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Early intervention for the management of acute low back pain: A single blind randomised controlled trial of biopsychosocial education, manual therapy and exercise

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Early intervention for the management of acute low back pain: A single blind randomised controlled trial of biopsychosocial education, manual therapy and exercise.

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Abstract

Design

A single blind randomised controlled trial comparing two models of care for patients with simple acute low back pain (ALBP).

Objectives

To compare two research-based models of care for ALBP, and investigate the effect of the timing of physical intervention.

Summary of Background Data

National guidelines offer conflicting information on the delivery of physical treatment in the management of ALBP. Review of guidelines suggests two different models of care. Direct comparisons between these models are lacking in the literature. The present study aims to compare these two approaches to the management of ALBP.

Method

Among 804 referred patients, 102 subjects met the specific admission criteria and were randomly assigned to an 'assess/advise/treat' group or an 'assess/advise/wait' group. The intervention consisted of biopsychosocial education, manual therapy and exercise. Assessment of short-term outcome enables comparison to be made between intervention and advice to stay active. Assessment of long-term outcome enables comparison to be made between early and late intervention. Study outcomes of reported pain (VAS), functional disability (RMDQ), mood (MZSRDS, MSPQ, STAIS), general health

(Euroqol) and quality of life (SF-36) were assessed at baseline, six weeks, three months and six months.

Results

At six weeks, the 'assess/advise/treat' group demonstrated greater improvements in disability, mood, general health and quality of life than patients in the 'assess/advise/wait' group ($p<0.05$). Disability and pain were not significantly different between the groups at long-term follow up ($p>0.05$). However, mood, general health and quality of life remained significantly better in the 'assess/advise/treat' group ($p<0.05$).

Conclusions

At six weeks physiotherapy intervention is more effective than advice on staying active, leading to more rapid improvement in function, mood, quality of life and general health. The timing of intervention affects the progression of psychosocial features. If treatment is provided later, the same psychosocial benefits are not achieved. Therefore an 'assess/advise/treat' model of care seems to offer better outcomes than an 'assess/advise/wait' model of care.

Key words: Acute low back pain, disability, manual therapy, exercise, biopsychosocial education, early intervention, psychosocial factors.

Key points

- International guidelines for ALBP differ in their support for physical therapy and in the suggested timing of physical intervention.
- Patients receiving physiotherapy treatment demonstrate better short term outcome than those given advice to stay active.
- There was no long term difference in pain and disability between early and late intervention.
- The timing of intervention affects the progression of psychosocial features. If treatment is provided later, the same psychosocial benefits are not achieved.

Mini abstract

Two models of care for ALBP were compared in a randomised controlled trial. Short term outcome is better in patients receiving physiotherapy. Long term outcome for pain and disability is not affected by the timing of treatment. However, the timing of treatment affects the long term progression of psychological features

Introduction

Evidence based guidelines for the management of acute low back pain (ALBP) have been formulated by the Health Authorities of a number of countries[1]. Clear evidence has emerged that 'advice on staying active' and appropriate drug therapies are effective interventions for ALBP and that bed rest and general back exercises are not.[2,3,4,5]

A major discrepancy between guidelines is in the use of physical therapy, particularly the timing of physical intervention. Based on the inconclusive evidence for physical therapy, the potential negative effect of treatment dependency, the cost, and the sometimes passive nature of the treatment, the Dutch and Australian authorities propose a 'wait and see' approach during the first 6 weeks.[1,6] More recent reviews have further strengthened this approach.[3,5] Alternatively the UK Clinical Standards Advisory Committee (CSAG) report[7], the American guidelines[2] and the more recent UK guidelines[4] recommend various forms of early physical intervention.

The discrepancies between these guidelines represent two different models of care for ALBP. In one system patients are assessed, advised to stay active and active treatment is commenced early (assess/advise/treat). In the alternative model active treatment is delayed (assess/advise/wait).

Direct comparisons between these two models are lacking in the literature. The present study aims to compare these two approaches to the management of ALBP.

The present study addressed three major research questions:

1. Do patients treated with an active intervention programme differ significantly at six weeks in outcome from patients who have received advice on staying active only?
2. At long-term follow-up do patients who received treatment early differ significantly in outcome from patients who were asked to wait six weeks for their treatment?
3. Are there any meaningful differences in outcome between an 'assess/advise/treat' model and an 'assess/advise/wait' model of care for ALBP?

Materials and Methods

Design

A randomised, controlled, single-blind trial, with the assessor independent and blind to the patient group allocation, was conducted in the Physiotherapy Outpatients Department at Central Middlesex Hospital, London.

Support was provided by the Department of Health Studies at Brunel University. Ethics approval was obtained from the local Health Authority Research Ethics Committee and informed consent was obtained from all study participants.

Recruitment

Subjects were recruited from ALBP patients referred to the Physiotherapy Department by either their General Practitioners or the Hospital Accident and Emergency Department. Patients were screened for eligibility within the Physiotherapy Department based on referral details and telephone screening. All eligible patients were contacted and invited to participate. The first patient was recruited on the 31st of March 1998 and the last patient on the 21st of December 1999.

Procedure

Following completion of their baseline questionnaires, subjects underwent a full physical examination by a physiotherapist to determine final eligibility for the study.

Each patient entering the trial was randomised to the 'assess/advise/treat' or 'assess/advise/wait' group using random number tables with odd/even number allocation to group and drawn by an independent person not involved in the study. Both groups underwent a physical examination, received information and advice on staying active[4] and a copy of the Back Book.[8] The 'assess/advise/wait' group were given an appointment to begin physiotherapy treatment at six weeks from baseline. Patients in the 'assess/advise/treat'

group received immediate physiotherapy treatment. All patients were followed up by postal assessment at six weeks, three months and six months from baseline. Patients who failed to return their questionnaires within two weeks were sent a second set. After a further two weeks patients were contacted by phone and encouraged to complete and return their questionnaires.

Outcome Assessment

The primary outcome measure was the Roland and Morris Disability Questionnaire (RMDQ)[9]. Secondary outcome measures were: Visual Analogue Scale (VAS) Usual Pain Intensity[10]; 6 Items from the Spielberger State-trait Anxiety Inventory (STAIS)[11]; Modified Zung Self Rated Depression Score (MZSRDS)[12]; Modified Somatic Perception Questionnaire (MSPQ)[13]; EuroQol health transition and health thermometer[14]; and the Short Form 36 (SF-36)[15].

Clinical Interventions

Investigations of physiotherapy have most often focused on individual elements of physiotherapy care and reflect neither the reality of clinical practice nor the philosophical framework of physiotherapy. The current study adopted a pragmatic, evidence-based approach to physiotherapy treatment. Patients were assessed using a locally developed biopsychosocial protocol. From the biopsychosocial assessment a goal directed treatment plan was formulated. The treatment protocol was explained to the subjects and short and long-term functional goals were agreed. All sections of the assessment were documented as well as the clinical reasoning process. Manual therapy,[16] rehabilitative exercises,[17,18,19,20,21,22,23,24,25,26,] advice on staying active[1,4] and

education,[8,27] were the major interventions used. Electrotherapy, traction and general back exercises were not included in the treatment model.[4]

The manual therapy intervention followed the regimen described by Maitland et al.[16] In this approach both low-velocity joint mobilization techniques and high-velocity manipulation techniques are used. In keeping with normal clinical practice the choice of initial and subsequent manual therapy techniques was at the treating therapist's discretion. Treatment decisions were based on the initial and progressive assessment of the patient's joint dysfunction. Patients could receive a combination of low- and high-velocity techniques as indicated as best clinical practice within the Maitland regimen.

The exercise therapy intervention could include exercises designed to: affect pain distribution and intensity;[22,26] improve spinal motion, alignment and posture;[17,24,25] enhance spinal stability;[23,24] or improve cardiovascular fitness and lower limb and back strength.[18,27] Therapist's were encouraged to ensure that all exercise treatment was delivered in a rehabilitative framework that attempted to increase the feeling of control over pain and increase confidence in the ability to carry out normal activities. All exercises were delivered on an individual basis. As with the manual therapy, the choice of initial and subsequent exercise treatment was at the discretion of the treating therapist.

The educational intervention was based on the information provided in The Back Book.[8] The education programme attempted to explain the nature of the patients symptoms, disavow the structural basis for simple low back pain,

emphasis the self limiting nature and favourable outcome of the condition, encourage graded return to activity, emphasise the therapeutic benefit of movement and participation in normal work and leisure activities, decrease the focus on pain, explain the principles of sensitisation if appropriate and make clear that hurt does not equal harm.

All of the recently developed clinical guidelines recommend that assessment should address psychological, occupational and socio-economic factors[1]. Evidence indicates that these are more important risk factors for the development of chronicity than biomedical symptoms and signs.[28] Every effort was made to ensure that psychosocial assessment and management strategies were integrated into the physiotherapy treatment model for this study. [27]

Advice to Stay Active

Evidence suggests that advice on staying active is an effective treatment strategy for simple low back pain, leading to faster recovery and less chronic disability.[4] Encouraging patients with simple low back pain to stay active and continue normal activities is included as first line treatment in most national guidelines.[1] However, whether advice on staying active is the optimal management for acute low back pain is, at present, unclear. Direct comparisons between advice on staying active and more active approaches to managing acute low back pain are lacking in the literature. There is some evidence from studies on sub-acute low back pain that more intensive treatments produce better outcomes.[29] Furthermore, there would seem to be some discrepancy between the evidence base and the clinical guidelines as far

as advice on staying active is concerned. The majority of studies included in the reviews on advice on staying active include more than simply advice.[21,30] This is not always explicit when reviewing the algorithms of care in management guidelines.[1] It is important that more studies investigate advice on staying active in the way that it has been interpreted by clinical guidelines and applied in everyday practice, that is, as a one-off intervention.

Sample size

Prospective sample size was calculated using the method of Altman[31]. Assuming a standard deviation of six points[32] on the primary outcome of the Roland and Morris Disability Questionnaire (RMDQ),[9] a clinically significant difference of four points could be detected with two groups of n=49 subjects (alpha = 0.05, power = 0.90).

Statistical Methods

The statistical analysis was performed using Stata Release 6 statistical software. Seven baseline co-variates (RMDQ,[9] VAS usual pain intensity,[10] MZSRDS,[12] MSPQ,[13] STAIS,[11] QTF Classification,[33] Acute low back pain screening questionnaire[34]) were used to adjust for baseline characteristics known to influence outcome and the potential confounding effects of missing data at follow up. Regression models investigated whether there was any interaction between group and follow-up responder status for each baseline characteristic.

After adjustments for baseline co-variates, regression co-efficients and their associated *p* values were calculated for each outcome variable at six weeks

and at long-term follow-up. The significance level was set at 0.05. Long-term follow-up estimates were derived from all available data at three months and six months. The regression models used robust sandwich estimates of the standard errors of the regression co-efficients to take account of any correlation between the repeated assessments on the same subject. All statistical analyses were based on an intention-to-treat methodology.

Fisher's exact tests (categorical variables) and t-tests (continuous variables) were used to compare the baseline characteristics of follow-up responders (those who did and did not complete the follow up assessments). Sensitivity analyses were performed by repeating the regression analyses using last value carried forward for those patients who did not respond to follow-up assessments.

Results

Sample Derivation

804 patients were considered for inclusion in the study. Following the application of the eligibility criteria, 102 (13%) patients were randomised to either the 'assess/advise/treat' (n=50) or the 'assess/advise/wait' (n=52) group (Figure 1). One patient from each group was excluded after randomisation due to commencing litigation. Reasons for exclusion are presented in Table 1.

Response rate

65 patients (64%) at six weeks and 63 patients (62%) at long-term follow-up returned their assessments. There was no significant difference between the groups in the proportion of patients who returned questionnaires at either six week (chi-square = 1.75, p=0.19) or long-term (chi-square=0.004, p=0.95) follow-up.

Baseline Characteristics

Following randomisation six patients failed to complete their baseline assessments and two patients were excluded due to commencing litigation. Baseline characteristics are presented in Table 2 for the 94 patients who provided baseline assessment. No significant differences were detected between groups at baseline (p>0.05).

Six weeks

There was a significant (p<0.05) effect of treatment on STAIS, RMDQ, MZSRDS, EuroQol Total Score, EuroQol Health Thermometer, SF-36 Vitality, SF-36 Social Functioning, and SF-36 Mental Health (Table 3). Patients randomised to the 'assess/advise/treat' group reported significantly lower disability, fewer symptoms of depression and anxiety and had better quality of life, vitality, social functioning and mental health at six weeks than those patients randomised to the 'assess/advise/wait' group.

Long-term follow-up

There was a significant (p<0.05) long-term effect of treatment on STAIS MZSRDS, MSPQ, EuroQol Health Thermometer and SF-36 Role Emotional, Mental Health and Health Transition (Table 4). Those patients in the 'assess/advise/treat' group reported fewer symptoms of depression, somatic

distress and anxiety, had better quality of life and mental health and reported less interference of emotional problems in everyday activities than those patients in the 'assess/advise/wait' group.

Sensitivity analysis

The potential effects of missing data were explored by re-fitting the regression models (which assessed short and long term effects of treatment) with missing data replaced by the last value carried forward (LVCF). Apart from VAS for usual pain intensity (short-term follow-up VAS was significantly lower for the 'assess/advise/treat' group (regression coefficient=-1.2, se=0.5, p=0.02)), there were no other differences between these models and the regression models using all available data. Furthermore there were no significant interactions between group and responder status for any baseline variable ($p>0.05$).

Discussion

Baseline

This study was undertaken in the physiotherapy department of a UK metropolitan National Health Service hospital. Patient baseline characteristics (table 3) indicated that on average patients fell within the normal range of distress or illness behaviour.[35] However 41% (n=38) of patients were assessed at baseline as either at Risk for Depression or Distressed – Depressive.[35] Similarly 31 patients (30%), demonstrated risk of long term work loss as assessed by the Yellow Flags Questionnaire.[34] These findings indicated that an important proportion of patients with ALBP referred for physiotherapy in a primary care setting exhibited psychosocial features associated with poor outcome.[28,34]

This study was driven largely by the discrepancies that exist in recently published LBP guidelines.[1] In this study the definition of simple low back pain offered by these reports was used as the inclusion criteria for the study, yet relatively few ALBP patients referred to the department fulfilled these criteria. Based on our data, 74% of ALBP patients referred fell outside the criteria for simple ALBP (table 1). These findings have clear implications for the utility of these guidelines in primary care, as the population presenting for treatment might not represent the population from which the evidence base is derived. Our first recommendation therefore is that health care professionals become aware of the demographics of their client group and interpret and implement guidelines in keeping with these characteristics.

Six-week follow-up

Analysis at this time point enabled comparison between advice on staying active and active physiotherapy treatment. Our findings suggested that early active physiotherapy treatment led to improved outcomes in disability, general health, social function, anxiety, depressive symptoms, mental health and vitality. In the short term it appears that physiotherapy is a superior intervention to advice on staying active for patients with ALBP. This is in keeping with findings on sub-acute LBP.[29]

A number of reviews have concluded that the evidence for the use of physical interventions in ALBP is negative, or at best weak.[3, 5, 36, 37, 38] This is reflected in the Dutch and Australian guidelines where physiotherapy is not recommended in the acute stage.[1] Our findings challenge these

recommendations. We have shown that patients obtain significant benefit from being involved in an early active physiotherapy programme. Further research is being undertaken to thoroughly analyse the content of treatment and the clinical reasoning process employed by the treating therapists so that the aspect or aspects of care that led to such favourable outcomes can be identified. It is our impression however that effective intervention needs to be multi-modal and delivered within a rehabilitative framework, with the individual interventions themselves probably of less importance than the philosophical construct in which the treatment is delivered.

Long- term follow-up

Neither pain nor disability was significantly different between the groups during the course of the long-term follow-up, indicating that these parameters were unaffected by the treatment model. ‘'assess/advise/wait'’ led to a delay in improvement of disability, but with no long-term consequences.

A number of other important outcome variables, however, were adversely affected by an 'assess/advise/wait' approach. Patients seen promptly had significantly less anxiety, depressive symptoms and distress. They also had better general health, social functioning, and mental and emotional health. Very few studies of physiotherapy intervention for ALBP have assessed psychosocial variables as part of long-term follow-up. This study provides evidence that early active treatment can improve psychosocial outcomes and that the effect on psychosocial function appears to be dependent on the timing

of intervention. Delaying the onset of treatment does not provide the opportunity for physiotherapy intervention to have this favourable effect.

Overall our study supports the hypothesis that 'assess/advise/treat' produces better long-term outcomes than an 'assess/advise/wait' approach. Furthermore, as it is recognised that psychosocial variables are predictive of chronicity in ALBP[28], early active treatment may have the potential to reduce the risk of chronicity developing.

Sensitivity analysis

All our sensitivity analyses to examine the consequences of missing follow-up data suggested that, although it comprised approximately one third of the randomised cases, this was unlikely to result in substantial bias to the results of the study.

The amount of missing data was similar for both groups at both six week and the long-term follow-up. Furthermore there was no difference between responders or non-responders in any of the baseline variables. For those patients for whom data were available, non-responders at six weeks did not differ significantly from the rest of the cohort at long-term follow-up. Similarly, non-responders at long-term follow-up for whom there were six week data available are not significantly different from the rest of the cohort at six weeks. The results of a sensitivity analysis using LVCF indicated little change in the regression coefficients. Finally, the finding that 16 patients (42%) were lost to follow-up due to changes of their address provided further

evidence that data were missing at random. However, despite these results and the strenuous efforts made to obtain follow up information on all randomised patients, bias is always a possibility when follow up rates are low.

Conclusion

In the UK the CSAG report[7] called for a change in the health service provided for patients with low back pain. The report concluded that although there is a high probability that an acute attack will settle, this should not be taken as grounds for complacency, inactivity or a policy of "wait and see" on the part of the health professionals. The report was criticized for basing recommendations on anecdotal evidence and on making a bold claim that the provision of 'services at the acute stage…will prevent chronic pain and disability'.[39] Our results do not specifically support the CSAG recommendation. Early intervention does not affect long term pain and disability. However, other important features of the low back pain experience are dependant on the timing of intervention. Further research is needed to fully clarify the role of early intervention.

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