal and lumbar paraspinal muscles[6 4;7].

NICE has reviewed the literature since the above systematic reviews and although supervised and tailored exercises were supported by NICE as one option for patients[8], the advice was tempered by the results from major UK BEAM trial[9] – which found modest effects of exercise alone or with manipulation[9]. However, attendance at exercise sessions in UK BEAM was poor, and exercises in UK BEAM[9] did not target the rehabilitation of deep abdominal and lumbar paraspinal muscles, which are known to require specific rehabilitation[10;11], suggesting that further trials could helpfully address both these issues.

Alexander Technique

The NICE systematic review included the MRC ATEAM trial of Alexander Technique in the section on exercises[8], but Alexander Technique is not a form of physiotherapy exercise. It involves learning what *not* to do as a first priority i.e. learning to become aware of, release, and avoid harmful habits of muscle use, and improve coordination of movement - which sets it apart from specific exercises[12]. It can be used during simple activities of daily living, such as walking, sitting, standing and bending - all activities adversely affected by back pain. The technique aims to teach the correct use of the postural mechanisms that regulate upright support and locomotion. These mechanisms involve coordination of the trunk, head and limbs and motor control of postural muscles can be poorly operating in individuals with chronic back pain[13-16].

Mostly habitual and unnoticed, an individual can be taught to be come more aware of these mechanisms and make different choices about movement, coordination and locomotion[14;15]. In particular it addresses the coordination of the trunk and head as a core relationship for good movement. It is taught by specialist gentle touch and verbal instruction and an individual learns self help through the combination of these methods.

Although there is limited evidence for mechanism, there is preliminary evidence of effectiveness: a small trial documented short term benefit[17] and more robust empirical proof of concept has come from a larger trial (MRC ATEAM trial), documenting that Alexander Technique is likely to effective after 1 year for chronic and recurrent back pain[12]. Massage was included as a comparison group in the ATEAM trial since it provided similar touch and attention to Alexander Technique but no self management skills. There was a shorter term effect of massage (at 3 months) but no longer term effect; in contrast the effect of the Alexander Technique, which is designed to provide life long self management skills, persisted for a year [12]. This suggests that

the effectiveness of the Technique is unlikely to be due to the non specific effects of touch and attention.

In the previous full application to the EME Board, the Board were concerned that there might be common elements in physiotherapy and AT. Whilst this can be best confirmed or refuted by the proposed investigation of efficacy and mechanism, there is good reason to believe that AT is distinct in principles, aims and practice from physiotherapy.

Physiotherapy aims to strengthen, stretch, increase aerobic capacity, improve motor control and uses specific supervised exercises which are then practiced at particular times. In contrast AT teaches awareness of and release of harmful muscle tension; teaches proprioceptive re-education; concentrates primarily on the key relationship of Head-Neck-Back; uses the semi-supine position as a core technique; movement and coordination is assessed and guided; and it is practiced during activities of daily living[12].

Key issues in the evidence base that require clarification are :

a) **Efficacy: the efficacy of an intermediate course of lessons in the Alexander Technique**.

The relationship between number of lessons and outcome is not linear (half the benefit of 24 lessons (full course) was provided by a short course (6 lessons)[12]. The ATEAM trial demonstrated that 6 lessons was highly cost-effective. However, although many patients having 6 lessons did achieve clinically meaningful benefit, the average benefit was at the lower end of clinically meaningful efficacy (an average increment of 1.4 on the Roland Morris scale after 1 year when compared to normal care). Thus more information is needed for the lower/middle part of the response curve.The study will provide key information in the range that is most likely to provide the most meaningful efficacy for patients (i.e. lessons required to achieve a Roland and Morris increment of 2-2.5 or more)[12;18].

b) **Efficacy: the efficacy of adding physiotherapy group exercises.**

If exercises and AT work by different mechanisms then it is plausible that they will have significant additive effects which might provide very substantial improvement for chronic back pain. The only way to demonstrate this is to estimate the single and combined effects of the two interventions.

c) **Mechanism and biomechanical/physiological markers of improvement.**

Alexander Technique.

AT may work through release of tension, decompression of the spine, more balanced muscle activity, and improved flexibility (not necessarily increase end range of motion) - based on observations that poor trunk coordination, torsion, spinal compression and muscle asymmetry are associated with chronic back pain[19] [13]. Preliminary evidence suggests that AT modifies muscle tone[14-16] and increases flexibility (n=20; T Cacciatore personal communication) which requires confirmation.

Physiotherapy exercises.

Weakness and wasting of the deep abdominal and lumbar paraspinal muscles, and altered recruitment of muscles (motor control), occur with low back pain and do not recover without specific rehabilitation exercises [10;11 20]. We predict that indices of strength and changes in muscle architecture of the abdominal and posterior paraspinal muscles (thickness measured by ultrasound imaging as an indirect measure of strength and activity) are likely to be confirmed as important non-invasive markers and that these should not only improve with exercise but will predict outcome [10;21;22].

The proposed study will also evaluate whether recovery of these muscles, and hence protection of the lumbar spine, occurs with AT; will enhance our understanding of how back pain recovers and how to combine both the Alexander Technique and physiotherapy; and provide data that could help modify/target treatment in future.

History of the application.

Following an outline phase the Board initially invited a full application for a 3x2 factorial trial of Alexander Technique lessons (0,8,16) and Physiotherapy exercises. This application was declined and the Board staff in feedback suggested we consider a feasibility study – which we gladly accepted and so submitted an outline for a feasibility study to address the following key issues raised by the Board following the full application (our response to the issue raised is in italics):

1) A simpler trial could produce the required answers. *We simplified the proposed study design from a 3x2 to a 2x2 factorial trial;*

2) Evidence is needed of feasibility of so many visits. *The ATEAM trial demonstrated that 24 lessons were both feasible and acceptable in this population and thus we have good reason to believe that even the combined AT and physio group in the proposed study (less than 24 attendances) will be acceptable. The feasibility study will allow us to confirm the feasibility of all intervention visits and of mechanistic measures to determine acceptability and attrition.*

3) Justify the number of lessons; *in the outline for the feasibility study we provisionally proposed 12 lessons and monitoring dose response using weekly measures from 6 to 12 weeks to gain information about likely dose response*

4) "Normal care" is complex, and there might be impact of the recent NICE guidelines. *We agree with the potential importance of the issue. In our area there has been minimal change in referral practice since the NICE guidance was released and in practice we anticipate little change in 'normal care'- since in the ATEAM study the normal care group was relatively stable. The feasibility study will also allow us to confirm whether/if the control group is stable, document referral patterns, and the likely nature and variability of normal care. However, even in the unlikely case of significant referrals to physiotherapy in the normal care group, patients in this region do not have long structured courses as proposed in the current study, so there would probably still be utility in exploring a comparison of the trial physiotherapy groups with the different groups of patients in 'normal care' (those not referred, those referred, and the type of service received).*

5) Concern about the use of 'prevalent' patients (this came from one referee). *The feasibility study will assess the implications of using both the invited (prevalent) population and opportunistically recruited (incident) populations.*

Following the outline phase of the feasibility study the Board made the following points (again with our suggestions in response in italics):

1. Would weekly measurements really demonstrate a reliable dose effect?. The Board suggested to either allocate participants to 6,9,or 12 lessons, or choose the dose the applicants think most likely to be effective. *Our group are experienced in managing complex factorial trials and would be happy with the suggested 4x2 factorial trial (0,6,9,12 AT lessons +/- physio – similar to the ATEAM study) . However to try and be consistent with the previous Board feedback regarding complexity of design we have opted for the second suggestion - which can be justified on the basis of consensus of senior teachers and patient case series.i.e.10 lessons*

2. The Board wondered if part of the difference between 6 and 24 lessons at 12 months demonstrated in the earlier study may have been due to the time since completion of treatment. *Empirical data suggests this important potential explanation is perhaps unlikely: the relative effectiveness of 6 lessons vs control in the ATEAM trial remained very similar after 12 months as after 3, so we can be reasonably sure that at least for fewer lessons there is no major decrement in relative effectiveness with time, making differential time decrements an unlikely explanation of the difference. If the effects of lessons occur quickly and are stable - as the ATEAM results and also teacher experience suggest - this perhaps indicates that there might still be some utility in measuring a key outcome on a weekly basis from 6 weeks onwards to give potentially more information on dose response (were the Board to agree).*

3. Justification of inclusion criteria since the desired outcomes for patients with acute and chronic back pain might be different. It was suggested that patients might be stratified by pain type or duration. *There are major advantages to a maintaining comparability with ATEAM and UK BEAM to facilitate modelling using comparable data sets- including any modelling prior to any future trial. Thus although we would like to keep the population as similar to ATEAM and UKBEAM trials as possible we agree with the Board that it is reasonable to expect there might be differing responses according to prior history. Rather than exclude we propose stratifying as suggested by the Board; empirical data from the ATEAM study supports stratifying by a history of <90 days of pain vs >90 days.*

4. The reason why patients dropped out of the trial should be collected and the analysis of the results should be performed on an intention to treat basis. *We agree and will do so*

2.2. Risks and benefits

No adverse effects were reported for the Alexander Technique [12], and adverse effect of physiotherapy exercises are also rare[8]. It is likely that this trial will not only provide evidence of benefit for individual interventions but also for combined intervention - which will provide a range of useful information to inform choice for patients, clinicians, and policy makers.

2.3. Rational for current study

There are two key efficacy questions that the study will answer, one related to phase 2 type evidence (whether an intermediate 'dose' of a 10 lesson course in the Alexander Technique achieves important clinical benefit) and one related to additive benefit (whether exercises are additive to Alexander Technique). We also propose enhancing our understanding of mechanisms by investigating the likely mechanisms using several plausible intermediate bio-mechanical markers that could mediate improved health outcomes. This should increase our understanding of the causes and treatment of back pain and could also be used in monitoring and targeting of future treatment.

3. Research objectives:

The key objectives for the main trial are to:

a) Estimate whether an 'intermediate' course of lessons in the Alexander Technique achieves clinically meaningful efficacy.
b) Estimate the efficacy of combining Alexander Technique and physiotherapy.
c) Understand the possible mechanisms and mediators of improvement for both the Alexander Technique and physiotherapy

The key objectives for the feasibility study are to:

a) Confirm the acceptability and attrition among individual and multiple groups in the proposed factorial trial including the feasibility of multiple visits.
b) Assess the feasibility of all mechanistic measures
c) Provide provisional data on the likely effectiveness of 10 lessons in the Alexander Technique
d) Given the potential complexity of "normal care" and possible impact of the recent NICE guidelines, to confirm whether/if the control group is stable, document referral patterns, and the likely nature and variability of normal care
e) Assess the implications of using both the invited (prevalent) population and opportunistically recruited (incident) populations.
f) Explore the sensitivity to change of different outcome measures in this population

4. Research design:

This is a factorial trial of Alexander Technique lessons and physiotherapy exercises. Clinical outcome and biomechanical/physiological measures will be taken on all patients for the feasibility study (whereas if the main trial were to be funded the mechanistic measures will be taken on a subset of patients for each combination of the factors).

Randomisation

The same procedure for randomisation will be used as was used in the ATEAM trial. The study statistician will supervise randomisation, blocked by group, and stratified by history of prior pain (<90 days and >90 days). The board suggested stratification by prior history which we accept is a very reasonable suggestion, and supported by empirical evidence from a post-hoc analysis of the ATEAM trial (those with a history of >90 days of pain had the most improvement; furthermore there was no evidence that making the criteria more stringent e.g. >180 days increased apparent effectiveness).

When an eligible patient has passed eligibility screening and consented to the study, and received their back assessment randomisation will be executed by the research team at the University of Southampton by ringing the external randomisation line, and patients will receive a letter informing them of their randomisation group with travel/appointment instructions.

5. Study population:

Although definitions of acute (<6 weeks) subacute (6-12 weeks) and chronic (>12 weeks) have been used NICE has pointed out that these are not very useful definitions in practice given the variable nature of chronic and recurrent back pain[8]. The working definition that we will use is 'pain in an area bounded by the 12th thoracic vertebra and 12th ribs superiorly, gluteal folds inferiorly and contours of the trunk laterally.'

Recruitment Methods

We propose two methods of recruitment - a mailed invitation of patients who have attended their GP in the past with back pain, and also inviting patients opportunistically who attend surgery. Patients who currently have a Roland Morris score of 4 or more and duration of pain for at least 3 weeks (i.e. patient with chronic or a non-trivial recurrent attack of pain) will be eligible. Patients will thus have chronic or recurrent back pain (attended their GP previously (prevalent) or currently (incident) with back pain). These were the key entry criteria we used in our previous trial[12] and similar to the UK BEAM trial [9] and has the great advantage of allowing comparison with these trials. In the previous trial these criteria facilitated timely recruitment, were feasible, provided a population that had predominantly chronic pain, and a control population which was relatively stable for a year despite having access to further care if needed (the control group reported on average 21 days of pain each month at the end of the year).

Exclusion criteria

1. Previous experience of AT;
2. the over 65s (serious spinal pathology more likely);
3. clinical indicators of serious spinal pathology [1];
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.

5. Planned interventions

We propose a 2x2 factorial design**:**

Normal Care
Patients will be free to consult their GP as normal and GPs will be free to prescribe analgesia or refer for further care according to NICE guidance as appropriate (including orthopaedic or routine physiotherapy assessment). This approach provided a stable control group in the ATEAM trial over the time course of a year[12]. As in the previous trial we will collect process information to monitor what additional NHS and non NHS treatment patients receive in all groups - to be able to estimate the likely effect of such additional care.

1) Alexander Technique vs normal care
Patients will be randomised to receive no lessons, or 10 lessons (see appendix for details of lessons). We already have information on the effect of 6 and 24 lessons[12]: since 6 lessons had half the benefit of 24 lessons the dose response is likely to be steepest in the lower mid range hence the choice of 10 lessons (which are also likely to be both effective and the most cost-effective for a future pragmatic trial[12]). Ten lessons is a reasonable choice based on a) consensus among senior teachers (CN and CC have consulted widely among their senior colleagues) b) the documentation of cases of 25+ consecutive patients from 4 teachers (CN personal communication). Six lessons is where most people report starting to see an improvement in pain, and between 9 and 12 lessons most patients report being more confident in their skills to prevent and manage further episodes.

2) Physiotherapy group exercises vs normal care
Half of each of the above groups will be randomised to receive supervised, tailored exercises in a group setting, following an initial clinical assessment. A group intervention although not commonly used currently in the NHS is supported by NICE as it is more likely to be cost-effective[8] - hence this package could have significant implications for future NHS care. We will base an optimal exercise package on those developed previously, and consistent with current recommendations and systematic reviews[4;10;11;23;24 6;7;9;25;26]: motor relearning, strengthening, stretching and aerobic exercises; exercises tailored to the individual that can also be performed at home; 20 hours of contact time (12 group sessions); and exercise targeting the rehabilitation of deep abdominal and lumbar paraspinal muscles. There will be time to share success and encourage other group members in group sessions and group exercises, and we will pay particular attention both in initial consenting and at each group session to gaining robust agreement from every individual to attend every session - since attendance was an important issue in the UK BEAM trial[9].

Both Alexander Technique teachers and physiotherapists will be trained centrally to deliver sessions and to record process measures in a consistent manner; this will help reduce variability and help monitor the quality control of the intervention.

Compliance

In practice, as we found in the ATEAM trial, the proposed trial participants are those with significant recurrent/chronic pain who are mostly very well motivated: patients in the ATEAM trial had at the end of one year on average 21 days of pain in the prior month in the normal care group. Thus we anticipate similar good compliance as we found in the ATEAM trial (81% of patients attended for 20 or more out of 24 lessons, and there will be fewer than 24 sessions in the combined group of the proposed trial). However, estimates of compliance and how these relate to baseline severity and duration is just the sort of information we trust the feasibility study will document so as to inform any subsequent changes needed in the main trial entry criteria.

For those offered both Alexander Technique and exercise, patients will start Alexander lessons first so that when exercise starts they are best able to take advantage of the Alexander Technique in facilitating exercise – we used a similar approach which proved acceptable in our previous factorial trial [12].

Proposed Trial Groups

	Normal care	**Normal care and 10 AT lessons**
Normal care	**Group 1**	**Group 2**
Physiotherapy group exercises	**Group 3**	**Group 4**

6. Proposed outcome measures:

Clinical outcome measures

Key outcomes

Primary outcome

- **Roland-Morris Disability questionnaire**. Patients indicate the number of specified activities/functions limited by back pain[27]. The scale is designed for self report, has been extensively validated, and is the most widely used primary outcome[28].

- **Number of days in pain reported during the last 4 weeks[29]** (a 4 week period facilitated recall): this is distinct from pain intensity or disability[29;30].

Secondary outcomes (which were all used without logistic problems in the previous trial) which have been suggested as a basic data set for back pain research):

- Secondary measures for back pain [27]:
- Pain and disability (Von Korff scale[29]
- Deyo 'Troublesomeness' scale [27]
- Overall improvement (Health transition [28])
- Fear of activity – the short version of TSK scale[31;32]
- Modified enablement scale [12]
- We will also measure quality of life (EQ5D) and NHS resource use. Health service resource use will be quantified using data collected from the 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.

Exploring other potential primary outcomes

To allow to explore sensitivity to change in this population we will also administer the Oswestry Disability Index and the Aberdeen pain and function scale [33;34] at baseline and follow-up and compare these with the RMDQ and the Von Korff measures, with a view to informing a definitive set of outcomes measures for the main trial.

Biomechanical and physiological measures

Intermediate markers which we propose will predict outcome are: trunk flexibility/axial tone[14;16]; trunk muscle strength[21;22]; pelvic loading[35]; spine length and curvature[36]; proprioception; abdominal muscle recruitment patterns using electromyography (EMG)[20]; and trunk muscle size measurements on ultrasound images[10;11]. We hypothesise that graphical CHAIN models will identify the following key relationships (the first three being perhaps the most important):

- Alexander Technique will particularly increase flexibility to imposed torsion and modify proprioception
- Physiotherapy will particularly increase muscle strength, deep muscle thickness and contractile ability
- The above variables (Flexibility to imposed torsion; proprioception; indices of muscle strength; deep muscle thickness and contractility) will all independently contribute to outcome, and also that that they might be related to each other.
- We anticipate that through the change in flexibility (but also possibly directly due to the Alexander Technique) there will be modification of spine length, curvature, and pelvic/head and neck angles which in turn might have a direct effect on outcome which are independent of the other intermediate markers.

The extent to which the intervention directly also contribute to outcome independently of the hypothesized intermediaries will give some estimation of the size of other potential mechanisms that we have not identified in this study. Clearly these analyses will be exploratory and may prompt further studies of mechanisms.

We will use valid and reliable measurement techniques:
Flexibility to imposed torsion (axial tone) will be measured with the participant standing on a rotating platform enclosed in a rigid frame (a 'Twister' device') that applies a small torsional strain and records the body's resistance through load cells[14;16].

Isokinetic and isometric strength of the trunk flexors and extensors will be measured using a Biodex dynamometer[21].

The active straight leg raise test (ASLR) assesses the ability of the lumbopelvic region to effectively transfer load and is closely related to lumbopelvic pain, and good (ICC = 0.87) test re-test reliability[35].

Proprioception will be tested using a motion analysis system (Vicon Oxford Ltd) to measure target and achieved movement, examining joint position sense of the lumbar spine and neck. Vicon for proprioception testing is much more straightforward than its conventional use for gait analysis, and the Vicon has been validated for proprioception testing. Vicon is more expensive than possible alternatives like Fastrak but since we have the system in current use in our group the marginal costs of using it are minimal.

Relative latency (timing of onset) of muscle activation can be altered in people with back pain [20]. Surface (EMG) will be recorded from the rectus abdominis (RA), External Oblique (EO) and

Internal Oblique (IO) muscles while subjects perform a clinically relevant manoeuvre, the active straight leg raise (ASLR) test [37]. Improvement in muscle recruitment pattern post-intervention, if correlated with reduction in symptoms, would suggest that better motor control contributed to the recovery mechanism.

The ultrasound technique will use a portable ultrasound scanner with 5-7.5MHz transducers to obtain images of the lateral abdominal (transversus abdominis, internal and external oblique muscles)[10] and lumbar multifidus muscles[11]. Protocols will follow international guidelines for obtaining images and measure muscle thickness at rest and during functional manoeuvres to assess contractile ability[10;11]. The reliability of the research fellow's scanning technique will be established following a period of training, if necessary.

Spine length and curvature measured using Vicon motion analysis system. We will measure spine length, lateral curvature, and sagittal alignment from posterior and lateral views. This approach will use anatomical markers placed at specific locations (on the spine, vertex , greater trochanter) which have previously been used to assess spinal alignment[15]. Spinal curvature (degree of lumbar lordosis /thoracic kyphosis) will be measured. Pelvic angle and head/neck angle will also be measured quickly using an inclinometer[38].

Myoton measurements of muscle tone

Muscle tone of the paraspinal muscles will be measured using a portable diagnostic device (the Myoton-3; Müomeetria Ltd CE0537, Tartu, Estonia; CE mark CE0537). The device uses accelerometer based sensing of muscle oscillation (induced by a brief mechanical tap) and computer processing to obtain objective information on the viscoelastic properties of muscle, including tone, which is characterised by the frequency of the dampened oscillations (f=1/T [Hz]), where T denotes the oscillation period in seconds (Lee et al., 2004).

The hand-held Myoton device is battery operated, and the technique is non-invasive, valid, reliable, painless and safe (Lee et al., 2004; Leonard et al., 2003). Recording from one muscle takes less than 30 seconds (mean of two recordings of a series of 10 taps of 1 second each). Several muscle sites will be tested along the paraspinal muscles from the cervical to the lumbar region, taking approximately 10 minutes. The participant will be in a relaxed prone lying position to assess resting tone. The Myoton results (resting tone) will be correlated with the Twister results (dynamic tone). Between-side symmetry of tone will also be compared pre- to post-intervention.

References

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Lee, H-M., Chen, J-J., Ju, M., Lin, C. and Poon, P. (2004) Validation of portable muscle tone measurement device for quantifying velocity-dependent properties in elbow spasticity. *Journal of Electromyography and Kinesiology*, 14(5):577-589

A summary of the likely timings of the main groups of biomechanical and physiological measures is as follows:

	Measure	**Time to perform measurements**
	Flexibility to imposed (axial tone)	20 mins
	Isokinetic/isometric strength	15 mins
	Active straight leg raise & EMG to assess muscle timing (and we also propose simultaneously with ultrasound)	20 mins (35 mins if with ultrasound)
	Proprioception & postural measures (motion capture	25-35 mins:

	system)	Low back (10 mins) Neck (10-15 mins) Postural measures (5-10 mins)
	Muscle tone (using Myoton-3 device)	10 mins

Thus the measures should take under 2 hours, but 2 hours would be a safe estimate. The experience of our physiotherapy investigators in regularly performing such laboratory measures is that such patients are a committed group and normally interested to have such detailed assessments, and will cooperate 3-4 times over the course of a year (and we are proposing baseline, 12 weeks, 6 months). If we need to, following the feasibility study (or even during – we will be as flexible as we need) we would prioritise the measures and not perform the ultrasound and postural measures - to get the assessment down to 1 hour. However, it would seem a shame not to at least initially try to get such measures, particularly as we anticipate that the postural and ultrasound measures may be important in our understanding of the mechanisms of improvement. The importance of not cutting down measures unless we have to is that we have our theories about how recovery takes place, but in practice the process is little understood, and therefore maintaining the range of measures to capture the likely changes during recovery is our best bet of moving our understanding forward.

8. Assessment and follow up

8.1. Assessment of efficacy/effectiveness

All outcomes will be measured at baseline, 3 months and 6 months (for the main trial a 12 month follow-up will be used but for the feasibility study 6 months should suffice).

Questionnaires: We will use well validated self completion postal questionnaires with up to two follow-up contacts for non response. With this approach we are likely to achieve at least 80% follow-up.[12] There is little methodological advantage in independent researchers ringing patients to document answers to self-report questions instead of patients providing the answers to the same self-report questions themselves; furthermore the questionnaire measures have been validated for self report[18;39].

The biomechanical and physiological assessments will be performed by a research fellow. Although we will ask patients not to reveal their exercises to the research fellow, full blinding here will be in practice difficult to enforce, given that patients in practice may well mention what exercises they have been doing.

8.2. Assessment of safety

We do not anticipate any safety issues but should any possible adverse events arise staff will provide a report of the event on standardised forms, and patients will be interviewed in detail by the trial team; patients will also be able to report adverse events directly to the trial team.

8.3 Qualitative Data

We will also interview patients (funding permitting) to help understand their perceptions of the process for the same interventions and to help inform trial results.

9. Proposed sample size

We aim to recruit 20-30 patients per group to provide feasibility information (no formal sample size calculation is appropriate) in one centre. For the exploratory analysis of mechanistic measures this sample (80+ patients) should be sufficient to detect a 0.66-0.75 SD change in key

intermediate outcomes (and for spine torque/flexibility more than 1 SD change has been reported with AT lessons -Tim Cacciatore personal communication).

10. Statistical analysis

For the feasibility and piloting elements (recruitment rates, attrition, compliance, characteristics of sample, acceptability etc), and for sensitivity to change of the outcomes, the analysis will be descriptive. Regression models will allow a preliminary exploration of whether the intervention modifies intermediate biomechanical markers, the relationship between the intermediate markers and outcome (using graphical CHAIN models), and the relationship between teachers' ratings and both intermediate markers and outcome. Although the analysis of effectiveness will be underpowered, we will perform an analysis of covariance to estimate the main effects of the interventions and the effect of combined versus single interventions on an intention to treat basis, and controlling for stratification variables and potential confounders as appropriate. We will collect data on the reasons for attrition and compare the characteristics of patients lost to follow-up with those followed up.

11. Ethical arrangements

We will obtain MReC approval which we anticipate will be no problem given the prior approval for the ATEAM trial. Where possible we will negotiate data sharing upon completion as appropriate (for example for individual patient data meta-analyses).

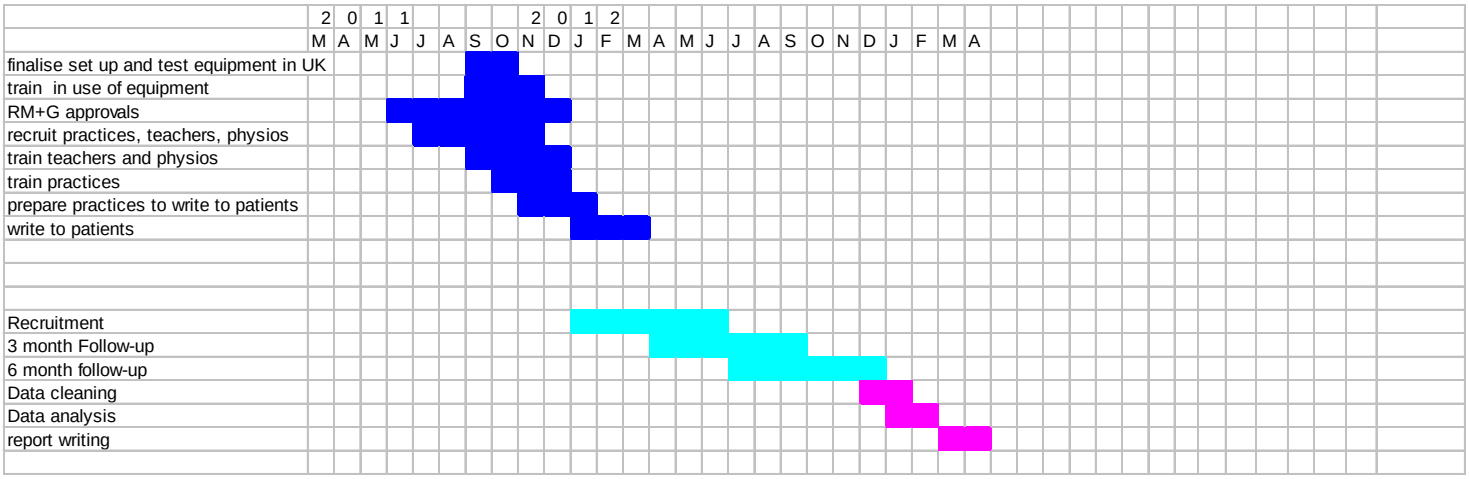
12. Research Governance

The University of Southampton has agreed to sponsor the study. The study will be subject to the normal conditions of research governance which will monitored by each participating Primary Care Trust, and an independent TSC (and DMEC as appropriate) will supervise trial progress and management.

13. Project timetable

0-6 m. Finalise ethical approval and research governance. Set up biomechanical equipment, recruit and train physiotherapists, Alexander Teachers, and GPs; prepare for recruiting patients.
7-12 m. Recruit patients using the existing network of practices (assuming same rate of recruitment as previously[12]);
13-18 m follow-up;
18-21m. Analysis, report writing.

14. Gantt chart as at 11 March 2011



15. Expertise

Professor Little is experienced in running clinical trials in primary care and was recently CI in a multi-centre MRC funded trial of Alexander Technique (MRC ATEAM trial). He will provide overall coordination and supervision of day to day running of the trial and lead the Southampton centre and with Professor Smith will perform the analysis

Professor Sharp is also an experienced triallist in primary care and was the co PI in the ATEAM trial, and will coordinate the second centre (Bristol) for the main trial (if funded)

Professor Stokes's expertise is in the physiology of back pain and rehabilitation and will (with LR and LY) specify the physiotherapy exercise package and supervise the physiological measurements. She also teaches ultrasound imaging of muscle to physiotherapists and has extensive experience of its use in research.

Dr Roberts is an experienced research and clinical physiotherapist, and has experience of leading primary care trials for back pain. She will (with MS and LY) specify the physiotherapy exercise package and supervise the training of the intervention physiotherapists

Professor Smith is experienced in both trial analysis and the analysis of observational data. He was the statistician on the factorial ATEAM trial. He will supervise the data cleaning and analysis of the trial data and the modelling of the role of intermediate markers.

Tim Cacciatore and Steve Preece both have expertise in Alexander Technique and in biomechanical assessment. In addition to developing the trial protocol and specifying the measurement protocols they will ensure the research physiotherapist can use, collect data and document output from the equipment.

Carolyn Nicholls and Caroline Chalk are experienced teachers of the Alexander Technique who are Heads of Training of Alexander Technique Teacher Training Courses and will supervise the selection of Teachers and training of the Teachers in study procedures.

Professor Yardley's expertise is in the application of theoretical models to behaviour change in practice, particularly primary care trials; she developed the package in the ATEAM trial and led the qualitative investigation. She will assist in developing the physiotherapy package with particular emphasis on techniques to enhance adherence.

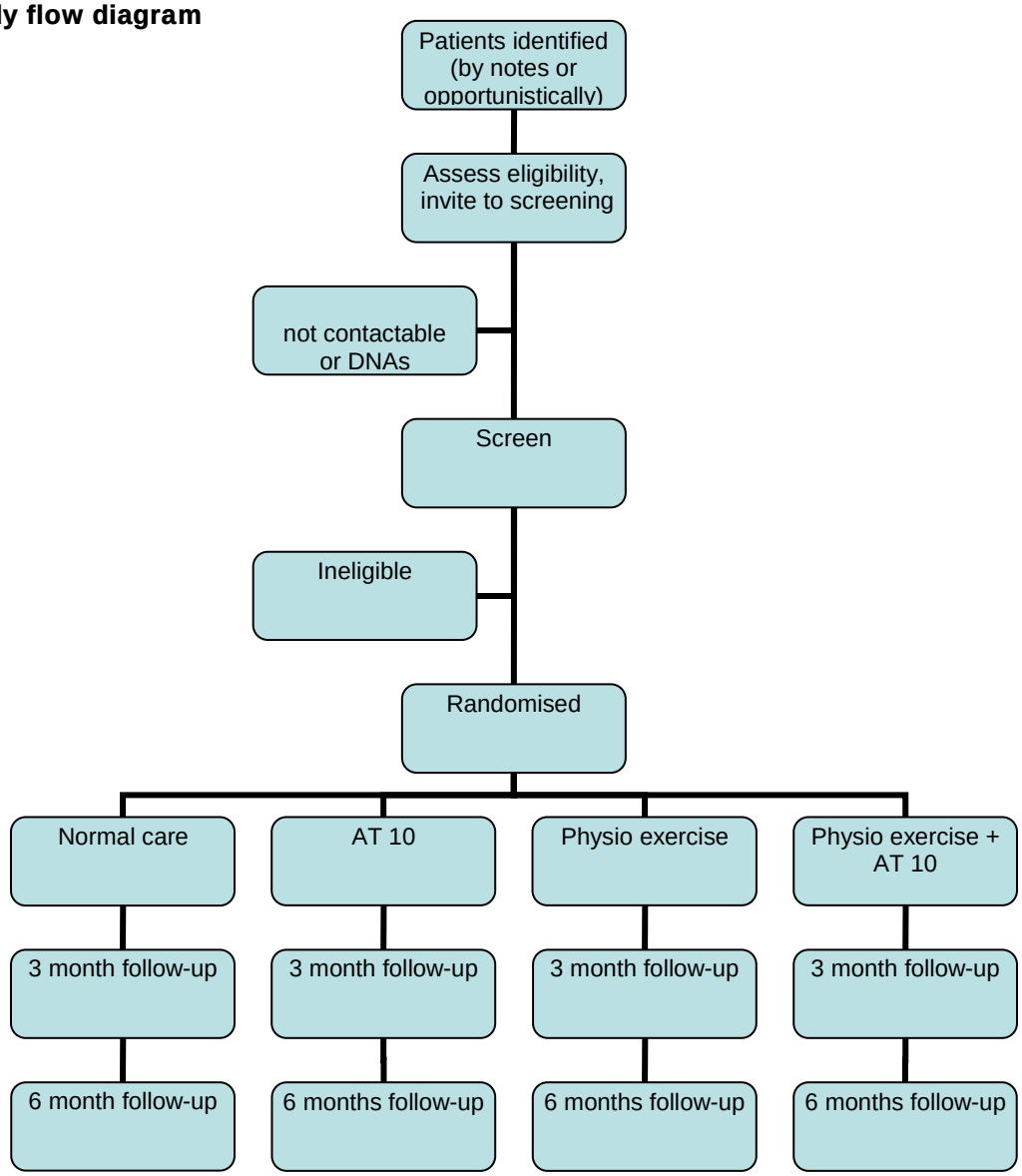
Professor Lewith's expertise is in researching complementary interventions. As in the ATEAM trial he will be instrumental in helping develop the protocol, supervise the development and running of the trial.

Dr David Turner (health economist) will advise data collection (quality of life; resource use) to allow modelling prior to a subsequent pragmatic trial (if appropriate)

16. Service Users

We are delighted that the Chair of the Southampton Branch of Back Care, Colin Steel, has agreed to be on the Steering Group as a service-user representative. Mr Steel will have full rights as a collaborator in the trial and will contribute to all stages of the trial. We acknowledge that it is good practice to have more than one patient representative for mutual support, so we will continue to explore possibilities of another service user joining the team.

17. Study flow diagram



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Appendix 1. Detailed description of the Alexander Technique.

Alexander Technique is a taught approach: anyone taking Alexander Technique (AT) lessons is regarded as learning the technique, not as a patient; lessons are not a form of passive therapy or treatment.

The teacher's aim is to teach the AT and how to make use of it to reduce the intensity and frequency of poor habits and facilitate improvements in co-ordination, muscle tone and musculoskeletal use.

Teachers first investigate whether there is something - perhaps a particular habitual way of standing, sitting or moving – that is underlying or exacerbating the problem. Habits that restrict freedom of movement of the head and neck, that cause stiffening and shortening of the spine and commonly result in pain, are given priority of attention and progressively reduced.

How is the AT taught?
During lessons, teachers use frequent hand contact to observe and interpret subtle changes in muscle tone and co-ordination and also to convey non-verbal information. This is integrated with oral and written advice and information.
Hand contact is also used to:

- clarify the meaning of verbal explanations and advice
- help people
- direct their attention where needed
- become aware of and release unwanted head, neck and spine muscle tension
- gain immediate feedback
- allow lengthening of the spine
- improve axial muscle tone and coordination
- facilitate the dynamic interrelationships of the head, neck and back
- improve musculoskeletal use
- maintain improvements during activity

Other teaching aids include diagrams, models and the example of the teacher's own manner of use.

The AT is taught through practical application to the way of going about simple activities:

- initially quiet standing, quiet sitting, then moving from one to the other; or lying semi-supine (see below) on a firm surface;
- preparation for and carrying out activity such as walking, crawling, turning, raising a hand, speaking;
- later, other activities of general value or of particular interest, such as playing a musical instrument, writing or using a computer.

Difficulties are discussed and resolved.

The content of each lesson varies according to the observed and reported needs and limitations of each individual. All are encouraged to spend some time each day (15-20 minutes) practicing the AT while in a semi-supine position (lying on the back with head supported, knees bent and feet flat on supporting surface), and to use the AT in their everyday activities.

Lesson pattern
All lessons are one-to-one.
Participants are usually asked to remove shoes, but otherwise remained fully clothed.
Lessons last 30-40 minutes and each participant is encouraged to record the time between lessons dedicated to practising the AT. They will be provided with a book on the Technique -

either *Body Breath and Being (Nicholls),* or *Illustrated Elements of Alexander Technique* (Glynn Macdonald) or *Body Learning* (Michael Gelb).

The first four lessons will be at twice-weekly intervals and subsequent lessons weekly.

In practice these schedules can be difficult to achieve in exactly the above format, and will be negotiated flexibly with patients as in the ATEAM trial. The practical activities used, what was taught, and the pupil's progress and difficulties will be recorded on forms designed for the trial.

AT teachers

All AT teachers in the trial will have successfully undergone a three-year training at a STAT-approved course; will be currently registered members of STAT; and had at least three years' post-qualification experience. Lessons will take place at the teacher's normal place of work, either their home or in a private clinic.