

Randomised trial of a brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: outcomes and patients' preference

Jennifer A Klaber Moffett, David A Jackson, Stewart Richmond, Seokyoung Hahn, Simon Coulton, Amanda Farrin, Andrea Manca, David J Torgerson

Abstract

Objectives Firstly, to compare the effectiveness of a brief physiotherapy intervention with "usual" physiotherapy for patients with neck pain. Secondly, to evaluate the effect of patients' preferences on outcome.

Design Non-inferiority randomised controlled trial eliciting preferences independently of randomisation.

Setting Physiotherapy departments in a community setting in Yorkshire and north Lincolnshire.

Participants 268 patients (mean age 48 years) with subacute and chronic neck pain, who were referred by their general practitioner and randomly assigned to a brief physiotherapy intervention (one to three sessions) using cognitive behaviour principles to encourage self management and return to normal function or usual physiotherapy, at the discretion of the physiotherapist concerned.

Main outcome measures The Northwick Park neck pain questionnaire (NPQ), a specific measure of functional disability resulting from neck pain. Also, the short form 36 (SF-36) questionnaire, a generic, health related, quality of life measure; and the Tampa scale for kinesophobia, a measure of fear and avoidance of movement.

Results At 12 months, patients allocated to usual physiotherapy had a small but significant improvement in NPQ scores compared with patients in the brief intervention group (mean difference 1.99, 95% confidence interval 0.45 to 3.52; $P = 0.01$).

Although the result shows a significant inferiority of the intervention, the confidence interval shows that the effect could be in the non-inferiority range for the brief intervention (below 1.2 points of NPQ score).

Patients who preferred the brief intervention and received this treatment had similar outcomes to patients receiving usual physiotherapy.

Conclusions Usual physiotherapy may be only marginally better than a brief physiotherapy intervention for neck pain. Patients with a preference for the brief intervention may do at least as well with this approach. Additional training for the physiotherapists in cognitive behaviour techniques might improve this approach further.

Introduction

In any one year, 30% of adults will report neck pain, and 5-10% will be disabled with it.¹⁻² Most physiotherapists in the United Kingdom provide between four and 10 treatment sessions for musculoskeletal conditions including spinal problems,³⁻⁴ whereas in the United States they provide between nine and 12 treatment sessions.⁵ Little evidence is available, however, with respect to the effectiveness and cost effectiveness of routinely used physiotherapy interventions for neck pain.⁶ A need therefore exists to assess the effectiveness of treatments for neck pain by physiotherapists.

Possible ways of dealing with neck pain

Psychosocial factors are known to be important predictors of outcome for neck pain.⁷ Interventions that deal with patient's individual concerns, such as applying principles of cognitive behaviour therapy to physiotherapy, may help to overcome barriers to recovery.⁸⁻⁹

Patients' preferences

Patients' expectations¹⁰ or preferences for treatment¹¹⁻¹² may influence outcomes of treatment, and this can be a confounding factor when it is not possible to blind participants to the treatment they receive. This problem is often dealt with by using a patient preference design.¹³

A more robust alternative is to randomise all consenting participants but to elicit preferences before randomisation and use these in the subsequent analysis.¹⁴ This approach has been used in an evaluation of a physiotherapy intervention for back pain.¹⁵ We report the results of a fully randomised preference trial of "usual" physiotherapy compared with a brief physiotherapy intervention based on cognitive behaviour principles.

Institute of Rehabilitation, University of Hull, Hull HU3 2PG

Jennifer A Klaber Moffett
professor of rehabilitation and therapies

David A Jackson
Hull and East Riding Community NHS Health Trust, effectiveness facilitator

Department of Public Health and Primary Care, University of Hull, Hull HU6 7RX
Stewart Richmond
clinical trials coordinator

Department of Health Sciences, University of York, York YO10 5DD

David J Torgerson
director, York Trials Unit

Seokyoung Hahn
lecturer

Amanda Farrin
medical statistician, York Trials Unit

Simon Coulton
data manager, York Trials Unit

Centre for Health Economics, University of York
Andrea Manca
research fellow

Correspondence to: J K Moffett
j.k.moffett@hull.ac.uk

BMJ 2005;330:75-8



The checklist for monitoring the consultations and the overall scores achieved by eight physiotherapists are on bmj.com



This is the abridged version of an article that was posted on bmj.com on 7 December 2004: <http://bmj.com/cgi/doi/10.1136/bmj.38286.493206.82>

Outcome measures at 12 months after randomisation

Outcome*	Brief intervention	Usual physiotherapy	Difference (95%CI)	P value (analysis of covariance)
Northwick Park neck pain score	-0.840	-2.825	1.985 (0.452 to 3.518)	0.0114
SF-36				
Physical functioning	4.755	7.015	-2.260 (-10.004 to 5.483)	0.5656
Social functioning	-6.466	0.350	-6.817 (-13.445 to 0.141)	0.0548
Role-physical	-0.637	6.064	-6.701 (-12.961 to -0.441)	0.0360†
Role-emotional	-7.268	4.446	-11.715 (-17.571 to -5.858)	0.0001†
Mental health	-9.568	-0.205	-9.362 (-15.053 to -3.671)	0.0014†
Energy and fatigue	-6.735	2.506	-9.241 (-14.663 to -3.819)	0.0009†
Pain	4.994	11.742	-6.749 (-13.18 to -0.380)	0.0379†
General health perception	-9.220	-1.074	-8.146 (-12.347 to -3.946)	0.0002†
Tampa kinesiophobia score	-0.309	-0.224	-0.085 (-1.755 to 1.585)	0.9205
Distress	-0.662	-1.047	0.385 (-0.282 to 1.052)	0.2564

*Adjusted for baseline value of the response variable.

†Significant difference at the 5% level (negative Northwick Park questionnaire, Tampa scores, and distress scores indicate improvement; positive SF-36 scores indicate improvement).

Method

Procedure

Twenty eight physiotherapists participated in the trial, in eight different community services offering physiotherapy to outpatients. Recruitment was from September 1999 to August 2001. Each service supplied a list of referring general practitioners and consultants, who were then contacted.

Referrals came from 198 different general practitioners and nine consultants. Patients were referred to the physiotherapy departments in the usual way, and potentially eligible participants were then referred to the research team who assessed their eligibility. Inclusion criteria were a minimum age of 18 years; neck pain of musculoskeletal origin lasting at least two weeks; referred to a participating physiotherapy department; and willingness to be randomised—that is, no overwhelming preference for either intervention.

Brief intervention

Twelve physiotherapists received a full day's training in the brief intervention. It aimed to improve communication skills,¹⁶ demedicalise the problem, and teach the application of principles of cognitive behaviour therapy. The programme included role play, the use of videotaped interviews, and discussion. It was backed up by a trial manual and a neck book for the patients, to encourage self management.

The intervention consisted of a one-off session usually but could be extended to a maximum of three sessions. The approach encouraged a return to normal daily activities as soon as possible, through self management. If patients or physiotherapists thought they were not improving they could switch over to usual physiotherapy.

Usual physiotherapy

The physiotherapists treated the patients in the same way as usual according to their individual professional judgment. See *bmj.com* for treatments actually used.

The same 12 physiotherapists delivered both interventions.

Assignments and blinding

The York Trials Unit (Department of Health Sciences, University of York) provided telephone randomisation. Further blinding was achieved through the allocation

sequence, using randomly permuted blocks. Patients were stratified by physiotherapy department, age group, history of previous episodes, and severity of their condition (as scored on the Northwick Park neck pain questionnaire).

Trial procedures and outcome measures

Patients with subacute or chronic neck pain were referred to participating physiotherapy departments. Eligible patients were invited to a face to face assessment with a research physiotherapist (DAJ). This meeting included a detailed explanation of the study, a physical assessment (to exclude serious pathology), and collection of baseline data. Participants were asked to complete a questionnaire including several outcome measures; the Northwick Park neck pain questionnaire (NPQ) (primary outcome measure)¹⁷; the short form 36 questionnaire (SF-36);¹⁸ the Tampa scale for kinesiophobia (TSK),¹⁹ and distress measured on a numeric scale of 0 to 10.

Participants were asked if they had a preference for one or the other treatment group and then randomised. The patient's stated preference was independent of randomisation and had no influence on it. Follow up questionnaires went out at three and 12 months. Although patients and therapists were not blinded to the treatment allocation, they had no influence over the process of allocation, and those assessing the outcomes were unaware of the intervention provided.

Sample size estimation and statistical analysis

The study was originally planned as a non-inferiority trial. We estimated that to establish non-inferiority between the two treatments would require about 400 participants to be randomised between the two groups in order to exclude an approximate effect size of 0.3 with a statistical power of 80% at the 5% significance level. In clinical terms, 0.3 of an effect size was at least a 1.2 point difference in our outcome measure given a standard deviation of four points. This could mean that, for example, a change in a patient reporting the pain as being "moderate" to be being "mild" on the NPQ.

We used analysis of covariance (ANCOVA) to estimate differences in change between the randomised groups, with baseline values of the response variables as the covariate along with group allocation. We extended the analysis of covariance to investigate the influence on outcome of patients' preferences at baseline for the primary outcome (NPQ at 12 months). We used intention to treat analysis.

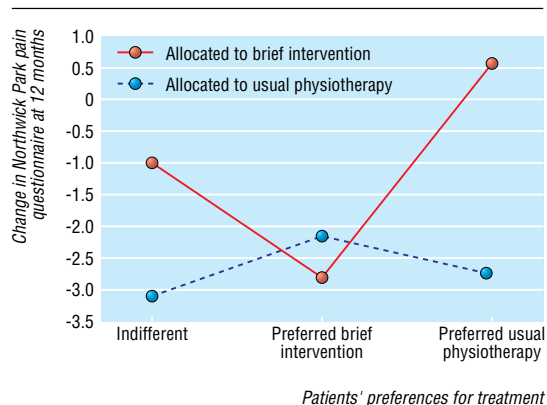
Results

Study population

Recruitment of participants was much slower than expected, and we failed to achieve our target sample size. We randomised 268 participants, 139 to the brief intervention and 129 to usual physiotherapy. At 12 months, loss to follow up was similar for both groups (17% for the brief intervention group and 18% for the usual physiotherapy group).

Baseline characteristics and outcomes

Baseline characteristics were similar for both groups. They were evenly balanced in age, quality of life scores,



Patients' preferences for treatment

Interaction between pre-randomised preferences and treatment allocation (negative scores indicate improved scores on the Northwick Park neck pain questionnaire)

and patients' preferences for usual physiotherapy or the brief intervention, with around 30% having a preference for usual physiotherapy.

For our main outcome, the NPQ score, both groups improved at three months; the group receiving usual physiotherapy tended to show greater improvement than the brief intervention group, although this difference did not reach significance. The eight SF-36 domains showed a similar trend favouring the usual physiotherapy group. At 12 months, although the brief intervention group's change scores (for NPQ) were significantly inferior to those of the group receiving usual physiotherapy, the confidence intervals imply that the effect could be still within the non-inferiority range for the brief intervention (below 1.2 points of the NPQ score; table). This small differential improvement was also reflected in most of the SF-36 domains, which again favoured usual physiotherapy at a significant level of probability. The small difference in change in the Tampa scores (fear of movement) was significantly in favour of the group receiving the brief intervention at three months ($P < 0.004$) but not at 12 months.

A clustering of outcomes is potentially possible since a single therapist was treating several patients. However, multilevel modelling to check for any clustering effects did not affect the conclusion.

Participants' preferences

We found that participants' preferences for treatment may influence outcome (see bmj.com). The figure shows an apparent interaction between participants' preferences and effect. Those who wanted the brief intervention and got it reported the biggest improvement on the NPQ scores, albeit a small and non-statistically significant difference.

In the "indifferent" group, the effects of patients' preferences are not present, and this analysis shows an advantage of being assigned to usual physiotherapy. For patients with a preference for usual physiotherapy, the overall effect of that treatment did not seem to be enhanced. However, those preferring usual physiotherapy but allocated to the brief intervention reported more pain according to their NPQ scores at 12 months. A formal statistical test of these interactions did not reach significance ($P = 0.19$), but we note that the trial was not balanced to test interaction formally and the interaction tests have relatively low power.

What is already known on this topic

Conclusive evidence for the management of neck pain is lacking

It is important to assess the effectiveness of physiotherapy as this common complaint is frequently referred to physiotherapy

What this study adds

Patients' preferences can be elicited in a fully randomised trial

Physiotherapy as usual (five sessions) can result in small benefits that are sustained at 12 months and are marginally better than a brief intervention

For some patients a brief intervention (two sessions) can be as beneficial if this is their treatment preference and costs less

In a clinical setting, patients should be given a choice of treatment approaches to include a brief intervention encouraging self management

To assess whether preference affected our main results, we added a preference interaction term in the analysis. This produced a smaller estimated difference of 1.58 (95% confidence interval -0.13 to 3.29) between the treatments at 12 months ($P = 0.07$), in contrast to the main analysis for 12 months shown in the table.

Discussion

Usual physiotherapy produced marginally better treatment outcomes at 12 months than the brief intervention based on cognitive behaviour principles.

Strengths and limitations of the study

The same physiotherapists who had been offered training in cognitive behaviour principles delivered both types of care. This is both a strength and a weakness. It was an advantage in that each physiotherapist acted as their own control, so that the influence of different personalities was taken out of the equation. However, there could have been a "contamination" effect, whereby usual physiotherapy patients benefited not only from effects of more treatment sessions but also some of the cognitive behaviour treatments used in the brief intervention. However, we had emphasised to the practitioners the importance of keeping both treatment approaches separate, and several trial procedures detailed in the manual should have helped the physiotherapists deliver the two approaches per protocol. An observational study of eight participating physiotherapists carried out by an independent researcher indicated that there was treatment fidelity (see bmj.com). It is possible that the cognitive behaviour training was insufficient to maximise the effects of the brief intervention and that more extended training is required.

Role of patients' preferences

We are not aware of previous analyses of clinical trials that show that patients' preferences may be effect

modifiers. A previous study, using a similar design with patients who had back pain, seemed to indicate that preferences did not increase or dilute quality of life treatment effects.¹⁵

Conclusion

In this non-inferiority trial, we failed to show clearly that the brief intervention for patients with neck pain was as effective as usual physiotherapy. The 95% confidence interval for the difference in improvement contains the value of 1.2, which indicates some evidence of inferiority of the brief intervention compared with usual physiotherapy. However, as the confidence interval is not entirely above this threshold, some may argue that there is a role for the brief intervention for all patients. It seems that the brief intervention should in any case be available for those who prefer it.

The authors thank all patients and staff in all the collaborating centres for their participation in this trial.

Contributors: See bmj.com

Funding: Northern and Yorkshire R&D Executive and Trent Region NHS Executive. Trial registration number: ISRCTN71946848.

Competing interests: None declared.

Ethical approval: Hull and East Riding Research Ethics Committee, Scarborough and North East Yorkshire Locally Organised Research Ethics Committee, South Humber Health Authority Local Research Ethics Committee.

- 1 Bovim G, Schrader H, Sand T. Neck pain in the general population. *Spine* 1994;19:1307-9.
- 2 Cote P, Cassidy J, Carroll L. The Saskatchewan health and back pain survey. The prevalence of neck pain and related disability in Saskatchewan adults. *Spine* 1998;23:1689-98.
- 3 Hackett G, Bundred P, Hutton J, O'Brien J, Stanley I. Management of joint and soft tissue injuries in three general practices: value of on-site physiotherapy. *Br J Gen Pract* 1993;43:61-4.

- 4 Foster N, Thompson K, Baxter G, Allen J. Management of non-specific low back pain by physiotherapists in Britain and Ireland. *Spine* 1999;24:1332-42.
- 5 Battie M, Cherkin D, Dunn D, Ciol M, Wheeler K. Managing low back pain: attitudes and treatment preferences of physical therapists. *Phys Ther* 1994;74:219-226.
- 6 Gross A, Aker P, Goldsmith C, Peloso P. Physical medicine modalities for mechanical neck disorders. *Cochrane Database Syst Rev* 2000(2):CD000961.
- 7 Croft P, Lewis M, Papageorgiou A, Thomas E, Jayson M, Macfarlane G, et al. Risk factors for neck pain: a longitudinal study in the general population. *Pain* 2001;93:317-25.
- 8 Mynors-Wallis L, Gath D, Lloyd-Thomas A, Tomlinson D. Randomised controlled trial comparing problem solving treatment with amitriptyline and placebo for major depression in primary care. *BMJ* 1995;310:441-5.
- 9 Foster N, Pincus T, Underwood M, Vogel S, Breen A, Harding G. Understanding the process of care for musculoskeletal conditions—why a biomedical approach is inadequate. *Rheumatology* 2003;42:401-3.
- 10 Metcalfe C. An investigation of patients' expectations of outpatient physiotherapy for peripheral musculoskeletal conditions and their effect on treatment outcome [PhD thesis]. Hull: University of Hull, 2003.
- 11 Torgerson D, Klaber-Moffett J, Russell I. Patient preferences in randomised trials: threat or opportunity? *J Health Serv Res Pol* 1996; 1:194-7.
- 12 Torgerson D, Sibbald B. Understanding controlled trials. What is a patient preference trial? *BMJ* 1998;316:360.
- 13 Brewin C, Bradley C. Patient preferences and randomised clinical trials. *BMJ* 1989;299:313-315.
- 14 McPherson K, Chalmers I. Incorporating patient preferences into clinical trials. *BMJ* 1998;317:78.
- 15 Klaber-Moffett J, Torgerson D, Bell-Syer S, Jackson D, Llewlyn-Phillips H, Farrin A, et al. Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. *BMJ* 1999;319:279-83.
- 16 Walker L. Communication skills: when not if to teach. *Eur J Cancer* 1996;32A:1457-9.
- 17 Leake A, Cooper J, Dyer S, Williams K, Turner-Stokes L, Frank A. The Northwick Park neck pain questionnaire, devised to measure neck pain and disability. *Br J Rheumatol* 1994;33:469-474.
- 18 Ruta A, Ruta D, Abdalla M, Russell I. SF36 health survey questionnaire: II Responsiveness to changes in health status in four common clinical conditions. *Qual Health Care* 1994;3:186-92.
- 19 Kori S, Miller R, Todd D. Kinesophobia: a new view of chronic pain behaviour. *Pain Manage* 1990;January:35-43.

(Accepted 18 October 2004)

doi 10.1136/bmj.38286.493206.82

A memorable mistake

None so blind

"Och aye, Freddy. Men make mistakes, not because they don't know but because they don't look." This was said to me in 1942 by my late friend Sandy Bell, quoting his professor of medicine at Queen's University, Belfast.

Years later, in the early 1960s, my wife and I were travelling in the high Andes of Peru. We had gone up to Cuzco to see our daughter, who was on voluntary service teaching English at the university there. While there, we were offered a trip into the surrounding countryside by Hugo—a tough, handsome truck driver, part Quechua Indian, part Basque—who was taking a load of potatoes to sell.

He had promised us an afternoon outing, but in fact only returned to Cuzco a week later. In the meantime, we ate and slept in the cab of the huge Dodge lorry, with Hugo selling his potatoes by day and driving the precipitous roads by night. These hair raising nocturnal journeys were made more hazardous by an unexpected medical problem.

Hugo had a large adhesive dressing on his forehead. He had recently been attacked by three young men, who had hurled a rock through the lorry windscreen in an attempt to rob him. However, Hugo had successfully fought them off, head butting the gang leader (hence the dressing on his forehead) and

knocking out the other two. To some mild surprise, the gang leader turned out to be the son of the local president of police, and so the attempted robbery with violence was deemed a mere youthful prank, a new windscreen was paid for, and the matter was quietly forgotten.

Hugo had thought the injury to his forehead no more than a minor abrasion and had dressed it himself. To his and my surprise, however, his forehead swelled intermittently and dramatically during our week long trip. The oedema almost closed his eyes, but fortunately I found a bottle of penicillin tablets in my pocket, and these kept the swelling in check. I did not remove the dressing because I had none to replace it with.

When we finally returned to Cuzco, after crossing swollen rivers on partly destroyed bridges, I was able to remove Hugo's dressing, and all was revealed. Firmly embedded in his forehead were two human incisors—mementos left by his would be robber.

"Och aye, Freddy. Men make mistakes, not because they don't know but because they don't look."

F Morgan *retiring general practitioner, Kingsweston Road, Henbury, Bristol*