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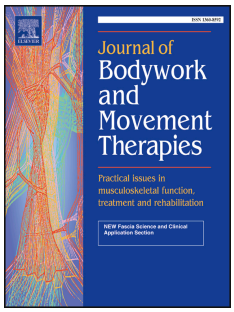

Musculoskeletal shoulder pain: Home exercise frequency and adherence to appointments are not mediators of outcome

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Title Page

Musculoskeletal shoulder pain: Home exercise frequency and adherence to appointments are not mediators of outcome.

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relevant to the submitted work; and (4) the authors have no non-financial interests that may be relevant to the submitted work."

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Ethics approval This was obtained from the National Research Ethics Service, East of England - Norfolk, UK in July 2011 (reference 11/EE/0212).

Transparency declaration: The lead author (the manuscript's guarantor) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Credit author statement

Rachel Chester: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Roles/Writing – original draft; Writing – review & editing. **Mizan Khondoker**: Conceptualisation, Formal analysis; Methodology; Investigation, Validation; Roles/Writing – original draft; Writing – review & editing. **Christina Jerosh Herold:** Conceptualization; Methodology; Supervision; Writing – review & editing. **Claire Gurney** Formal analysis; Investigation; Methodology; Writing – review & editing. **Jeremy Lewis** Conceptualization; Supervision; Validation; Writing – review & editing. **Lee Shepstone** Conceptualization; Methodology; Supervision; Validation; Writing – review & editing.

Data sharing: No additional data available.

Patient involvement: Patient and public representatives were involved in the design of the study, in particular, details associated with the timing and procedures for recruiting and follow up of participants, and the design and layout of questionnaires for data collection, including the original and amended versions of the 6 week exercise diary. A lay version of results, designed with patient and public representatives, were disseminated to all study participants who at their final data collection replied that they would like a copy. Patients were not involved in the actual recruitment or conduct of the study.

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Main Manuscript

INTRODUCTION

Up to 18% of people visiting their general practitioner or primary care physician with musculoskeletal shoulder pain are referred to a physiotherapist [24]. Current research favours exercise and promotion of self-management as ~~key interventions~~ treatment [1]. This may be supported by a limited amount of additional treatments such as manual therapy and acupuncture [33]. However, response to treatment is variable [10 11]. Several baseline prognostic factors have been associated with outcome after a course of physiotherapy for shoulder pain [2 10 13] A Classification and Regression Tree analysis reported the predictive value of baseline prognostic factors in a hierarchy of importance [12]. In 810 people with shoulder pain attending physiotherapy, apart from baseline pain and disability, baseline pain self-efficacy and patient expectation of recovery "as a result of physiotherapy treatment" were the two most important predictors of patient rated pain and disability six months later [12]. Self-efficacy is a construct introduced by Bandura [4]. In the context of this paper, pain self-efficacy is defined as the confidence a person has in his or her own ability to complete certain tasks or behaviours, despite their shoulder pain, and is measured using the pain self-efficacy questionnaire (PSEQ) [31].

Patient expectation and pain self-efficacy may be associated with outcome directly and/or through a third variable, or "mediator". That variable may be adherence. Generally, adherence to physiotherapy treatments is low [31]. We hypothesise that low adherence, that is, not attending appointments and not carrying out an agreed home exercise programme (HEP) as frequently as prescribed detrimentally impacts the effectiveness of physiotherapy. We hypothesise that patients will have increased motivation to attend physiotherapy appointments and carry out home exercises more frequently if they already have an expectation of a good outcome and high pain self-efficacy [12 16].

Self-efficacy is measured specific to a task or context. *Exercise self-efficacy* is a specific measure of ~~one's~~ a person's confidence to carry out an exercise rehabilitation programme. Research shows that higher levels of exercise self-efficacy, have been associated with greater adherence to physiotherapy prescribed home exercise programmes for low back and neck pain [21 27], and heart failure [21 37]. However, these studies do not report whether there is an association between exercise self-efficacy and the actual outcome of treatment[21, 23, 27, 37]. Pain s*elf-efficacy* in the context of this study, does not specifically refer to the patient's confidence in their ability to exercise, or engage with physiotherapy but rather their confidence engaging with everyday activities. It's association with adherence has not been investigated.

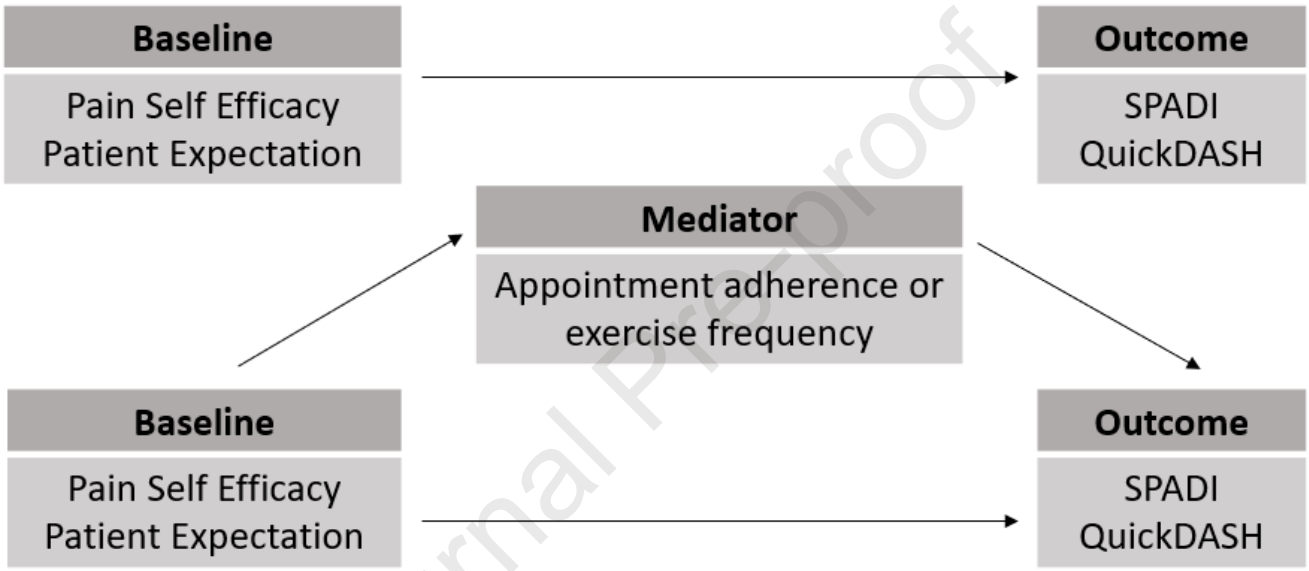
The aims of this exploratory analysis were to investigate whether adherence to physiotherapy appointments and frequency of home exercise, mediate (indirectly influence) the association between:

i) Baseline pain self-efficacy with pain and disability six months after starting a course of physiotherapy

ii) Baseline expectation of recovery with pain and disability six months after starting a course of physiotherapy

We hypothesise that the effect of pain self-efficacy and patient expectation on outcome at six month follow up is mediated (indirectly influenced) by adherence to home exercise appointments and frequency of home exercise. In summary, is adherence one of the mechanisms by which pain self-efficacy or patient expectation effects outcome.

Figure 1: Hypothesized causal pathway between baseline pain self-efficacy and patient expectation with outcome at 6 months.



METHODS

Study design and participants

Six months follow up data was available for 810 of 1030 people (79%) with musculoskeletal shoulder pain who participated in a multicentre, longitudinal cohort study in East Anglia, United Kingdom between 2011 and 2013. The study protocol, including patient and public involvement (PPI), has been published [14]. Participants, recruited from primary and secondary care, were eligible if they were 18 years and over and presented with any type of musculoskeletal shoulder pain reproduced on movement of the shoulder rather than the spine. Patients presenting with previous shoulder fractures, traumatic dislocations, shoulder surgery, cervical radiculopathy or a systemic source of shoulder pain were excluded. Treatment and referral pathways were unaffected by participation in the study.

Baseline measures

Participants were sent and completed an 8-page booklet of questions prior to their first physiotherapy appointment. This included measures of pain self-efficacy and patient expectation of recovery.

Pain self-efficacy at baseline

The Pain self-efficacy questionnaire (PSEQ), consisting of 10 items ranging from a score of 0 to 6 [31] was selected given its reported psychometric properties for musculoskeletal conditions [28 31]. A score of 60 represents the highest pain self-efficacy and a score of zero represents the lowest.

Patient expectation at baseline

Patient expectation of recovery was determined in response to the following question "How much *do you expect* your shoulder problem to change as a result of physiotherapy treatment". Responses were recorded on a 7-point Likert scale ranging from "completely recover" to "worse than ever". Twenty four percent of participants expected to "completely recover", 52% "much improve", 19% slightly improve, and 4% "no change", "slightly worse", "much worse" or "worse than ever". These responses were dichotomised into two categories for this analysis: "completely recover" and "much improve" (higher expectation) versus "slight improvement", "no change", "slightly worse", "much worse" or "worse than ever" (lower expectation).

Proportion of appointments attended

Participant attendance and whether they completed their course of physiotherapy was recorded by the treating physiotherapist on a custom designed clinical record form. Proportional appointment adherence was calculated by dividing the number of appointments attended by the total number of appointments provided, expressed as a percentage. The total number of appointments provided included those which i) the patient attended, ii) the patient later changed ("unable to attend") and iii) the patient did not attend and did not cancel in advance ("did not attend"). Completing a course of physiotherapy was defined as attending or proactively cancelling the final appointment as opposed to nonattendance without contact. This data was available for all 810 participants with 6 months outcome data.

Proportion of days home exercises completed

Over 99 percent of participants were prescribed a home exercise programme. Home exercise completion within the first six weeks after the initial physiotherapy appointment, irrespective of the agreed frequency with which exercises were prescribed, was recorded by the participant in an exercise diary, custom designed for the study and provided by the assessing physiotherapist at the first appointment. There are currently no reliable measures of frequency of exercise or adherence to a physiotherapy prescribed home exercise programme and no consensus on how these should be measured [3 8 26]. Self-report exercise diaries are the most common method of data collection for this population [3]. The participant was sent two reminders if the exercise diary had not been returned by email or the United Kingdom's Royal Mail service to the Chief Investigator by seven weeks post initial physiotherapy appointment. Six hundred and twenty-four (77%) of the 810 participants who provided 6 months

outcome data also completed and returned their 6-week exercise diaries. The proportion of days on which exercises were completed was calculated by dividing the number of days exercise participation had been recorded in the home exercise diary during the first six weeks/42 days (n=x/42). This proportion is presented as a percentage. The results are therefore not a measure of adherence but rather proportional frequency of home exercise.

Outcome measures

Two patient rated outcome measures were collected prior to participants' first appointment and via postal questionnaire at six months follow up: the Shoulder Pain and Disability Index (SPADI) [25 35] and Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) [6]. Our analysis includes both the total SPADI score and the pain and disability sub-scores independently. Scores are expressed as a percentage where zero represents no pain or disability and 100 represents maximum pain and/or disability.

Statistical Analysis

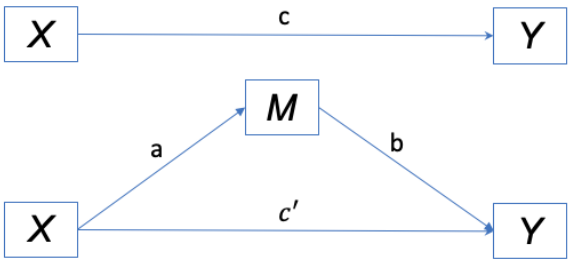
The mediation analysis in this paper was based on secondary data already collected for another study by our team[14]. The original study was adequately powered to detect a small effect size of 0.25 with 90% power. The sample size with available data for fitting various analytical models in our mediation analyses ranged between n=624 and n=810. These sample sizes are well within the limits recommended by Fritz and MacKinnon[17] for detecting even a small mediation effect (0.14) with 80% power.

Our mediation analysis investigates if the association between baseline pain self-efficacy or patient expectation (represented as X in figure 2) and outcome (the SPADI or QuickDASH represented as Y in figure 2) is affected by one or more additional variables or "mediators" (represented by M in figure 2). See figure 1 for a clinical explanation and figure 2 for details of our statistical model. Our hypothesised mediators (M) are measures of appointment adherence and proportion of days on which exercises were completed.

Our mediation analysis used the four-step method described by Baron and Kenny [5]. This is illustrated in figure 2. Step 4 is only needed if the results of step 3 are significant. Initial *simple mediation* (using just one mediator at a time) allowed us to use all the available data rather than omitting those participants without full records, for example, no exercise diary. If the simple mediation analyses identified two or more mediating variables as statistically significant, the next step would be to assess the role of all significant mediating variables simultaneously using a multiple mediation model. The 95% confidence intervals of the mediation effects were constructed via the bootstrap method (i.e., by taking 5000 repeated random samples from the original study cohort). using the process macro for SPSS (25). Baseline pain and disability scores were significantly correlated

with pain self-efficacy and patient expectation and were therefore not included in this analysis. This was to avoid potential unstable results due to multicollinearity.

Figure 2: (A) Simple mediation model; (B) Baron & Kenny four-step approach for mediation analysis.



(A): Simple Mediation Model.

Step 1: Use a simple regression model of Y on X to show that the exposure is associated with the outcome: $Y = i_1 + cX$.

Step 2: Use a simple regression model of M on X to show that the exposure is associated with the mediator: $M = i_2 + aX$.

Step 3: Use a multiple regression model of Y on X and M to show that the mediator (after controlling for the exposure) is associated with the outcome: $Y = i_3 + c'X + bM$.

Step 4: Use same model in Step 3 to quantify the direct effect (c') of the exposure (after controlling for the mediator) on the outcome.

(B): Baron and Kenny (1986) four-step approach for simple mediation analysis.

In our simple mediation model, we hypothesise that the total effect (***c***) of pain self-efficacy or patient expectation (X), on outcome (Y) can be via *two pathways*:

- A *direct effect* (path $\boldsymbol{c'}$)
- An *indirect effect* (path **ab**), the focus of this paper.

Path **a** represents the effect of pain self-efficacy or patient expectation (X) on adherence (M).

Path **b** represents the effect of adherence (M) on outcome (Y).

The total effect (**c**) of self-efficacy and patient expectation on outcome = $\boldsymbol{c' + ab}$

Both our outcomes and two of our three mediators ("proportion of days exercises completed" and "proportion of appointments attended") are continuous variables. Linear regression modelling using the Baron and Kenny[5] method followed by the test of indirect effect via the bootstrap approach was therefore applicable.

We included one binary mediator, whether the patient completed their course of physiotherapy. For this binary mediator the standard formula for calculating indirect effect does not hold. Instead, we interpreted the results along the lines of the Baron and Kenny method[5] with path **a** estimated via a logistic regression model, reported as odds ratio [OR=exp(a)].

RESULTS

Descriptive Statistics

The 810 participants who provided six-month outcome data were different to those who did not. Those who provided outcome data had higher pain self-efficacy scores by a mean of almost 4 out of a possible 60 points, attended a higher proportion of appointments (93% versus 82%), were more likely to complete their course of physiotherapy, (86% versus 59%), and return their exercise diary to the Chief Investigator (77% versus 16%). Participants who provided 6-month outcome data did not differ from those who did not provide 6 months outcome data in terms of patient expectation of recovery.

Table 1: Descriptive data for Demographics, Adherence, Proportion of days on which exercises were completed and Outcome at six-month follow up (n=810)

Variable		Frequency (%)/Mean (SD)
Age		59 (40)
Male/Female		363/447 (45/55)
Duration of Shoulder Pain (Months)		13 (26)
Baseline: Severity of shoulder pain at rest (0-10 NRS*)		3 (3)
Baseline: SPADI Total Score		49 (21)
Baseline: SPADI Pain sub score		28 (10)
Baseline: SPADI Disability sub score		35 (19)
Baseline: QuickDASH		38 (18)
Baseline : Pain self-efficacy Questionnaire Score x/60		45 (13)
Baseline: "*Patient expectation of outcome as a result of physiotherapy*"	Improve	617 (76)
	Same or Worse	196 (24)
Exercise Diary returned to Chief Investigator	No	186 (23)
	Yes	624 (77)
Adherence: Completed Course of Physiotherapy	No	110 (14)
	Yes	700 (86)
Adherence: Proportion of days home exercises completed in first 6 weeks		24/42 (SD=9) (n=624)
Outcome: SPADI Total Score		24 (24)
Outcome: SPADI Pain Subscale		28 (26)
Outcome: SPADI Disability Subscale		21 (23)
QuickDASH		20 (20)

Step 1

Without exception i) higher pain self-efficacy and ii) a higher expectation of recovery as a result of physiotherapy at baseline, are significantly associated with a reduction in pain and disability for all outcomes at six month follow up.

Further details: This analysis can be viewed as "path c" in tables 2, 3 and supplementary file 1. For example, the association between baseline PSEQ and six-month QuickDASH has an estimate of -0.74, p<0.001, 95% CI: -0.83, -0.64. An estimate of -0.74 indicates that for every one-point increase in baseline pain self-efficacy score there is a 0.74% decrease in pain and disability (measured by the QuickDASH) at six month follow up. We have 95% confidence that the true value lies between 0.83% and 0.54%. A p value of p<0.001 means that there is less than one in a thousand probability of these findings being due to chance.

Step 2

Pain Self-Efficacy and Adherence

Higher pain self-efficacy was associated with higher appointment adherence and higher odds of completing a course of physiotherapy but not the proportion of days the participant stated they completed their home exercises.

Further details: Table 2, path a: 0.11, p=0.003, 95% CI: 0.19, 0.04 indicates that for every one-point increase in baseline pain self-efficacy score, the proportion of appointments attended increased by 0.1%. We can be 95% confident that the true value lies between 2% and 0.4% and that there is a three in a one thousand probability that these findings are due to chance.

Supplementary file 1, Path exp a: OR 1.02, p=0.001, 95% CI: 1.01, 1.03 indicates that for every one-point increase in baseline pain self-efficacy score, the odds of completing a course of physiotherapy increased by 2%. We can be 95% confident that the true value lies between 1% and 3% and that there is a one in a one thousand probability that these findings are due to chance.

Expectation of Recovery and Adherence

Higher expectation of recovery was associated with a higher proportion of days the participant stated they completed their home exercises but was not significantly associated with appointment adherence or completing a course of physiotherapy.

Further details

Table 3, path a: 5.45, p=0.006, 95%CI 1.56, 9.34 indicates that for participants expecting to recover compared to those not expecting to recover, there is 5.4% increase in the proportion of days with which they complete their home exercises. We can be 95% confident that the true value lies between 1.6% and 9.3% and that there is a six in one thousand probability that these findings are due to chance.

Steps 3 & 4

After controlling for the effect of pain self-efficacy and patient expectation, neither appointment adherence, completing a course of physiotherapy, or the proportion of days on which exercises were completed, had a significant effect on outcome. This indicates that the effect of pain self-efficacy and patient expectation on the outcomes we measured are not mediated (indirectly influenced) by these adherence factors. Adherence is not the mechanism by which pain self-efficacy or patient expectation effect our outcomes. These results can be viewed in table 2 and supplementary file 1 for self-efficacy (paths b and c' and then path ab) and table 3 and supplementary file 1 for expectation (paths b and c').

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Table 2: Results of mediation analysis for Pain Self-Efficacy and continuous adherence measures at 6 months: Baron and Kenny method and the bootstrap test of indirect effect (ab). Legend: Outcome Y, Exposure X: PSEQ score, Mediator(s) M: proportion of appointments attended, and proportion of days home exercises completed

		Baron and Kenny Method						
Outcome (Y), Exposure (X) and Mediator (M)	**Paths (Coef.)**	Step 1: $\boldsymbol{Y = i_1 + cX}$ Step 2: $\boldsymbol{M = i_2 + aX}$ Steps 3 & 4: $\boldsymbol{Y = i_3 + c'X + bM}$			**Test for the indirect (mediated) effect: ab = 0 (Bootstrap method)**			
		Estimate (SE)	p-value	95% CI	*Coefficient*	*Estimate*	*SE*	*95% Bootstrap CI*
Y: SPADI at 6 months	c	-0.76 (0.06)	<0.001	-0.88, -0.64				
X: PSEQ	a	0.11 (0.04)	0.003	0.04, 0.19	Indirect effect	-0.002	0.005	-0.013, 0.007
M: Proportion of	b	-0.02 (0.06)	0.685	-0.14, 0.09	(ab)			
appointments attended	$\boldsymbol{c'}$	-0.76 (0.06)	<0.001	-0.88, -0.64				
Y: SPADI at 6 months	c	-0.76 (0.06)	<0.001	-0.88, -0.64				
X: PSEQ	a	0.05 (0.07)	0.433	-0.08, 0.19	Indirect effect	-0.001	0.004	-0.012, -0.007
M: Proportion of days	b	-0.03 (0.04)	0.446	-0.11, 0.05	(ab)			
exercises completed	$\boldsymbol{c'}$	-0.64 (0.07)	<0.001	-0.78, -0.50				
Y: SPADI Pain at 6 months	c	-0.78 (0.07)	<0.001	-0.92, -0.65				
X: PSEQ	a	0.11 (0.04)	0.003	0.04, 0.19	Indirect effect	-0.002	0.005	-0.015, 0.008
M: Proportion of	b	-0.03 (0.06)	0.648	-0.15, 0.09	(ab)			
appointments attended	c’	-0.78 (0.07)	<0.001	-0.92, -0.65				

Y: SPADI Pain at 6 months	c	-0.78 (0.07)	<0.001	-0.92, -0.65				
X: PSEQ	a	0.05 (0.07)	0.433	-0.08, 0.19	Indirect effect	-0.002	0.005	-0.014, 0.007
M: Proportion of days	b	-0.05 (0.04)	0.307	-0.13, 0.04	(ab)			
exercises completed	c’	-0.66 (0.08)	<0.001	-0.82, -0.51				
Y: SPADI Disability at 6 months	c	-0.73 (0.06)	<0.001	-0.85, -0.61				
X: PSEQ	a	0.11 (0.04)	0.003	0.04, 0.19	Indirect effect	-0.0014	0.005	-0.012, 0.008
M: Proportion of	b	-0.02 (0.06)	0.749	-0.13, 0.09	(ab)			
appointments attended	c’	-0.73 (0.06)	<0.001	-0.85, -0.61				
Y: SPADI Disability at 6 months	c	-0.73 (0.06)	<0.001	-0.85, -0.61				
X: PSEQ	a	0.05 (0.07)	0.433	-0.08, 0.19	Indirect effect	-0.001	0.004	-0.010, 0.008
M: Proportion of days	b	-0.02 (0.07)	0.674	-0.10, 0.06	(ab)			
exercises completed	c’	-0.62 (0.07)	<0.001	-0.76, -0.48				
Y: QDASH at 6 months	c	-0.74 (0.05)	<0.001	-0.83, -0.64				
X: PSEQ	a	0.11 (0.04)	0.003	0.04, 0.19	Indirect effect	-0.003	0.004	-0.012, 0.004
M: Proportion of	b	-0.04 (0.05)	0.425	-0.13, 0.05	(ab)			
appointments attended	c'	-0.74 (0.05)	<0.001	-0.83, -0.64				
Y: QDASH at 6 months	c	-0.74 (0.05)	<0.001	-0.83, -0.64				
X: PSEQ	a	0.05 (0.07)	0.433	-0.08, 0.19	Indirect effect	-0.001	0.003	-0.008, 0.006
	b	-0.01 (0.03)	0.734	-0.07, 0.05	(ab)			

M: Proportion of days exercises completed	c'	-0.66 (0.06)	<0.001	-0.77, -0.55

Table 3: Results of mediation analysis for Patient Expectation and continuous adherence measures at 6 months: Baron and Kenny method and the bootstrap test of indirect effect (ab). Legend: Outcome Y, Exposure X: PSEQ, Mediator(s) M: proportion of appointments attended and proportion of days home exercises completed

		Baron and Kenny Method						
Outcome (Y), Exposure (X) and Mediator (M)	**Paths (Coef.)**	Step 1: $\boldsymbol{Y = i_1 + cX}$ Step 2: $\boldsymbol{M = i_2 + aX}$ Steps 3 & 4: $\boldsymbol{Y = i_3 + c'X + bM}$			**Test for the indirect (mediated) effect:** ab = 0 **(Bootstrap method)**			
		Estimate (SE)	p-value	95% CI	*Coefficient*	*Estimate*	*SE*	*95% Bootstrap CI*
Y: SPADI at 6 months	c	-11.17 (1.96)	<0.001	-15.02, -7.31				
X: Patient Expectation	a	2.20 (1.16)	0.058	-0.07, 4.67	Indirect effect	-0.095	0.144	-0.450, 0.113
M: Proportion of	b	-0.05 (0.06)	0.384	-0.17, 0.07	(ab)			
appointments attended	c'	-11.12 (2.00)	<0.001	-14.99, -7.27				
Y: SPADI at 6 months	c	-11.17 (1.96)	<0.001	-15.02, -7.31				
X: Patient Expectation	a	5.45 (1.98)	0.006	1.56, 9.34	Indirect effect	-0.090	0.293	-0.712, 0.475
M: Proportion of days	b	-0.01 (0.04)	0.731	-0.10, 0.07	(ab)			
exercises completed	c'	-10.97 (2.20)	<0.001	-15.29, -6.64				
Y: SPADI Pain at 6 months	c	-11.91 (2.14)	<0.001	-16.12, -7.70				

X: Patient Expectation	a	2.20 (1.16)	0.058	-0.07, 4.47	Indirect effect	-0.105	0.158	-0.511, 0.134
M: Proportion of	b	-0.06 (0.07)	0.375	-0.19, 0.07	(ab)			
appointments attended	c′	-11.87 (2.15)	<0.001	-16.08, -7.65				
Y: SPADI Pain at 6 months	c	-11.91 (2.14)	<0.001	-16.12, -7.70				
X: Patient Expectation	a	5.45 (1.98)	0.006	1.56, 9.34	Indirect effect	-0.168	0.300	-0.816, 0.413
M: Proportion of days	b	-0.03 (0.05)	0.551	-0.12, 0.06	(ab)			
exercises completed	c′	-11.70 (2.39)	<0.001	-16.39, -7.01				
Y: SPADI Disability at 6 months	c	-10.43 (1.90)	<0.001	-14,16, -6.69				
X: Patient Expectation	a	2.20 (1.16)	0.058	-0.07, 4.47	Indirect effect	-0.084	0.138	-0.436, 0.128
M: Proportion of	b	-0.05 (0.06)	0.425	-0.16, 0.07	(ab)			
appointments attended	c′	-10.39 (1.90)	<0.001	-14.13, -6.65				
Y: SPADI Disability at 6 months	c	-10.43 (1.90)	<0.001	-14.16, -6.93				
X: Patient Expectation	a	5.45 (1.98)	0.006	1.56, 9.34	Indirect effect	-0.011	0.291	-0.583, 0.588
M: Proportion of days	b	-0.002 (0.04)	0.966	-0.08, 0.08	(ab)			
exercises completed	c′	-10.23 (2.15)	<0.001	-14.46, -6.00				
Y: QDASH at 6 months	c	-9.90 (1.61)	<0.001	-13.07, -6.74				
X: Patient Expectation	a	2.20 (1.16)	0.058	-0.07, 4.47	Indirect effect	-0.119	0132	-0.443, 0.072
M: Proportion of	b	-0.07 (0.05)	0.181	-0.17, 0.03	(ab)			
appointments attended	c'	-9.80 (1.61)	<0.001	-12.96, -6.63				

Y: QDASH at 6 months	c	-9.90 (1.61)	<0.001	-13.07, -6.74				
X: Patient Expectation	a	5.45 (1.98)	0.006	1.56, 9.34	Indirect effect	0.004	0.235	-0.491, 0.503
M: Proportion of days	b	-0.001 (0.04)	0.987	-0.07, 0.07	(ab)			
exercises completed	c'	-8.93 (1.81)	<0.001	-12.47, -5.39				

DISCUSSION

Our previous publications reported that high compared to low baseline pain self-efficacy and patient expectation of recovery predicted less pain and disability at six month follow up [10 12]. The objective of this analysis was to estimate whether i) attendance adherence and ii) the proportion of days on which home exercises were completed, are mechanisms by which pain self-efficacy and patient expectation of recovery, affect the outcome of physiotherapy.

As hypothesised, patients with high baseline pain self-efficacy were more likely to i) complete their course of physiotherapy (attend the final appointment, as opposed to nonattendance without contact) and ii) attend a higher proportion of scheduled appointments. Patient expectation was not significantly associated with completing a course of physiotherapy or appointment attendance.

People with a higher expectation of recovery reported doing their home exercises more frequently, although this was not associated with outcome. Pain self-efficacy did not predict the proportion of days with which home exercises were completed.

Appointment adherence, completing a course of physiotherapy, and proportion of days home exercises are completed do not appear to be the mechanisms by which baseline pain self-efficacy and patient expectation affect outcome at six month follow up.

Exercise self-efficacy has been associated with and identified as a potential predictor of adherence to home exercise programmes provided by physiotherapists in other studies. [21 37] Exercise self-efficacy refers to beliefs specifically associated with the confidence to carry out and persist with exercises despite the challenges, examples of which include, time constraints, boredom, social and work responsibilities. Pain self-efficacy, measured by the PSEQ, does not measure, or refer to self-efficacy for exercise but rather activities of daily living, leisure, socialising, and working. The PSEQ does not have any items related to perceived confidence in the ability to carry out rehabilitation or home exercises. This may explain the disparity between our results and those of other researchers with respect to the absence of an association in the current study between self-efficacy and exercise frequency. In addition, we cannot rule out the possibility that the relationship between pain self-efficacy and our outcomes may be in part attributed to some similar items within the respective questionnaires.

Self-efficacy theory originally differentiated patient outcome expectancies from self-efficacy,[4] although emerging evidence suggests that outcome expectancy and self-efficacy are positively associated [7, 38]. However, this refers to expected outcomes that are a result of the task for which self-efficacy is being measured. In our study, this was not the case; outcome expectancy was a judgement of the "likely recovery as a result of physiotherapy treatment" and did not explicitly refer to home exercise. When we collected data, patients may not have known that exercise was a key component of physiotherapy and may have envisaged the physiotherapist offering more hands-on treatment.

Strengths and Limitations

This is the first published study investigating whether appointment adherence and frequency of exercise completion are mechanisms by which baseline pain self-efficacy and/or patient expectation contribute to outcome at six month follow up. This multicentre cohort study is the largest in Europe and the first worldwide to investigate the association of a range of biopsychosocial factors at the start of treatment with the outcome of physiotherapy.

Twenty percent of participants were lost to follow up at 6 months and were different from those who completed the study. They were nearly 5 times less likely to return their exercise diary, two thirds less likely to complete their course of physiotherapy and had slightly less pain self-efficacy. Patient expectation of recovery, rated prior to starting treatment, and whether participants received "hands on treatments" in addition to exercise did not differ between the groups. However, the differences between those available at follow up and those who were not, whist unavoidable, does raise the question of whether the results would be different had six weeks exercise diaries and six months outcome data been available for all study participants.

Self-reported exercise diaries have limitations, especially the accuracy of inputting correct data. They may be completed retrospectively and confounded due to under or over reporting. Social desirability bias may lead to a systematic error, in which adherence is over-reported and hides true differences associated with lower levels of exercise frequency or adherence [15 20] Self-reported physical activity rates are often higher than observed rates [15 32] and this may have led to lack of statistical significance in terms of the mediating effect of exercise frequency. Technological advances, including real time capture, may result in more accurate measures of exercise frequency [9].

There is no evidence base and no consensus on the optimal frequency of home exercise [30]. Many physiotherapists advocate a period of recovery and repair in between exercises that incorporate heavy loads, plyometrics or fatiguing exercise [30] However, some exercises, for example, for immediate post-operative management, may be designed primarily to facilitate patient confidence and restore basic shoulder function and be advised on a more frequent basis. A primary target of treatment and exercises may be improving low pain self-efficacy or reducing fear avoidance. In this instance daily exercises or for some patients, physical activity rather than specific exercises may be more appropriate. Daily frequency does not reflect the complex individualised approach to exercise prescription and the nuances of exercise adherence, for example, that some participants may have initially adhered and then stopped if recovery was quick. It is therefore not surprising that it was not associated with outcome for the broad spectrum of shoulder symptoms experienced by participants in our study. We recommend that future randomised controlled trials, in which treatment protocols are developed that require uniform frequency of prescribed exercises for all participants in any one treatment category, include measures of pain and exercise self-efficacy and adherence to see if our findings are replicated.

Rather than strict adherence to a prescribed home exercise programme, contemporary practice favours patient activation, defined as having the knowledge, skills and confidence to competently manage one's health [19 20]. This may require for example, goal setting to identify the factors most important to the patient. However, this is not a straight forward process. [28 36] Higher self-efficacy has been associated with higher patient activation levels in patients with heart failure [15]. However, this has not been investigated in people with musculoskeletal conditions and is a recommended area for future research.

Our findings highlight that the promotion of pain self-efficacy and patient expectations of recovery should be considered an essential component of treatment. Other unknown mechanisms may affect (mediate) the association between pain self-efficacy and outcome. For example, people with high pain self-efficacy, if they need reassurance at all, may be more receptive to reassurance that physical activity is safe, with consequent reduction in fear avoidance and pain related worrying, and increased movement of the shoulder in functional activities. Indeed, some participants with high pain self-efficacy may have chosen not to complete their home exercises on a more regular basis and attend follow up appointments because they felt able to accomplish their goals, self-manage their symptoms and return to activities independent of their physiotherapist.

Conclusion

Clinical outcome at six months does not appear to be predicted by either appointment adherence, or self-reported proportion of days on which home exercises are completed. The findings of this mediation analysis suggest that these ~~variables~~ factors are not the mechanisms by which pain self-efficacy and patient expectation ~~predict~~ are associated with outcome. This study was not designed to address the effectiveness or ideal dose of HEP for which no conclusions should be drawn. However, our results do support the need for a greater emphasis on the assessment and incorporation of techniques to facilitate high pain self-efficacy and expectation of recovery.

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HIGHLIGHTS

Pain self-efficacy (PSE) and patient expectation are associated with 6 months outcome

Appointment adherence is not the cause of this association

Frequency of home exercise (HE) is not the cause of this association

Higher PSE is significantly associated with appointment adherence

Patient expectation is significantly associated with self-reported HE frequency

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