People with low back pain typically need to feel 'much better' to consider intervention worthwhile: an observational study

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Question: How much of an effect do five common physiotherapy interventions need to have for patients with low back pain to perceive they are worth their cost, discomfort, risk, and incovenience? Are there any differences between the interventions? Do specific characteristics of people with low back pain predict the smallest important difference? **Design**: Cross-sectional, observational study. **Participants**: 77 patients with non-specific low back pain who had not yet commenced physiotherapy intervention. **Outcome measures**: The smallest worthwhile effect was measured in terms of global perceived change (0 to 4) and percentage perceived change. **Results**: Participants perceived that intervention would have to make them 'much better', which corresponded to 1.7 (SD 0.7) on the 4-point scale, or improve their symptoms by 42% (SD 23), to make it worthwhile. There was little distinction made between interventions, regardless of whether smallest worthwhile effects were quantified as global perceived change (p = 0.09) or percentage perceived change (p = 1.00). Severity of symptoms independently (p = 0.01) predicted percentage perceived change explaining 9% of the variance, so that for each increase in severity of symptoms of 1 point out of 10 there was an increase of 4% in the percentage perceived change that participants considered would make intervention worthwhile. **Conclusions**: Typically people with low back pain feel that physiotherapy intervention must reduce their symptoms by 42%, or make them feel 'much better' for intervention to be worthwhile. **[Ferreira ML, Ferreira PH, Herbert RD, Latimer J (2009) People with low back pain typically need to feel 'much better' to consider intervention worthwhile: an observational study. *Australian Journal of Physiotherapy* 55: 123–127]**

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Introduction

The main intent of randomised clinical trials and systematic reviews is to provide estimates of the effect of intervention. Interpretation of the *statistical significance* of the estimated effect of intervention is usually not problematic, but interpretation of *clinical significance* (or *clinical importance*) can be difficult (Chan 2001).

Several approaches have been used to investigate the clinical significance of the effect of interventions on health-related quality of life (Bombardier 2001, Cella 2002; Chan 2001, Devereaux 2001, Farrar 2001, Gallagher 2001, Guyatt 1998, Haag 2003, Man-son-Hing 2002, Middel 2001, Norman 2001, Redelmeier 1996, Samsa 1999, Schunemann 2003, van Walraven 1999, Yelland and Schluter 2006, Zisapel 2003). Most studies have assessed clinical significance by determining how large the effect must be for patients to say the intervention made them 'a bit better' or 'much better'. Threshold values (the degree of patient-rated change considered to be clinically important, eg, 'much better') are usually nominated by researchers or clinicians (Wells 2001). Such studies do not directly assess how beneficial the intervention must be for patients to feel that the intervention was worth receiving.

Only one study has sought patients' opinions on what constitutes the minimum worthwhile reduction in symptoms of low back pain. Yelland and Schluter(2006) asked 110 patients with chronic low back pain about both their desired reduction in symptoms as well as the minimum reduction in symptoms they would expect for the intervention to be considered worthwhile. The minimum worthwhile reduction for pain was 25% and for disability was 35%. It was not clear, however, whether patients considered the discomforts, risks, and incoveniences of the intervention when making these decisions (Yelland and Schluter 2006).

In our opinion, the decision of whether an intervention is clinically significant must involve consideration of whether the estimated effect of intervention is big enough to be worth its costs, discomforts, risks, and inconveniences. Barrett and colleagues (Barrett 2005, Barrett 2007) have called this construct the 'sufficiently important difference'. We will refer, synonymously, to the 'smallest worthwhile effect'. This construct has three characteristics. First, it can only be evaluated by the beneficiary of care (usually the patient). Second, because this decision involves consideration of the cost, discomfort, risk, and incovenience of the intervention, the estimate of what constitutes the smallest important difference must generally be intervention-specific. Finally, because the sufficiently important difference is the effect of intervention it must be thought of as the hypothetical difference between the outcome a person would experience if they had the intervention and the outcome the same person would have if they had no intervention.

The aim of this study was to assess patients' perceptions of what constitutes the smallest worthwhile effect of specific interventions. We sought the opinions of patients with non-specific low back pain about a range of commonly-administered conservative interventions. Our specific research questions were:

1. What is the smallest effect perceived by patients with non-specific low back pain to make five common physiotherapy interventions worth their cost, discomfort, risk and incovenience?
2. Are there any differences in smallest worthwhile effect between the interventions?
3. Do specific characteristics of people with low back pain (age, duration of symptoms, severity of symptoms, and past experience with intervention) predict the smallest worthwhile effect?

Box 1. Questions asked to ascertain perception of the 'smallest worthwhile effect'

Global perceived change

I would see a physiotherapist for *exercise*:

0 = even if it made me no better
1 = only if it made me a little better
2 = only if it made me much better
3 = only if it made me very much better
4 = only if it made me fully recover

Percentage perceived change

I would see a physiotherapist for *exercise* if it made me:

0%	100%
no better	fully recovered

Method

Design

A cross-sectional study was conducted involving people with non-specific low back pain. Participants were interviewed before commencing physiotherapy intervention at a large hospital outpatient department. By interviewing prior to intervention we avoided contaminating perceptions of smallest important difference with improvement or deterioration in symptoms due to the intervention. Each participant was told about five physiotherapy interventions commonly provided for people with non-specific low back pain (exercise, spinal manipulation, ultrasound, local heat, and massage) (Turner 2002). The interventions were described using a standardised script which outlined how the intervention was administered, the usual number and length of intervention sessions, and the proposed benefits and risks of intervention (see Appendix 1 on eAddenda for script). Thus the patient was familiar with the interventions before he or she was asked about what constituted a worthwhile effect of intervention.

Participants

Consecutive patients with non-specific low back pain presenting to an outpatient physiotherapy department in a large teaching hospital were included in the study. Participants were excluded if they were aged less than 18 or more than 80 years, or if they had been diagnosed by the referring medical practitioner as having specific spinal pathology (nerve root involvement, inflammatory disorders, fracture, or malignancy).

Measurement of smallest important difference

The smallest worthwhile effect was measured in terms of both global perceived change and percentage perceived change. Global perceived change was measured by asking participants to rate the smallest important difference where 0 = 'no better', 1 = 'a little better', 2 = 'much better', 3 = 'very much better' and 4 = 'fully recovered'. Percentage perceived change was measured by asking participants to rate the smallest worthwhile effect on a visual analogue scale where 0% indicated 'no better' and 100% indicated 'fully recovered'. The same questions were asked in regard to each of the five interventions (Box 1).

Data analysis

Responses were summarised with descriptive statistics. ANOVA was performed to investigate differences in response among the five interventions on continuous measures of effect. Friedman's test was performed to analyse differences in response across interventions of discrete variables. Multiple linear regression was used to predict the smallest worthwhile effect expressed as global perceived change, and percentage perceived change based on four explanatory factors. Predictors included in the model were: past experience with all interventions (total number of sessions across all interventions), severity of symptoms in the past seven days, age, and duration of symptoms in weeks. Predictors were chosen *a priori* and forced into the model, ie, a selection procedure was not used. The significance level was set at 0.05.

Results

Participants

Eighty-eight consecutive patients with low back pain were invited to participate in the study and 77 (88%) agreed to participate. Eleven (12%) patients declined to participate because they were unable to speak English (n = 4), were unable to attend the appointment (n = 3), did not have non-specific low back pain (n = 2), or were not willing to participate (n = 1). Fifty-one (66%) participants were female with a median duration of symptoms of 4 weeks (IQR 9, range 1 week to 40 years). Fifty-five (42%) participants had previously experienced at least one of the five interventions for low back pain, exercise being the most commonly experienced (22%), followed by spinal manipulation (20%), local heat (18%), massage (15%), and ultrasound (8%). Characteristics of the 77 participants are presented in Table 1.

Table 1. Mean (SD) characteristics of participants.

Characteristic	(n = 77)
Age *(yr)*	53.2 (15.1)
Severity of symptoms *(1 to 10)*	6.9 (2.1)
Past experience with intervention *(number of sessions for participants with past experience)*	
Exercise	4.1 (10.0)
Spinal manipulation	3.0 (7.9)
Ultrasound	0.9 (3.9)
Local heat	2.1 (5.3)
Massage	1.6 (4.2)

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