ARE PATIENT EXPECTATIONS ASSOCIATED WITH TREATMENT OUTCOMES IN INDIVIDUALS WITH CHRONIC LOW BACK PAIN? A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS

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Abstract

Aim The importance of patient expectations (PEs) on treatment outcomes is poorly understood in clinical practice. The aim of this review is to investigate the evidence behind association between pre-treatment PEs and treatment outcomes such as pain intensity (PI), level of function (LF) and health-related quality of life (HRQOL) among individuals with chronic low back pain (CLBP) Methods A systematic search was conducted for randomised controlled trials published between 1946 and May 2019 across major databases using the key MeSH terminologies. The association between PEs and PI, LF and HRQOL were extracted and categorized into positive, negative or no association for analysing the data. A descriptive synthesis was conducted and the association between PEs and PI, LF and HRQOL were reported. Results Among the total of 7 trials, 2 trials demonstrated a positive association between PEs and PI in short ([?] 6 weeks) and long term ($>$ 6 months), while another 2 trials demonstrated no association at medium term ($>$ 6 weeks - [?] 6 months). About 4 trials demonstrated a positive significant association between PEs and LF, 2 at medium and 2 at long terms. The only available trial demonstrated no association between PEs and HRQOL at medium term. Conclusion Positive PEs as measured at the start of treatment is associated with PI. Inconclusive evidence exists on the association between PEs and LF. Limited studies show no evidence of association between PEs and HRQOL. Further studies with valid tools to measure PE are warranted among individuals with CLBP.

Introduction

Patients' expectations (PEs) are defined as a set of beliefs an individual holds in regard to the treatment and its outcomes with an anticipation that a given event is likely to happen as a consequence of an intervention (1). In musculoskeletal practice, PEs are reported to be a valuable predictors to treatment outcomes in patients with acute, sub-acute and chronic low back pain (2, 3, 4). PEs have the potential to influence outcomes regardless of the type of intervention (5). Patients with higher expectations on the treatment sessions reported better outcomes when compared to those with lower expectations who had showed lesser improvements in their treatments particularly in terms of disability, levels of functional activity and pain (5, 6, 7). Patients' awareness of their expectations regarding their care is a potentially crucial aspect in developing policies and delivering healthcare services (8). Therefore, investigating the influence of positive and negative PEs on treatment outcomes among people with CLBP may be beneficial for clinical practice, as an understanding of these expectations from care providers could arguably help them to better consider these expectations in their clinical practice.

A huge heterogeneity exists in the literature with unclear terminologies in terms of understanding the term 'patient expectation' (9-11). Patient preference, treatment motivation, treatment credibility and self-efficacy are some of the terms that have been used interchangeably with the term patient expectation (9, 10). Yet some of these terms may arguably be differentiated from PEs (8-10). Furthermore, the term PEs have also been demonstrated as desires, wishes and hopes about the future (11). However, it could be argued that an individual could desire an event, yet, not expect it. Similarly, the term 'patient hopes' are not similar to PE, as expectations are cognitive, while hopes are motivational (12). Therefore, these differing terminologies will not be included for consideration in this systematic review as these terms are not true reflection of PEs. Also, the intention of this review is not to focus on specific definitions and conceptualisations of PEs, instead the review focuses to screen the evidence on how PEs are associated with treatment outcomes among patients with low back pain. Thus in this review, the term PEs includes the three concepts namely expectancy probability, process expectations, and outcome expectations. It will consider other 4 distinct types of expectations namely unformed, ideal, predicted or normative, or value or probability expectations (13,14).

An international multidisciplinary panel in low back pain recommended physical functioning, pain intensity and health-related quality of life as the core outcome domains to be measured in people with LBP in research papers and clinical practice (15). Thus in this review, the impact of PEs were specifically focussed into these outcomes that are related to functional status, pain and quality of life. Past systematic reviews and existing evidences that investigated PEs have focussed on outcomes such as limitation of daily living activities, absence from work and return to work and supports an inconsistent association between PEs on these outcomes among people with low back pain (16,17,18). Therefore to our knowledge, no previous systematic review has addressed the influence of PEs on functional status, pain and quality of life among people with CLBP. Thus, the current review may claim originality and significance in terms of shedding new evidence and knowledge to clinicians on the influence of PEs on treatment outcomes related to functional status, pain and quality of life. The significance of the review finding may assist clinical practice and health care providers to explicitly capture and document process of patient engagement in their care set up and care process. Thus, the main objective of the systematic review is to synthesise the evidence on the influence of PEs on the treatment outcomes related to functional status, pain and quality of life among people with low back pain. The current review would summarise the evidence on the association between PEs on Physiotherapy interventions and the treatment outcomes such as pain intensity, functional status and quality of life among individuals with CLBP.

Methods

The review was conducted according to the reporting standards of the PRISMA (the Preferred Reporting Items of Systematic Reviews and Meta-Analyses guidelines for reporting systematic review findings) guidelines (19,20).

2.1 Study criteria

The studies were included if 1) they are published in the English language; 2) they are randomised control trials (RCTs) or a secondary analysis of RCTs; 3) report data from participants aged between 18 and 70 years; 4) only examine people with CLBP ([?] 12 weeks) or have a subgroup for people with CLBP; 5) have at least one therapeutic intervention which is not medication, surgery or an injection intervention, with separate data for this intervention; 6) measure PEs prior to the intervention; 7) examine the association between any type of PEs and the outcomes; and 8) have at least one of the outcomes of pain intensity, physical status and HRQOL.

The studies were excluded if 1) they have participants with other health issues rather than LBP; 2) are a secondary analysis of an RCT study that has already been included in this review; 3) have participants with back pain without specifying its region to the lumber region; and 4) do not state clearly that all participants (or 85% at least) had LBP.

2.2 Information sources

The studies were identified by searching the following electronic databases which include AMED (EBSCOhost), CINHAL Plus (EBSCOhost), Cochrane, Health Research Premium Collection (ProQuest), Medline (Ovid), PEDro, PsycINFO (EBSCOhost), PubMed and SPORT Discus (EBSCOhost). These databases were chosen based on their coverage of studies related to physiotherapy. Thus, systematic searches were conducted for RCTs archived in the 9 major databases and published between 1946 and May 2019.

2.3 Search strategy

The search strategy had three main terms which were extracted from the research title. They included *expectations, low back pain* and*treatment outcome(s)* . For all databases (except PEDro and PubMed), the search terms for the three main terms were mapped to MeSH terms or subject headings whenever possible. If MeSH terms or subject headings were not available, key words within the database itself were used when possible and if not, synonyms were used. Synonyms were only used when neither MeSH terms, subject headings nor key words were available. Synonyms were only needed for the term *expectations* . Appendix 1 provides descriptions of all the searches conducted in each database with the number of results and the dates of each search.

2.4 Screening process

The screening process was conducted by two authors independently. After the studies were identified from search strategy, the studies were transferred into Endnote^{TM} to check for duplication and the studies were removed accordingly. The initial screening was conducted first on study title and abstract. In the second level screening, these articles were then checked within the full text to make sure of their relevancy and eligibility. Any disagreements among reviewers were resolved by discussion and reflection. Finally, the reference lists from the selected articles were reviewed to identify any other relevant trials.

2.5 Quality assessment of the included trials

Two independent authors assessed the quality of all the included studies using the Physiotherapy Evidence Database (PEDro) scale which includes 11 items: 1) eligibility criteria and source; 2) random assignment; 3) concealment of allocation; 4) baseline comparability; 5) blinding of participants; 6) blinding of therapists; 7) blinding of assessors; 8) obtainment of the follow-up for over 85% of the participants; 9) intention to treat analysis; 10) between-group statistical comparison; and 11) point estimates and variability measures. The quality of the included studies was assessed as to how many out of these items were clearly satisfied within the study. Each of these 11 criteria was answered with 'Y' (criteria satisfied) or 'N' (criteria not satisfied). Trials with a score of 6 or above were considered high quality trials, those scoring 4 or 5 were considered moderate quality trials and any trial with a score of 3 or less was considered low quality (21).

2.6 Assessment of risk of bias in the included trials

The Cochrane risk of bias tool was used to assess the risk of bias in the included studies. The tool contains six items addressing the possible different types of bias within clinical trials which include selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias (22). The first domain of selection bias is divided into random sequence generation and allocation concealment (22). RevMan Web 5.3 software application (Review Manager Web. The Cochrane Collaboration, 2019) was used to plot the results of the risk of bias assessment (23). The judgments were of a low, high or unclear risk of bias for each study, regarding each domain.

2.7 Data extraction

Data from each included paper were extracted using an extraction form. Two authors independently extracted data from each eligible paper and recorded all the extracted data in the data extraction table. Any variation in the extracted data between the authors were identified and settled through discussion. Regarding the trials' characteristics, extracted data included population, the intervention, type of expectations, measure of expectations, timing of measuring PEs, outcomes, outcome measurement tool and follow-up points of outcomes. The primary outcomes of interest considered in the systematic review were pain intensity, levels

of function and quality of life. Follow-up periods were divided into three subdivisions; short ([?] 6 weeks), medium (> 6 weeks - [?] 6 months), and long (> 6 months) respectively from a previously published protocol (2).

2.8 Data synthesis

The association between PEs and the outcomes of interest was extracted as stated within the trials' reports and considered as positive association, negative association or no association. Positive association was marked when higher PEs were associated with better outcomes or lower PEs were associated with lesser improvement. Negative association was marked when higher PEs were associated with lesser outcomes or lower PEs were associated with better outcomes. Non-significant associations were considered as no association. Also, a mutable associations was marked when the association between PEs and the outcomes were reported at different follow-up points, different groups and different interventions within the trial. Data regarding the association between PEs and the outcomes were extracted individually and reported for all of these mutable reported associations.

As the included studies featured a wide variety of interventions, as well as heterogeneity in expectations and outcomes measurement tools, it was difficult to conduct a quantitative synthesis. Therefore, a descriptive synthesis was carried out to qualitatively summarise the findings, which reported extracted data about the association between PEs and the outcomes of pain intensity, functional status and HRQOL. Results were stratified by the type of outcome (pain intensity, level of function (disability) or HRQOL) and the period of follow-up; short ([?] 6 weeks), medium (> 6 weeks - [?] 6 months), and long (> 6 months).

Results

3.1 Search and study selection results

A total number of 2,050 pertinent results were found across all the searches performed. After restricting the searches to RCTs within the databases, this number was eventually reduced to 1,405 citations. After removing the duplications, 562 citations were retrieved to enable the screening of each result's title and abstract. A total of 37 full text articles were identified as being relevant to the topic. After the inclusion and exclusion criteria were applied to the 37 relevant trials, only 7 trials which met the criteria were included in the review. In addition, three studies were identified through reviewing the reference lists from the included trials. However, they were all excluded after the eligibility criteria were applied to them. Figure 1 represents the flow chart of the study selection process.

3.2 Characteristics of the studies reported on PEs

Four trials out of the seven included studies were secondary analyses of RCTs. The number of participants ranged between 40 (7) and 477 (24). Participants' ages did not vary considerably among the included studies: 18-60 years of age in two trials (25, 26), 20-70 years in two trials (5, 24), 18-64 years (27), 18-65 years (6) and 21-65 years of age (7). Interventions varied significantly between the included trials with some having more than one type of the same intervention. All of the included seven trials addressed the outcome expectations. For measurement of PEs, five trials used different types of scales with different numbers of data points. Four trials used an eleven-point scale (0 to 10) (5, 7, 24, 27), while one trial used a two-point scale (25). The remaining two (6, 26) used questionnaires to measure PEs. In addition, all trials assessed PEs at the baseline, while some of them provided a specific time point (5, 6, 7, and 24), however, others did not (25-27).

Regarding the outcomes of interest namely pain, functional level and HRQOL, four trials addressed only one of the outcomes of interest (5-7, 25), two trials (6, 26) addressed two and only one trial addressed three of the outcomes of interest (27). The outcome of levels of function (disability) was addressed in six trials, pain intensity in four trials and HRQOL in only one trial. In addition, a variety of measurement tools were used to measure these outcomes. The Roland Disability Questionnaire (RMDQ) was used in four trials to measure disability and levels of function. The ODI was used in one trial to measure disability (25). Additionally, the Low Back Rating Scale was used in one trial (26) to measure both disability and pain intensity. Numerical rating scales were used in two trials to assess pain intensity, while the visual analogue scale (VAS) was used

in only one trial. The 36-Item Short Form Survey (SF-36) was used only by one trial to assess the outcome of HRQOL (27).

Finally, the follow up points of outcomes varied between short ([?] 6 weeks), medium (> 6 weeks - [?] 6 months) and long (> 6 months) with some studies having two follow-up points (6, 24, 25). One trial assessed the outcomes immediately after the treatment (7). One trial had a follow-up point after an 8 week period (24), two were at 10 weeks (5, 6), one at 12 weeks (27) and one at 14 weeks (26). The longest follow-up point was 52 weeks (24) and as well as 1 and 5 years (25). Table 1 provides the characteristics of these included trials.

3.3 Quality of the studies reported on PEs

Overall, there were two high quality trials (7, 24), three moderate quality trials (6, 26, 27) and two low quality trials (5, 25). None of the seven trials included the blinding of the therapists; all trials except two (7, 24) did not satisfy the domain for blinding of the participants. Similarly, all trials except one (24) met the criteria on the allocation of concealment; and all trials except two (6, 24) did not blind the assessors. The PEDro scores of the individual studies were shown in the Table 2.

3.4 Risk of bias among the studies reported on PEs

The results of the risk of bias evaluation was shown in Figure 2a and the summary of the risk of bias expressed in percentage were shown in Figure 2b. In general, about 75% of the reported studies on PEs scored only low risk to moderate risk. Only 25% of the reviewed studies on PEs showed high risk of bias. The different domains of the risk of bias reported among the individual studies were shown in Figure 2a.

3.5 Association between PEs on the outcomes (pain, functional levels and health related quality of life)

Table 3 shows the association between the PEs and the outcome measures (pain, functional status and health related quality of life) reported among the reviewed studies. The results showed that a total of four trials addressed the association between PEs and pain intensity. Two of these trials demonstrated a positive association between PEs and pain intensity, in both the short (7) and long term (26). The other two trials demonstrated no association between PEs and pain intensity within the medium term follow-up (6, 27). A total of 6 trials addressed the outcome of levels of function. Three of the 6 trials demonstrated a positive significant association between PEs and levels of function, two trials (5, 6) registered at medium term (> 6 weeks - [?] 6 months) while the other one (26) at long term (> 6 months). Three other trials demonstrated no significant associations between PEs and function levels (24, 25, 27). None of the included trials addressed the outcome of function levels in the short term ([?] 6 weeks). Neither short ([?] 6 weeks) nor the long term (> 6 months) association was reported between PEs and the HRQOL. Only one study (27) reported the association between PEs and HRQOL over the medium follow-up term (> 6 weeks - [?] 6 months), however the association was not significant.

Discussion

This study investigated the evidence behind the association between PEs and specific treatment outcomes such as pain intensity, functional level and HRQOL among people with CLBP. The findings supported evidence on the association between PEs and the pain and functional levels. Positive PEs prior to the treatment were shown to be associated with the pain intensity in both shorter and longer terms among CLBP individuals. Evidence suggests that PEs have an influence on the pain outcome by means of a 'placebo' effect (28, 29). In addition, several psychological factors such as individual's beliefs about their pain; fear avoidance beliefs; patient's behaviours; emotions such as anxiety, depression etc., as well as the regulation of these emotions; lack of support; coping strategies; faith and religious beliefs; and patient's recovery expectations have been discussed in the pain literature as underlying factors that might influence the pain outcomes (30, 31). However, the current findings need to be interpreted with caution in acute and nonspecific low back pain, as the effects might be different because PEs change over time (32-34). Currently, studies that have examined the association between PEs and treatment outcomes on acute low back pain

are lacking and hence, the influence of PEs is unknown among people with acute low back pain. Also, the studies have only measured the PEs at one point in time, it would be interesting to know if or how they change throughout a course of treatment

Past studies reported that the positive PEs on an intervention have positively influenced the functional outcomes (5, 35). However the current review finding suggests that there is equivocal evidence between PEs and levels of function. While three studies showed a positive association between PEs and the levels of function at both medium and long term (5, 6, 26), three other trials demonstrated no significant associations between PEs and function levels (24, 25, 27). The therapist-patient encounter, information provided to the patients during the encounter, different timings of measuring PEs and use of various methods to measure PEs might have contributed to this equivocal evidence (10). While patients with higher expectations for benefiting from joint replacement surgery had greater gains in HRQOL (36), the findings of the current review clearly demonstrated no evidence behind PEs and HRQOL among people with CLBP. Neither short ([?] 6 weeks) nor the long term (> 6 months) association was reported between PEs and the HRQOL. Only one study (27) reported the association between PEs and HRQOL over the medium follow-up term (> 6 weeks - [?] 6 months), however the association was not significant. Further studies are warranted to investigate the influence of PEs on HRQOL among people with CLBP in order to revaluate and reflect on this evidence again in practice.

The review findings have some implications for policy makers and clinical managers in the health care sector. The Care Quality Commission (CQC) ensures the quality of healthcare provided by the majority of hospital-based care for the National Health Service (NHS) in the UK (37). PEs of a given care is one of the major determinants for satisfaction in the quality of health care provided to people (38). While the CQC's quality surveillance tool effectively monitors the quality of care through monitoring care profile indicators such as mortality rates, timeliness of intervention, waiting times etc. (37), there is no explicit mention about collecting or documenting PEs on the care provided. Similarly, NHS collect feedback on the quality of care provided to the patients, however, it does not collect information on the PEs of care (39, 40). Perhaps, a lack of sufficient understanding and evidence behind the influence PEs could have on the treatment outcomes might be one of the reasons that PEs are not fully represented in both CQC and NHS audit policies. In the above given context, the current review might contribute to CQC and NHS policies in future as it provide preliminary evidence on the impact of PEs on the treatment outcomes in CLBP care. As patients are ultimately the receivers of health care provision, understanding and managing their expectations of care in clinical practice is pivotal (41).

However, PE is often handled as a challenging concept in clinical practice. Firstly, a huge overlap and differences in the terminologies used to define PE often cause challenges to practitioners and researchers to measure and understand the concept of PEs in clinical practice. Secondly, although many practitioners might sometimes informally ask the patients about their expectations about treatment, PEs are not explicitly measured and documented in health care practice. Thirdly, even if practitioners do inquire about PEs, it might be generally asked only prior to the initial treatment, however, PEs might not be followed up in consecutive treatment sessions in practice. The timing of measuring PEs is relevant in practice especially when PEs were reported to change over a course of three months among people with CLBP (32-34). Also, one could argue that monitoring PEs may help clinicians in the process of decision making (29). However, there is a lack of a standardized and valid tool in clinical practice to measure PEs (8, 9, 14), hence PEs might be measured differently by different practitioners in day to day practice. Another challenge in practice includes the practitioners measuring PEs at different point of time, as the current review findings supported that the timing of measuring PEs varied between immediately after treatment to the 1- and 5-year follow-up among the studies. In the context of the above mentioned challenges in clinical practice, the findings of the review emphasize to clinicians and researchers the importance and relevance of considering PEs in the development and delivery of health care services. Equally, the review findings identifies a need for a valid tool to measure PEs in practice and calls the international research community towards the development of a clinical tool to measure PEs.

Conclusion

In summary, PEs have a positive association on both the short and long term pain outcomes among individuals with CLBP. The influence of PEs on the functional outcomes among people with CLBP are inconclusive as the evidence on the association between PEs and functional outcomes is equivocal. Limited available studies showed no evidence of an association between PEs and HRQOL among CLBP patients. Further studies investigating the influence of PEs with valid tools to measure PE across standardized time periods and during a treatment programme are warranted in people with CLBP.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figure 1 Flow chart.docx available at https://authorea.com/users/308869/articles/439908-are-patient-expectations-associated-with-treatment-outcomes-in-individuals-with-chronic-low-back-pain-a-systematic-review-of-randomised-controlled-trials

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