

## Independent validation of the Pain Management Plan in a multi-disciplinary pain team setting

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#### **Abstract**

**Context/background:** The Pain Management Plan (PP) is a brief cognitive behavioural therapy (CBT) self-management programme for people living with persistent pain that can be individually facilitated or provided in a group setting. Evidence of PP efficacy has been reported previously by the pain centres involved in its development.

**Objectives:** To provide a fully independent evaluation of the PP and compare these with the findings reported by Cole et al.

**Methods:** The PP programme was delivered by the County Durham Pain Team (Co. Durham PT) as outlined in training sessions led by Cole et al. Pre- and post-quantitative/patient experience measures were repeated with reliable and clinical significant change determined and compared to the original evaluation

**Results:** Of the 69 participants who completed the programme, 33% achieved reliable change and 20% clinical significant change using the Pain Self-Efficacy Questionnaire (PSEQ). Across the Brief Pain Inventory (BPI) interference domains between 11% and 22% of participants achieved clinical significant change. There were high levels of positive patient feedback with 25% of participants scoring 100% satisfaction. The mean participant satisfaction across the population was 88%.

**Conclusion:** The results from this evaluation validate those reported by Cole et al. It demonstrates clinically significant improvement in pain and health functioning and high patient appreciation results. Both evaluations emphasise the potential of this programme as an early intervention delivered within a stratified care pain pathway. This approach could optimise the use of finite resources and improve wider access to pain management.

## **Keywords**

Persistent pain, pain management plan, cognitive behavioural therapy, self-management, early intervention, clinical significance, reliable change index, improve access

## Introduction

The Pain Management Plan (PP)<sup>1</sup> is a self-management programme for people living with persistent pain. The PP was written by Lewin, at the suggestion of Cole, as a way to bring cognitive behavioural therapy (CBT)-based pain management to a greater number of people from diverse backgrounds. It provides a useful tool with which evidence-based self-management<sup>2,3</sup> can be introduced into this field. Lorig and Holman defined a self-management programme as a process for people to learn skills to manage their health and

maintain active fulfilling lives. This includes managing the physical symptoms due to their clinical conditions,

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emotional needs and gaining skills of problem solving, decision-making, resource utilisation, the formation of patient-provider partnership, action planning and self-tailoring. However, there is no single one definition of a self-management programme. Perhaps the lack of a specific definition is in part due to the wide application of this type of programme to include various long-term conditions such as diabetes, asthma, chronic obstructive pulmonary disease, pulmonary heart disease and arthritis. The PP, however, would fall within Lorig's definition of a self-management programme, including all tasks and skills described.

The self-management approach such as the PP is an effective6 and low-cost option that can ensure more people receive prompt pain management input. This is significant since across England over one in three adults reported chronic pain (men 31% women 37%). Only a third of these accessed specialist pain services at a hospital or clinic that included a doctor, nurse or physiotherapist.7 This is wholly inadequate when considering the social, psychological and financial impact pain has on the British society. Twentyfive percent of people with persistent pain reported losing their job, with 16% changing jobs or working hours and 25% are diagnosed with depression.8 An independent evaluation of the PP is important to determine if this is an effective intervention to be used with those people in persistent pain, and also for how it could transform the delivery of finite pain management resources.

Evidence of PP efficacy has only been published by Cole et al. Training sessions delivered by Cole and others have resulted in around 30 healthcare providers adopting the PP for use with people suffering from persistent pain. The first of these training days was in December 2011 hosted by the Co. Durham Pain Team (Co. Durham PT) who conducted the first independent service evaluation reported here. This evaluation of the PP employed the same outcome measures as the original evaluation of self-efficacy, health functioning and patient feedback; the only exception being Cole et al. who used the Pain Disability Questionnaire (PDQ) and this evaluation the Brief Pain Inventory (BPI) short form.

#### Aim

To provide an independent evaluation of the PP as delivered in a NHS Pain Team and compare these with the findings reported by Cole et al.

## **Methods**

PP participants were under the care of Co. Durham PT and had attended a medical assessment prior to PP

referral. There were three referral routes including the following:

- Referral by the Pain Medicine Specialist at an initial assessment or subsequent reviews;
- Multi-disciplinary team referral, that is, Nurse, Physiotherapist, Psychologist and Occupational Therapist;
- Self-referral at educational talks co-led by Physiotherapy and Psychology, which gives a biopsychosocial explanation of persistent pain and orientates the patient to the pain management approaches.

#### Selection criteria

The inclusion and exclusion criteria are based upon the British Pain Society<sup>9</sup> guidelines for Pain Management Programmes. All those referred for the individual PP programme would attend an initial appointment with the Pain Management Worker. This session is used to determine if the person fulfils the inclusion criteria and is receptive to the self-management approach. The PP groups were recruited predominately via patient opt-in following attendance of educational talks. The opt-in process is guided by the Psychologist and Physiotherapist who use these educational talks to conduct an informal assessment of people's suitability for a group programme.

#### Recruitment process

Figure 1 describes the recruitment process in terms of numbers of people selected for PP, non-completers and incomplete data sets.

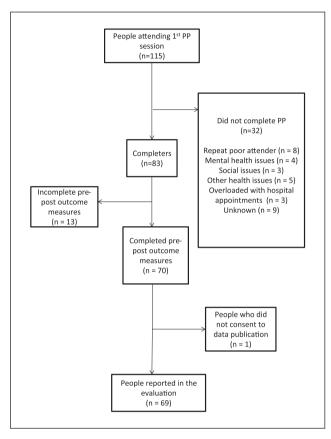
## Delivery of the PP

The PP delivery (both individual and groups sessions) closely followed a specific training programme issued by Cole et al. (Table 1). Sixty participants opted for 3–6 individual sessions and 10 opted for 4×2 hour group sessions. The Pain Management Worker facilitated all the individual sessions and co-led the groups. The groups were also co-led by a Physiotherapist Specialist. The Pain Management Worker role is unique to this team but is essentially a graduate band 5 position that is managed by the multi-disciplinary team (MDT) and supervised by Psychology. This person provides pain management advice and education as well as drawing on psychological theories such as CBT.

## Training

The Pain Management Worker and Physiotherapist Specialist had attended the recommended one day

training led by Cole et al. as well as optional 'skills topup' days ran within the North East of England. Although, the competency of these health-care professionals to deliver the PP was not assessed both had spent more than 4 years providing pain management education and being supervised within in a multi-disciplinary pain team in a NHS service.



**Figure 1.** The number of participants and dropouts in the evaluation process.

## Statement of ethics approval

The project was granted permission for publication by the Co. Durham and Darlington NHS Foundation Trust (CDDFT) Clinical Quality and Patient Experience committee.

#### Informed consent

One participant did not provide full written and informed consent to the completion, collection and presentation of quantitative outcome measures and closed evaluative questions. This reduced the cohort to n=69.

#### Outcome measures

The quantitative outcome measures selected were Pain Self-Efficacy Questionnaire (PSEQ)10 and short form BPI.11 These measures were chosen since they are recognised persistent pain measures,12 internally stable,13 sensitive to change14 and have a defined minimal clinical improvement. 15 Both evaluations used the same statistical analysis of the PSEQ to allow for a direct comparison of reliable change index/clinically significant change (RCI/CSC) percentages between Cole et al. and Co. Durham PT. This was possible since Cole et al. re analysed their PSEQ data (Cole F, Ashworth P and Lewin R, personal communication, 2015). The BPI was not used in the original evaluation as the PDQ was their second quantitative measure. In this evaluation, the BPI was preferred over the PDQ since it was being used routinely within the Co. Durham PT and could inform pain pathways within this service. Two other measures included a health needs assessment (HNA) and an evaluative questionnaire. Both were used in the original evaluation, although only the evaluative questionnaire data were published.

Table 1. Outline of the PP.

Sections	Description			
Diary sheets	Goals are set and documented which initiate key behavioural changes needed for the long-term self-management of pain.			
	The diary sheets allow for the monitoring and gradual progression of goals related to physical activity, relaxation and fun.			
Relaxation CD	Ten tracks to assist with relaxation using breathing, autogenic and concentration/meditation techniques.			
Book	The book has a multi-ethnic context, with a reading age of 9–10 (Flesch–Kincaid formulae), short stories, guizzes, cartoons and humour.			
	Part 1: Introduces self-management and tackles the common misconceptions that can lead to the pain cycle. Key pain management skills of stress awareness, pacing and goal-setting.  Part 2: An opportunity to highlight issues related to life with pain and devise potential solutions.  The areas covered include sleep problems, low mood, anxiety, relationships and flare-ups.			

PP: Pain Management Plan.

#### **PSFQ**

PSEQ measures the confidence people have in doing various tasks despite their pain such as enjoying hobbies/interests or becoming more active. The PSEQ is a 10-item tool with a series of 0–6 scales, where 6 = fully confident.

## BPI (short form)

BPI short form has been used since it is the standard for use within clinical and research settings. <sup>16</sup> This version of the BPI measures the *intensity* of pain over a 24-hour time period, that is, the worst, least and average pain and the *interference* in seven particular domains such as sleep, activity and mood. It is an 11-item tool with a series of 0–10 scales, where 0=least interference/intensity. All BPI domains are documented as a value between 0 and 10 to allow for easy comparison between pre–post values.

#### HNA

People were asked to select their top three 'important to change' problems as part of a HNA that included 18 domains such as walking or moving about, disturbed sleep and managing mood. People's responses to the HNA assessment determine which aspects of the PP are covered in detail for that individual.

# Closed programme evaluative questions

Seven closed evaluative questions designed by the original evaluators were used to measure the patients' view of the programme. The questions covered areas around explanation of programme, time and support given, ease to understand content and confidence to work on goals. On a five-point scale, responses are: 'yes' (3 points), 'mostly yes' (2 points), 'mostly no' (1 point) and 'no'/'don't know' (0 points). A person with a 100% satisfaction would score a maximum of 21 points.

## Statistical methods

A Real Statistics Resource<sup>17</sup> Pack has supplemented the existing Excel 2010 programme to extend its statistical analyses. CSC and RCI have been determined using a Jacobson and Truax<sup>18</sup> method and computer programme designed by Morley and Dowzer.<sup>19</sup>

#### **RCI**

The RCI defines a baseline value from which individuals have 'improved' and made a reliable change.<sup>20</sup>

In order to calculate RCI, pre–post scores are required as well as a value of internal consistency for each outcome measure such as Cronbach's alpha. The Cronbach's alpha value for PSEQ is defined as 0.92. The RCI was calculated as a gain of 10 PSEQ points or more for both evaluations. For the BPI interference domains the Cronbach alpha coefficient was 0.88 (0.85 for pain intensity)<sup>21</sup> and RCI was a 1.80–2.61 point or more improvement depending on the particular BPI domain.

## CSC

CSC is movement towards a normal functioning population. CSC is calculated using cut scores which are continuous variables that essentially relate to normal distribution. CSC has occurred when an individual has made a reliable change and has scores within these defined cut scores. Jacobson describes three methods of defining the cut scores, of which only one is possible here. Since, there are no suitable control groups for the PSEQ measure only 'criterion a' can be used. 'Criterion a' is defined as: when the post treatment scores have moved two standard deviation (SD) units beyond the clinical population towards a functioning population, that is, those who are now confident in the management of their pain post this PP intervention. 'Criterion a' is calculated using the mean pre-PSEQ PP intervention score and SD. 'Criterion a' is 43.6 and 52.5, respectively, for the Co. Durham PT and Cole et al. evaluation. In relation to the BPI also no suitable control groups were found and so 'criterion a' was applied. The CSC cut score for the BPI pain intensity and interference domains is 30% change which is consistent with recent studies.22

#### Results

This evaluation had 69 participants who completed the PP from December 2012 until August 2015 compared to 88 in the original evaluation. The demographic details of participants, delivery time and percentage of those completing were similar in both evaluations (Table 2).

Both PSEQ data sets show normal distribution with acceptable levels of kurtosis and skewness as determined by Shapiro-Wilk Test. Cole et al. had a mean 2 points greater PSEQ improvement at 9 points. A distinction between evaluations is the lower mean pre PSEQ score of Co. Durham PT at 21 points compared to 28 of Cole et al. (Table 3), which is further highlighted in the individual patient level (Figure 2(a) and (b)). There are no significant PSEQ differences found related to delivery of PP (group or individual), sex<sup>23</sup> or whether a patient had already attended a Pain Management Programme.

The Co. Durham PT collected BPI data (Table 4) whereby pain intensity is calculated as a collective mean of four domains, including pain now, worse pain, average pain and least pain. Pain interference is highlighted as collective mean of all seven domains, but also as individual and separate domains. The percentage of participants achieving reliable change ranges between 14% and 31% across each of the BPI pain interference domains such as activity, sleep, mood and so on. Those achieving clinical significant change varied between 11% and 22% with activity, mood and relationships being the most successful.

Nearly half of participants (46%) identified sleep as one of their top three HNA problems with over a third (37%) identifying walking/moving about (Figure 3). A quarter (25%) cited pain relief as one of their top three, similar to mood (24%) and managing energy (24%).

Positive patient feedback was gained from the seven closed evaluative questions<sup>24</sup> with comparable percentages of patient satisfaction observed (Supplementary

**Table 2.** Participant demographic and delivery details comparing Co. Durham PT with the original evaluation.

Description	Co. Durham PT (SD, range)	Original evaluation Cole et al.
Demographic details		
Mean age (years)	52.2 (10.5, 59.5)	47.5
Mean pain duration (years)	13.0 (12.0, 49.0)	10.8
% female	70%	88%
Mean school- leaving age (years)	18.2 (5.6, 30)	16.8
Comparing delivery	E00/	BE0/
% completing	72%	75%
Mean number of contacts	4.0 (1.0, 4.0)	4.5
Mean number of contact (hours)	3.2 (0.8, 5.3)	2.9

Co. Durham PT: County Durham Pain Team; SD: standard deviation.

Appendix 1(a) and 1(b)). Supplementary Appendix 1(a) shows a very high rate of satisfaction to these seven evaluative questions, that is, over 90% in both evaluations, with at least 25% having the maximum score of satisfaction.

#### **Discussion**

## Strengths

The aim of this article was to provide an independent evaluation of the PP against Cole et al.'s findings. This has been achieved. Patients obtained reliable and clinical significant change for both the PSEQ and specific BPI pain interference domains. Another strengthening aspect is that the PP is a self-management approach for which there is a large body of evidence suggesting that these programmes are effective with people who have a long-term health condition. Examples would include the use of the 'Heart Manual'<sup>25</sup> as a cardiac rehabilitation programme which has undergone three randomised controlled trials and effectively treated hundreds of thousands of people.<sup>26</sup>

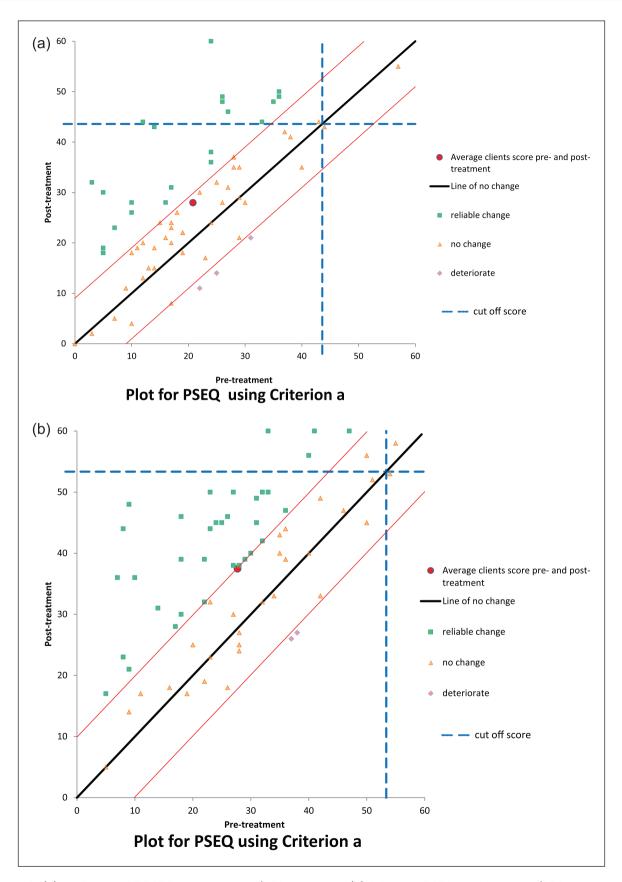
#### Limitations

The Co. Durham PT evaluation employed only one Pain Management Worker and then a Physiotherapist to co-lead the groups, whereas, the original evaluation used a number of health-care professionals. Although, no significant differences are noted between the use of groups and individual sessions this could also be a limitation between the evaluations since the original evaluation only used individual PP sessions. There are several limitations that are common to both evaluations. Examples are while engaging with the PP, people were also attending other Medical/Pain Management appointments, which potentially could have influenced the results. A standardisation sample has not been used for the outcome measures such as the PSEQ and BPI.

Table 3. PSEQ pre-post comparing Co. Durham PT to the original evaluation.

Outcomes	Number (P value)	Pre (SD) (range)	Post (SD) (range)	Change (SD) (range)	% of reliable change (no.)	% of CSC (no.)
Cole et al.	65 (<0.001)	28.03 (12.45) (50)	37.48 (13.04) (55)	9 (10.97) (50)	52% (34)	46% (30)
Co. Durham	66 (<0.001)	20.92 (11.57) (57)	27.75 (13.49) (60)	6.83 (9.96) (47)	33% (22)	20% (13)

SD: standard deviation; PSEQ: Pain Self-Efficacy Questionnaire; Co. Durham PT: County Durham Pain Team; CSC: clinically significant change.

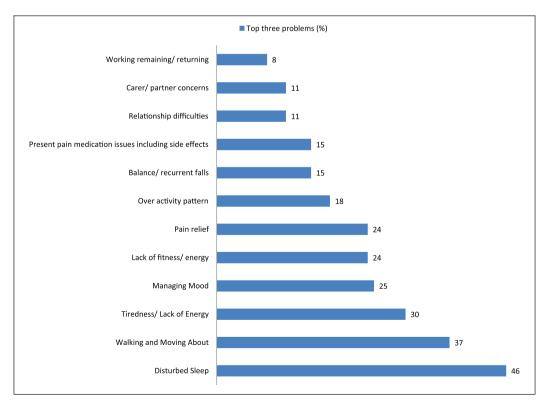


**Figure 2.** (a) Co. Durham PT PSEQ reliable change/CSC results and (b) Cole et al. PSEQ reliable change/CSC results. PSEQ: Pain Self-Efficacy Questionnaire; CSC: clinically significant change.

Table 4. BPI pre-post test Co. Durham PT evaluation.

Outcomes	Number (P-value)	Pre (SD) (range)	Post (SD) (range)	Change (SD) (range)	RCI value	% of reliable change (no.)	% of CSC (no.)
Intensity	64 (0.04)	6.39 (1.68) (8.75)	6.06 (1.81) (9.25)	0.33 (1.53) (11.5)	1.80	9% (6)	6% (4)
Interference	60 (<0.002)	6.91 (2.18) (10)	6.21 (2.31) (9.86)	0.70 (1.78) (11.57)	2.07	17% (10)	13% (8)
Activity	64 (<0.0007)	7.34 (2.05) (8)	6.44 (2.29) (10)	1.00 (2.13) (11)	1.96	31% (20)	22% (14)
Normal work	63 (<0.006)	7.11 (2.25) (8)	6.42 (2.61) (10)	0.69 (2.12) (12)	2.14	13% (8)	11% (7)
Relation others	65 (0.02)	5.94 (2.73) (10)	5.34 (2.67) (10)	0.59 (2.31) (14)	2.61	20% (13)	20% (13)
Enjoyment life	64 (<0.0008)	7.02 (2.28) (9)	6.05 (2.89) (10)	0.97 (2.32) (12)	2.18	17% (11)	17% (11)
Mood	64 (0.0004)	6.97 (2.41) (10)	5.92 (2.71) (10)	1.05 (2.33) (13)	2.30	23% (15)	22% (14)
Walking	65 (<0.006)	7.16 (2.61) (10)	6.58 (2.59) (10)	0.58 (1.77) (10)	2.49	14% (9)	14% (9)
Sleep	65 (<0.0005)	7.94 (2.00) (8)	7.09 (2.69) (10)	0.84 (1.96) (12)	1.90	25% (16)	12% (8)

BPI: brief pain inventory; Co. Durham PT: County Durham Pain Team; SD: standard deviation; RCI: reliable change index; CSC: clinically significant change.



**Figure 3.** HNA in Co. Durham PT evaluation. HNA: health needs assessment.

## Pain pathways

A few questions remain such as: when and for whom is this PP intervention suitable for? The British Pain Society has published five new care pathways; one of which is the 'Initial Assessment and Management of Pain'.<sup>27</sup> In this pathway, it is suggested that patient education and supported self-management (which includes the PP) should be available at an early stage. The PP would be appropriate within a community setting and delivered by Health Trainers.<sup>28</sup> Alternatively, the PP could provide self-management for those people within a pain management service who would be termed as low or medium-high pain risk. For those in the medium-high pain risk categories further input post the PP may be required.

In relation to who the PP is suitable for it is important to emphasise a distinction between the evaluations. The Co. Durham PT evaluation had lower pre-PSEQ scores, and these participants had been in pain for a mean of 3 years longer. This cohort was arguably a more entrenched population<sup>29</sup> and so in a sense it is no surprise that the percentage of reliable and clinical significant change was lower in this Co. Durham PT evaluation. This is one possible theory, although there may also be other factors involved. If confirmed by a Randomised Control Trial (RCT), it would then suggest that pre-PSEQ scores could be a factor in participant engagement and selection for this programme.

#### Future directions

As the evaluation continues and the dataset increases, one future direction would be to gain a better understanding of who benefits most from this intervention and whether PP can improve the issues that are most important to that individual. Patients undergoing the PP are also using pharmacological methods of pain relief and a second direction maybe to include data collection on pharmacological interventions such as medication, injections and so on. The Co. Durham PT evaluation had a 28% drop out rate and these data have not been analysed here. Another area of exploration would be to find a means of handling the data lost using a technique such as baseline-observation-carried-forward (BOCF).30 A final future direction is to collect follow-up data on those participants who have completed the programme.

#### Conclusion

The clinically significant benefits and high patient appreciation reported by the developers of the PP are equally observed when the PP is used as part of routine service provision within the NHS (following 1 day staff

training). The PP can be used as an early intervention and part of a stratified care approach.<sup>31</sup> Further studies could gain a better understanding of who benefits most from the PP and should include a 1 year follow-up data collection, as well as an analysis of those who did not complete.

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