Arthritis Research Campaign
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Measuring practitioner/therapist effects in randomized trials of low back pain and neck pain interventions in primary care

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Background

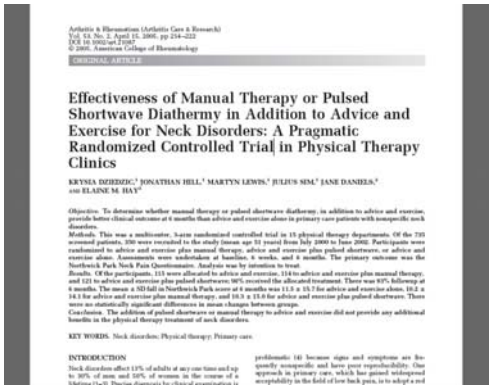
- Effects of treatment - 'specific' and 'non-specific'
- Non-specific effects
  - 'placebo' effect (related to the patient)
  - 'therapist' effect (related to differences in patient-therapist interactions)
- Placebo effects well known in tests of pharmacological medicines
- Therapist effects evident in psychotherapy but not known in other areas (e.g. musculoskeletal disorders)

Background

- In RCTs baseline factors (therapist and patient) need to be balanced between treatment groups
- Therapist effects potentially give rise to confounding bias
- Increased therapist effects associated with decreased precision of effect estimates (wider confidence intervals)
- Consequences for interpretation of results and planning of new trials needing larger sample sizes
- Therapist effects addressed by design (e.g. cluster-randomisation) and analysis (e.g. multilevel analysis)

Aims & Objectives

- To evaluate the therapist effects in "treatments for" back or neck pain in primary care
- The key objectives were to assess:
  - (i) the proportion of variability in outcome apportioned to differences between therapists (the 'therapist effect')
  - (ii) homogeneity in effect across different treatments
  - (iii) the impact on estimates and precision of overall treatment effects
- Evaluation of 3 RCTs of primary care interventions for non-specific low back pain or neck pain



Effectiveness of Manual Therapy or Pulsed Shortwave Diathermy in Addition to Advice and Exercise for Neck Disorders: A Pragmatic Randomized Controlled Trial in Physical Therapy Clinics

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Dziedzic et* al. *(Arthritis Rheumatism, 2005)

- 3 physiotherapy treatments: advice and exercise (A&E); A&E plus manual therapy (MT); A&E plus pulsed shortwave diathermy (PSWD)
- Design: individual patient randomisation
- Therapists were not treatment-specific
- 350 patients (aged 18 years and over) participated
- 55 physiotherapist agreed to take part (across 15 centres); 38 actively recruited at least one patient

Should treatment of (sub)acute low back pain be aimed at psychosocial prognostic factors? Cluster randomised clinical trial in general practice

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Abstract

Objective To compare the effects of a minimal intervention strategy aimed at assessment and modification of psychosocial prognostic factors and usual care for treatment of (subacute) low back pain in general practice.

Design Cluster randomised clinical trial.

Setting 59 general practitioners in 41 general practices.

Participants 314 patients with non-specific low back pain of less than 12 weeks' duration, recruited by their general practitioner.

Interventions In the minimal intervention strategy group the general practitioner explored the presence of psychosocial prognostic factors, discussed these factors, set specific goals for reactivation, and provided an educational booklet. The consultation took about 20 minutes. Usual care was not standardised.

Main outcome measures Functional disability (Roland-Morris disability questionnaire), perceived recovery, and sick leave because of low back pain assessed at baseline and after 6, 12, 26, and 52 weeks.

Results The drop-out rate was 9% in the minimal intervention strategy group and 9% in the usual care group. Multilevel analyses showed no significant differences between the groups on any outcome measure during 12 months of follow-up in the whole group or in relevant subgroups (patients with high scores on psychosocial measures at baseline or a history of frequent or prolonged low back pain).

Conclusion This study provides no evidence that Dutch general practitioners should adopt our new treatment strategy aimed at psychosocial prognostic factors in patients with (subacute) low back pain. Further research should examine why our new strategy was not more effective than usual care.

Introduction

Non-specific low back pain is common; the 12 month prevalence in the general population has been estimated at 41%.[1] Although ranking among the top five most common reasons for consultation in the Netherlands,[2] The Dutch guideline on low back pain for general practitioners, however, lacks explicit guidance for assessing psychosocial factors.[3] We therefore developed a minimal intervention strategy aimed at assessment and modification of psychosocial prognostic factors in patients with (subacute low back pain, which can be carried out by general practitioners.

Previous studies have evaluated booklets with biopsychosocial information provided by a general practitioner, but these did not have beneficial effects on disability or pain.[4–6] Only one of these studies reported a significant effect in a subgroup of patients with initially strong fear-avoidance beliefs.[6] We are not aware of (other) studies in which psychosocial interventions for low back pain were delivered by a general practitioner.

To compare the effects of a minimal intervention strategy with the effects of usual care, we did a cluster randomised trial. We hypothesised that patients in the minimal intervention strategy group would improve more on functional disability, perceived recovery, and sick leave due to low back pain than would patients receiving usual care. Assuming that patients with high scores on psychosocial measures or patients with prolonged or frequent low back pain would especially benefit from the minimal intervention strategy, we studied effect modification by baseline levels of fear avoidance beliefs, catastrophising thoughts or distress, and history of low back pain (pre-planned subgroup analyses).

Methods

Randomisation and training sessions

Randomisation took place at the level of the general practice in blocks of four practices, according to a random numbers table prepared before recruitment of general practitioners. General practitioners were informed about their allocation after they had given final consent to participation. Twenty practices (29 general practitioners) were randomised to the minimal intervention strategy group and 21 practices (32 general practitioners) to the

Jellema et* al. *(BMJ, 2005)

- 2 GP treatments: psychosocial intervention (PI); usual care (UC)
- Design: GP-practice cluster randomisation (41 practices)
- 314 patients (aged 18 years and over) participated
- 60 GPs agreed to take part; 54 actively recruited at least one patient

Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice

Summary

Background Recommendations for the management of low back pain in primary care emphasise the importance of recognising and addressing psychosocial factors at an early stage. We compared the effectiveness of a brief pain-management programme with physiotherapy incorporating manual therapy for the reduction of disability at 12 months in patients consulting primary care with subacute low back pain.

Methods For this pragmatic, multicentre, randomised clinical trial, eligible participants consulted primary care with non-specific low back pain of less than 12 weeks' duration. They were randomly assigned either a programme of pain management (n=201) or manual therapy (n=201). The primary outcome was change in the score on the Roland and Morris disability questionnaire at 12 months. Analysis was by intention to treat.

Findings Of 544 patients assessed for eligibility, 402 were recruited (mean age 40·4 years) and 329 (82%) reached 12-month follow-up. Mean disability scores were 13·5 (SD 4·8) for the pain-management group and 13·3 (4·9) for the manual-therapy group. The mean decreases in disability scores were 5·8 (6·4) and 5·8 (6·1) at 12 months (difference 0 [95% CI −1·3 to 1·4], p=0·99), and median numbers of physiotherapy visits per patient were three (IQR one to five) and four (two to five), respectively (p=0·001). One adverse reaction (an exacerbation of pain after the initial assessment) was recorded.

Interpretation Brief pain management techniques delivered by appropriately trained clinicians offer an alternative to physiotherapy incorporating manual therapy and could provide a more efficient first-line approach for management of non-specific subacute low back pain in primary care.

Introduction

In the UK, primary-care guidelines for the management of acute low back pain encourage early referral to a physiotherapist for patients with non-specific pain for whom first-line management by general (family) practitioners with medication, advice to stay active, and simple messages about self management has not been effective.[1] Evidence from systematic reviews of the effectiveness of specific types of physiotherapy in such patients, including exercise and manual techniques, is broad approach to the primary-care management of low back pain within the biopsychosocial model of care, which emphasises the importance of early attention to psychosocial factors. In secondary care, multidisciplinary pain-management programmes based on cognitive behavioural techniques have reduced disability and increased the likelihood that patients with chronic low back pain are able to return to work.[2,3] Such programmes are labour intensive, expensive, and impracticable for the many patients with back pain

Hay et* al. *(Lancet, 2005)

- 2 physiotherapy treatments: brief pain management (BPM); physical and manual therapy (PT)
- Design: individual patient randomisation
- Therapists were treatment-specific
- 402 patients with acute low back pain (aged 18 years and over) participated
- 6 treating physiotherapists – 3 per treatment group

Methods

- Outcomes included validated pain/disability and psychological health measures
- Evaluation of therapist effect (% variance in outcome attributable to differences between practitioners)
- Analysis by multilevel models (random effects)
- Analysis first performed on total samples (for each study), and then stratified by treatment subgroups
- Analyses on total study samples included treatment as a covariate to isolate the *non-specific* variance

Results

Therapist effects for each of the three trials

	Dziedzic *et al.*	Jellema *et al.*	Hay *et al.*
Disability			
6 weeks	3.9%	5.9%	-
3 months	-	2.6%	2.7%
6 months	7.1%	-	-
12 months	-	6.0%	2.8%
Psychological health			
6 weeks	0.8%	1.2%	-
3 months	-	-	5.1%
6 months	4.5%	-	-
12 months	-	8.0%	3.7%

Results

Therapist effects, stratified by treatment group.

	Dziedzic *et al.*			Jellema *et al.*		Hay *et al.*	
	PSWD	MT	A&E	UC	PI	BPM	PT
Disability							
6 weeks	0.6%	3.1%	7.1%	4.6%	7.9%	-	-
3 months	-	-	-	<0.1%	14.6%	5.0%	0.3%
6 months	8.6%	<0.1%	16.2%	-	-	-	-
12 months	-	-	-	2.2%	14.1%	6.7%	0.5%
Psychological health							
6 weeks	5.3%	1.6%	<0.1%	0.6%	2.2%	-	-
3 months	-	-	-	-	-	12.3%	0.7%
6 months	4.7%	3.5%	4.8%	-	-	-	-
12 months	-	-	-	14.3%	1.7%	10.1%	1.8%

Results

Treatment effect estimates before-/after- adjustment for therapist effects
[study of Dziedzic et al.]

	PSWD – A&E		MT – A&E	
	Before	After	Before	After
Disability				
6 weeks	3.29 (2.27)	2.95 (2.24)	3.98 (2.29)	4.00 (2.27)
3 months	-	-	-	-
6 months	2.74 (2.63)	2.35 (2.59)	3.60 (2.67)	3.19 (2.63)
12 months	-	-	-	-
Psychological health				
6 weeks	-3.87 (2.93)	-3.88 (2.92)	0.06 (2.99)	0.16 (2.99)
3 months	-	-	-	-
6 months	-0.54 (3.10)	-0.41 (3.06)	0.33 (3.13)	0.61 (3.10)
12 months	-	-	-	-

Results

Treatment effect estimates before-/after- adjustment for therapist effects
[study of Jellema et al.]

	PI – UC	
	Before	After
Disability		
6 weeks	-0.08 (0.61)	0.04 (0.71)
3 months	-0.01 (0.57)	-0.03 (0.62)
6 months	-	-
12 months	0.20 (0.52)	0.17 (0.61)
Psychological health		
6 weeks	-1.36 (0.64)	-1.38 (0.66)
3 months	-	-
6 months	-	-
12 months	-0.76 (0.71)	-0.63 (0.84)

Results

Treatment effect estimates before-/after- adjustment for therapist effects
[study of Hay et al.]

	PT - BPM	
	Before	After
Disability		
6 weeks	-	-
3 months	-0.84 (0.66)	-0.70 (1.05)
6 months	-	-
12 months	-0.76 (0.62)	-0.52 (1.01)
Psychological health		
6 weeks	-	-
3 months	1.32 (1.04)	1.74 (1.94)
6 months	-	-
12 months	1.25 (0.99)	1.52 (1.72)

Summary of findings

- Therapist effects ranged between 3%-7% for disability
- Effects varied between treatments groups – and were higher in psychosocial-based treatments
- Therapist effects partly explained by contrasting patient-profiles across different therapists (attributable therapist characteristics – not measured)
- Little difference in treatment effects
- Therapist effects decreased the precision of treatment effect estimates - particularly for the Hay et al. study which has a large patient-per-therapist “cluster” ratio

Conclusions

- Evidence of small, but quantifiable therapist effect in trials of back pain and neck pain in primary care
- Appreciation of potential influences of varying attributes of therapists including experience and skills (e.g. communication)
- Influences vary across different types of interventions
- Adjustment by design & analysis important to avoid compromising the integrity of trials findings
- Bias of treatment effect limited by random allocation, but therapist effects adversely affect sample size & power

Acknowledgements

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