Self-management programme for ankylosing spondylitis
(Protocol)

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Self-management programme for ankylosing spondylitis

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of a self-management programme on people with AS in terms of their: health status, self-efficacy in symptom management, health-related quality of life, healthcare utilization and participation in paid and unpaid work.

BACKGROUND

Ankylosing spondylitis (AS) is a musculoskeletal condition belonging to a family of disease known as sero-negative spondyloarthropathies. AS is a chronic inflammatory disease of unknown etiology characterised by inflammation of spinal joints and adjacent structures that may lead to progressive and ascending bony fusion of the spine (Davis 2005). The disease is however, strongly associated with HLA-B27 antigen (Gran 1998; Alamanos 2004). The prevalence of AS ranges from 0.15%-1.8% in the Caucasian population (Will 1990; Burgos-Vargas 1995; Kaipianen 1997; Akkoc 2006). Back pain is the cardinal symptom of AS (Husby 1987). Enthesitis which is characterised by inflammation at the sites of insertion of ligaments, tendons, or joint capsules to bone is responsible for the pain, stiffness, and limitations of the spinal joints (Granfors 2002; Khan 2003).

Strategies for managing AS aim to reduce symptoms of pain and stiffness, improve and/or maintain function and mobility, prevent disability, improve quality of life and prevent structural damage (Maksymowych 2006). Over the last few years, the treatment of AS has evolved from symptomatic relief to modification of disease activity and the associated morbidity and mortality (Scalapino 2003). Though there is no known cure for AS, recent studies suggest that biological therapies which target the inflammatory process underlying AS may hinder progression of the disease and provide relief from symptoms (Seiper 2002). Current therapy for AS include physical therapy, non-steroidal anti-inflammatory drugs (NSAIDS), anti-rheumatic disease modifying drugs (DMARDS) and the newly developed biological agents targeting tumour necrosis factor alpha (TNF-α) (Scalapino 2003).

People with AS have two main tasks: 1) medical management such as taking medications, following a regimen of exercises, diet, etc. and 2) psycho-social adaptations such as coping with anger, fear, frustration, and accommodating various new life roles in relation to jobs, family and friends (Corbin 1988). This implies that in addition to adherence to treatment guidelines, it is essential to incorporate psychological and social management in living with AS (Newman 2004). Self-management techniques are an emerging approach that accommodates management of medical, social and emotional aspects of AS (McGowan 2005). Self-management...
education is concerned with problem-solving, decision making, legitimate use of resources, and building up of partnership with the healthcare providers that internally motivates an individual to get empowered to manage his/her illness effectively (Arnold 1995; Anderson 1996; Von Korff 1997; Lorig 2003a).

The core concept in self-management skill is the realisation of self-efficacy, i.e., the confidence in oneself to carry out the required behaviour to acquire the desired goal (Bandura 1997). Self-management has been defined as ‘the individual patient ability and competence regarding the management of symptoms, treatment, physical and psychosocial consequences and the lifestyle changes inherent in living with a chronic condition’ (Barlow 2000b). A self-management programme was first applied to arthritis that was originally developed by Kate Lorig, DrPH, at Stanford University, in the late 1970s (Brady 2003). Since then, the programme has been applied to various chronic conditions such as osteoarthritis, rheumatoid arthritis, diabetes mellitus, hypertension, asthma, depression and stroke and the outcomes achieved include improved self-efficacy, improved health status on pain, depression and disability, decreased healthcare utilizations and reduction in healthcare cost (Lorig 1993; Lorig 1999; Barlow 2000a; Lorig 2003b; Chodosh 2005; Lorig 2005; Lorig 2006; Osborne 2006; Elzen 2007).

The objectives of the self-management programme include (Osborne 2004):

- engagement in activities such as exercise to promote health, build physiological reserve, and prevent adverse sequela;
- appropriate interaction with health care providers and adherence to recommended treatments;
- monitoring of physical and emotional status and making appropriate use of non-pharmacological pain management techniques, relaxation, and cognitive distraction; and
- development of an action plan that individuals can confidently accomplish.

OBJECTIVES

To assess the effects of a self-management programme on people with AS in terms of their: health status, self-efficacy in symptom management, health-related quality of life, healthcare utilization and participation in paid and unpaid work.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), cluster randomised controlled trials and controlled clinical trials (CCTs) that fulfil the following criteria will be included in the review:

- Studies with a control group either receiving no interventions or receiving only specific interventions such as information or instructions on medications, exercise, information booklets, or social supports, or self-management programmes lacking interaction with a programme leader.
- Pre- and post-results available separately for AS, either in the publication or from the studies’ authors;
- Participants who have been randomly or quasi-randomly assigned to one of 2 or more treatment groups. Random assignments must give each participant entering the trial an equal chance of receiving each of the possible treatments (e.g. by using sequentially numbered opaque sealed envelopes or computer generated random numbers). Quasi-random assignment must prospectively allocate participants to receive a treatment in a manner, which would produce balanced groups, but which is not necessarily strictly random (e.g. allocated alternatively or according to day of the week or bed availability).

Types of participants

Inclusion criteria

Studies with participants who are over 18 years with a clinical diagnosis of AS as defined by the modified New York criteria which state that, AS is definite if there is a presence of unilateral grade 3 to 4 or bilateral 2 to 4 sacro-iliitis in addition to any clinical criteria such as low back pain for three or more months that is improved by exercise and not relieved by rest, limitation of lumbar spine mobility and reduction in chest expansion (Van der Linden 1984).

Exclusion criteria

The diagnostic criteria have not been met or there is uncertainty in the diagnosis.

Types of interventions

Inclusion Criteria

Self-management programme designed for people with AS. Programme content must include at least one component each from the biological, psychological and social management consisting of disease information about AS, managing medications, exercise, disease-related problem solving, cognitive symptom management, management of emotions, communication skills and use of community resources (Holman 2004). Participants should have a face-to-face interaction with a programme leader, who is either a health professional or a trained layperson. The duration should have been a minimum of 12 hours of contact programme distributed over a period of time.
Exclusion criteria
Studies in which the interventions focus only on a specific component such as exercise, cognitive symptom management or consisting only of social support
Not face-to-face or peer support.
Duration less than 12 hours.

**Types of outcome measures**

a) Primary outcomes:
1. Measurement of health status in terms of physical function, pain, spinal mobility, morning stiffness, fatigue, anxiety, depression;
2. Self-efficacy in symptom management.

b) Secondary outcomes:
1. Health care utilization (e.g.: number of physician visits, days of hospital admission, frequency and dosage of analgesics)
2. Health-related quality of life
3. Participation in paid and unpaid employment
c) Outcome measures:
1. Health status
   - The Bath AS functional index (BASFI)
   - Bath AS metrology index (BASMI)
   - The Stanford Arthritis Center Health Assessment Questionnaire (HAQ)
   - The McGill Pain Questionnaire
   - The Oswestry Low Back Pain Disability Questionnaire
   - The Index of Activities of Daily Living (ADL)
   - The Beck Depression Inventory
   - The Center for Epidemiologic Studies Depression Scale (CES-D)
2. Self-efficacy
   - General Self-Efficacy Scale
   - Stanford Self-Efficacy Scale (SSES)
3. Health-related quality of life
   - Health assessment questionnaire for the spondyloarthropathies (HAQ-S)
   - Bath AS global (BASG) to assess global well being
   - Ankylosing Spondylitis quality of life (ASQoL) questionnaire
   - The Arthritis Impact Scale (AIMS)
   - Short Form - 36 Health Survey
   - The Sickness Impact Profile
   - The Nottingham Health Profile
   - WHOQoL
   - Patient Generated Index (PGI)
   - EUROQoL
4. Employment outcomes
   - Extension to working life (retain, or return to, paid employment)
   - Absenteeism (excluding pregnancy-related sickness absences)
   - Sick-leave
   - Sick-pay
   - Workers' compensation claims

5. Other validated measures of health status, self-efficacy and (health-related) quality of life will also be included in the review.

d) Outcomes measured at 3 months, 6 months and 12 months post-intervention.

**Search methods for identification of studies**

See Cochrane Musculoskeletal Group methods used in Reviews
The search strategy developed by the Cochrane Musculoskeletal Group will be used. We will carry out a search in the following databases: The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PSYCinfo, PEDro and SIGLE.
The full search strategy in Appendix 1, using controlled vocabulary (MeSH) and free text terms will be used to identify additional studies comparing the different self-management programmes for AS. This strategy will be used to search MEDLINE and The Cochrane Central Register of Controlled Trials (CENTRAL), and will be modified to suit other bibliographic databases.
Besides searching in the electronic databases, grey literatures such as reports and conference proceedings will be searched. Experts in the field of public health, rheumatology, medicine and rehabilitation, will also be contacted to get information about any additional unpublished or ongoing trials of self-management programmes for AS. The reference details of all trials found using the above search methods will also be searched.

**Data collection and analysis**

1 Selection of Trials
All the studies fulfilling the eligibility criteria will be retrieved. The title and the abstract will be screened for inclusion by the two review authors (LF and PM) and specific trials will be retrieved. If there is doubt from the title and the abstract whether allocation of the intervention had been conducted in a randomised manner or whether the intervention included a contact programme or educational component, the full report will be reviewed.
Examination and screening of suitability for inclusion in the meta-analysis will follow. The full reports will be examined by both review authors. Tables will be provided for the characteristics (population, size, intervention and treatment effect) of the trials included and excluded from the systematic review.
2 Assessment of quality

Both the review authors will assess potential biases resulting from the trial design. Any discrepancies between review authors will be resolved by discussion to achieve a consensus. The results of the quality assessment of included studies will be tabulated and described narratively. Quality assessment will be based on the following aspects of methodology:

(i) Randomisation:
- Was the method really random?
  A Done  
  B Not done  
  C Unclear  
- What method was used to generate the random sequence?

(ii) Allocation concealment:
- Was allocation of participants to groups adequately concealed?
  A Adequate  
  B Unclear  
  C Inadequate  
  D Not used  
- What method was used to conceal allocation?

(iii) Blinding:
- Were the following people involved in the trial adequately blinded to group allocation?
  (Each group is rated as done, not done or unclear)
  A Participants?  
  B Providers?  
  C Outcome assessors?  
  D Data analysts?
- What methods were used and were they effective?

(iv) Implementation fidelity
- Was any monitoring done to evaluate the adherence of the instructor to the prescribed programme content?
  A Done  
  B Not done  
  C Unclear  
- What method was used to monitor the instructor’s adherence to the programme?

(v) Baseline comparability:
- Were the groups comparable at the start of the study on important characteristics?

(vi) Follow-up:
- Was follow-up complete?
- How many participants completed the study for each group (and each outcome)?
- How many participants did not complete the study for each group (and each outcome)?
- What reason was given for not completing the study?

(vii) Intention-to-treat analysis:
- Were participants analysed in the groups to which they were assigned? That is, were all participants analysed according to their allocated group, not by whether they actually received the intervention, or whether they remained in the study?
  A Done  
  B Not done  
  C Unclear

3 Data management

3.1 Data extraction

This will be performed independently by the two review authors (LF, PM). All the necessary data will be retrieved and entered in RevMan 4.2. The authors of trials will be contacted to provide missing data, where further clarification is needed.

4 Data analysis

4.1 Binary data

For binary data, relative risk (RR), Peto odds ratio (for rare events <10%) and 95% confidence intervals (CI) will be estimated according to the intention-to-treat principles. For pooled data, the fixed-effect model will be preferred, but the random-effects model will be used when heterogeneity is present.

4.2 Continuous data

4.2.1 Skewed data: continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data the following standards will be applied to all data before inclusion: (a) standard deviations and means must be reported in the paper or to be obtainable from the authors; (b) when a scale starts from a finite number (such as zero), the standard deviation, when multiplied by two, must be less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distributions (Altman 1996)). Endpoint scores on scales often have a finite start and end point and this rule can be applied to them. When sample sizes are thought to be too small, assistance from the CMSG statistician will be sought on this issue.

4.2.2 Summary statistic: For continuously distributed outcomes the weighted mean difference (WMD) will be calculated when the same scale is used in a similar manner across studies, otherwise, the standardised weighted mean difference (SMD) will be used. A fixed-effect model will be used in the first instance but random-effects models will be used to investigate the sensitivity of results to the choice of statistical method.

4.2.3 Endpoint versus change data: where possible endpoint data will be presented and if both endpoint and change data are available for the same outcomes, these can be pooled in a sub-group analysis.

4.2.4 Cluster trials: studies increasingly employ ‘cluster randomisation’ (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems as the authors often fail to account for intra class correlation in clustered studies, leading to a ‘unit of analysis’ error (Divine 1992) - whereby P
values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated - causing type I errors (Bland 1997; Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, then we will also present these data in a table. A sensitivity analysis will be performed to assess the effect of including or excluding these data from cluster randomised studies.

5 Test for heterogeneity
Heterogeneity will be assessed using the Chi-square test in conjunction with the $I^2$ statistic. Significance for the Chi-square test will be set at $p = 0.10$ due to the low power of this test (Higgins 2005d). The cut point for $I^2$ will be kept at 50%. When significant heterogeneity is present, an attempt will be made to explain the differences based on the clinical characteristics of the included studies.

6 Sensitivity analyses
Sensitivity analysis will be performed by excluding studies having:
(i) high $I^2$;
(ii) inadequate allocation concealment;
(iii) low attrition rates.

7 7 Addressing publication bias
Data from all included studies will be entered into a funnel graph (trial effect against trial size) in an attempt to investigate the likelihood of overt publication bias (Egger 1997).

8 General
Where possible, reviewer authors will enter data in such a way that the area to the left of the line of no effect indicates a favourable outcome for the treatment groups.

Acknowledgements
The review authors would like to thank the Cochrane Musculoskeletal Group (and in particular Bev Shea) for their valuable comments on the protocol and also for all their support received during the development of this protocol.

References


Davis 2005

Divine 1992

Egger 1997

Elzen 2007

Gran 1998

Granfors 2002

Gulliford 1999

Higgins 2005d

Holman 2004

Husby 1987

Kaipianen 1997

Khan 2003

Lorig 1985

Lorig 1993

Lorig 1999

Lorig 2003a

Lorig 2003b

Lorig 2005

Lorig 2006

Maksymowych 2006

McGowan 2005

Newman 2004

Osborne 2004

Osborne 2006

Scalapino 2003
Seiper 2002

Van der Horst 2006

Van der Linden 1984

Von Korff 1997

Will 1990

* Indicates the major publication for the study

**APPENDICES**

**Appendix 1. Search strategy**

1. Musculoskeletal Diseases/
2. exp bone diseases/
3. exp Arthritis/
4. (ankylosing or spondyl$).mp.
5. (bekhterev$ or bechterew$).tw.
6. (Marie adj struempell$).tw.
7. or/1-6
8. exp Self Care/
9. ((self or symptom$) adj (care or help or manag$ or directed or monitor$ or efficacy or admin$)).tw.
10. exp Patient Education/
11. (patient$ adj2 (educat$ or information)).tw.
12. ((health or patient$) adj2 (educat$ or information)).tw.
13. ((health or patient$) adj2 (educ$ or information)).tw.
14. exp Patient Participation/
15. exp Consumer Participation/
16. ((patient$ or consumer$) adj part$).tw.
17. "Power (Psychology)"/
18. empower$.tw.
19. exp Holistic Health/
20. (holistic or wholistic).tw.
21. exp Rehabilitation/
22. rehab$.tw.
23. exp "Activities of Daily Living"/
24. (activit$ adj2 daily adj living).tw.
25. exp Social Support/
26. (social adj (support or network$)).tw.
27. (support adj system$).tw.
28. exp Adaptation, Psychological/
29. (psychologic$ adj (adjust$ or adapt$)).tw.
30. (cope or copes or coping).tw.
31. exp Behavior Therapy/

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32. (adapt$ adj behav$).tw.
33. (behav$ adj (therap$ or intervention$)).tw.
34. or/8-33
35. 7 and 34
36. clinical trial.pt.
37. randomized.ab.
38. placebo.ab.
39. dt.fs.
40. clinical trials/
41. randomly.ab.
42. trial.ti.
43. groups.ab.
44. or/36-43
45. animals/
46. humans/
47. 45 and 46
48. 45 not 47
49. 44 not 48
50. 35 and 49

WHAT’S NEW

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HISTORY
Protocol first published: Issue 1, 2008

CONTRIBUTIONS OF AUTHORS
Lambert Felix - Formulated the title and the writing-up of the background, objectives, criteria and the search section of the protocol.

Dr. Paul Montgomery - Edited the above. Also played a major role in developing the methods section of the protocol.
DECLARATIONS OF INTEREST

None