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Why and how back pain interventions work: What can we do to find out?



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A B S T R A C T

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Mediation analysis is a useful research method that potentially allows identification of the mechanisms through which treatments affect patient outcomes. This chapter reviews the theoretical framework, research designs and statistical approaches used in mediation analysis. It describes what can be learnt from previous mediation research, much of which has investigated mediating factors of psychosocial interventions in other health conditions. It also summarises the few treatment-mediation studies of psychosocial interventions conducted in back pain.

This chapter shows that there is emerging evidence about the role of some psychological factors as potential treatment mediators, such as self-efficacy and catastrophising. Mediation analysis can equally be applied to non-psychological factors. Pre-planned and appropriately conducted mediation analysis in adequately powered clinical trials would be a step forward in understanding treatment effects in back pain and improving patient management.

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Introduction

A recurring conclusion of high-quality systematic reviews and randomised controlled trials (RCTs) in the field of back pain is that most treatments show modest effects compared to natural course and small or no differences between the effectiveness of different interventions [1–4]. This leads to equivocal and sometimes contradictory messages in clinical practice guidelines [5,6] and frustration in clinicians attempting to provide evidence-based care for their patients. In part, the underwhelming results reported by these studies are likely due to incomplete understanding of what factors might be necessary to be included in interventions to help influence outcome. Studies have examined the physical [7,8], psychological [9,10] and social [11,12] aspects of interventions to try to identify these factors. To date however, satisfying answers remain elusive.

Mediation analysis offers a method of testing theories regarding the causal links between a predictor and an outcome. The establishment of causal mechanisms as opposed to simply associative links is critical to the understanding of the processes of treatment effect. Mediation analysis can be applied to data from various types of study designs: cross-sectional surveys, clinical registries, longitudinal cohorts and randomised and non-randomised clinical trials. While different study designs impose different restrictions on the explanatory power of mediation analysis, this flexibility makes mediation analysis a useful supplement to other, more commonly used, methods of analysis.

Mediation analysis tests whether the influence of a predictor or treatment on an outcome occurs via change in a particular intermediate variable, the mediator. For example, a treatment could aim to influence fear-avoidant behaviours, which if successfully changed could be responsible for change in outcomes such as disability or pain intensity. Where the predictor variable is a 'clinical feature' associated with a condition, such as pain intensity or psychological distress, mediation analysis helps us understand the pathway between it and the outcome of interest. This information can be very useful in identifying factors that should be targeted in treatment. Where the predictor is a 'specific treatment', such as allocation to a particular treatment arm in an RCT, mediation analysis provides insight into whether the effectiveness or ineffectiveness of a treatment is consistent with theories regarding its mechanism.

Currently in the management of back pain, many interventions are based on imprecise theoretical rationales, rather than empirically derived hypotheses. It is potentially very useful to disentangle factors merely associated with outcome from those that could potentially help to explain treatment effects. Making distinctions between causes, consequences and epiphenomena is vital, as treatments that target factors that are not modifiable or influential are unlikely to be successful. For example, anxiety has been shown to be predictive of poor recovery from low back pain (LBP) [13] and is commonly associated with pain. However, a recent mediation study [14] showed that the relationship between pain and disability in patients with LBP is not mediated by anxiety. This suggests that a treatment designed to only target anxiety in LBP patients would be unlikely to have an important effect on pain-related disability.

Identifying the mechanism of action of a particular treatment offers the opportunity to optimise its effectiveness. Investigation of the relationship between an intervention and its effect via mediation analysis can provide information as to whether and to what extent the hypothesised action is real. This information can be used to modify the intervention in order to target the appropriate mediating factor more directly and enhance the capacity of the treatment to reach its full potential effect.

To date, relatively few mediation analyses have been conducted in back pain research despite such studies being potentially capable of providing important insight into questions relevant to the field. The aim of this article is to introduce the theory and practice of mediation analysis and discuss some of the issues involved with study design, conduct and interpretation.

What is a mediator?

It is important to define what we mean by the term 'mediator' along with some other, related terms, as these terms can have slightly different meanings in different fields [15,16] and this can be a source of confusion.

Mediators, also known as intermediate variables [17] or indirect effects [18], are variables that help explain how a treatment might work [15,19] and are by definition on the pathway between predictor

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