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RESEARCH REPORT

Are illness perceptions and patient self-care enablement mediators of treatment effect in best practice physiotherapy low back pain care? Secondary mediation analyses in the BetterBack trial

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ABSTRACT

Introduction: A best practice physiotherapy model of care (BetterBack MoC) for low back pain (LBP) aimed to improve patients' illness perceptions and self-care enablement, according to the Common-Sense Model of Self-Regulation (CSM).

Objective: To confirm if illness perceptions and patient self-care enablement, in line with the CSM, are mediators of treatment effects on disability and pain of the BetterBack MoC for patients with LBP compared to routine primary care. A secondary aim was to explore if illness perceptions and patient self-care enablement are mediators of guideline adherent care.

Methods: Pre-planned single mediation analyses tested whether hypothesized mediators at 3 months mediated the treatment effect of the MoC ($n = 264$) compared to routine care ($n = 203$) on disability and pain at 6 months. Secondary mediation analyses compared guideline adherent care with non-adherent care.

Results: No indirect effects were identified. The BetterBack intervention did not have superior effects over routine care on the hypothesized mediators. Illness perceptions and self-care enablement were significantly associated with disability and pain at 6 months. Secondary analyses showed significant indirect effects of guideline adherent care through tested mediators.

Conclusion: Despite no indirect effects, patients' illness perceptions and self-care enablement were associated with disability and back pain intensity outcomes and are potentially relevant treatment targets.

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Physiotherapy; illness perception; self-management; mediation analysis; low back pain

Introduction

Low back pain (LBP) is a prevalent condition and one of the leading causes of disability worldwide (Wu et al., 2020). Even though the prognosis of a new LBP episode is good with often rapid recovery (Menezes Costa et al., 2012), recurrence of LBP is common (Hartvigsen et al., 2018). Treatment guidelines for the management of LBP emphasize interventions that improve patients' self-management and these are recommended to be given at all steps of the management pathway. Such interventions are information and education, advice on management and exercise (Foster et al., 2018; National Clinical Guideline Centre, 2016; Oliveira et al., 2018).

The Common Sense Model of Self-Regulation (CSM) (Leventhal, Phillips and Burns 2016) purports that illness perceptions affect outcome through their influence on coping and the development of management strategies. The CSM describes how individuals develop and self-regulate emotional and cognitive illness representations based on their experiences and understanding of the illness. These illness representations have an impact on emotional responses and behavior. This may in turn affect health outcomes and emotional well-being (Leventhal, Phillips and Burns 2016). There is support for the cross-sectional association between illness perceptions and disability and pain in individuals with musculoskeletal pain (de Raaij et al., 2018), including LBP (Morton et al., 2019). The association with longitudinal outcomes is more uncertain, due to a lower number of longitudinal studies, their methodological weaknesses and differing use of constructs that may be

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representative of illness perceptions (de Raaij et al., 2018; Morton et al., 2019). Studies have shown that some illness perception dimensions are more associated with longitudinal outcomes than others in people with LBP (Campbell, Foster, Thomas, and Dunn, 2013; Fors et al., 2022; Foster et al., 2008, 2010; Glattacker, Heyduck, and Meffert, 2013). Illness perceptions have also shown to be modifiable by interventions (Glattacker, Heyduck, and Meffert, 2012; Løchting et al., 2016; Sandal et al., 2021; Siemonsma et al., 2013) and change over time in patients with LBP who recover (Foster et al., 2008).

There is a need to better understand the mechanisms underlying the treatment effects in interventions for individuals with LBP to further develop effective treatments. Mediation analysis has the potential to help identify how an intervention produces improvement in an outcome through a selected mechanism of interest, or it can help us understand why an intervention failed (VanderWeele, 2015). Mediation analysis can be used to investigate if maladaptive illness perceptions and patient self-management are important to target in interventions for patients with LBP.

Only few studies have, to our knowledge, investigated illness perceptions' role in the improvement of disability and pain in patients with LBP. Mansell et al. (2017) found illness perceptions to be a potential mediator of treatment effect on disability in a cognitive education intervention for patients with LBP. Cashin et al. (2022) found back beliefs to be a mediator of treatment effect on disability in patients with acute LBP when comparing a patient education intervention with sham education. Some studies have investigated coping as a potential mediator in interventions for LBP (Lee et al., 2016; O'Neill et al., 2020), but any firm conclusion cannot be drawn. To our knowledge, no studies have investigated if enabling patients to self-manage their LBP is important for treatment effects.

A best practice physiotherapy primary health-care model for patients with LBP (i.e. the BetterBack model of care (MoC)) was developed and implemented in Swedish primary care setting in the BetterBack trial. The BetterBack MoC focused on enhancing physiotherapist adherence to guidelines (Abbott et al., 2018). The patients' outcomes improved significantly when treated both according to the BetterBack MoC and routine care, without statistically significant differences between the interventions (Schröder et al., 2021). The proportion of patients receiving guideline adherent care was 59% when treated according to the BetterBack MoC compared to 26% when treated according to routine care (Schröder et al., 2022). An additional explorative analysis showed that the patients who received guideline adherent care improved significantly more in patients' outcomes compared to those who received non-adherent care irrespective of group allocation (Schröder et al., 2021). In line with treatment guidelines, the content in the BetterBack MoC aimed to target patients' maladaptive perceptions regarding their back problem and enable patients' self-care through enhancing their development of adequate coping and self-management strategies (Abbott et al., 2018). The primary aim of the present study was to confirm if illness perceptions and patient self-care enablement, in line with the CSM, are mediators of treatment effects on disability and pain of a best practice physiotherapy primary health-care model for patients with LBP compared to routine care. A secondary aim was to explore if illness perceptions and patient self-care enablement mediate treatment effects on disability and pain in patients with LBP receiving guideline adherent care compared to non-adherent care. In line with our prespecified hypothesis, we expect that illness perceptions and patient self-care enablement are mediators of treatment effects on disability and pain.

Methods

Study design

This study was a planned secondary causal mediation analysis of a single blinded stepped cluster randomized controlled trial within a hybrid type 2 effectiveness-implementation trial that analyzed physiotherapy care after implementation of the BetterBack MoC compared to previous routine care. The current study secondary analysis followed the a-priori published research protocol (Abbott et al., 2018) registered on ClinicalTrials.gov (NCT03147300).

Participants and setting

The original BetterBack trial methods and intervention details have been reported in the study protocol (Abbott et al., 2018). Briefly, the BetterBack MoC was implemented in 15 primary care physiotherapy rehabilitation clinics in the Region of Östergötland, Sweden. The rehabilitation clinics were divided into three clusters based on geographical and organizational structure to minimize contamination between clusters. Random concealed allocation was used when clusters were randomized to either routine care or intervention study condition. The implementation of the BetterBack MoC followed a stepped cluster dogleg structure (Hemming et al., 2015; Hooper and Bourke, 2015), where the physiotherapists (PTs) in the three different clusters

received training in using the BetterBack MoC at different timepoints during the study period. The study participants were patients seeking physiotherapy care for LBP. They received either routine care or care from BetterBack MoC trained PTs depending on the time and location when they sought care. The PTs in the first cluster initially received training in using the BetterBack MoC, which was encouraged to be used in their management of patients with LBP (Intervention group). The PTs in the second cluster treated patients according to routine care (Control group) in the first half of the trial. They thereafter received training in the BetterBack MoC and were encouraged to apply this in their management of patients with LBP throughout the rest of the trial (Intervention group). The PTs in the third cluster treated their patients according to routine care throughout the trial (Control group). Data on PTs characteristics were gathered throughout the study. Evaluation of PT-related outcomes in the BetterBack trial is reported elsewhere (Schröder et al., 2020, 2022).

Patients seeking care for LBP at the 15 public financed primary care physiotherapy rehabilitation clinics between April 2017 and March 2018 were consecutively recruited by PTs working at the rehabilitation clinics. The study included 467 patients. Ethical approval for the study was obtained from the Regional Ethics Committee in Linköping (Approval Number: Dnr 2017–35/31) and all participants provided written informed consent before enrollment. The eligible participants were aged between 18 and 65, fluent in Swedish, and accessed public primary care due to a first-time or recurrent episode of acute, subacute or chronic-phase benign LBP with or without radiculopathy. Exclusion criteria were current diagnosis of malignancy or previous malignancy during the past 5 years, spinal fracture, infection, cauda equina syndrome, ankylosing spondylitis or systemic rheumatic disease, spinal surgery during the last 2 years, current pregnancy or previous pregnancy up to 3 months before consideration of inclusion, participants who fulfilled the criteria for multimodal/multiprofessional rehabilitation for complex long-standing pain, and severe psychiatric diagnosis.

Intervention

Patients in the control group received routine physiotherapy care for LBP. The PTs delivering the routine care had no knowledge or training in the use of the BetterBack MoC. Patients in the intervention group received care from PTs trained in and encouraged to use the BetterBack MoC. The BetterBack MoC was based on two international clinical practice guidelines for LBP (National Clinical Guideline Centre, 2016; Sundhedsstyrelsen, 2016a, 2016b). An adaptation of the existing clinical practice guideline recommendations was made to fit the Swedish context. The BetterBack MoC contains support tools that matched the adapted recommendations including patient-centered coordinated pathways, assessment and clinical reasoning tools, a patient education brochure and group education material on LBP and self-care, and functional restoration program resources. The BetterBack MoC aimed to encourage PT's delivery of care coherent with locally adapted clinical practice guideline recommendations. Detailed information on the development and implementation strategy of the BetterBack MoC are published in the study protocol (Abbott et al., 2018). Duration of the treatment period and number of treatment sessions were gathered from medical record data.

Mediation analysis

When working with continuous mediators and outcomes, mediation analysis allows for the total effect to be broken down into separate effects (paths) using regression coefficients (Figure 1). The *c*-path between the intervention and outcome is the total effect of the intervention on the outcome, inclusive of the effect through the mediator. The *a*-path between the intervention and the potential mediator can describe the intervention's ability to impact the mediator. The *b*-path between the potential mediator and the outcome can describe the mediator's ability to impact the outcome. The mediating pathway is the average intervention effect through the potential mediator and a product of the *a*-path and *b*-path (i.e. *ab*-product, the indirect effect). The direct effect (c') is the average intervention effect that works through all other mechanisms, excluding the selected potential mediator (MacKinnon, 2008).

The indirect effect, when broken down into the *a*- and *b*-path, can be interpreted according to action theory and conceptual theory. A strong *a*-path would be interpreted as that the intervention successfully targets the mediator. A strong *b*-path would be interpreted as that the mediator is the correct factor to target in order to improve the outcome (MacKinnon, 2008). This conceptualization helps to improve the understanding which factors might be mediators affecting the outcome (conceptual theory) and if an intervention succeeds to target these key factors for patient improvement (action theory) (MacKinnon, 2008). These theories provide a framework with which to understand how to improve treatment effectiveness (Lee, 2020).

Theoretical rationale for the BetterBack trial

The rationale for causal mediation effects was based on the CSM (Leventhal, Phillips and Burns 2016).

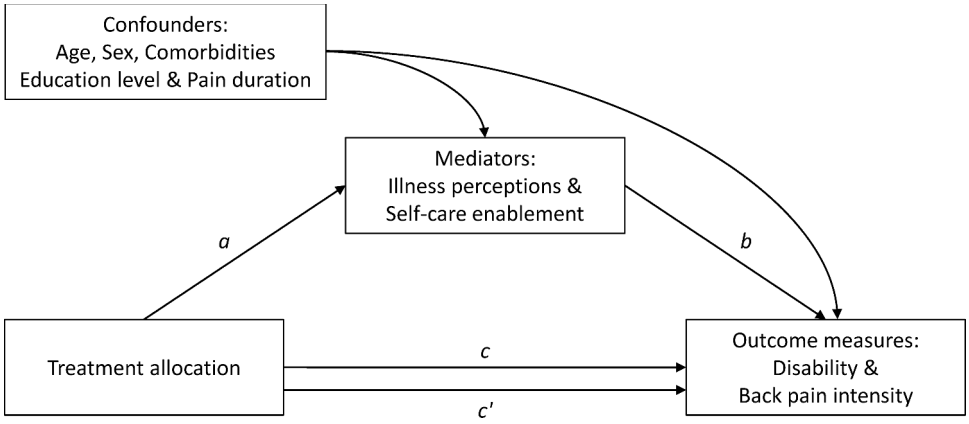

Figure 1. Directed acyclic graph of hypothesized mechanisms in single mediator models in the BetterBack trial and the estimated averaged effects adjusted for confounding effects. The indirect effect (ab-product) is the average intervention effect through the mediator. *a*, a-path (the intervention-mediator effect); *b*, b-path (the mediator-outcome effect); *c*, c-path (the total effect of the intervention on the outcome, inclusive of the effect through the mediator); *c'* (the direct effect of the intervention on the outcome that works through all other mechanisms excluding the selected potential mediator).

This suggests that a potential positive effect of the BetterBack MoC on patient outcomes may be mediated by improved patient illness perceptions, such as cognitive and emotional illness representations, as well as adequate coping and management strategies through self-care enablement (Leventhal, Phillips and Burns 2016). The patient target behaviors were therefore focused on the understanding of the mechanisms and natural course of benign LBP and the enablement of self-care. The content of the BetterBack MoC aimed to target patients' impeding barrier behaviors such as low self-care enablement and low physical activity, as well as impeding maladaptive illness perceptions (such as the misconceptions regarding the cause and course of LBP; low recovery and treatment expectation; and unhelpful emotional responses to their back problem e.g. concern and anxiety/depression).

As mentioned in the introduction, an additional exploratory analysis in the BetterBack trial showed significant improvement of patient outcomes in those patients who received guideline adherent care compared with patients who received non-adherent care. These comparative analyses were therefore performed based on the actual treatment received irrespective group allocation. Guideline adherent care was defined as care fulfilling the five clinical practice guideline recommendations having the highest clinical priority ranking in the locally adapted clinical practice guidelines: no referral to specialist consultation and no medical imaging for nonspecific LBP, use of patient education interventions, use of exercise interventions and no use of non-evidence-based interventions (Schröder et al., 2021, 2022). Based on the CSM (Leventhal, Phillips and Burns2016), illness perceptions and patients' self-care enablement could potentially mediate the effect of receiving guideline adherent care.

Patient reported outcome measures (PROMs)

The PROMs were collected at baseline by the treating PT at the first visit. Data at follow-ups 3 and 6 months after baseline were collected through postal questionnaires sent to the patients. All PROMs have been used and most of them validated in a Swedish or Scandinavian context and in persons with LBP (Abbott et al., 2018). In the present study, we analyze assessment of mediators at baseline and at 3-month follow-up, and outcome measures at baseline and at 6-month follow-up. The time-point for collection of the data was a-priori planned to ensure a temporal sequence between the treatment, mediator, and outcome. Participant characteristics and potential confounders were assessed pre-treatment.

Outcomes

The primary outcomes of this secondary analysis were mean group difference in disability and lower back-related pain intensity at 6 months post baseline. The Oswestry disability index (ODI) (Fairbank and Pynsent, 2000) was used to assess disability. The Numeric Rating Scale for lower back-related pain intensity (NRS-LBP) (Jensen, Turner, Romano, and Fisher, 1999) was used to assess pain intensity on a numerical

scale ranging from 0 (no pain) to 10 (worst pain imaginable). Internal consensus recommends change in ODI and NRS-LBP over 6 months as a core metric for pain improvement and functional restoration (Clement et al., 2015), also reflecting core outcome domains recommended to be included for clinical trials in nonspecific LBP (Chiarotto et al., 2015).

Potential mediators

We hypothesized that care according to the BetterBack MoC would lead to reductions in disability and pain intensity through effect on mediators; patients' illness perceptions and patients' self-care enablement. Patients' illness perceptions were assessed with the Brief Illness Perception Questionnaire (BIPQ) (Broadbent, Petrie, Main, and Weinman, 2006) which has been developed based on the CSM (Leventhal, Phillips and Burns2016). The questionnaire includes nine items comprising cognitive and emotional illness representations. Eight items are assessed on a scale from 0 to 10 summarized in a total score ranging from 0 to 80, where a higher score reflects a more threatening view of the illness. The Patient Enablement Instrument (PEI) (Howie, Heaney, Maxwell, and Walker, 1998; Rööst, Zielinski, Petersson, and Strandberg, 2015) was used to assess patients' self-perceived ability to understand and cope with illness and can be considered a proxy for self-care enablement. The total score ranges from 0 to 12, where higher scores indicate better/more enablement. PEI is a transition score, not measured at baseline.

Potential confounders

In order for the primary mediation analyses to assume causal interpretation, four assumptions are required: 1) no (unmeasured) confounder in the treatment-outcome relationship; 2) no (unmeasured) confounder in the mediator-outcome relationship; 3) no (unmeasured) confounders of the treatment-mediator relationship; and 4) no mediator-outcome confounder that is influenced by the treatment (Valeri and VanderWeele, 2013). The randomization to groups ensures that, in the long run, the groups are on average comparable in terms of baseline characteristics. It is therefore plausible to assume that randomization reduces potential for confounding in the relationships between the treatment and the hypothesized mediators and between the treatment and the outcome (i.e. assumption 1 and 3) by generating groups that are comparable with respect to known and unknown confounding variables. The association between the mediator and the outcome may, however, be confounded (assumption 2). Potential pre-treatment covariates that may confound this relationship were selected based on empirical findings and consensus in the research group. The potential confounders were age, sex, comorbidities, education level, and pain duration (Figure 1). In the secondary exploratory aim examining if the potential mediators explain the effect of guideline adherent care compared to non-adherent care, there was no randomization of patients. Thus, assumption 1 or 3 cannot be verified. The mentioned pre-treatment covariates may also be potential confounders of these relationships. Other potential measured confounders were characteristics of the treating PT: sex, age, and clinical experience.

Statistical analysis

Baseline characteristics were presented as means with standard deviations or proportions. The primary mediation analyses followed an a-priori planned analysis (Abbott et al., 2018). The mediation models were estimated using path-analyses within the framework of Structural Equation Modeling, where all the variables are manifest (i.e. measurable). Multilevel adjustment of the models was not needed due to the minimal clustering effects in the data reported by Schröder et al. (2021). Mediation analyses were conducted using Mplus version 8.2. Non-responders at 3- and 6-month follow-up had similar demographic and clinical characteristics compared to responders. Characteristics were also similar when comparison was made between different patterns of missing values. Analyses of handling data under the assumption of missing at random and not missing at random were made following the example of Enders (2011). These supported that the missing data could be handled under the assumption of missing at random. The model parameters were obtained with full information maximum likelihood estimation (Enders, 2011). The principle of intention-to-treat was followed in the primary mediation analyses.

Single mediator models were constructed for each hypothesized mediator (i.e. illness perception and patient enablement) assessed at 3-month follow-up on the dependent variable assessed at 6-month follow-up (disability and pain intensity). The mediator models were constructed with the treatment allocation (binary coded variable 0 = control group, 1 = intervention) as the independent variable. In the secondary exploratory mediation analyses, the models were constructed with patients receiving guideline adherent care or non-adherent care as the independent variable. For each mediator model, the intervention-mediator effect (*a*-path), the mediator-outcome effect (*b*-path), the average causal mediation effect (indirect effect, *ab*-

product), the average direct effect (c'), and the average total effect (*c*) were estimated. The indirect effect is the average intervention effect through the mediator; the direct effect is the average intervention effect that works through all other mechanisms, excluding the selected mediator; and the total effect is the average effect of the intervention on the outcome (Figure 1). The mediation models were adjusted for the dependent variable as well as the potential pre-treatment confounders. In case of the BIPQ mediation models, the baseline BIPQ level was also adjusted for. The number of subjects per variable in the current study's analyses ranged from 14 to 20, which provides accurate estimation of regression coefficients (Austin and Steyerberg, 2015). The significance level was set to $p = .05$ in line with the a-priori protocol. Effects were reported with 95% confidence interval.

Modeling assumptions for linear regression models (linearity and normally distributed residuals) were checked and fulfilled. In line with recent recommendations in mediation analysis (MacKinnon, Valente, and Gonzalez, 2020), the interaction term between the mediator and the independent variable (e.g. treatment allocation and for secondary analysis guideline adherent care) was analyzed to examine the impact on the indirect effects. Since the interaction between treatment and mediator did not change the results qualitatively, the interaction term was not adjusted for in the analyses.

Results

From a total of 1034 consecutive patients with LBP seeking physiotherapy in the public financed primary care rehabilitation clinics, 500 fulfilled inclusion criteria and accepted participation. Cluster randomization allocated 222 patients to control group and 278 to intervention group. Baseline assessments were completed by 467 patients. The retention rate to follow-up assessment at 3-month follow-up was 71% for the control group and

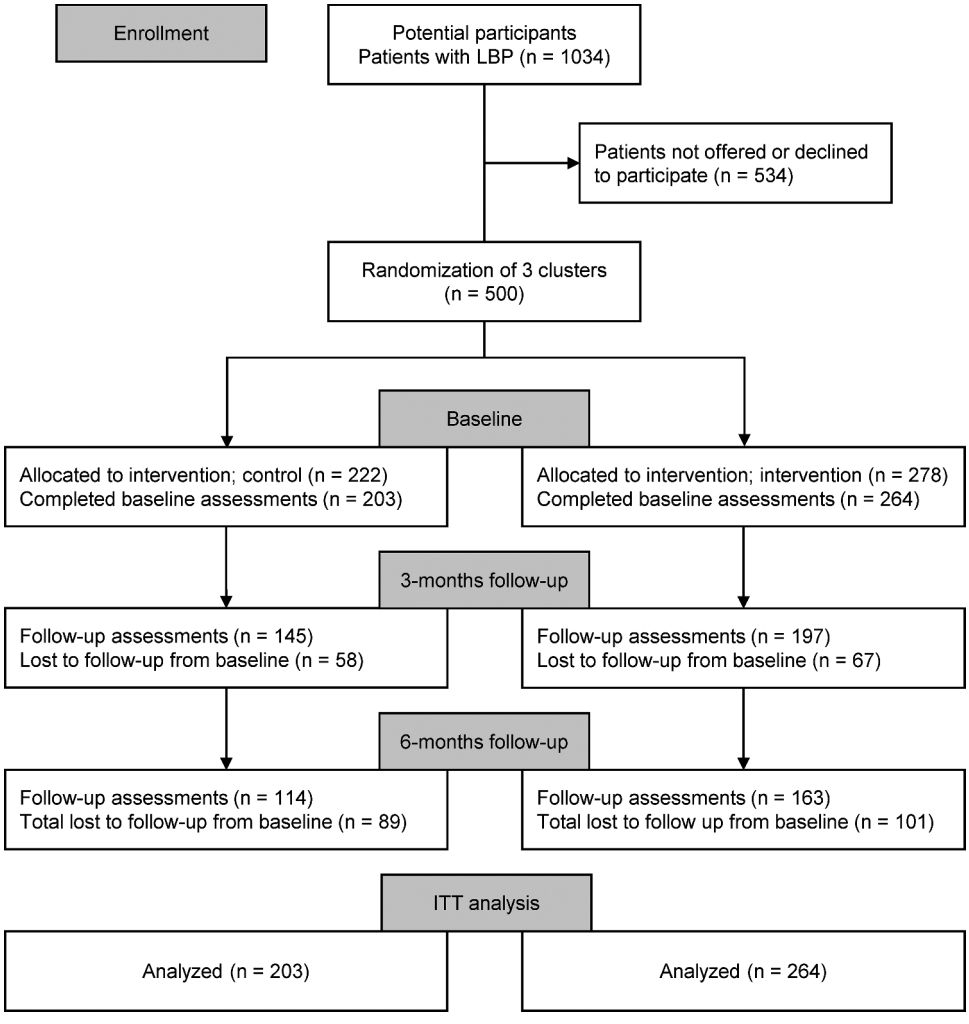

Figure 2. Flow chart of study participants throughout the trial.

Table 1. Baseline characteristics of the included patients and the physiotherapists treating the patients, split by treatment condition and guideline adherence of received care.

	Control group *n* = 203	Intervention group *n* = 264	p-value	Non-adherent care *n* = 191	Guideline adherent care *n* = 164	p-value
Age, mean (SD)	46 (12)	45 (12)	0.694	45 (13)	45 (12)	0.944
Sex, female, n (%)	109 (54)	152 (58)	0.402	104 (55)	88 (54)	0.881
Educational level, n (%)			0.412			0.847
Elementary	24 (12)	34 (13)		22 (12)	21 (13)	
High school	112 (55)	158 (60)		118 (62)	97 (59)	
University	66 (33)	71 (27)		50 (26)	46 (28)	
Leg pain, n (%)	142 (72)	182 (69)	0.465	141 (74)	102 (62)	**0.011**
Leg pain NRS, mean (SD)	3.7 (3.3)	3.7 (3.3)	0.986	3.9 (3.2)	3.3 (3.3)	0.068
Pain duration, n (%)			0.562			0.488
<12 weeks	120 (59)	149 (56)		106 (55)	97 (59)	
>12 weeks	83 (41)	115 (44)		85 (45)	67 (41)	
Comorbidities, n (%)			0.535			0.681
0	128 (63)	179 (68)		126 (66)	109 (67)	
1	53 (26)	62 (23)		45 (23)	42 (26)	
2–5	22 (11)	23 (9)		20 (11)	13 (8)	
Number of treatment sessions, mean (SD)	3.4 (2.9)	5.1 (5.2)	**<0.001**	3.7 (3.1)	4.6 (3.9)	**0.016**
Duration PT intervention period, mean days (SD)	66 (74)	65 (59)	0.487	65 (73)	64 (54)	0.876
Characteristics of the treating PTs						
Total number of PTs		104			84	
Number of PTs	69*	51*		64**	50**	
Age, mean (SD)	36 (12)	36 (12)	0.775	36 (12)	35 (10)	0.478
Sex, female, n (%)	49 (71)	35 (69)	0.778	45 (70)	35 (70)	0.971
Education level, n (%)			0.893			0.492
Bachelor's degree	43 (86)	34 (85)		54 (90)	42 (86)	
Post graduate major or higher	7 (14)	6 (15)		6 (10)	7 (14)	
Clinical experience, n (%)			0.149			0.829
1–5 years	24 (47)	26 (61)		34 (54)	28 (56)	
≥6 years	27 (53)	17 (49)		29 (46)	22 (44)	

NRS, Numeric Rating Scale (0–10, where higher score indicates higher pain intensity); PT, Physiotherapist; SD, standard deviation.
*16 PTs treated patients in both intervention and control group.
** 30 PTs provided both guideline adherent and non-adherent care.
p < 0.05.

75% for the intervention group and 56% and 62%, respectively, at 6-month follow-up (Figure 2).

The baseline demographics and clinical characteristics of participating patients are provided in Table 1. The patients in the control group and the intervention group were similar in characteristics and demographic variables. The PTs who treated the patients in the control group and the intervention group had similar levels of clinical experience and education. Table 2 presents the mean scores of the outcome measures for disability and back pain intensity and for the potential mediators illness perceptions and self-care enablement at the assessment points, split by treatment condition and by guideline adherence of received care.

The results from the estimated mediation models examining the average treatment effects of care according to the BetterBack MoC compared to routine care on disability and back pain intensity are presented in Table 3. There were no statistically significant differences between the interventions in scores for illness perceptions or patients' self-care enablement at 3-month follow-up adjusted for baseline scores (*a*-path). There was a statistically significant association between having more maladaptive illness perceptions at 3-month follow-up and greater disability (0.453; 95% CI 0.367 to 0.538) and higher back pain intensity (0.082; 95% CI 0.065 to 0.098) at 6-month follow-up (*b*-path). Similarly, having higher self-care enablement at 3-month follow-up was associated with less disability (−1.515; 95% CI −1.874 to −1.156) and lower back pain intensity (−0.247; 95% CI −0.318 to −0.176) at 6-month follow-up (*b* path). There were no statistically significant indirect effects on disability and back pain intensity through the tested mediators.

The results from the estimated mediation models examining the average treatment effects of guideline adherent care compared to non-adherent care on disability and back pain intensity are presented in Table 4. Patients who received guideline adherent care had statistically significant less maladaptive illness perceptions and higher self-care enablement at 3-month follow-up compared to those who received non-adherent care (*a*-path). There was a statistically significant association

Table 2. Mean score and 95% confidence interval at assessment points for outcomes and tested mediator variables split by treatment condition and by guideline adherence of received care.

	Baseline mean (95% CI)		3-month follow-up mean (95% CI)		6-month follow-up mean (95% CI)	
Variable	Control n = 203	Intervention n = 264	Control n = 145	Intervention n = 197	Control n = 114	Intervention n = 163
Disability (ODI)	31.3 (29.0 to 33.7)	30.8 (28.9 to 32.6)	19.9 (17.4 to 22.3)	21.6 (19.4 to 23.8)	20.1 (17.1 to 23.1)	18.4 (16.2 to 20.6)
Back pain intensity (NRS-LBP)	6.1 (5.6 to 6.4)	6.4 (6.1 to 6.7)	3.5 (3.1 to 3.9)	3.5 (3.1 to 3.8)	3.7 (3.2 to 4.3)	3.5 (3.1 to 3.9)
Illness perceptions (BIPQ)	44.9 (43.2 to 46.5)	45.2 (43.9 to 46.4)	35.5 (32.4 to 38.5)	35.6 (33.2 to 38.1)	35.5 (32.1 to 38.9)	34.8 (32.1 to 37.5)
Self-care enablement (PEI)	-	-	4.6 (3.8 to 5.4)	4.8 (4.2 to 5.4)	4.6 (3.6 to 5.6)	5.1 (4.3 to 5.8)
	Care non-adherent to guideline *n* = 191	Guideline adherent care *n* = 164	Care non-adherent to guideline *n* = 138	Guideline adherent care *n* = 126	Care non-adherent to guideline *n* = 111	Guideline adherent care *n* = 104
Disability (ODI)	32.4 (29.9 to 34.9)	29.1 (26.9 to 31.2)	22.5 (19.7 to 25.2)	16.9 (14.6 to 19.2)	21.8 (18.8 to 24.8)	15.2 (12.6 to 17.8)
Back pain intensity (NRS-LBP)	6.3 (6.0 to 6.7)	6.3 (6.0 to 6.4)	3.8 (3.4 to 4.2)	2.8 (2.4 to 3.2)	4.1 (3.6 to 4.7)	2.9 (2.5 to 3.4)
Illness perceptions (BIPQ)	46.0 (44.4 to 47.7)	44.2 (42.5 to 45.9)	37.4 (34.4 to 40.7)	31.2 (28.3 to 34.1)	37.9 (34.7 to 41.1)	30.3 (26.9 to 33.7)
Self-care enablement (PEI)	-	-	4.1 (3.4 to 4.7)	5.4 (4.8 to 6.1)	4.1 (3.3 to 4.9)	5.7 (4.9 to 6.5)

BIPQ, Brief Illness Perception Questionnaire (0–80) (higher score represent a more threatening view of the illness); CI, confidence interval; NRS-LBP, Numeric Rating Scale – Low Back Pain (0–10) (higher score indicates higher pain intensity); ODI, Oswestry Disability Index (0–100) (higher score indicates greater disability); PEI, Patient Enablement Instrument (0–12) (higher score indicates greater ability to understand and cope with illness).

Table 3. Average treatment effect decomposition for each single-mediator model of the BetterBack intervention on disability and back pain intensity.

	Illness perceptions (BIPQ)		Self-care enablement (PEI)	
ANALYSIS	Mean difference on outcome scale (95%CI)	p-value	Mean difference on outcome scale (95%CI)	p-value
Disability (ODI) at 6 months				
Intervention-mediator effect (*a*-path)	−0.612 (−4.022 to 2.797), *n* = 457	0.725	0.146 (−0.694 to 0.986), *n* = 458	0.733
Mediator-outcome effect (*b*-path)	0.453 (0.367 to 0.538)	<0.001*	−1.515 (−1.874 to−1.156)	<0.001*
Total effect (c)	0.310 (−2.688 to 3.308)	0.839	0.368 (−2.632 to 3.368)	0.810
Direct effect (c′)	0.587 (−2.039 to 3.214)	0.661	0.590 (−2.171 to 3.351)	0.676
Indirect effect (ab)	−0.277 (−1.822 to 1.268)	0.725	−0.222 (−1.496 to 1.052)	0.733
Back pain intensity (NRS-LBP) at 6 months				
Intervention-mediator effect (*a*-path)	−0.710 (−4.070 to 2.650), *n* = 461	0.679	0.254 (−0.576 to 1.084), *n* = 463	0.549
Mediator-outcome effect (*b*-path)	0.082 (0.065 to 0.098)	<0.001*	−0.247 (−0.318 to−0.176)	<0.001*
Total effect (c)	−0.079 (−0.647 to 0.489)	0.784	−0.095 (−0.666 to 0.476)	0.745
Direct effect (c′)	−0.021 (−0.529 to 0.486)	0.934	−0.032 (−0.573 to 0.508)	0.907
Indirect effect (ab)	−0.058 (−0.333 to 0.217)	0.679	−0.063 (−0.268 to 0.143)	0.551

BIPQ, Brief Illness Perception Questionnaire (0–80, where higher score represent a more threatening view of the illness); CI, confidence interval; NRS-LBP, Numeric Rating Scale - Low Back Pain (0–10, where higher score indicates higher pain intensity); ODI, Oswestry Disability Index (0–100, where higher score indicates greater disability); PEI, Patient Enablement Instrument (0–12, where higher score indicates greater ability to understand and cope with illness). All estimates are unstandardized beta-coefficient for between group mean difference.

* $p < 0.05$.

Table 4. Average treatment effect decomposition for each single-mediator model of guideline adherent care on disability and back pain intensity.

	Illness perceptions (BIPQ)		Self-care enablement (PEI)	
ANALYSIS	Mean difference on outcome scale (95%CI)	p-value	Mean difference on outcome scale (95%CI)	p-value
Disability (ODI) at 6 months				
Intervention-mediator effect (*a*-path)	−4.228 (−7.830 to−0.626), *n* = 347	0.021*	1.008 (0.091 to 1.924), *n* = 348	0.031*
Mediator-outcome effect (*b*-path)	0.445 (0.347 to 0.544)	<0.001*	−1.380 (−1.788 to−0.972)	<0.001*
Total effect (c)	−5.208 (−8.403 to−2.014)	0.001*	−5.200 (−8.402 to−1.997)	0.001*
Direct effect (c′)	−3.325 (−6.167 to−0.484)	0.022*	−3.809 (−6.819 to−0.800)	0.013*
Indirect effect (ab)	−1.883 (−3.538 to−0.228)	0.026*	−1.390 (−2.717 to−0.064)	0.040*
Back pain intensity (NRS-LBP) at 6 months				
Intervention-mediator effect (*a*-path)	−4.789 (−8.342 to−1.236), *n* = 350	0.008*	1.197 (0.300 to 2.095), *n* = 352	0.009*
Mediator-outcome effect (*b*-path)	0.084 (0.065 to 0.103)	<0.001*	−0.240 (−0.322 to−0.159)	<0.001*
Total effect (c)	−1.029 (−1.643 to−0.415)	0.001*	−1.098 (−1.714 to−0.482)	<0.001*
Direct effect (c′)	−0.628 (−1.183 to−0.073)	0.027*	−0.810 (−1.404 to−0.216)	0.008*
Indirect effect (ab)	−0.402 (−0.714 to−0.089)	0.012*	−0.288 (−0.527 to−0.049)	0.018*

BIPQ, Brief Illness Perception Questionnaire (0–80, where higher score represent a more threatening view of the illness); CI, confidence interval; NRS-LBP, Numeric Rating Scale - Low Back Pain (0–10, where higher score indicates higher pain intensity); ODI, Oswestry Disability Index (0–100, where higher score indicates greater disability); PEI, Patient Enablement Instrument (0–12, where higher score indicates greater ability to understand and cope with illness). All estimates are unstandardized beta-coefficient for between group mean difference.

* $p < 0.05$.

between having more maladaptive illness perceptions at 3-month follow-up and greater disability (0.445; 95% CI 0.347 to 0.544) and higher back pain intensity (0.084; 95% CI 0.065 to 0.103) at 6-month follow-up. Having higher self-care enablement at 3-month follow-up was associated with less disability (−1.380; 95% CI −1.788 to −0.972) and lower back pain intensity (−0.240; 95% CI −0.322 to −0.159) at 6-month follow-up (*b*-path). Subsequently, there were statistically significant indirect effects on disability and back pain intensity at 6-month follow-up through illness perceptions (NRS-LBP: −0.402; 95% CI −0.714 to −0.089, ODI: −1.883; 95% CI −3.538 to −0.228) and self-care enablement (NRS-LBP: −0.288; 95% CI −0.527 to −0.049, ODI: −1.390; 95% CI −2.717 to −0.064) at 3-month follow-up.

All the mediation analyses were adjusted for covariates. Minimal changes in the estimates for the *b*-paths in the mediation analyses were seen after adjusting for potential confounding factors.

Discussion

In this study, we aimed to test the theoretical underpinnings of the treatment in the BetterBack trial by investigating if illness perceptions and patient self-care enablement, in line with the CSM, are mediators of the effects of a best practice physiotherapy primary healthcare model for patients with LBP. No significant indirect effects of the treatment on disability or back pain intensity via change in illness perceptions or self-care enablement were found. The analysis, however, showed significant associations between both illness perceptions and patient self-care enablement at 3-month follow-up and disability and back pain intensity at 6-month follow-up (*b*-paths). To summarize, the results do not support our hypotheses that illness perceptions and patient self-care enablement are mediators of the treatment effects. Despite no indirect effects, according to conceptual theory, the significant *b*-paths can be interpreted as showing support for illness perceptions and self-care enablement being treatment targets theoretically. This is in line with the theoretical underpinning of the CSM.

Research on mediators of treatment effects in interventions for patients with LBP has investigated foremost psychosocial factors (Alhowimel, AlOtaibi, Radford, and Coulson, 2018; Lee et al., 2016) such as: fear avoidance beliefs (Fordham et al., 2017; O'Neill et al., 2020; Stevens et al., 2019; Whittle, Mansell, Jellema, and van der Windt, 2017); catastrophizing (Cashin et al., 2022; Mansell et al., 2017; Whittle, Mansell, Jellema, and van der Windt, 2017); and pain self-efficacy (Cashin et al., 2022; Fordham et al., 2017; O'Neill et al., 2020; Stevens et al., 2019). These factors can be considered as specific aspects included in an overarching illness perception construct for LBP (Leventhal,Phillips and Burns2016). The BIPQ, used in the present study, has been proposed as an instrument to measure both specific and overarching illness perception (Broadbent et al., 2015). To our knowledge, two randomized controlled trials have investigated illness perceptions as a treatment mediator in patients with LBP (Cashin et al., 2022; Mansell et al., 2017). Mansell et al. (2017) found a small indirect effect on disability via change in illness perceptions (BIPQ) of a cognitive patient education intervention in addition to usual care compared to only usual care in patients with sub-acute and chronic LBP. The authors propose that illness perceptions are an important treatment target. Cashin et al. (2022) found that a similar illness perception concept regarding back beliefs partly mediated the effect on disability of a patient education compared to sham education in patients with acute LBP. Even if no indirect effects were found and the result estimates of the *b*-path in the present study are not entirely comparable to those in the previous studies (Cashin et al., 2022; Mansell et al., 2017) the studies together support that illness perceptions are relevant to target in interventions for LBP. The results from the present study also showed significant association between self-care enablement and disability and back pain intensity (*b*-paths). The estimates of the *b*-paths indicate that an intervention would need to greatly improve illness perceptions and self-care enablement for them to produce larger and clinically significant reduction in disability and pain. Even if the content in the BetterBack MoC is designed to target illness perceptions and patients' enablement to self-manage their LBP, the multifaceted nature of the BetterBack MoC opens for other potential factors to contribute to the reduction of disability and pain. Therefore, one might not expect change in illness perceptions or self-care enablement to entirely explain the improvement in the outcomes.

There is a vast body of literature supporting the relationships between illness perceptions, coping procedures/self-management behaviors and health outcomes (Breland, Wong, and McAndrew, 2020; Hagger and Orbell, 2003). This provided a basis for a process model that included direct effects of illness representations on outcomes and indirect effects mediated by strategies to cope and manage symptoms and treatment (Hagger, Koch, Chatzisarantis, and Orbell, 2017). The present study analyses support that both illness perceptions and patients' self-care enablement are associated with outcomes. Patients' self-care enablement involves their perceived ability to understand and cope with their

illness (Howie, Heaney, and Maxwell, 1997). This can be interpreted to also reflect the self-regulatory system in the CSM (Leventhal, Phillips and Burns 2016) describing an ongoing appraisal of the effectiveness of coping and management strategies. Improved self-care enablement may therefore also involve the patient finding management strategies or ways of thinking about their back problem that they find helpful in their management of their LBP. Such management strategies may result in a perceived increased control over symptoms described as controllability, one of the core cognitive dimensions, in the CSM (Leventhal, Phillips and Burns 2016). Across different patient groups, controllability has been found to be a modifiable perception and central to target for behavior change (Broadbent et al., 2015). Beliefs about the controllability have been seen to predict outcome in patients with LBP (de Raaij et al., 2018; Foster et al., 2008, 2010) and results from a multiple single-case experimental study indicate controllability to be a potential mediator and moderator of treatment effect (de Raaij et al., 2022). Besides providing patients with knowledge and management strategies, a practical important implication of this is to ensure that patients put theory into practice and gain control and confidence in managing their LBP. Patients may need support in learning how to develop, plan and modify their management strategies and identify their barriers for behavioral change. This could be done in dialogue and through shared understanding between the therapist and patient, to make information and education more consistent to the patient's experience and increase patient's understanding of their role in the process of building their own sufficient management routines.

The patients' illness perceptions and self-care enablement improved significantly when treated both according to the BetterBack MoC and routine care, without statistically significant differences between the interventions (*a*-path). According to action theory, this can be interpreted as if the BetterBack MoC did not target the tested mediators more effectively compared to routine care. However, this may be due to the already existing 26% prevalence of guideline adherence in routine care potentially targeting the test mediators compared to the 59% prevalence after the implementation of the BetterBack MoC. The secondary mediation analyses showed that both illness perceptions and self-care enablement mediated the effects of guideline adherent compared to non-adherent care on disability and back pain intensity. Based on the results reported from the BetterBack trial (Schröder et al., 2022) 87% of the patients receiving care non-adherent to guideline did not receive information or educational interventions. Less patients did not receive interventions in line with the other criteria for guideline adherent care. Only 20% did not receive exercise interventions and 31% received non-evidence-based interventions. One can therefore interpret the PT's non-adherence to information or educational interventions had the greatest impact on the secondary mediation analyses. Clinical guidelines for LBP recommend information and education as a part of the treatment of patients with LBP to endorse patient enablement to self-manage, even if there is low certainty in the current best available evidence for educational intervention for patients with LBP (Chiarotto and Koes, 2022; National Clinical Guideline Centre, 2016; Sundhedsstyrelsen, 2016a, 2016b). A network meta-analysis showed psychological interventions, including pain education and behavioral therapies, to be most effective in reducing disability and pain in people with persistent LBP when delivered in conjunction with physiotherapy care (mainly exercise) (Ho et al., 2022). There is moderate-quality evidence supporting self-management intervention programs, where education is included, to reduce disability and pain in patients with persistent LBP (Du et al., 2017). Interventions that include patient education have been shown to have impact on maladaptive LBP perceptions (Cashin et al., 2022; Glattacker, Heyduck, and Meffert, 2012; Løchting et al., 2016; Sandal et al., 2021; Siemonsma et al., 2013; Traeger et al., 2015). Even though no causal conclusion can be drawn from the secondary mediation analyses, the results suggest that information and education may be important parts of the treatment in order to improve maladaptive illness perceptions and patients' self-care enablement.

Strengths and limitations

The results of this study should be interpreted considering its strengths and limitations. The primary mediation analyses were planned prior to the trial start and follow the recommendations for mediation analyses (Lee et al., 2021). Although the randomization of groups and adjustments for b-path confounding strengthens the validity of a null result regarding differences in effects of the interventions, this is potentially confounded by the PT's guideline adherence and patient adherence to the interventions. It was not possible to apply complier adjusted causal effects analyses (CACE) because patient intervention adherence data was not collected in the trial and there was 24% missing data on guideline adherence of the delivered health-care interventions. Therefore, the randomized distribution between groups could not be maintained in the secondary "as treated" analyses opening the possibility of confounding factors

despite covariate adjustment of *a*-path and *b*-path for patient and therapist baseline characteristics. The measured patient and therapist characteristics were similar between the group who received guideline adherent care and non-adherent care, except for a minor proportion of patients with leg pain.

The time-points for assessments ensure the temporal sequence between the treatment, mediator, and outcome, which strengthen the findings from the mediation analyses. Nevertheless, there is uncertainty whether change in the mediators preceded effects on the outcomes as most of the improvement in the mediators and outcomes occurred within 3 months. To further strengthen the methodology, repeated assessment points during and after the intervention may better establish the temporal relation that change in mediators more reliably precede effect in the outcome.

The large study sample ensured sufficient power for the mediation analyses (Austin and Steyerberg, 2015) and also provides a reliable description of the study population. The participating patients were recruited from rehabilitation clinics in a region where the populations' socioeconomic and health status are representative of the Swedish population (Public Health Agency of Sweden, 2019). The non-responder analyses and the similar participants' characteristics to those reported in previous studies on this patient group in primary care settings in Sweden and internationally indicate no selection bias (Bier et al., 2018; Enthoven, Skargren, Cartensen, and Öberg, 2006; Foster et al., 2010). The characteristics of the PTs were similar between the compared groups and overall representative for PTs working in primary care in Sweden (Swedish National Board of Health and Welfare, 2022) which strengthens the internal and external validity. With a reasonably good external validity, the present study results are generalizable to patients with LBP treated in physiotherapy care in Swedish primary health-care and in similar health-care systems internationally.

Conclusion

This study provides further insight into best practice physiotherapy for patients with LBP by formally testing the hypotheses for the underlying theoretical rationale. No indirect effects were identified mainly due to the BetterBack intervention not having superior effects over routine care on the hypothesized mediators. The study results support that patients' illness perceptions and self-care enablement are associated with disability and back pain intensity outcomes. This indicates that these are potential treatment targets in interventions for patients with LBP, and also suggests that these factors in the CSM underpin the target of the BetterBack intervention in line with evidence-based practice. This adds to the theoretical understanding and development of treatment for patients with LBP. Still, the causal mediating relationships and the importance of patients' illness perceptions and self-care enablement for treatment effect on disability and back pain intensity need to be confirmed in future studies.

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