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

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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 kinesiophobia, 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

Neck pain accounts for 15% of all soft tissue problems seen in general practice¹ and is a common reason for referral for physiotherapy treatment. In any one year, 30% of adults will report neck pain, and 5-10% will be disabled with it.^{2,3} Although neck

pain has been regarded as self limiting and benign, it consumes a substantial proportion of healthcare resources.⁴ A recent survey of 10 community physiotherapy departments in the east Yorkshire area has shown that of 7899 subjects referred, 1060 (13.4%) had neck complaints. Most physiotherapists in the United Kingdom provide between four and 10 treatment sessions for spinal problems such as back pain,⁵ whereas in the United States they provide between nine and 12 treatment sessions.⁶ Little evidence is available, however, with respect to the effectiveness and cost effectiveness of routinely used physiotherapy interventions for neck pain.⁷ A criteria based appraisal of review articles reported finding 12 systematic reviews on the management of neck pain but found that conclusive evidence was lacking.⁸ 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,⁹ and interventions that deal with the patient's individual concerns, particularly their beliefs and worries, may therefore help to overcome the barriers to recovery. Brief interventions based on a problem solving approach for conditions such as depression have been developed for general practitioners.¹⁰ In physiotherapy, two studies have shown that for neck sprain, advice to return to previous activities is useful.^{11,12} One way to achieve this would be to apply principles of cognitive behaviour therapy to the physiotherapeutic management of neck pain.¹³ Physiotherapists often give advice about changing lifestyles with an emphasis on posture, in addition to teaching specific exercises.¹⁴ They may quite often do this as a one-off session, encouraging the patient to take responsibility for his or her problem. This may be the preferred approach with some patients.

Patients' preferences

Patients' expectations¹⁵ or preferences for treatment^{16,17} may influence outcomes of treatment, and this can be a confounding factor in a trial when it is not possible to blind participants to the treatment they receive. This problem, long recognised, is often dealt with by using a patient preference design.¹⁸ Where this is used, only participants who have no preference for treatment are randomised, whereas those who express a preference are allocated to their preferred treatment group. This design,



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

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however, does not take us very far.¹⁹ Since the design allows patients to select themselves into their treatment groups, any comparisons between the preference groups and the randomised arms could be confounded and therefore unreliable.²⁰

A more robust alternative is to randomise all consenting participants but to elicit preferences before randomisation and use these in the subsequent analysis. This approach allows for a full, unbiased estimate of the effects of preferences on outcomes of treatment. This approach has previously been used successfully in an evaluation of a physiotherapy intervention for back pain.²¹ We report the results of a fully randomised preference trial of "usual" physiotherapy compared with a brief physiotherapy intervention based on cognitive behaviour principles.

Method

Procedure

Twenty eight physiotherapists participated in the trial, in eight different community services offering physiotherapy to outpatients in East Riding, north Yorkshire, and north Lincolnshire. We staged the recruitment over a period from September 1999 to August 2001. Each service supplied a list of referring general practitioners and consultants, who were then contacted by post to inform them of the study.

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 on to the research team, who assessed their eligibility for the trial. 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 having consented to participate in the study; and willingness to be randomised—that is, no overwhelming preference for either intervention. We excluded participants with any of the following: potentially serious pathology; main pain below the elbow or in some other part of the body or coexisting "serious other problem" (such as capsulitis of the shoulder or tennis elbow) that would require additional treatment other than that required for the neck pain; recent treatment for a neck problem (in the previous six weeks) or intention to pursue additional (private) treatment concurrent with that provided by the physiotherapy department; and surgery on the neck.

Brief intervention

Twelve physiotherapists received a full day's training to enable them to deliver the brief intervention. The training aimed to improve communication skills, demedicalise the problem, and teach the application of principles of cognitive behaviour therapy, but it did not aim to turn physiotherapists into cognitive behaviour therapists. 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. A consultant clinical psychologist with extensive experience in teaching communication skills²² and two research physiotherapists with experience in developing cognitive behaviour approaches for the management of musculoskeletal problems gave the training.

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 their physiotherapists thought that their condition was not improving they could switch over to usual physiotherapy.

Table 1 Components of usual physiotherapy treatments given

Treatment Group	Specific	No of instances when this treatment was used (n=129)
Electrotherapy	Interferential	14
	Ultrasound	13
	Pulsed short wave	6
	Likon	5
	TENS	3
	Laser	0
	Rebox	1
Total for electrotherapy*		42/513 (8.2%)†
Manual therapy or mobilisation	Cyriax	5
	Passive stretching	5
	Maitland	62
	McKenzie	28
	Nags and snags	13
	Traction	13
Total for mobilisation*		126/513 (25.5%)†
Advice	Postural	99
	Lifting	33
	Lifestyle	65
Total for advice*		197/513 (38.4%)†
Total for (home) exercises*		107/513 (20.8%)†
Other	Acupuncture	21
	Collar	1
	Relaxation	5
	Massage	5
	Hot packs	5
	Ice	0
Total for "other"*		37/513 (7.2%)†
Total for "other"—not included in above specified list*		4/513 (0.7%)†

*Total represents the number of times that the treatment (or group of treatments) was allocated to the group of patients randomised to usual physiotherapy.

†In all, 513 treatments were recorded. The percentage figure is a percentage of this number.

Usual physiotherapy

The physiotherapists treated the patients in the same way as usual according to their individual professional judgment. Table 1 shows the treatments that were actually used.

The same 12 physiotherapists delivered both interventions. The physiotherapists who had not been trained in the delivery of the brief intervention delivered only usual physiotherapy. Therapists documented the content of each treatment session and the number of sessions provided.

Assignments and blinding

The York Trials Unit (Department of Health Sciences, University of York) provided telephone randomisation. Apart from remote randomisation, further blinding was achieved through the allocation sequence, in which randomly permuted block sizes of two and four were used. Patients were stratified by physiotherapy department, age group (younger or older than 40 years), history of previous episodes, and severity of their condition (as scored on the Northwick Park neck pain questionnaire). Because this was a fully randomised trial, all participants were randomised irrespective of their baseline preferences. This approach avoids selection bias.

Trial procedures and outcome measures

Patients with subacute or chronic neck pain who were referred to participating physiotherapy departments and seemed eligible received an invitation to participate in the study. If patients were willing they received a phone call to obtain verbal consent and were invited to a face to face assessment (fig 1) with a research physiotherapist (DAJ). This meeting included a full detailed explanation of the study, with opportunities for discussion, and a

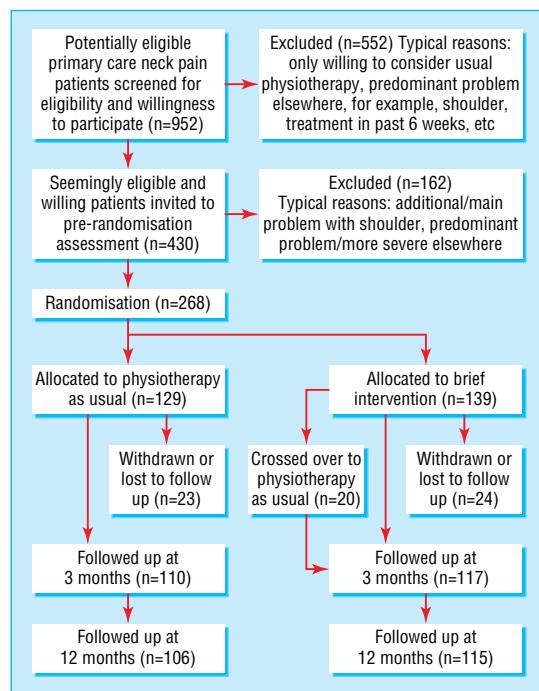


Fig 1 Flow of participants through the trial

physical assessment (to exclude potentially serious pathology), followed by the collection of written consent and baseline data. Participants were asked to complete a questionnaire including several outcome measures. The Northwick Park neck pain questionnaire (NPQ), which measures the level of neck pain and the resulting disability, (primary outcome measure), is a nine item questionnaire with five possible responses for each question.²³ The short form 36 questionnaire (SF-36) is a generic, health related, quality of life questionnaire that includes both psychological and physical factors.²⁴ The Tampa scale for kinesiophobia (TSK) is a measure of fear and avoidance of movement.²⁵ Distress was measured on a numeric scale of 0 to 10, where 0 was not at all distressed and 10 was as distressed as it could be.

After completing the questionnaires the participants were asked by the research physiotherapist if they had a preference for one or the other treatment group and then randomised to a group. The patient's stated preference was independent of randomisation and had no influence on it. An appointment was then arranged to start treatment. The physiotherapist documented treatment provided in terms of time and components. Follow up questionnaires went out to the participants at three and 12 months after randomisation. Although it was not possible for patients or therapists to be 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. We used a commercially available software package (Arcus QuickStat, Research Solutions Cambridge, biomedical version 1.1, 1997) for an unpaired *t* test to calculate our sample size and came up with 346. We inflated this to 400 to allow for

Table 2 Baseline characteristics of participants included in the study. Values are means (standard deviations) unless indicated otherwise

	Brief intervention (n=139)	Usual physiotherapy (n=129)
Age in years	48.8 (16.56)	47.8 (16.62)
No (%) of patients:		
Women	86 (62)	82 (66)
Expressed preference	64 (46)	62 (48)
Had brief intervention	24 (38)	19 (31)
Had usual physiotherapy	40 (62)	43 (69)
Were indifferent to intervention	75 (54)	67 (52)
Duration of neck pain <6 months	87 (62.6)	88 (68.2)
Northwick Park neck pain score (0-36)	11.33 (4.20)	11.46 (4.32)
SF-36 (0-100):		
Physical functioning	77.15 (17.31)	75.09 (20.40)
Social functioning	73.47 (23.04)	72.19 (22.71)
Role-physical	67.36 (22.87)	67.97 (22.87)
Role-emotional	79.74 (24.12)	76.56 (24.72)
Mental health	70.25 (17.19)	69.71 (18.09)
Energy and fatigue	50.63 (18.81)	48.69 (18.20)
Pain	44.18 (14.68)	45.10 (16.85)
General health perception	66.98 (19.75)	66.10 (17.59)
Tampa kinesiophobia score (17-68)	35.15 (6.27)	33.53 (5.55)
Distress (0-10)	4.37 (2.26)	4.09 (2.26)

Higher scores are related to greater severity for all variables, except SF-36, in which lower scores imply worse quality of life.

dropouts. 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 being "mild" on the NPQ.

The analysis was based on an intention to treat, and outcomes were analysed in terms of change from baseline. 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 original target sample size. We were able to include 268 participants in the trial, 139 were randomised to the brief intervention and 129 to usual physiotherapy. Figure 1 shows their progress through the trial. 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

Table 2 shows the clinical and demographic characteristics of the two groups. Both groups were evenly balanced in age and quality of life scores. Patients' preferences for usual physiotherapy or the brief intervention were similar in each group, with around 30% having a preference for usual physiotherapy (see table 4).

Table 3 shows the mean changes in outcome measures over time, from randomisation to follow up at one year. For our main outcome, the NPQ score, both groups improved at three months; the group receiving usual physiotherapy tended to show

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Table 3 Changes in outcome measures at three and 12 months after randomisation

Outcome	Brief intervention	Usual physiotherapy	Difference (95%CI)	P value (analysis of covariance)
At 3 months' follow up				
Northwick Park neck pain score	-1.481	-2.101	0.620 (-0.444 to 1.684)	0.2518
SF-36:				
Physical functioning	-1.167	1.834	-3.001 (-7.363 to 1.361)	0.1765
Social functioning	2.222	3.005	-0.784 (-6.460 to 4.893)	0.7858
Role-physical	1.932	4.638	-2.706 (-8.646 to 3.234)	0.3703
Role-emotional	-0.179	4.355	-4.533 (-10.020 to 0.954)	0.1049
Mental health	-2.278	2.399	-4.677 (-8.371 to -0.983)	0.0133*
Energy and fatigue	-2.221	2.327	-4.548 (-8.804 to -0.292)	0.0363*
Pain	10.406	11.482	-1.076 (-6.026 to 3.874)	0.6688
General health perception	-4.787	-4.441	-0.346 (-4.076 to 3.385)	0.8552
Tampa kinesophobia score	-1.038	1.196	-2.234 (-3.729 to -0.739)	0.0036*
Distress	-0.693	-0.709	0.016 (-0.520 to 0.552)	0.9545
At 12 months' follow up†				
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 kinesophobia 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

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

†Adjusted for baseline value of the response variable.

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; two of the domains showed significant differences (table 3). 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). 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 (see table 3).

Although the participants were individually randomised, a clustering of outcomes is potentially possible since a single therapist was treating several patients. If these clustering effects were strong then this might alter the results. We therefore used multilevel modelling to check for any clustering effects by undertaking an analysis on the primary outcome. The point estimate remains the same as that in table 4, albeit with a slightly enlarged 95% confidence interval (0.452 to 3.518 *v* 0.184 to 3.767), which does not affect the conclusion.

None of the patients reported any adverse effects or side effects.

Participants' preference

Table 3 and figure 2 show that participants' preferences for treatment may influence outcome. Figure 3 shows an apparent interaction between participants' preferences and effect. Interestingly, the direction of treatment effect is reversed for those patients who wanted the brief intervention at baseline compared with the

patients who were either indifferent or who wanted usual physiotherapy. Those who wanted the brief intervention and got it therefore 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.

To assess whether preference affected our main results, we included a preference term in a further analysis of the NPQ scores. Including only the preference main effect term hardly changed the original result. However, adding a preference inter-

Table 4 Change in Northwick Park neck pain scores at 12 months by patients' baseline preference

Initial preference	Brief intervention	Usual physiotherapy	Difference (95% CI)
	Mean score (95% CI)*	Mean score (95% CI)*	
Indifferent	-1.007 (-2.454 to 0.439) (n=75)	-3.094 (-4.655 to -1.532) (n=67)	2.087 (-0.043 to 4.217)
Brief intervention	-2.811 (-5.431 to -0.190) (n=24)	-2.142 (-4.905 to 0.620) (n=19)	-0.668 (-4.464 to 3.128)
Usual physiotherapy	0.567 (-1.384 to 2.518) (n=40)	-2.750 (-4.650 to -0.849) (n=67)	3.316 (0.589 to 6.044)

*Adjusted for baseline score. Negative scores indicate improvement.

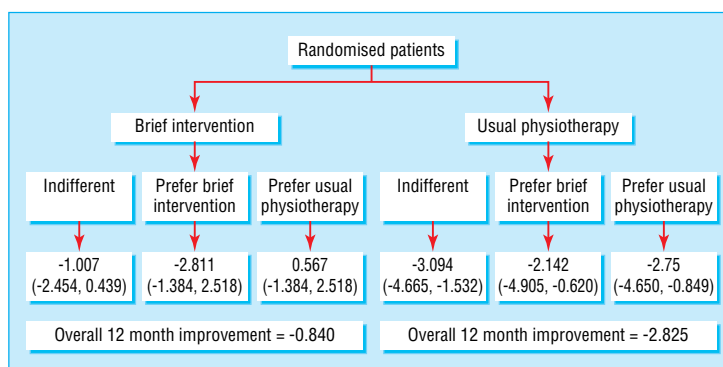


Fig 2 Influence of patients' preferences on outcomes of treatment shown as mean change in scores on the Northwick Park neck pain questionnaire with 95% confidence intervals (negative scores indicate improvement)

action term in the analysis 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 table 3.

Discussion

Usual physiotherapy produced marginally better treatment outcomes at 12 months than the shorter, hands-off intervention. In this non-inferiority trial, we have been unable to show clearly that the brief intervention based on cognitive behaviour principles was as effective as usual physiotherapy.

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 of the study. 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, it is possible that the study may have inflated the benefit of usual physiotherapy. 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, in that cognitive behaviour elements were observed more commonly in the brief intervention than in physiotherapy as usual. The researcher used a standardised proforma (see appendix 1 on bmj.com) to observe and check whether or not particular cognitive behaviour elements were present (or absent). Using this list of items, he noted that these elements were 2.6 times more likely to be observed in the brief intervention as in usual physiotherapy (93% v 36%, appendix 2 on bmj.com). This crude measure showed that at least in part the training of the physiotherapists was successful. However, 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.²¹ We observed a non-significant but potential effect of preference on outcome. Further large studies are needed to ascertain whether this effect is real.

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 to 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: JKM conceived and developed the study design and protocol, and was the main grant holder and principal investigator. She took the lead in writing the paper, submitted successive drafts, and is the guarantor. SC was a member of the trial management team contributing to the development and implementation of the trial protocol with specialist contribution to the design, development, and implementation of the data management strategy and randomisation procedure. He contributed to the analysis and interpretation of results and reviewed successive drafts of this paper. AF was the statistician who carried out the preliminary statistical analysis and contributed to drafts of the paper. SH designed, carried out, and interpreted the statistical analyses of clinical outcomes. She contributed to writing up the paper, principally the methods and results. DAJ was a grant holder and helped with the development of the trial protocol and training materials used in the trial. He also assessed most of the patients included in the trial and contributed to early and later drafts of the paper.

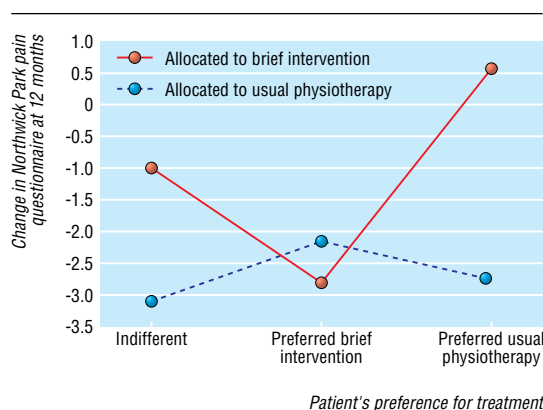


Fig 3 Interaction between pre-randomised preferences and treatment allocation (negative scores indicate improved scores on the Northwick Park neck pain questionnaire)

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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

AM was assistant trial economist, responsible for designing and implementing the economic analysis plan. He estimated unit costs, interpreted economic data, and contributed to drafting the paper. Stewart Richmond was the trial coordinator from November 2000 onwards. He contributed to drafting the paper. DT contributed to drafts of the paper, advised on analysis and study design, and supervised the economic analysis. He is a grant holder for the project. Other contributors include Ian Russell, previously director of Health Sciences, University of York, who was a grant holder and provided advice with the trial design. Leslie G Walker, clinical psychologist and director of the Institute of Rehabilitation, University of Hull contributed to the training of physiotherapists for the brief physiotherapy intervention. The late Patty Collier acted as trial coordinator for eighteen months.

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