“The parts are greater than the sum of the whole”

Exploring the Process of Change in a Pain Management Programme using Single Case Study Design

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

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Overview

This three-part thesis reviews the effectiveness of psychological interventions for chronic non-cancer pain on healthcare use and sick leave from work, and explores the process of change in a pain management programme using single case methods.

Part 1 is a meta-analysis of 16 randomised controlled trials of psychological interventions in a chronic pain population. Small to moderate effect sizes were found for reduced healthcare use but no significant benefit for sick leave.

Part 2 is a study using single case design methodology to explore trajectories of change in 8 patients attending a CBT-based chronic pain management programme. Baseline, intervention and bi-weekly follow-up self-report of catastrophic thinking, mood, self-efficacy, and goal attainment, and of process variables of working alliance and adherence, were supplemented by a post treatment change telephone interview which was qualitatively analysed. Detailed examination of change for each participant provided rich data: three participants improved significantly over the course of the programme, three deteriorated, and all improved in at least one goal. Therapeutic alliance was high and participants rated central elements of the programme, explanations of their pain, and peer support/group membership as important.

Part 3 is a critical appraisal of the study and the review, contrasting the approaches, and concluding with a personal reflection on the process.

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Part 1: Literature Review.

Effectiveness of Psychological Interventions for Chronic Pain on Healthcare Utilisation and Sick Leave Days. A Meta-Analysis.

Abstract

Background: Studies have reported that chronic pain tends to be associated with increased healthcare usage (e.g. doctor or hospital visits, medication) particularly when it is severe and enduring, or where there are multiple sites of pain and increased pain related disability. As yet there are no clear evidence for chronic pain and work absence. Psychological interventions are designed to treat chronic pain and its sequelae yet there has been no systematic review that has specifically examined its efficacy for healthcare utilisation (HCU) and sick leave days (SLD) as treatment outcomes. **Aim:** To extend a 2012 systematic review of randomised controlled trials (RCT) to evaluate the effectiveness of psychological therapies for chronic pain in adults using healthcare utilisation (HCU) and sick leave days (SLD) outcomes. **Method:** The 2012 review searches were updated to cover the intervening period. A systematic search of Cochrane Central Register of Controlled Trials (CENTRAL 2013), MEDLINE, EMBASE and PsycINFO. Sixteen studies met criteria. 12 studies measured HCU and 9 measured SLD. 13 provided data that were entered into a meta-analysis. **Results:** There were small positive effects for psychological interventions compared to active, treatment as usual (TAU) and waiting list controls in reducing HCU. The SLD analysis showed no significant effects of psychological interventions, although there were trends showing reduction overall but not significant. The overall quality of trials was comparable with the previous review but analysis was restricted by problems of heterogeneity of reporting metrics, particularly with SLD data. **Conclusions:** Since the number of eligible trials was small, it is difficult to draw any firm conclusions about efficacy. Ideally, a consensus needs to be reached as to which domains are measured and the most appropriate metric to synthesise these outcomes across trials.

Introduction

Background

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage” (International Association of the Study of Pain, 1987). Many people have persistent pain that is not relieved or cured by physical therapy or medicines. Chronic pain (CP) effects one in five European adults (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006) and can have a significant and lasting impact on people's lives, causing sleeplessness and depression and interfering with normal physical and social functioning. Ways of coping that are clinically encouraged and adaptive in acute pain episodes, can become unhelpful and maladaptive in persistent pain (Zarnegar & Daniel, 2005).

The relationship between thoughts, emotions, biological and behavioural responses are well documented in the CBT literature (Beck, Rush, Shaw & Emery, 1979, Clark, 1986). Responses to pain are no exception. Unhelpful beliefs and thoughts, for example, ‘pain means that I am damaging my body’ or ‘moving will damage my body further and cause pain’, lead to anxiety and fear about movement and the pain it might cause (Zarnegar & Daniel, 2005). They can therefore become barriers to revisiting activity, contributing to increased patient disability (Vlaeyen & Linton, 2000, 2012).

The search for a diagnosis and subsequent pain relief is often unsuccessful. Patients can spend many years seeking help. They often get stuck in a ‘revolving door’, seeing a variety of specialists (Clare, Andiappan, MacNeil, Bunton & Jarrett, 2013), which can be damaging both psychologically and physically (Eccleston, 2001). Unsurprisingly, CP can have a significant impact on patients’ healthcare usage and healthcare resources in general. Across Europe, Breivik et al. (2006) reported that

60% of those surveyed with CP had been to see their health care professional between 2-9 times in the last six months. Yet relatively small numbers have seen a pain specialist.

CP generates 4.6 million GP appointments per year at a cost of £69 million in the UK (The Pain Proposal, 2010). Chronic low back pain alone is responsible for £12.3 billion (22% of total UK healthcare spending) and half a billion pounds is spent annually by the UK National Health Service on pain medication (Department of Health, 2008). Von Korff, Lin, Fenton & Saunder's (2007) US based study suggests that comorbidity of other physical and mental health problems is common in CP and needs to be factored in when analysing healthcare usage.

Chronic or persistent pain is also a major cause of loss of work days and underperformance in the workplace (Blyth, March, Brnabic & Cousins, 2004). Twenty six percent of the 4215 surveyed participants in the pan-European study by Breivik et al. (2006) had indicated that their pain had impacted on their employment, with an average of 7.8 days lost to pain-related sick leave in the last six months. UK CP patients are 7 times more likely to abandon their jobs compared to a healthy population, while 25% will eventually lose their jobs. CP is also the second most common reason to claim Incapacity Benefit and a significant economic factor in the aforementioned 22% UK health care budget spending (DoH, 2008).

In an attempt to understand possible clinical correlates and causation for increased health care utilisation (HCU) and sick leave days (SLD), a prospective cohort study of people with chronic lower back pain (Keeley, Creed, Tomenson, Todd, Borglin & Dickens, 2008) reported that anxiety, depression and fear/avoidance beliefs relating to work and back pain-related stressors predicted increased healthcare contacts. In a study of chronic low back pain patients, the authors reported that the greater the patient's attention to his or her pain, the greater was perceived pain intensity and subsequent increased HCU (McCracken, 1997).

Studies have also reported that chronic pain tends to be associated with increased use of healthcare, particularly when it is severe and enduring, or where there are multiple sites and increased pain related disability (Blyth, March, Brnabic & Cousins, 2004; Von Korff, Wagner & Dworkin, 1991*)*. Other hypothesised explanations for increased HCU focus on preoccupied attachment style (Ciechanowski, Sullivan, Jensen, Romano & Summers, 2003) and, in female patients, on a suggested association in cases where there is a history of sexual abuse (Finestone, Stenn, Davies, Stalker, Fry & Koumanis, 2000). Studies of SLD data are less clear. For example, a systematic review by Kuijer, Groothoff, Brouwer, Geertzen and Dijkstra (2006) suggests that no predetermined set of predictors can be found for sickness absence in chronic lower back pain, echoing findings from previous studies (Crook, Milner, Schultz & Stringer, 2002; Elders, van der Beek & Burdorf, 2000; Truchon & Fillion, 2000; van der Hulst, Vollenbroek-Hutten & Zerman, 2005). Although there is a body of literature that suggests it may be linked to fear-avoidance in the work place (Sullivan, Ward, Tripp, French, Adams & Stanish, 2005; Vlaeyen & Linton, 2012).

Treatments are based on robust psychological principles and practices and have been in use and in development for about 40 years. Patients are encouraged to adopt more helpful beliefs and behaviours that lead to less emotional distress and disability and, to some extent therefore, less dependence on medical services or withdrawal from everyday activities, including work. Current evidence suggests that psychological characteristics are more reliable determinants of outcome from CBT than demographic data, medical diagnosis or physical findings (McCracken & Turk, 2002).

Multidisciplinary Pain Management Programmes (PMPs) are the recommended treatment of choice for chronic pain (NICE, 2009). They have been proved to be effective in “reducing negative mood (depression and anxiety), disability,

catastrophic thinking and, in some cases, pain" (Williams, Eccleston & Morley, 2012. p2). However, in the current climate, is it enough for a treatment to be solely clinically effective? For example, PMPs utilise numerous professionals over eight-twelve weeks and so, as a consequence, could be seen as expensive. But, if they could also be proved to reduce ineffective healthcare use where patients continue to seek recourse to healthcare professionals that have no new answers and recommend treatments that increase the risk of further complications. Therefore reducing HCU would be good not just for the budget but for the patient's welfare.

Comprehensive measurement and reporting of psychological outcome data is already a regular feature of PMP protocols, and so could easily be extended to behavioural variables such as HCU and SLDs. Clare et al. (2013) used an appointment system cross referenced for pain visits, to calculate and compare the costs of secondary healthcare usage one year before and after a PMP. Using an NHS trust outpatient tariff, they reported a 90.5% saving. Turk (2002) had also made similar observations in the USA and added that psychological interventions can also reduce the risk of iatrogenic consequences and adverse events, which can also increase patient HCU.

The systematic review by Guzmán, Esmail, Karjalainen, Malmivaara, Irvin & Bombardier (2001) found contradictory evidence of PMP effectiveness on SLDs, with some studies showing no significant reduction in sick leave whilst others reporting improvements in work readiness (not the same as SLD as readiness to work may have little to do with actually getting employment). Whereas the meta-analysis by Flor, Fydrich & Turk (1992) reported that patients were almost twice as likely to return to work when treated by a MDT compared with a unimodal intervention or no treatment controls.

Despite a general acknowledgement of the literature, health care usage and sick leave days are generally under-reported in studies (Blyth et al., 2004; Van Korff,

et al., 1991). As a result, little is known about treatment outcome in chronic pain on healthcare consumption and sick leave. Difficulty in ensuring the reliability of data might also provide clues as to why it is so under reported. For example, Caudill, Schnable, Zuttermeister, Benson & Friedman (1991) reported a 36% reduction in visits to healthcare professionals 12 months after a PMP, but did not differentiate pain from non-pain visits in their questioning. Cipher, Fernandez and Clifford (2001) reported fewer visits by chronic pain patients following psychological and medication treatment, compared with medication only controls, but they questioned the accuracy of the finding as the data was self-reported and not from medical records.

Whilst collating data for the most recent Cochrane review of the effectiveness of psychological therapies for the management of chronic pain (Williams et al*.,* 2012), the authors noted that a small sample of the final studies had measured and reported healthcare utilisation (HCU) and sick leave days (SLDs) as outcome data. However, they did not use those outcomes, restricting their meta-analyses to pain, disability, distress, and catastrophic thinking. Acknowledging the perceived current gap in the literature, undertaking a systematic review and synthesis of all relevant available data would seem useful and informative.

Therefore, this study's objective is to extend the 2012 Cochrane review and evaluate the effectiveness of psychological therapies for chronic pain in adults, compared with treatment as usual, waiting list control, or placebo control, to HCU and SLDs. It will exclude headache which, as reported in the 2012 review, is treated separately from other chronic pain, aiming to reduce pain intensity, frequency and duration as much as to help with adaptation. Notably, of the 53 studies included in the most recent systematic review of headache treatment by psychological methods by Nestoriuc, Rief & Martin (2008), medication consumption is a common measure of improvement.

Aim

To extend the 2012 systematic review by updating the trial set and using previously unanalysed outcomes of healthcare utilisation (HCU) and sick leave days (SLD) to evaluate the effectiveness of psychological therapies for chronic pain in adults, compared with treatment as usual or waiting list controls.

Method

Search Strategy

The 2012 review searches were replicated and extended. RCTs of any psychological therapy were extracted from the Cochrane Central Register of Controlled Trials (CENTRAL 2013), MEDLINE, EMBASE and Psychinfo. The searches focused on the 2 years since the review (January 2011 to October 2013), using the same search strategy but taking account of changes in search terms or search processes. Searches of the literature were conducted from the beginning of the year of the last review to capture any studies that were in the process of being published or were awaiting classification. An example search strategy is given in Appendix 1. No language restrictions were applied. Additional studies were identified using an ancestral approach from the reference lists of retrieved papers.

Inclusion and Exclusion Criteria

In order to ensure accurate replication of trials from the previous review, this study adopted the same inclusion and exclusion criteria. Studies were included if they:

- were available as a full publication or report of a randomised controlled trial.

- had a design that placed a psychological treatment[1] as an active treatment of primary interest.
- had a psychological treatment with definable psychotherapeutic content.
- at least one trial arm consisted of a psychological intervention, with at least one comparator arm of a placebo condition, other active treatment, treatment as usual or waiting list control.
- were published (or electronically pre-published) in a peer-reviewed science journal.
- were with participants (aged 18 years or older) reporting chronic pain in any body site (i.e. at least three months' duration).
- were not concerned with headache or associated with a malignant life-threatening disease.
- were with participants meeting criteria for diagnosis of fibromyalgia or chronic fatigue syndrome.
- had 10 or more participants in each treatment arm at the end of treatment (returning to previous criteria set out in 2009 Cochrane review criteria to include previously excluded studies).
- measures healthcare utilisation and/or sick leave days post treatment as a primary or secondary outcome.

The trials used in the previous systematic review and meta-analysis (Eccleston, 2009a: Williams et al., 2012) were automatically included if they reported HCU or SLD data. Previously excluded studies from the 2009 review which met all inclusion criteria but had N<20 in any arm at the end of treatment were now included

[1] A psychological treatment was deemed credible if it was based on an existing psychological model or framework, and its delivery was by, or was supervised by, a healthcare professional qualified in psychology

if they also reported the required data, for maximum inclusiveness. Where there were either poster abstracts or missing data and contact details were available, authors were contacted for clarification. Of the 13 authors that were contacted, 1 provided SLD data (Schmidt, Grossman, Schwarzer, Jena, Naumann & Walach, 2011) and 5 confirmed that they had not measured HCU or SLD outcomes. 7 did not respond to requests and so this should be considered when assessing the final analysis.

This produced a set of possible titles and abstracts. From these, one rater (AP) selected for examination all full papers that appeared to meet inclusion criteria. Both authors read the papers independently and agreed on which trials were eligible. The final set of papers (including those now eligible from the previous systematic review) were rated independently for risk of bias and quality. Consensus was established between raters where there were disagreements in rating scores.

Results of the Search

This review identified 25 randomised controlled trials that reported HCU or SLD data. Ten trials were from the 2012 Cochrane review (Alaranta, Rytokoski, Rissanen, Talo, Ronnemaa, Puukka et al., 1994; Geraets, Goossens, de Bruijn, Koke, de Bie, Pelt et al., 2006; Jensen, Dahlquist, Nygren, Royen & Stenberg, 1997 and Jensen, Bergstroem, Ljungquist, Bodin & Nygren, 2001; Kaapa, Frantsi, Sarna & Malmivaara, 2006; Lindell, Johansson & Strender, 2008; Schmidt et al., 2011; Thieme, Gromnica-Ihle & Flor, 2003; Turner, Mancl & Aaron, 2006; Williams, Richardson, Nicholas, Pither, Harding, Ridout et al., 1996) and 5 excluded trials with N < 20, from the previous 2009 review (Ersek, Turner, McCurry, Gibbons, Miller & Kraybill, 2003; Flor & Birbaumer, 1993; Johansson, Dahl, Jannert, Lennart & Andersson, 1998; Marhold, Linton & Lennart, 2001; Moore & Chaney, 1985). Two were identified from reference lists of other studies (Turk, Rudy, Kubinski, Jazaki &

Greco, 1996; Busch, Bodin, Bergstrom & Jensen, 2011) and eight trials from the new search (Bendix, Bendix & Ostenfeld, 1995 & Bendix, Bendix, Vaegter, Lund, Frølund & Holm, 1996; Gustavsson, Denison & Koch, 2011; Huibers, Beurskens, Van Schayckk, Bazelmans, Metsemakers, Knottnerus et al., 2004; Overmeer, Boersma, Denison & Linton, 2011; Sattel, Lahmann, Gundel, Guthrie, Kruse, & Noll-Hussong et al., 2012; Van Eijk-Hustings, Kroese, Tan, Boonen, Bessems-Beks & Landewe, 2013).

Excluded studies. Nine of the 25 studies were excluded on closer examination. Bendix et al. (1995 & 1996) and Vibe-Fersum et al. (2012) due to insufficient psychological content; Huibers et al. (2004) and Sattell et al. (2012) did not sample chronic pain patients and Gustavsson et al. (2011) used physiotherapists to provide psychological treatment; details suggested low quality of therapy. Three studies provided HCU and SLD data not as outcomes but as a baseline measures only (Ersek et al., 2003; Overmeer et al., 2011; Turner et al., 2006).

Data extraction and management

Descriptive characteristics of participants and treatments including setting, mode of delivery, and treatment data were collected. However, the primary area of interest for this review was outcomes in the domains of post-treatment HCU and SLDs. HCU eligible data was defined as any mainstream health service resources which were freely available (or referred to if under an insurance-based healthcare system) to patients and measured post treatment. Generally recorded as numbers of visits by patients to general practitioners/doctors/physicians, physiotherapists, osteopaths, specialists, chiropractor, nurse or other healthcare professionals.

Also acceptable were more generic terms such as doctor visits, outpatient medical resources, medical visits and hospital days or healthcare visits. Not all were

corroborated as pain-related due to the method of data collection i.e. self-report or general medical records. Some were non-specific as to the nature of the visit or a yes or no answer to the specific question about healthcare usage. However, for the purposes of this study they were considered eligible. Less traditional alternative therapies or complementary medicines were not included in the data as they were considered non-mainstream healthcare resources. Medication prescription and usage was also included as HCU data.

Eligible SLD data was any post treatment measurement of sick leave or absence from work and were typically recorded as days or numbers of episodes from either self-report, insurance-based or work-based records. Identifiable terms such as sick leave days, sick days, work absence, sick leave greater than 14 days, or sick listed days were eligible. There was significant variation in the methods of reporting or analysis, varying from yes or no answers to a specific question about SLD to categorising patients by their number of sick leave days or reporting group percentages. There was also variation in the time point of measurement. This was further considered at the analysis phase of this study.

Data Analysis

Due to the variation in methods of data collection and reporting of healthcare utilisation and sick leave days in the studies, this review included both continuous and dichotomous scales. Where continuous data were reported, treatment effects were estimated using standardised mean differences by extracting means, standard deviations and sample size at follow-up, and random rather than fixed effects given the likely heterogeneity (Higgins & Green, 2011). Where data were dichotomous, treatment effects were estimated using odds ratios by extracting and calculating number of events data and sample sizes at follow-up. When data were not available from published studies or from authors, no parameters were inferred. All meta-

analyses were conducted using Review Manager (RevMan) [Computer program] (The Cochrane Collaboration, 2012).

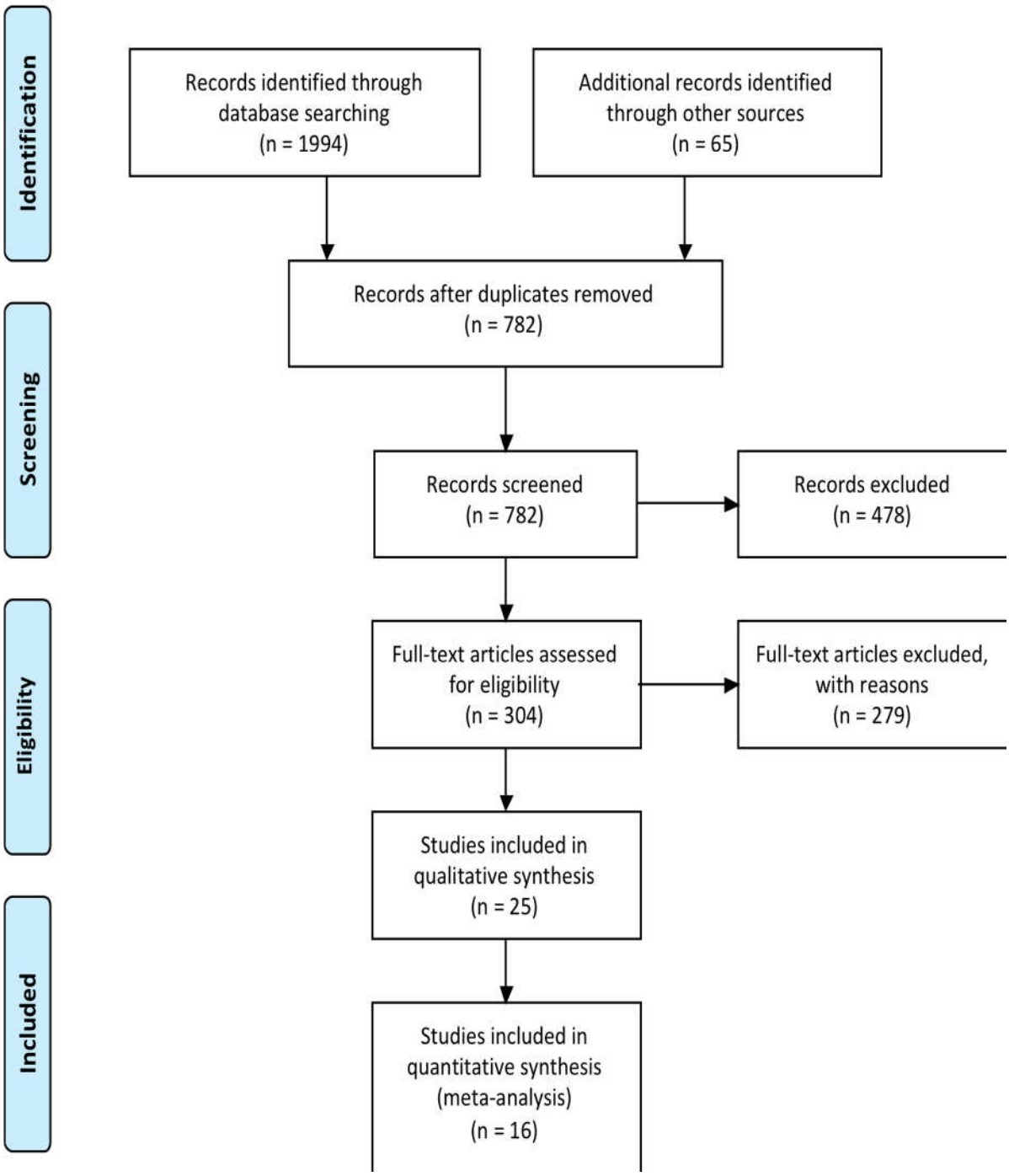


Figure 1: PRISMA (2009) Study flow diagram

Quality of Studies

Risk of bias was assessed using the recommended Cochrane guidance (Higgins & Green, 2011). Of the five suggested 'Risk of bias' categories, random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) and selective reporting (reporting bias) were included. The option of 'blinding participants and personnel' was excluded because neither therapists nor patients can be blinded to whether they deliver or receive treatment. As in the previous reviews (Eccleston et al., 2009a, Williams et al., 2012), a quality rating scale specifically designed for psychological interventions in pain was applied (Yates, Morley, Eccleston & Williams, 2005). Two authors (AP, AW) scored all studies and they reached a consensus after initial comparison or ratings.

The scale (see Appendix 2) provides an overall total score (0 to 35) consisting of two subscales: a treatment quality scale (0 to 9) covering stated rationale for treatment, manualisation, therapist training and patient engagement; and a design and methods scale (0 to 26) covering inclusion/exclusion criteria, attrition, sample description, minimisation of bias (randomisation method, allocation bias, blinding of assessment, equality of treatment expectations), selection of outcomes, length of follow-up, analyses and choice of control. The first four 'Risk of bias' items from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, 2011) are represented in the design section of the Yates et al. (2005) scale, accounting for up to five of the nine points available.

Measures of Treatment Effect

Studies where psychological treatment was as an active treatment of primary interest were investigated. Most studies used cognitive behavioural therapy or behavioural therapy as an arm of treatment or as part of a multi-disciplinary approach

to treatment. Three classes of comparator treatments are investigated and labelled active control, treatment as usual and wait list. The active comparator involves a treatment designed to manage pain such as physical therapy, education or medical regime.

Patients randomised to the active control within each trial all receive the same treatment. For patients assigned to waiting list, trials vary in whether they provide further care and patients vary in whether they seek further care. For patients assigned to treatment as usual, this treatment can consist of anything from regular consultations or care to nothing; waiting list patients may also receive some or no treatment. Thus, patients in these conditions receive variable and usually unrecorded treatment.

Where a trial had more than two arms, treatments that were either more robust, which best matched description of a psychological intervention and, where there was a choice, the more intensive version, were selected: for example, if a trial had an enriched CBT (that is, CBT with additional non-core components such as biofeedback), a minimum CBT and a waiting list condition, we compared the enriched CBT with the waiting list.

This review endeavoured to align assessment time points at follow-up. Follow-up is the assessment point at least three months after the end of treatment, but not more than 24 months, and the longer of the two if there were two follow-up assessments within this timeframe. Therefore, 2 comparisons were designed comprising the class of psychological treatment under investigation, one of the three forms of comparator (active control, treatment as usual, waiting list), and one best aligned assessment time point (follow-up). They are labelled: Psychological Intervention versus treatment control - HCU and Psychological Intervention versus treatment control - SLD.

For each comparison we identified two outcomes of interest i.e. healthcare utilisation and sick leave days. Although standard trial reporting guidance promotes

the definition of primary outcomes (Boutron, Moher, Altman, Schulz & Ravaud, 2008), most of the included trials reported HCUs or SLDs as secondary outcomes.

Risk of Bias in Included Studies

This study adopted five 'Risk of bias' categories: random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) and selective reporting (reporting bias). Four of the final 14 studies had not been rated previously by the 2009 and 2012 reviews (Busch et al., 2011; Flor et al., 1993; Turk et al., 1996; Van Ejik-Hustings et al., 2013) and so it seemed sensible to follow the same risk of bias procedures.

Assessment of Heterogeneity

Between-trial heterogeneity is automatically calculated in RevMan and expressed using the I^2 statistic. I^2 values above 50% indicate high heterogeneity, between 25% and 50% medium heterogeneity, and below 25% low heterogeneity.

Results

Included Studies

The full characteristics of all included studies are detailed in tables in appendix 3. There were only two eligible new studies since the previous Cochrane review that report HCU or SLD data. All included trials represented a total number of participants of 1873 at the end of treatment (mean per study 117, SD 72) out of the 2084 that started treatment. This equated to a mean study completion rate from point of entry to completion of 88.5% (SD 7.5%) and ranged from 73.5% - 100% using data from all 16 studies. 1441 women (mean 91 SD 55 range 1-195) and 623 men (mean 39, SD

42, range 0-133). Women usually outnumbered men (mean 69 %; SD 26%; range 2% - 100%). The mean age was 45 (range 33 - 53) and mean duration of pain symptoms from those that provided data (12 of the 16 studies) was 3.9 years (range 1.3 - 16.3).

Participants were recruited from numerous sources. Seven studies used patients from pain/rehabilitation clinics (including one veterans' hospital; three treated patients from outpatient clinics); 2 used primary care referrals. Not all studies sampled solely patients. One study advertised for volunteers in a newspaper to supplement referrals from GPs, specialists, and a patient self-help group; 2 studies sampled community volunteers; 1 study recruited current employees from a national insurance authority register in Sweden. Half of the 16 studies were from Scandinavian countries with 6 trials from Sweden, and 2 from Finland. Three were from Germany, 2 from the Netherlands, 2 from the USA and 1 from the UK.

Three studies were solely for patients with fibromyalgia; two studies were solely for low back pain; 3 treated mixed back or neck pain; one study focused solely on shoulder pain; another recruited chronic back pain or temporomandibular joint pain patients; 3 were mixed pain sites as long as it was of greater than three months duration; one study was solely temporomandibular joint pain and 2 studies recruited chronic musculoskeletal pain patients.

Nine studies had 2 arms, 4 studies had 3 arms and 2 studies had 4 arms. There was a significant diversity in types and modalities of psychological intervention such as intensive physiotherapy and psychosocial therapy, graded exercise therapy, group rehabilitation, CBT, operant pain therapy, biofeedback, behavioural management, behavioural therapy, couple therapy, multi-disciplinary therapy and mindfulness based stress reduction. Control or comparator arms, if not treatment as usual or a wait list control, were medical intervention or individual physiotherapy. Each study was scored for quality of treatment, which produced a mean 5 (SD 1.96 range

= 2-8) and study and design quality, which produced a mean 16.43 (SD 3.80 range = 11-23).

Of the sixteen remaining studies 13 provided analysable data (Alaranta et al., 1994; Flor et al., 1993; Geraets et al., 2006; Jensen et al., 2001; Kaapa et al., 2006; Lindell et al., 2008; Marhold et al., 2001; Moore et al., 1985; Schmidt et al., 2011; Thieme et al., 2003; Turk et al., 1996; Van Ejik-Hustings et al., 2013; Williams et al., 1996). The results of the remaining trials are summarised in the results.

Unit of Analysis Issues

There was significant disparity in how HCUs and SLDs were measured in each of the final studies which made data synthesis and analysis more difficult. Twelve studies measured HCU – Alaranta et al. (1994); Flor et al. (1993); Geraets et al. (2006); Jensen et al. (2001); Kaapa et al. (2006); Lindell et al. (2008); Moore et al. (1985); Schmidt et al. (2011); Turk et al. (1996); Thieme et al. (2003); Van Ejik Hustings et al. (2013); Williams et al. (1996). Table 1 describes the HCU metric extracted from each trial and calculated summary statistic for comparison.

Nine studies measured SLDs Alaranta et al. (1994); Geraets et al. (2006); Kaapa et al. (2006); Jensen et al. (1997) and (2001); Johansson et al. (1998); Lindell et al. (2008); Marhold et al. (2001). Table 2 describes the SLD metric extracted from each trial and calculated metric applied for comparison.

Table 1.

Derived metrics from HCU trials and calculated summary statistics

Study	Metric	Summary Statistic Used	Analysed
Alaranta 1994	Doctor and O/P visits	Percentage Difference	Not analysed
Flor 1993	Pain related healthcare visits	Mean & Sd	Analysis 1.1
Geraets 2005	Mean utilisation of various HCPs	Pooled means and Sd	Analysis 1.1
Kaapa 2006	Mean no of healthcare visits to various	Mean and Sd	Analysis 1.1
Lindell 2008	Mean group visits to HCP acute and sub-acute	Mean only no Sd	Not analysed
Moore 1985	Mean outpatient visits (pain & non-pain) from med records	Mean and Sd	Analysis 1.1
Thieme 2003	No. of doctors visits.	Mean and Sd	Analysis 1.1
Van Eijk-Hustings 2013	Mean no of contacts with various HCPs	Pooled mean and Sd of all categories of visits	Analysis 1.1
Schmidt 2011	Count of yes/no answers to any pain related medical visits	Count of visits	Analysis 1.2
Turk 1996	Self-reported use of prescribed and over the counter analgesic medication	Counts of self-reported meds	Analysis 1.3
Williams 1996	Number of patients surgery, pain relieving tx & manipulative tx	Counts of self-reported meds	Analysis 1.2 & 1.3

Table 2

Derived metrics from SLD trials and calculated summary statistics

Study	Metric	Summary Statistic	Analysed
Alaranta 1994	group percentage grouped into numerical bands	No of events > 30 days	Analysis 2.3
Geraets 2005	Mean days	Mean and Sd	Analysis 2.1
Kaapa 2006	group percentage grouped into numerical bands	No of events > 30 days	Analysis 2.3
Jensen, 1997/2001	Mean working days lost per year	Calc net days – possible days	Analysis 2.2
Johansson. 1998	Mean percentage after 1 month	No summary	Not analysable
Lindell, 2008	Net sick days in 6 month periods	Calc net days – possible days	Analysis 2.2
Marhold, 2001	Mean sick leave days	Mean and Sd	Analysis 2.1

Quality of Studies

A full summary of risk of bias assessment are detailed below in figures 2 and 3.

Allocation (selection bias). Five studies described a convincing method of randomisation and were judged to have a low risk of bias, and a further 8 provided an inadequate description so were judged to be unclear. Three had a high risk of bias, mainly because the method of randomisation was not described; two of these studies were almost 20 years old.

Seven studies were judged to have adequate allocation concealment, five uncertain and four high risk, again mainly because there was no description of designated procedures.

Blinding (performance bias and detection bias). Four studies were judged at low risk of bias for outcome assessment since they used blinded assessors; eight were unclear; and four at high risk of bias since they gave no details of outcome assessment procedures. It should be borne in mind, however, that almost all outcomes were assessed by self-report so that there were restricted opportunities for influencing patients' scores. Thus most judgements of high risk of bias were because of inadequate reporting. This study recognises this is that some studies may have exercised proper precautions in some or all of these areas.

Incomplete outcome data (attrition bias). Four studies reported attrition fully, including finding no difference between dropouts and completers, and were judged to have low risk of bias; six were unclear risk, mainly because of lack of testing for differences between dropouts and completers; six were judged to have high risk of bias, predominantly because they provided no or implied details of attrition or were only partially reported.

Selective reporting (reporting bias). Thirteen studies were at low risk of bias for selective reporting of outcome since they reported all outcomes; three studies did not report all outcomes which they described in assessment sections of their Methods, and so were judged them at high risk of bias.

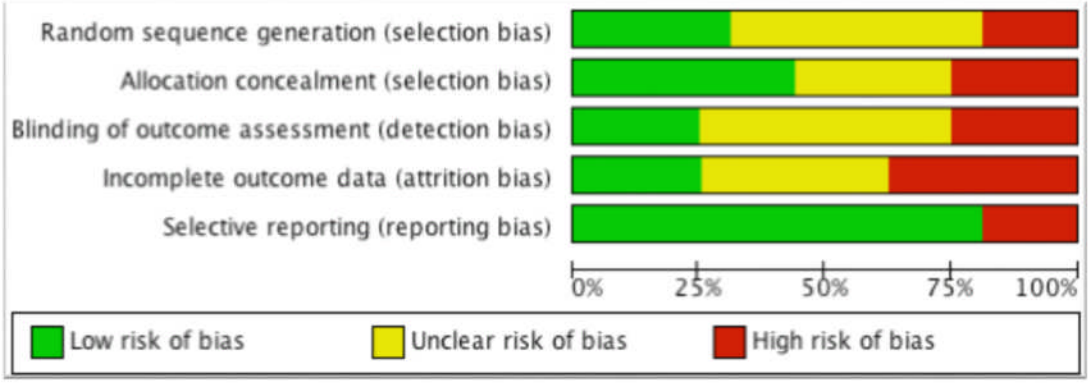


Figure 2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

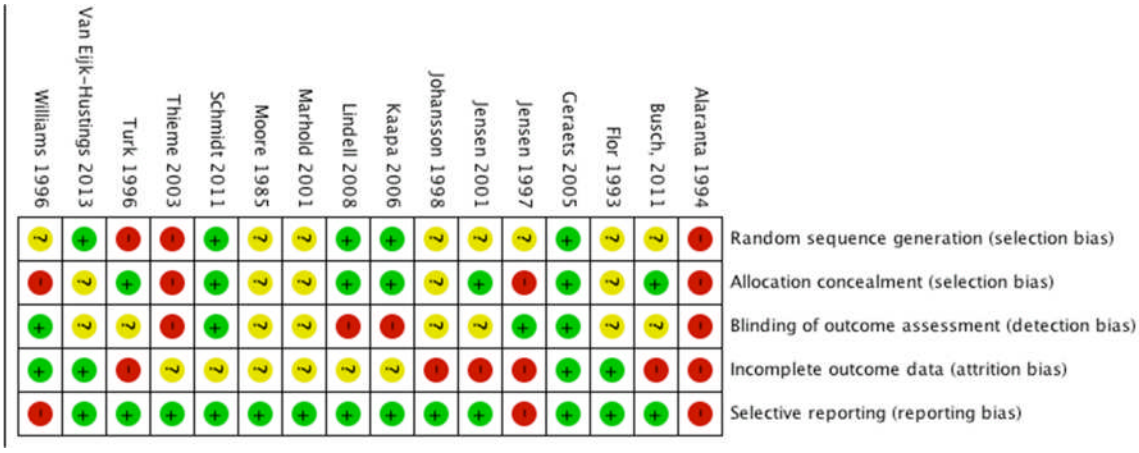


Figure 3: Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Other potential sources of bias. The comprehensive quality assessment scale (Yates, 2005) is reported in the characteristics of included studies. For the 16 studies which met the inclusion criteria, the mean overall quality of the studies was 21.0 (SD 4.8, range 15 to 31). The mean treatment quality score was 5.1 of a possible 9 (SD 1.8, range 2 to 8) and the mean design quality score was 16.0 of a possible 26 (SD 3.8, range 11 to 23).

Of the 5 analyses reported (intervention versus treatment control for HCU mean difference, HCU Events, Sick Days, Net Group Sick Days, Sick Days > 30), 4 showed low heterogeneity of less than 25%, none showed moderate heterogeneity of greater than 25% and less than 50%, and one showed high heterogeneity greater than 50%.

Effects of Interventions

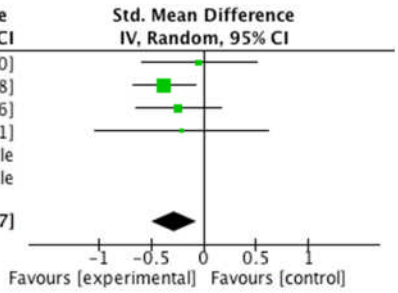
Intervention versus treatment control - healthcare utilisation. Six trials reported mean and SD for HCU as visits, contacts or use of GPs, physicians, physiotherapists, outpatient medical resources, nurses, medical specialists and paramedical specialists and other healthcare professionals over 6-12 month follow-up periods involving 563 participants. They were analysed for the effect of psychological intervention on healthcare utilisation using standard mean difference.

Table 3.

Analysis 1.1

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Flor 1993	7.712	22.39	26	8.675	22.381	26	15.2%	-0.04 [-0.59, 0.50]
Geraets 2005	0.47	1.89	87	1.7	4.17	89	50.6%	-0.38 [-0.68, -0.08]
Kaapa 2006	3.4	7	49	5.3	8.6	46	27.6%	-0.24 [-0.65, 0.16]
Moore 1985	1	0.9	11	1.21	1.01	12	6.7%	-0.21 [-1.03, 0.61]
Thieme 2003	14.7	9.9	40	37.8	22.03	21		Not estimable
Van Eijk-Hustings 2013	1.2	0.31	108	0.975	0.43	48		Not estimable
Total (95% CI)			**173**			**173**	**100.0%**	**-0.28 [-0.49, -0.07]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.20$, df = 3 (P = 0.75); $I^2 = 0\%$
Test for overall effect: Z = 2.57 (P = 0.01)



The initial overall effect was non-significant (Z=1.23, P>0.05). However, the heterogeneity was 89%. The previous review (Williams et al., 2012) had noted the significant contribution to heterogeneity of the Thieme et al. (2003) study and so it was deemed prudent to experiment with, first, the removal of studies until heterogeneity was acceptable. Removal of the Thieme et al. (2003) study and the Van

Eijk Hustings et al. (2013) study reduced I^2 value to 0% and gave a significant benefit (Z=2.57, P<0.05) with small effect size of -0.28 (CI 95% -0.49, -0.07) in favour of reduced visits in the treatment (labelled experimental) condition. Exploring the reasons for the high heterogeneity of these two trials was not in this study's remit.

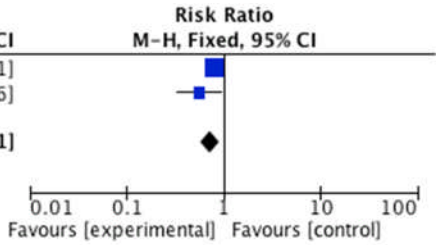
Specifically, the four trials included in the final analysis measured pain related healthcare visits at 6 month follow-up (Flor et al., 1993); patient utilisation of GP, physician, physiotherapist and manual therapists at 12 months (Geraets et al., 2006); mean number of visits to physician, physiotherapist and other health care professionals at 12 months (Kaapa et al., 2006); and use of outpatient medical resources at 8 months (Moore et al., 1985).

Table 4.

Analysis 1.2

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Schmidt 2011	35	53	46	56	65.6%	0.80 [0.64, 1.01]
Williams 1996	13	43	24	45	34.4%	0.57 [0.33, 0.96]
Total (95% CI)		**96**		**101**	**100.0%**	**0.72 [0.58, 0.91]**
Total events	48		70			

Heterogeneity: $Chi^2 = 1.65$, df = 1 (P = 0.20); $I^2 = 39\%$
Test for overall effect: Z = 2.82 (P = 0.005)



Two trials of 197 participants during a 2 -12 month follow-up period were analysed using a risk ratio. Data indicated a positive response to the experimental condition. The test for overall effect was very significant (Z = 2.82; P = 0.005) in favour of the treatment (experimental) condition with a risk ratio of 0.72 [95% CI 0.58, - 0.91] but there was high heterogeneity (I^2 = 63%).

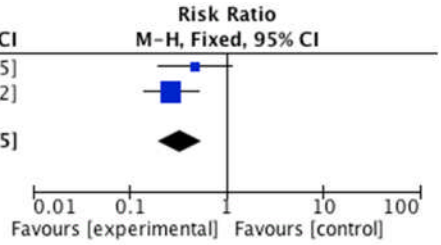
Table 5**.**

Analysis 1.3

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Turk 1996	5	21	10	20	27.8%	0.48 [0.20, 1.15]
Williams 1996	7	30	27	31	72.2%	0.27 [0.14, 0.52]
Total (95% CI)		**51**		**51**	**100.0%**	**0.33 [0.19, 0.55]**
Total events	12		37			

Heterogeneity: $Chi^2 = 1.05$, df = 1 (P = 0.31); $I^2 = 4\%$

Test for overall effect: Z = 4.18 (P < 0.0001)



Two trials of 102 participants were analysed for effects on pain medication use. Turk et al. (1996) reported the percentage of self-reporting participants using over the counter analgesic medication at 6 month follow-up. A risk ratio was calculated using N values from Williams et al. (1996) of self-reporting participants using “no drugs” subtracted from the group N value to calculate those that were using pain medication. The percentages in the Turk et al. (1996) study were then converted to actual participants to provide a number of events metric for analysis (specific pain medications were also reported in Williams et al. (1996) but did not include analgesics and so this was deemed as the closest metric for analysis). The test for overall effect was positive (Z = 4.18, P = 0.0001) with a risk ratio of 0.33 [95%, 0.19, -0.55] in favour of the intervention and low heterogeneity at ($I^2 = 4\%$).

The excluded studies which increased heterogeneity showed significant results when comparing treatment arms. Thieme et al. (2003) reported a significant interaction of group and time for female fibromyalgia patients and only the psychological intervention group reduced doctor visits (53.5%) and hospital days (80.3%). There was a significant reduction in use of anti-depressant medication, non-steroidal anti-inflammatory drugs and opioid medication. However, they used mean and SD metrics which could not be added to the medication analysis. Van Eijk-Hustings et al. (2013) reported within a multi-disciplinary therapy (MDT) significant reduction in GP visits compared to TAU controls. Within both the MDT and TAU group,

a significant reduction was observed in specialist visits during the study. A small non-significant reduction in medical visits between MDT & TAU in favour of TAU was reported at the end of the intervention.

There were small to moderate significant effect sizes for psychological interventions on HCU. The remaining trials with HCU outcomes that did not provide analysable data reported mixed findings. Alaranta et al. (1994) reported that visits to doctors at 12 months follow-up compared to the 12 months pre-treatment diminished by 74% in the treatment group compared to 67% in the control group and that outpatient physiotherapy visits reduced by 66% in the treatment group and 77% in controls. Lindell et al. (2008) was less convinced of treatment effects between CBT and primary care, acute and chronic pain patients but did acknowledge a trend in reduction of HCU that was sustained up to 18 months follow-up .

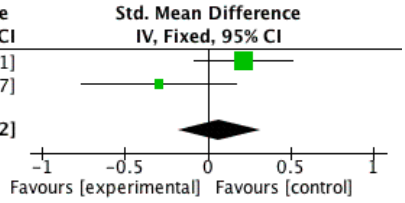
Intervention versus treatment control - sick leave days.

Table 6

Analysis 2.1

	Experimental			Control				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Geraets 2005	2.5	9.7	87	0.9	4.12	89	71.1%	0.21 [-0.08, 0.51]
Marhold 2001	49.4	17.4	36	53.7	10.5	36	28.9%	-0.30 [-0.76, 0.17]
Total (95% CI)			**123**			**125**	**100.0%**	**0.07 [-0.18, 0.32]**

Heterogeneity: $Chi^2 = 3.30$, df = 1 (P = 0.07); $I^2 = 70\%$
Test for overall effect: Z = 0.53 (P = 0.60)



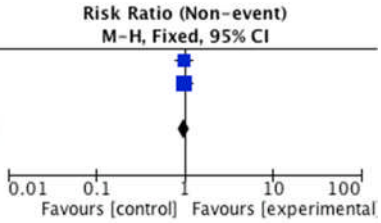
Two trials totalling 248 participants were analysed for the effect of psychological intervention on mean sick leave days for paid and unpaid work (Geraets et al., 2005) and those on long term sick leave (Marhold et al., 2001). The overall effect was non-significant (Z=0.53, P>0.05).

Table 7.

Analysis 2.2

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio (Non-event) M-H, Fixed, 95% CI
Jensen 2001	13	49	12	48	44.4%	0.98 [0.77, 1.24]
Lindell 2008	16	61	16	62	55.6%	0.99 [0.81, 1.23]
Total (95% CI)		**110**		**110**	**100.0%**	**0.99 [0.84, 1.15]**
Total events	29		28			

Heterogeneity: $Chi^2 = 0.01$, df = 1 (P = 0.93); $I^2 = 0\%$
Test for overall effect: Z = 0.15 (P = 0.88)



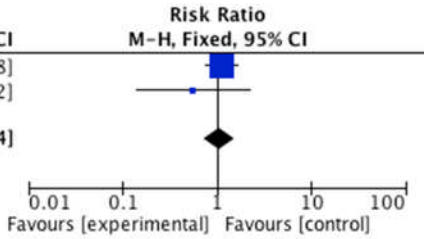
Two studies with 220 participants provided total sick days converted to events as the metric for analysis. It was calculated over a 26 week period, which assuming a five day working week would equal 130 days. Therefore the total number of sick days for the sample is 130*N and the calculated non-sick days (130*N)-net sick days reported in both studies and divided by 1000 (so that events were not bigger than the number of participants). Based on these calculations for each study, effect sizes were non-significant with a risk ratio of 0.99 [CI 95% 0.84, 1.15].

Table 8.

Analysis 2.3

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Alaranta 1994	40	152	33	141	86.9%	1.12 [0.75, 1.68]
Kaapa 2006	3	49	5	46	13.1%	0.56 [0.14, 2.22]
Total (95% CI)		**201**		**187**	**100.0%**	**1.05 [0.72, 1.54]**
Total events	43		38			

Heterogeneity: $Chi^2 = 0.90$, df = 1 (P = 0.34); $I^2 = 0\%$
Test for overall effect: Z = 0.25 (P = 0.80)



Two studies with 388 participants were selected for risk ratio analysis. The two studies grouped percentages of participants by the number of sick days reported over 12 months. Percentages were converted to actual participants and combined with the subgroup ‘participants with greater than thirty days sick leave days’ which both studies reported post treatment. The overall effect was non-significant (Z=0.25, P = 0.80) with a risk ratio of 1.05 demonstrating no difference between intervention or control.

There were no significant effects of psychological interventions and control groups on sick leave days. Of the studies that could not be analysed, Johansson (1998) reported no effect of inpatient CBT on sick leave compared with wait list controls. The authors suggest this may be explained by follow-up being too short (1 month) considering improvement patients had shown in other areas of disability. A replication of the same study with follow-up at 1 year reported a decrease in average level of sick leave from 70% pre-treatment to 29.4%. The 10 year follow-up by Busch et al. (2011) of Jensen et al. (2001), whilst not included in any of the analyses, also reported no significant between-groups results but, observed that MDT interventions reduced sickness absence by 42.98 days/year compared to TAU.

Discussion

A systematic review and meta-analysis of the effectiveness of psychological interventions in reducing healthcare use and sick leave days in chronic pain patients included sixteen studies that compared psychological interventions with treatment as usual, waiting list or active controls.

Summary of Main Results

The primary objective of this review was to evaluate the effectiveness of psychological therapies for chronic pain in adults using previously unanalysed outcomes of healthcare utilisation (HCU) and sick leave days (SLD). This review found 25 trials of which 16 were eligible and provided data representing 1873 participants from 6 different countries with a mean age of 45 and mean pain duration of 3.9 years. Twelve measured healthcare utilisation and nine used sick leave days as outcomes, with fifteen trials providing data suitable for analysis; 9 for HCU and 6 for SLD. Psychological interventions were predominantly based on CBT principles, or

adaptations of CBT, as part of combined exercise, medication or stress reduction interventions.

Meta-analysis demonstrated small but positive effects for psychological interventions compared to active, treatment as usual (TAU) and waiting list controls in reducing HCU. The SLD analysis showed no significant effects of psychological interventions, although there were trends showing reduction overall but not significant when compared with active and TAU controls. The overall quality of trials was comparable with the previous review but analysis was restricted by problems of heterogeneity of reporting metrics, particularly with SLD data.

Inpatient PMP performed more favourably than an outpatient PMP across healthcare usage including self-reported medical appointments and self-reported medication use (Williams et al., 1996). Similar results were found in a mindfulness based stress reduction intervention and active relaxation controls (Schmidt et al., 2001).

All psychological (e.g. CBT, couple CBT and MDT rehabilitation) and control (e.g. medication, individual CBT and individual physiotherapy) interventions reduced HCU, and there was no difference between the magnitude of these benefits between psychological and control conditions, with the exception of one trial. In Flor et al. (1993), the biofeedback control condition had greater long-term improvements for HCU than the psychological intervention. The authors suggest that patients with few physical disabilities in a musculoskeletal pain population may benefit more from short term biofeedback treatment.

There were also reported significant reductions in medication usage but not all studies were able to be analysed together due to the difference in measurement. The two studies compared by risk ratio elicited a small effect in favour of psychological intervention. They both reported significant results between intervention and controls

and were both forms of pain management programs that generally perform well in reducing medication.

Closer examination of the individual studies suggests that whilst there was a general towards reduction in SLD post intervention, there were no noticeable effects between psychological interventions and control groups. Most trials reported a general reduction in SLD in both intervention and active control arms but it was not significant between intervention and control groups. The earlier review of the literature would concur with these findings with SLD studies reporting conflicting findings although the difficulties in calculating summary statistics with the SLD data was problematic and so further investigation is needed.

Quality of the Evidence

Using the Yates et al. (2005) quality rating nomenclature, the mean score of the sixteen studies was 21/35, with a range between 15 and 31. It is difficult to ascertain what effect this has on the final analysis but should be considered when measuring the final results. The overall quality of trials was comparable with the previous review (Williams et al., 2012) but analysis was restricted by problems of heterogeneity of reporting metrics, particularly with SLD data. Therefore it is difficult to report these effects as conclusive.

Agreements and Disagreements with Other Studies or Reviews

This review's findings tend to agree with previous studies of HCU data. For example, a study compared cost-effectiveness of three treatment groups by examining treatment outcome, post treatment health care costs, and post-treatment health care visits (Cipher et al., 2001). Results revealed that patients receiving both medical and psychological treatment (multidisciplinary pain management) exhibited the largest improvements in functional capacity, whilst being the least costly after their

treatment program had ended. In contrast, patients who received only medical treatment exhibited significant deterioration in outcome after their treatment ended, and used three or more times post treatment health care in dollars.

Trials indicate multidisciplinary pain management programmes reduced HCU and SLDs. Flor et al. (1992) cited both HCU and SLD reductions in their meta-analysis of pain treatment centre efficacy. They reported a 50% return to work after PMP and that 25% of disability claims are closed with a one third reduction in the number of surgeries and hospitalisations. Hoffman, Papas, Chatkoff & Kerns (2007) meta-analysis of psychological effects for chronic lower back pain reported the opposite of this reviews findings. They report no effect of psychological interventions on HCU and HC visits (where 36% of 22 studies had reported HCU data). However, there was a moderate effect size of MDT for long-term return to work outcomes.

This study recognises the lack of trials that measure both HCU and SLD outcome data. Of the 71 screened trials only16 used HCU or SLD outcomes. When one considers that most pain management interventions explicitly aim to reduce healthcare use/costs and have been proven to reduce disability that can hinder return to and maintenance of employment (Flor et al., 1992; Hoffman et al., 2007) the small number of trials is surprising. Over 50% of data from included studies were from Scandinavia, particularly for SLD data that can be accessed through a national registry. Importantly, it remains unclear how generalizable these findings are to other Western countries, including the UK.

Implications for Practice

A recent report commissioned to assess the current impact of chronic pain in Europe, highlight current management failings and share good practice, outlines some of the current systemic measurement issues affecting progress:

"A significant barrier in initiating change at a political level, is the lack of clinical and economic measurement for chronic pain. … there is no evidence to show that effective management of chronic pain can result in a decrease in hospital admissions although common sense tells us that there is likely to be a relationship between the two. Chronic pain is essentially 'invisible' within the NHS, and so the evidence to support calls for improved diagnosis, management and interventions from a political level is lacking. This problem is compounded by the lack of outcome data from 'effective' services and lack of data on the economic impact of chronic pain.

(The Pain Proposal, 2010; p11)"

Knowing which subgroups of chronic pain respondents use the most services and what types of services or are the most vulnerable to employment issues such as sick leave, provides some of the information needed for good health services policy and planning (Blyth et al., 2005). This review highlights how little is currently known or reported in these areas of pain research and yet the indicators are that it is something that health providers are requesting. Most services are funded according to the number of patients seen, rather than the complex services they provide. Where new and innovative ways of working reduce the number of patients who need to be seen in specialist clinics, this can result in a significant loss of funding for the service, further discouraging innovation and threatening the viability of local services.

Pain management claims to enable self-management and reduce recourse to healthcare use. Despite some good supporting evidence reviewed in this study, this needs to be demonstrated. A number of reports cite the significant cost of pain to the health budget, therefore there is a need to show cost effectiveness, however beneficial treatment is to the patient in other ways. It is true that perhaps there are issues around obtaining reliable accurate data e.g. the accuracy of self-report data.

They can pose threats to validity when incorporating them into RCT yet it has been achieved successfully by a number of studies, as we have seen in this review.

HCU and SLD factors are common complaints from patients when entering treatment and are actively discussed, yet it appears not to be regularly monitored or reported. Fear and anxiety, high levels of pain and high levels of disability or the need for certification for welfare or sick pay can be important reasons for patients to seek help. The time and money spent getting to appointments or the results of treatments/consultations can also cause unwanted psychological effects for patients. Therefore collection and analysis of HCU and SLD data already fits with the existing self-help ethos of pain management intervention.

Willingness and understanding of employers is also a factor in addressing SLDs. Return to, or remaining in, employment needs more than just psychological rehabilitation. For example, a prospective cohort study surveying CLBP patients in an orthopaedic outpatient setting for predictors of HCU reported work-related fear avoidance as a significant factor (Keeley et al*.,* 2008). If the causation of increased HCU is assessed to be employment related, there is an opportunity for health care professionals to intervene effectively at both a work, and a health care level.

Practical support at the employer level is required. Helping employers to become ready to accept those that have been put off employment for so long as well as meeting the risk and expense of workplace adaptations must be part of the solution. There is comprehensive NICE guidance on how to approach the treatment of people with long term sickness absence and they recommend joint working between health care professionals and employers during treatment (NICE, 2009).

Implications for Research

The findings of this research were consistent with prior research on the variation of reported metrics, particularly for the SLD data. The meta-analysis by Flor

et al. (1992) of psychological interventions for pain, reports their study was also 'hampered' by failures to report extractable data. In some circumstances they had to rely on graphical display to determine the required outcome data. This review highlights a need for development of common measures of HCU and, in particular, sick leave data. Future research could focus on establishing a consensus amongst providers and professionals alike in order to facilitate valid and reliable comparisons in meta-analyses. The current high levels of heterogeneity across metrics make it difficult to synthesise the outcomes across trials and, therefore, inform decision-making.

The use of national registry of sick leave data, as demonstrated by the Scandinavian based studies, would appear to be the solution to the reliability issues but has some limitations. For example, it usually relies on the absentee reporting the reason for the leave and sometimes records episodes of leave and so 3 days may be calculated as one week (Ostelo & de Vet, 2005). There is evidence against the convergent validity of registry and self-report data (Burdorf, Post & Bruggeling, 1996; van Poppel, de Vet, Koes, Smid, & Bouter, 2002). Both studies measured sensitivity (the percentage of people with back pain who report sick leave in the registry) and specificity (the percentage where the patient had reported no incidents of sick leave where there had been none). Specificity was high meaning that generally tallied with the registry. Sensitivity varied from 88% (Burdorf et al., 1996) to 55% (van Poppel et al., 2002). Both found sensitivity was dependant on the period of recall, the level of education of the reportee and the duration of the period of the sick leave.

Patient medication diaries or self-reported medication usage can offer richer data of actual consumption rather than a record of prescription alone. It can elicit patterns of consumption, adherence and supplementary medications that solely interrogating prescription records perhaps cannot. For example, self-reporting could also encompass over-the-counter medication such as non-steroid anti-inflammatory

drugs that may not be recorded as they are not generally prescribed medications. This approach to HCU and SLD outcomes has been observed successfully in Williams et al.'s (1996) RCT where patients successfully completed healthcare and medication usage.

A recent study on patient-defined measures of clinical outcomes following a focus group, were rated by people with chronic pain. Employment was rated as an important measure by almost 70% of respondents (Beale, Cella & Williams, 2011). When one considers the social, physical and financial costs of excessive sick leave, this is perhaps no surprise (Vingård, Alexanderson & Norlund, 2004). It is unclear from the study by Beale et al. (2011) whether the same study population would rate HCU as highly as employment or if they would consider it worthy of measurement. Medication understanding and usage is usually high on a patient's list of concerns coming into treatment. HCU outcomes could also be linked to quality or enjoyment of life which was also rated highly as a desired measure. HCU perhaps has some influence here in terms of unwanted side effects or unnecessary visits to doctors or hospitals.

Conclusion

This review demonstrated small positive effects for psychological interventions compared to active, treatment as usual (TAU) and waiting list controls in reducing HCU. The SLD analysis showed no significant effects of psychological interventions, although there were trends showing reduction overall but not significant when compared with active and TAU controls. The overall quality of trials was comparable with the previous review but analysis was restricted by problems of heterogeneity of reporting metrics, particularly with SLD data. Only 25 trials from a possible 71 reported HCU and SLD data with 16 providing suitable data for this review. When one considers the health care provider's focus on economic as well as clinical

performance, the small number of studies is surprising. There are undoubtedly some benefits here for pain management programmes when one compares the general trends in efficacy shown in these outcomes particularly for HCU with the ease of implementing the data collection. Routine measurement of HCU and SLD outcomes could become part of assessment and treatment protocols and could not only justify, but increase funding for what is generally considered as an expensive intervention. This review, therefore, makes the following recommendations:

1. A commitment to measurement to be included in all future pain trials of HCU and SLD data e.g. number of visits, days, periods of absence.
2. An agreed metric for reporting HCU and particularly SLD data to improve ease of analysis and comparison e.g. individual or group means and SDs.
3. Identification at assessment of patients with significant HCU or employment difficulties assessed to be interfering with quality of life. For example, employment issues are measured on the Sickness Impact Profile and so could be explored further.
4. Regular reporting of pre, post and follow-up HCU and SLD outcome data from healthcare teams to commissioners, managers and a national database.

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Part 2: Empirical Paper

"The parts are greater than the sum of the whole"

Exploring the Process of Change in a Pain Management Programme using Single Case Study Design

Abstract

Aims: Cognitive Behavioural Therapy (CBT) has been proven as an effective treatment in the management of chronic pain although it is not yet understood what components of treatment are most influential for beneficial outcomes. Building on previous findings of multicomponent multi-outcome Randomised Controlled Trials (RCT), this study uses an idiographic approach to identify relationships or trajectories, which might lead to hypotheses about participant change in a CBT pain management programme.

Method: Eight participants were recruited from a London based pain management programme using twice weekly measures selected for previous evidence of efficacious change from pain management interventions i.e. mood, self-efficacy, catastrophic thought, goal attainment, adherence and working alliance. Participants completed measures at a baseline, intervention and follow-up period. A telephone interview was also carried out.

Results: One participant made significant improvement across all measures and 3 in self-efficacy and mood. 3 participants showed significant deterioration in self-efficacy. All participants made progress on agreed goals and some potential associations were found with adherence. There was a high and consistent consensus in working alliance and participants agreed that CBT, pacing, explanation and biology of pain, therapeutic alliance, and peer support were contributing factors in their change. Graphical representation of scale scores indicates the fluctuation in scores across the three phases.

Conclusion: Single case methods provide further insight as to the trajectory of change for individual participants before, during, and after a pain management programme. They also offer some insight into possible components of change and the fluctuation of scores that are sometimes concealed in pre and post mean scores or group comparison alone.

Introduction

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” (International Association of the Study of Pain, 1986). Many people have pain that lasts for a long time that is not relieved or cured by physical therapy or medicines. It is a subjective experience that affects one in five European adults (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006) and interferes with emotional, social, as well as physical functioning. Exploring psychology’s role in managing pain, Eccleston (2001) observes patients’ search for a diagnosis and for pain relief is often long, discouraging, and inevitably is damaging psychologically and physically. Ways of coping that are clinically encouraged and adaptive in acute pain episodes can become unhelpful and maladaptive in persistent pain (Zarnegar & Daniel, 2005).

The relationship between thoughts, emotions and biological and behavioural responses are well documented in the Cognitive Behavioural Therapy (CBT) literature (Beck, Rush, Shaw & Emery, 1979; Clark, 1986) and responses to pain are no exception. Distorted perceptions of increased pain equating to more damage are associated with anxiety and unhelpful fears or beliefs that ‘pain means that I am damaging my body’ or ‘moving will damage my body further’ (Zarnegar & Daniel, 2005). Patients’ then become avoidant of activity which, in turn, contributes significantly to disability in many pain patients (Vlaeyen and Linton, 2000 & 2012).

Though not always inevitable, these behaviours are thought to be reversible, at least to some extent, using a rehabilitation or management approach which aims to reduce disability and distress despite continuing pain (Williams, Eccleston, Morley, 2012). The treatments are based on robust psychological principles and practices and have been in continuous development for about 40 years. Patients are encouraged to adopt more helpful beliefs and behaviours that lead to less emotional distress and disability and therefore less dependence on medical services and better quality of life.

Current evidence suggests that psychological characteristics are more reliable determinants of outcome from CBT than demographic data, medical diagnosis or physical findings (McCracken & Turk, 2002).

A recent systematic review of cognitive behavioural therapy (CBT) for chronic pain has shown that, compared with waiting list controls, CBT has small effects on pain and disability respectively but is effective in altering mood and catastrophising outcomes which are sustained over 6 months (Williams et al., 2012). However, they conclude that attempting to determine which components of pain management programmes are factors in better outcomes is not possible given that components interact in their effects on outcomes. Thorn and Burns (2011) are in agreement when they observe that we can state that many psychosocial interventions reduce pain and distress and increase physical function, but we cannot state definitively why this is the case.

Some of the difficulty lies in the heterogeneity of the population. Even when pain patients experience similar symptoms, there are differences in underlying physical and psychological contributions, existing coping mechanisms, general health and social and cultural background. It may also be that change in some outcomes may be needed to facilitate change in others. For example, changes in beliefs and thinking might mediate other changes that outcome studies are not designed to identify (Laurenceau, Hayes & Feldman, 2007; Thorn & Burns, 2011). Psychological therapies are one way of helping people with chronic pain reduce negative mood (depression and anxiety), disability, and in some cases pain, but empirical evidence is lacking on the best content, duration, intensity, and format of treatment.

Turk (2005) suggests that pain management programmes need to be more tailored to individual needs and characteristics in order to increase their effectiveness. The lack of a coherent theory means patients tend to get sub-grouped by non-psychological means such as diagnosis or from superficial non-functional

characteristics elicited by questionnaires (Williams et al., 2012). Neither strategy is likely to be helpful in identifying what works for whom (Vlaeyen and Morley, 2005).

While there is solid evidence that rehabilitative cognitive and behavioural treatment for persistent pain is effective in improving activity levels, mood, and to a lesser extent, reducing pain, those results use averages across people. They therefore cannot tell us about the process of change, which is important to understand in order to maximise benefits to patients. Single case design is the repeated collection of quantifiable data on a single case or client. Unlike case studies it adopts a more idiographic, scientific approach where the level of analysis is primarily the client (Kazdin, 1982; Morley, 1996), and the focus is on within-subject variability (Barlow, 2008). It can also answer questions around process variables as well as efficacy.

Therefore, by utilising a more individually-focused research method that follows patient change trajectories over time (such as single case design) clinicians can contribute significantly to generating hypotheses about how to distinguish these patients from one another. Previously successful studies by single case researchers in depression have, for example, identified a pattern of early rapid response where symptoms significantly decrease by session four and then level off (Ilardi & Craighead, 1999). Another example is the *sudden gains* theory of Tang and DeRubeis (1999), who noticed a large improvement in a between- session interval that does not reverse.

Pain management programmes are manualised multidisciplinary CBT programmes that aim to help patients learn self-management strategies to reduce the distress and disabilities associated with chronic musculoskeletal, orofacial and urogenital and pelvic pain, and to improve function and quality of life (Lee, Daniel & Brook, 2009). The overall aim is not to cure the pain, which has proved resistant to medical and physical attempts to treat it, but to reduce the distress and disability that pain causes. It usually employs a multidisciplinary team consisting of clinical psychologists, physiotherapists, specialist pain doctors and a pain nurse. The team

help the patient understand and implement a self-management approach to their pain by first assessing beliefs about cause of their pain, associated thoughts, feelings and behaviours, coping strategies currently employed and the impact on their life. These then form the basis of agreed goals for intervention.

The Pain Management Centre of a Central London University College Hospital runs well established pain management programmes involving an experienced team of psychologists, physiotherapists, pain specialists and nursing staff. They regularly show good results in routine evaluation and so provided a useful platform for this research. Individual pain patients were recruited from the Pain Management Centre and repeatedly assessed before, during and after treatment, as well as during intervention to gain insight into the individual process of change for pain patients.

Aims

CBT has been proved as an effective treatment for the management of chronic pain although it is not yet understood what components of treatment are most influential for beneficial outcomes. Building on previous findings of multicomponent multi-outcome Randomised Controlled Trials (RCT), this study uses an idiographic approach to identify relationships or trajectories which might lead to hypotheses about participant change in a CBT pain management programme.

Method

Setting

The research took place at the Pain Management Centre of a Central London University College Hospital. It is well established as a centre of excellence for the treatment and management of chronic pain as well as the UK's largest dedicated Neurological and Neurosurgical hospital.

Participants

Sampling method. Clinicians screened patients at assessment for their ability and willingness to cope with the nature and commitment required to participate in this study. Information sheets and consent forms were utilised as part of the recruitment following favourable ethics approval detailed below.

Inclusion and Exclusion Criteria. Participants were required to meet the inclusion and exclusion criteria for the relevant pain management programme. Inclusion criteria were: 1) 18 years or older and 2) have a diagnosed chronic pain condition. Exclusion criteria were: 1) actively suicidal 2) actively using illicit drugs or excessive alcohol; 3) have current cancer pain due to a malignancy and 4) an inability to understand English in a group. The only additional inclusion criterion for this research was that in order to complete the required data set they needed to be willing or able to use the internet, email or post.

Ethical Approval

The research was granted proportionate ethical approval by The National Research Ethics London Fulham Committee – 13/LO/0940 (see appendix 4)

Procedure

Recruitment. Patients were identified at the formal assessment stage and approached by the assessing Clinical Psychologist, independently of the research team. Following their informal consent to be considered they were given an information sheet (see appendix 5) to read. Their contact information was passed to the researcher by the clinical lead either directly by telephone or via secure email to

preserve confidentiality of patient information. A follow-up contact was then made by phone by the researcher no later than seven days after the assessment. The patients were asked if they understood the purpose and requirements of the study and were encouraged to ask questions. Arrangements were then made with the researcher to complete consent forms (see appendix 6) and instructions were relayed as to how they would receive the surveys (i.e. by email or post) and a start date was agreed for their participation.

Data collection. Consenting patients commenced completing standardised outcome measures on a twice-weekly basis up to four weeks before the start of their allocated programme, and using the data response mechanism of their choice (internet, email or post). This was to establish a baseline that enabled the research team to analyse how stable their current difficulties are before treatment commences. The patients then started their therapy, and completed twice-weekly assessments up to, and including, four weeks after their programme finished. The research culminated with a short telephone interview conducted by the researcher.

The collected data was downloaded and stored securely for future analysis on University password-protected computers. Patients were offered the opportunity to ask any questions during the telephone interview and referred back to the information sheet that contained full contact details. Once the researcher had ascertained that all the data was present then the patient was thanked for participation, and given the cash incentive in vouchers via a thank you letter and offered inclusion in the wider dissemination post write up.

Software. To facilitate secure electronic data collection this study used a University College London in-house web-based survey tool called Opinio v6.7.2. It provided a framework for authoring and distributing surveys via the internet and email as well as multiple reporting formats. Participants who elected to use this method

would receive bi-weekly email hyperlinks that would prompt and remind them to complete that day's survey. The software also allowed the researchers to monitor incomplete surveys and remind participants to help prevent missing data.

Treatment Intervention

Pain management programme. Patients are commonly referred to pain management programmes following unsuccessful attempts to resolve their pain by specialist pain care teams or consultants. The programme first offers patients an initial information session to orient them to the theory and practice of pain management where, if they decide to opt into treatment, they are offered a choice of assessment dates where they are asked to complete some standardised questionnaires and basic physical ability tests by the team physiotherapist.

Patients are then allocated a pain management programme tailored to their specific type of, or location of pain i.e. chronic musculoskeletal, orofacial and urogenital and pelvic pain. There they receive a manualised multidisciplinary CBT programme of differing durations (COPE for chronic musculoskeletal pain - eight day-long sessions usually once per week but in some cases twice per week; LINK for urogenital and pelvic pain - seven day-long sessions over seven weeks; ABOUT FACE for facial pain - 3 hours once a week for six weeks.

In each of the programmes a multidisciplinary team consisting of clinical psychologists, physiotherapists, specialist pain doctor and pain nurse help the patient understand and implement a self-management approach to their pain. They are first educated about the biological mechanisms of pain. The team will then assist them to uncover beliefs about causes of their pain, associated thoughts, feelings and behaviours, coping strategies currently employed and the impact on their life. These then form the basis of agreed goals for intervention using cognitive/ behavioural and acceptance and commitment approaches designed to increase psychological

flexibility. The overall aim is not to cure the pain, which has proved resistant to medical and physical attempts to treat it, but to reduce the distress and disability that it causes. Other practical self-management strategies to reduce the distress and disability associated with their pain are also introduced such as relaxation and mindfulness, stretching and pacing and advice about sleep.

All programmes come with the addition of a one month, five month and twelve month follow-up session. The programme is run in a group format, with 8-10 participants all starting at the same time. There are approximately 6-8 weeks between the assessment and the start of their intervention, during which time the participants would complete their baseline measures twice weekly. Following the start of treatment and up to the one month follow-up session patients would also be measured twice weekly by the researcher.

Design

This study utilises an AB single case design (Barlow, Nock & Herson, 2008). A and B represent series of repeated observations under two conditions: baseline (A) and treatment and post treatment (B). By taking repeated measures, issues of reactivity, regression and maturation can be controlled for as any unusual trends in these would be expected to show in the baseline data (McMillan & Morley, 2010). “Hence if the participants’ problems are reasonably stable during baseline and treatment phases, despite the documented presence of various events, it is not unreasonable to infer that any major change occurring at the time of introducing treatment is due to the treatment” (p112).

This study chose a twice weekly frequency of data collection that represented a two to four day gap between measurements (allowing for weekends). By minimising the time lag between the experience of an event and the recording of an event it was hoped that this might lessen any biases due to length of recall (Laurenceau, Hayes &

Feldman, 2007). This schedule was maintained throughout the baseline, intervention and follow-up. During intervention it was ensured that measurement was before and after participants' pain programme session to allow time for reflection of their learning and to experiment with new techniques while not inducing fatigue. Using what Bolger, Davis & Rafaeli (2003) call a *signal-contingent design,* participants would then receive email links as prompts to complete assessments at the allocated time points (except those who that opted for postal assessment where calendar entries were agreed for all measures and provision for day and date was included in the assessment sheets).

Measures

Outcome measures were selected that had clinical relevance to this study population and complimented the current assessment battery used by the PMC (except where some had single items extracted from them). This allowed continuity in measurement by aligning this study with the aims of the programme. There is also good evidence of improvement in these domains following PMP interventions and so it was increasingly likely that we would see change and enable single case methods to explore why, how and when. In addition, the authors sourced measures that assessed other facets of the programme, i.e. goal setting, what might be happening outside of the programme, adherence and process issues and therapeutic alliance. In addition, a qualitative measure and question about external factors were included to capture patients own reflections on the process of change and factors outside of therapy that may have had an influence on them. All measures were completed at multiple time points before, during and four weeks after treatment (see table 2):

Pain Catastrophizing Scale (PCS; Sullivan & Bishop, 1995). This is a 13- item self-completion measure of catastrophizing, sampling the tendency to attend to pain, to overestimate its threat value and to underestimate the ability to handle that threat.

Each statement is rated for frequency of having these responses when in pain, ranging from 0 (not at all) to 4 (all the time), so total scores range from 0 to 52. Internal consistency is high (Cronbach's α=0.91: Sullivan & Bishop, 1995) and the test–retest reliability is satisfactory for the whole scale (ICC = 0.82) (Chatzidimitriou et al. 2006).

Working Alliance Inventory Short Version (WAI-S) (Tracey & Kokotovic, 1989) is a shortened version of the WAI (Horvath & Greenberg, 1989). The scale is completed by both client and therapist separately and consists of twelve items; ten positively worded and two negatively worded. It uses a seven point Likert scale to measure three factors of the therapeutic alliance based on Borden's working alliance theory: agreement of *goals* for therapy, *tasks* or agreement on what is important for the client to work on and *bond* between the client and therapist. It is a well-triangulated measure that is widely used and has good validity data (Elvins & Green, 2008). This measure was administered at the midpoint and towards the end of the programme to ensure that both parties had sufficient exposure to each other to form an accurate assessment of their therapeutic relationship.

Single Item Questions. The use of single item questions is preferred to repeatedly administering whole measures (apart from the PCS which was more difficult to deconstruct), which could become burdensome for participants when repeated over numerous time points. Therefore single items from reliable measures currently in use in the Pain Management Programme assessment at the NHNN or from other validated measures in this patient group have been extracted. Specifically, the items for each measure that proved most reliable and sensitive in the original or subsequent factor analysis of the measure were extracted to offer maximum sensitivity.

Mood. As a repeated measure of mood this study used an item from the Brief Pain Inventory (BPI) (Cleeland, 1994). The BPI is a self-report measure designed with the intention of assessing pain intensity and pain interference. It uses a numeric rating

scale where 0 represents “does not interfere” and 10 indicates “interferes completely.” The item asks the participant:

Circle the one number that describes how, during the past 24 hours, pain has interfered with your mood.

Does Not Interfere								Interferes Completely		
0	1	2	3	4	5	6	7	8	9	10

Self-efficacy. Taken from the *Pain Self-Efficacy Questionnaire* (PSEQ; Nicholas, 2007) a self- report questionnaire used to assess confidence in being active in ten different areas despite pain. Each statement (e.g. I can enjoy things despite the pain) is followed by a seven-point scale ranging from 0 (not at all confident) to 6 (completely confident). This measure has been shown to have good test–retest reliability and a high internal consistency (e.g., Cronbach’s α= 0.92: Asghari & Nicholas, 2001). Item 1 was used to represent the whole set:

I can still enjoy things despite the pain

	0	1	2	3	4	5	6
Not at all confident							Completely confident

Medication. This single item is also from the PSEQ and reflects any changes in the participant’s reliance on medication during the study that would be an indicator of improvement in symptoms.

I can cope with my pain without medication

	0	1	2	3	4	5	6
Not at all confident							Completely confident

Adherence to intervention. Taken from previous study by Curran, Williams and Potts (2009), the measures of adherence are designed to assess how much participants are adhering to the programme outside of the sessions by using frequency data.

Exercise frequency. Patients reported the frequency with which they completed an individualised set of exercises practiced during treatment by endorsing one of six categories, from 1, stopped completely, to 6, performed daily.

Stretch frequency. Patients reported the frequency with which they practiced stretching routines learned during treatment. They did this by endorsing one of six categories, from 1, stopped completely, to 6, performed daily.

Pacing frequency. Patients reported the frequency of using activity pacing methods (breaking activities down into small manageable steps and building up gradually; regularly taking breaks or changing position) as developed during treatment. They did this by endorsing one of six categories, from 1, stopped completely, to 6, performed at least daily.

Pacing occasion. Using a categorical scale, patients reported how they used pacing methods by endorsing one or more of six categories, where 1 = not at all, 2 = when I remember, 3 = when the pain is bad, 4 = for some activities, 5 = indoors only and 6 = as a daily approach.

Cognitive techniques frequency. Patients reported how often they were using the methods taught for challenging and changing unhelpful thoughts (e.g. identifying thought biases and looking for evidence). They did this by ticking one of six categories, where 1 = stopped completely and 6 = at least once a day.

Cognitive techniques occasion. Using an ordinal scale, patients reported how they used the cognitive techniques, where 1 = not at all, 2 = when I remember, 3=when the pain is bad, 4=when I am anxious, 5=when I'm depressed, 6 = when someone upsets me, and 7 = as a daily approach. These were recoded into a

hierarchy as follows: 1 = not at all, 2 = when the pain is bad or when I remember, 3 = when I'm depressed, when I'm anxious, or if someone upsets me, and 4 = as a daily approach. As with occasion of pacing, this reflected the least to most desirable use, according to treatment recommendations.

External Factors

Cook and Campbell (1979) highlight potential threats to internal validity faced by single case design and suggest measures are included to validate that any change is due to the intervention and not other external or social factors. Therefore, a question to address this has been included:

Have other factors outside of this treatment affected how you are now?

not at all - - - - - - - completely

Please explain further if you wish

.....

Personal goals for therapy. As part of the programme, participants were asked to formulate some personal goals for treatment and progress towards these were assessed weekly using goal-based outcomes (GBOs). Designed originally for activation and engagement with young people in a Child and Adolescent Mental Health setting, this is a way to evaluate progress towards a goal. They simply compare how far a participant feels he/she has moved towards reaching a goal they set at the beginning of an intervention, compared to where they are at the end of an intervention (or after some specified period of input). GBOs use a simple scale from 0-10 to capture the change (0 = not at all met, 5 = half way to reaching this goal, 10 = goal reached). The outcome was the amount of movement along the scale from the start to the end of the intervention. (CORC website, www.corc.uk.net)

Qualitative interviews. Specific questions that were considered useful for this study were selected by the author from the Change Interview (Elliott et al., 2001). The rationale being that a qualitative interview may be more sensitive to negative or unexpected effects McLeod (2001). A short 'debriefing' interview was conducted with each participant by phone approximately one month after the end of the programme and once all data was complete. The interview was audio recorded with the participant's consent. Interviews lasted approximately 20-30 minutes and participants were informed that the researcher was independent of the service and encouraged to be open and honest:

1. What changes, if any, have you noticed in yourself since therapy started? (For example, are you doing, feeling, or thinking differently from the way you did before? What specific ideas, if any, have you gotten from therapy so far, including ideas about yourself or other people?)
2. What areas, if any, do you feel you made the most change and why?
3. Has anything changed for the worse for you since therapy started?
4. Is there anything that you wanted to change that hasn't since therapy started? (Goals)
5. What were the most useful aspects of therapy?
6. In general, what do you think has caused these various changes? In other words, what do you think might have brought them about?

Analysis

Recent developments in quantitative statistical analysis of single case data either require randomised, alternating or reversal treatment study design of more than 30 – 40 time point measurements to be reliable. This would require more than bi-weekly sampling in this case and so was deemed unsuitable for this population.

Outcome data of single case studies can instead, or also, be analysed graphically following guidance by Morley & Adams (1991). They offer methods of systematically exploring data using measures of central tendency, linear and non-linear trend, and displaying variability and non-variability over time. Hayes, Laurenceau, Feldman, Strauss, Cardaciotto (2007) suggest that plotting these measures on a chart can also demonstrate the trajectory of change.

Table 1.

Time points of measurement of outcome measures

Time Points	**Measures administered**
Baseline (0-4 wks)	PCS, BPI SIQ, PSEQ SIQ x2,
Programme (5–14 wks)	PCS, BPI SI, PSEQ SI x2, FOT, GBO, ADR
Mid & End Point	WAI Therapist and Participant
Follow-up (14-18 wks)	PCS, BPI SI, PSEQ SI x2, FOT, GBO, ADR
Follow-up Interview	ECI

Note: PCS = Pain Catastrophising Questionnaire; BPI SIQ = Brief Pain Inventory; Single Item Question (Mood); PSEQ SIQ = Pain Self Efficacy Questionnaire Single Item Question; WAI = Working Alliance Inventory; FOT = Factors Outside Treatment; GBO = Goal Based Outcomes; ADR = Adherence to programme; ECI = Elliot Change Interview.

The reliable change index (RCI) (Jacobson & Truax, 1991) was computed for each measure that had a reliable reported coefficient (i.e. PCS, BPI Mood, PSEQ). Where single items had been extracted from standardised measures then the overall coefficient was adopted. It was considered that RCI methodology has the advantage of setting criteria for determining whether the magnitude of observed change is or is

not spurious (attributable to measurement error) (see Morley, Williams & Hussain, 2008).

Qualitative Analysis

Interview data was transcribed verbatim and all personal information was removed to preserve anonymity. Transcripts were then subjected to thematic analysis (Braun & Clarke, 2006) involving familiarisation with the data and extraction and coding of meaningful and interesting features of the dialogue that had a bearing on the research question. Any commonalities or patterns in codes were organised into themes. The proposed themes were reviewed in order to maintain an accurate representation of the data and audited by the research supervisor before adopting them for reporting.

Results

Due to unforeseen delays in receiving local NHS Trust R&D approval the August/September 2013 intake assessments were missed which restricted the pool of potential participants available for selection due to the time restrictions for completion and submission. Of the fifteen patients that were approached and informally consented to a follow-up call, eight patients were recruited to the study of whom seven provided a full set of data. (see Figure 1).

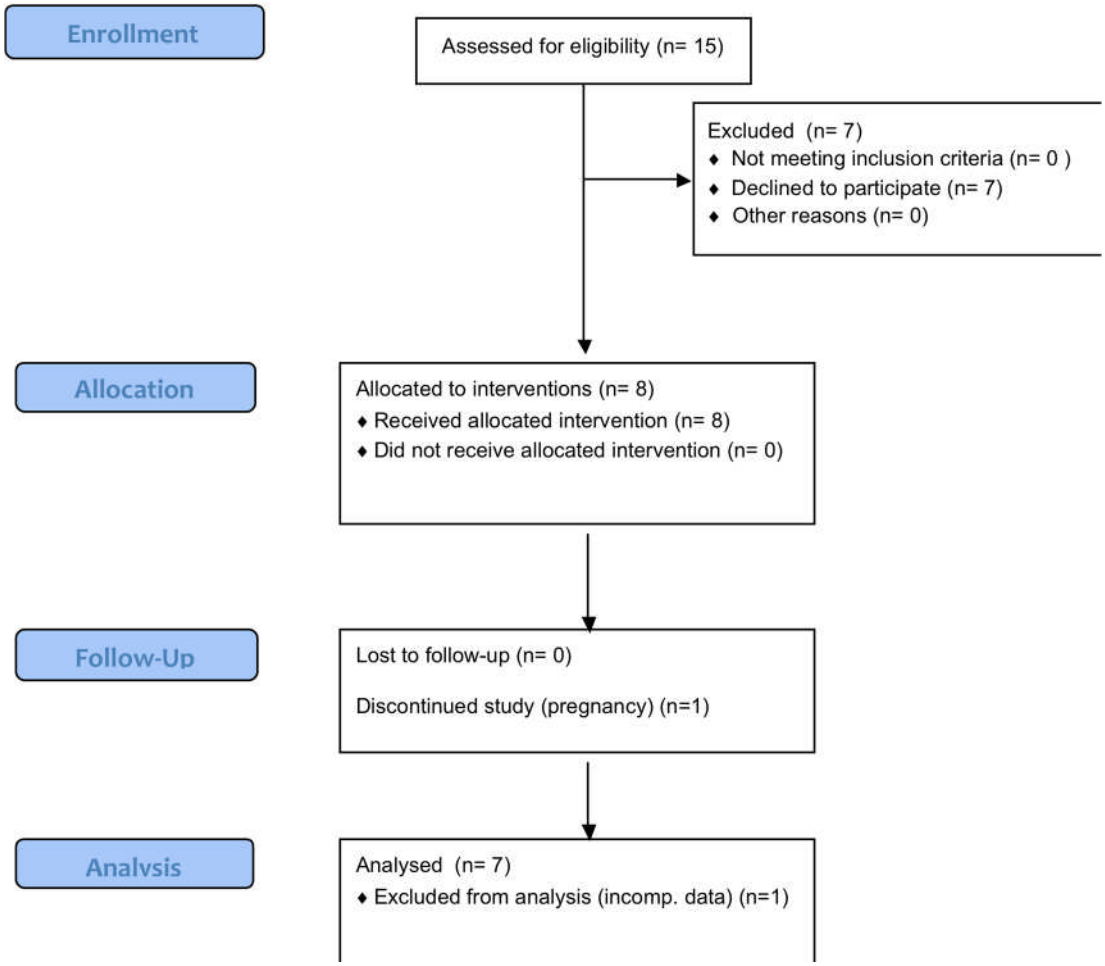


Figure 1: CONSORT (2010) Participant flow diagram

Five participants were female and two were male. Six participants opted to complete the surveys via email and one by post. All participants met criteria for chronic pain (see table 2). One participant dropped out mid-programme for personal reasons and so did not complete a full data set (P8). The three ABOUT FACE facial pain patients were the only participants that attended an intervention group together (including the participant that dropped out of the study). There was no reported non-attendance by any of the participants, as the programme rules state that they will be asked to delay their intervention in the case of missing one or two sessions. All

participants completed a post research change interview by telephone and the analysed data for each is reported here.

Reliable Change

Table 3 shows participants' mean scale scores for each measure summarised at each phase of the intervention (with the exception of the adherence and therapeutic alliance measures which are summarised separately below). Progress in terms of the statistical significance of their mean baseline and follow-up scores were calculated using reliable change based on the co-efficient of each measure cited in the measures section (see figures in appendices for graphical representation of RCI and all other measures). The RCI figures in brackets represent where participant scores were considered below clinical cut off and therefore were unlikely to improve further. However, these were monitored to check there was no deterioration.

Pain Self-Efficacy Questionnaire item – "*I can cope with my pain without medication".* Additional background to the scores in table 3 and the graphs for this item, assessment data obtained from the PMC reported that all seven participants were taking medication for their pain. P2 and P5 both had programme goals to stop medication and their scores on this item appear to validate their progress. P5 stopped her medication completely while on the programme. P1 also reported trying to reduce medication on the programme but was less successful. Both P1 and P7 completed the intervention and follow-up reporting no confidence at all in coping with their pain without medication.

Table 2.

Participant demographic data

Participant	Prog. Type	Age	Gender	Pain Location	Pain Duration (years)	Employment Status	Referrer
P1	L	56	F	Pelvic Pain	12	Employed	GP
P2	C	34	F	Back/Hip	18	Unemployed	PMC
P3	L	62	M	Pelvic Pain	3	Unemployed	PMC
P4	C	25	F	Multiple sites(JHS)	3	Employed	Rheumatology
P5	AF	46	F	Facial Pain	14	Employed	Dentist
P6	AF	33	M	Facial Pain	12	Employed	Dentist
P7	AF	73	F	Facial Pain	11	Retired	Neurologist
P8 (discontinued)	AF	48	F	Facial Pain	10	Employed	GP

Note: Prog Type: L = LINK; C = COPE; AF = About Face. Pain location: JHC = Joint Hypermobility Syndrome. Referrer Source: PMC = Pain Management Centre; JHS = Joint Hypermobility Syndrome.

Goal attainment – goal based outcomes measure. All 7 participants reported progress on at least one of their goals. P3 and P5 follow-up mean scores indicated that they had achieved one of the three goals. P6 did not set any goals until post intervention which is why his start at 0. Also P7 only had one goal set but managed to show marked improvement on a scale of 1-10. P4 reported little progress towards achieving goals and showed a reduction in progress between intervention and follow-up on their primary goal. However P4 had a high initial rating of attainment, so perhaps this was showing a more realistic level of current attainment whilst on the programme. P1 and P2 also reported progress on all three goals.

Table 3.

Summary of mean scale scores per participant across baseline, intervention and follow-up with RCI interpretation.

Measure	**P1**	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**
PCS:							
Baseline	39.1	33.0	12.6	34.5	6.6	18.8	24.4
Intervention	40.9	26.5	7.9	34.3	14.3	18.1	37.5
Follow-up	37.5	20.3	5.9	26.9	7.4	18.3	34.4
RCI	NC	*RC**	(NC)	NC	(NC)	NC	NC
Single Items:							
MOOD:							
Baseline	9.9	9.0	3.4	6.5	2.8	4.9	7.3
Intervention	9.8	5.9	2.6	6.7	3.4	4.8	7.0
Follow-up	9.5	4.0	1.3	5.5	1.9	5.8	5.4
RCI	NC	*RC**	(NC)	NC	(NC)	NC	NC
ENJOY LIFE:							
Baseline							
	0.5	1.5	3.8	2.3	4.5	3.5	2.6
Intervention	1.1	2.3	4.7	2.3	3.7	2.8	3.5
Follow-up	1.3	3.0	5.0	3.0	4.9	2.1	3.4
RCI	NC	*RC**	*RC**	NC	NC	*DET*	NC
COPE WITHOUT MEDS:							
Baseline	1.8	1.0	4.8	3.0	0.9	0.9	1.8
Intervention	0.2	2.0	4.9	2.2	1.4	1.0	0.1
Follow-up	0.2	2.6	5.6	2.3	4.6	1.0	0.1
RCI	*DET*	*RC**	(NC)	NC	*RC**	NC	*DET*
PROGRESS TOWARDS GOALS:	*3 of 3*	*3 of 3*	3 of 3	1 of 3	*3 of 3*	2 of 3	*1 of 1*

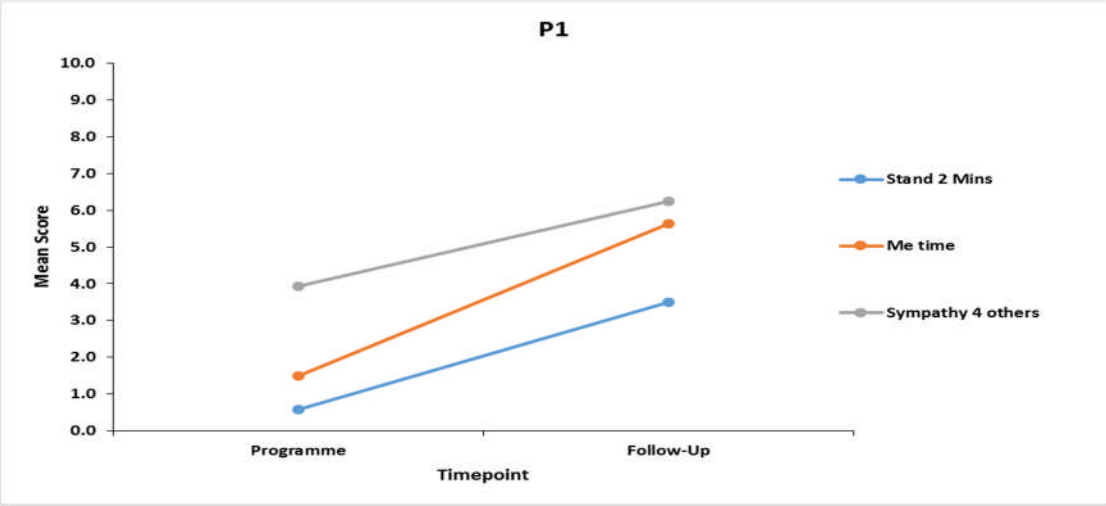
*Note: RCI = Reliable Change Index; RC = Reliable Change; NC = No Change; DET = Deterioration: * denotes reliable change at 95% confidence interval.*

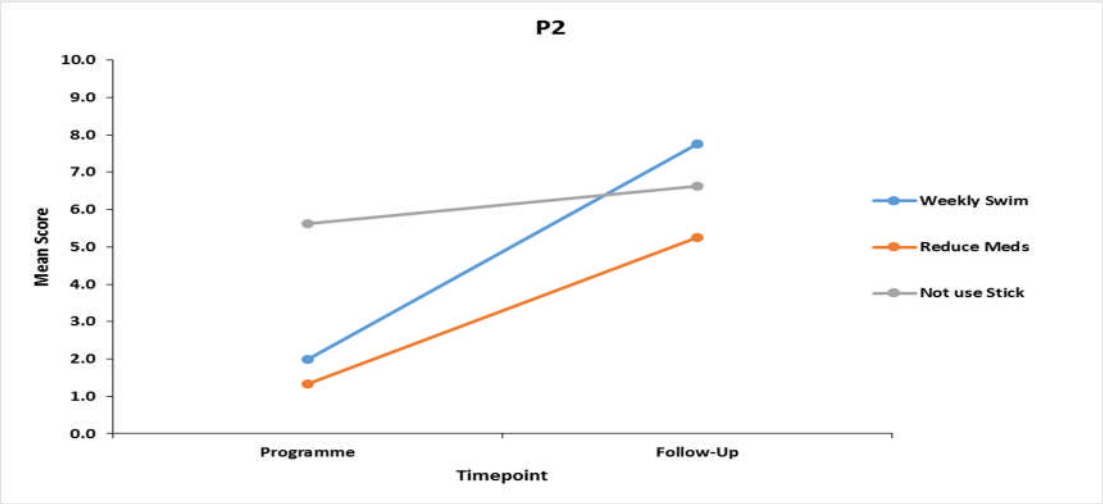
Programme adherence

Exercise and stretching frequency/pacing and cognitive occasion. Similar to goal attainment, programme adherence could only be measured following attendance on the programme. Exercise and stretching were frequency data and P2 showed the most consistent scores reporting adherence to exercise and stretching and utilising cognitive techniques daily throughout the programme and follow-up. P1 showed erratic adherence in both, as did P5, with the exception of cognitive techniques which remained at least once per day until follow-up. P3 and P4 remained relatively stable on both domains throughout the programme, with P3 showing a slight dip in cognitive techniques and pacing adherence into the follow-up period. P6 had a lot of data missing so it was hard to reliably assess adherence. From the data provided it was at a relatively low daily level. P7 maintained a stable pattern of adherence to exercise and stretching from once or twice per week to three or four times per week. Their cognitive techniques and pacing also increased to five to six times per week at the end of the follow-up measures.

Therapeutic alliance

The Working Alliance Inventory. Table 4 details mean scores and ranges to assess agreement across four participants and therapists as to their working alliance. There was some missing or incomplete data for the three remaining participants. Generally there was consensus for working alliance and no stand out differences at mid or post intervention. The range of scores tended to be within one or two points for both participants and therapists with the exception of the participant mid-point score for item Q7 regarding appreciation of each which showed a range of scores between 1-4.





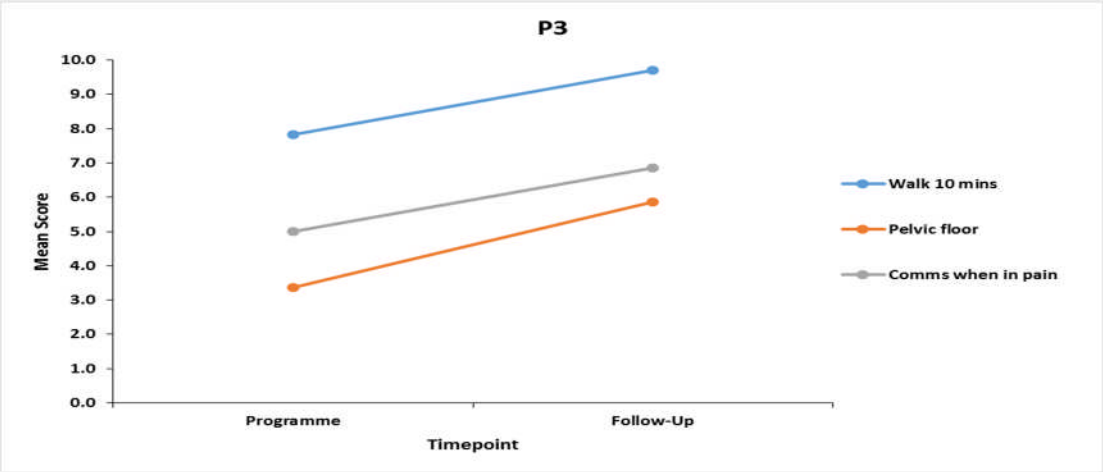
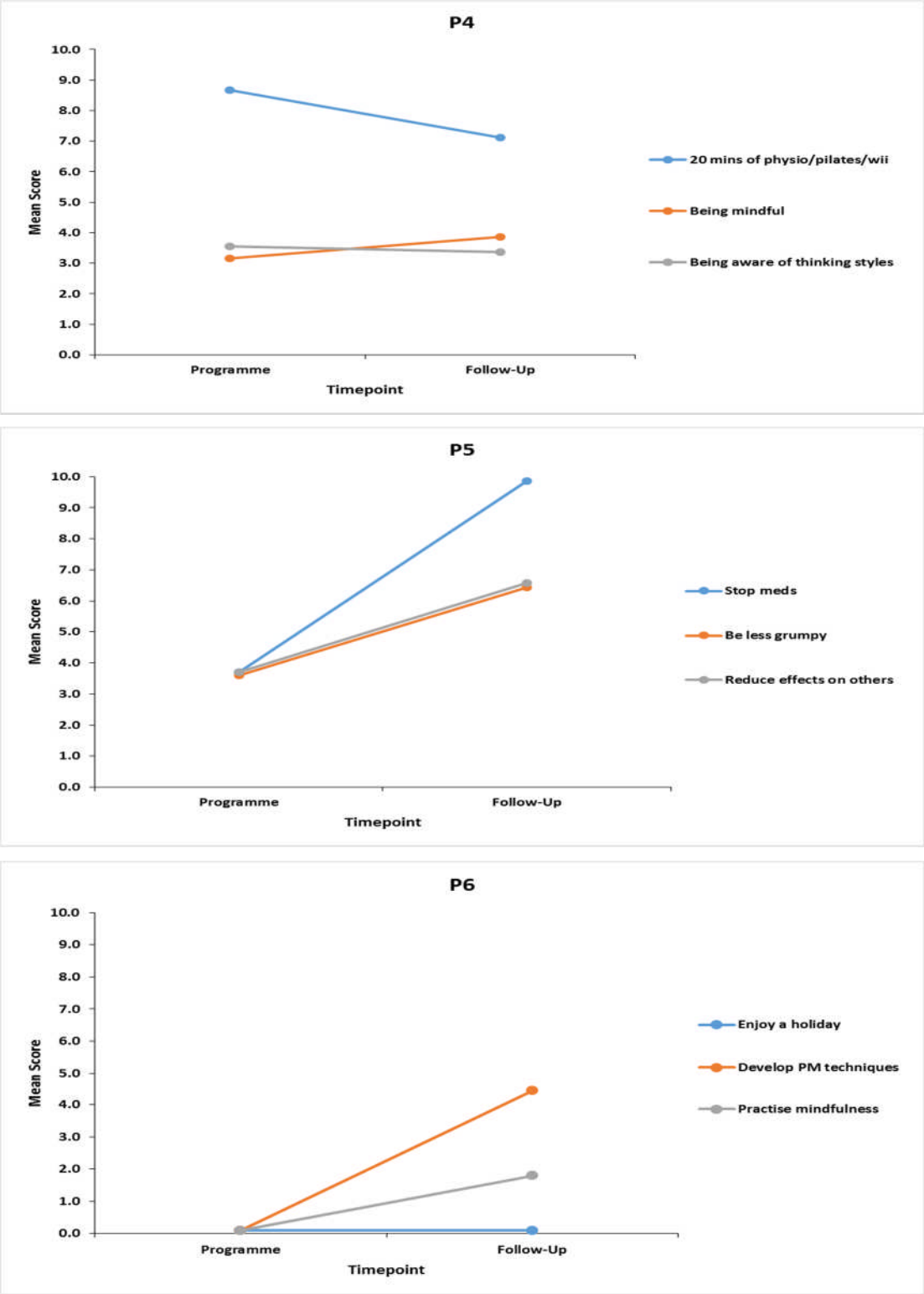


Figure 2: Mean programme and follow-up scores towards individual goals set in the programme where 0 = no progress and 10 = goal attained.



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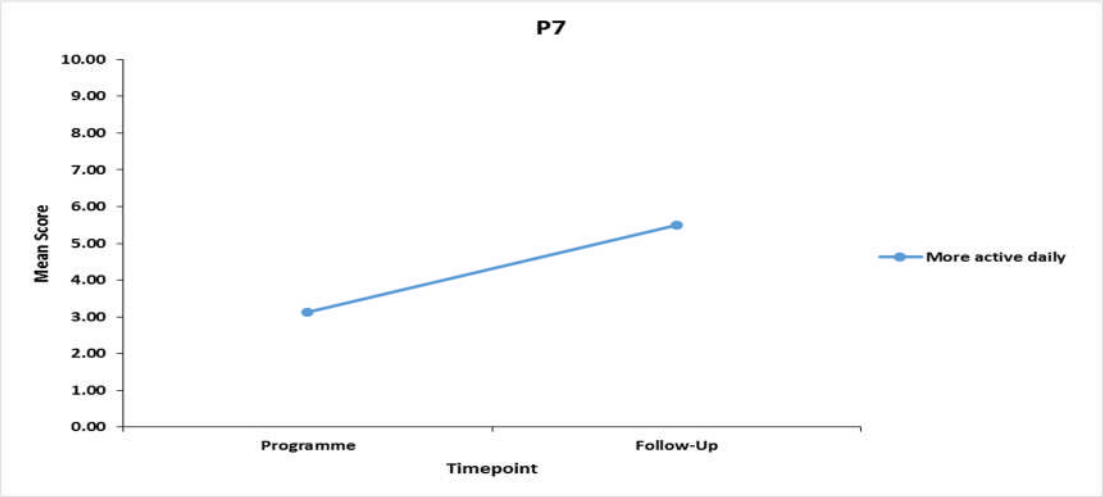

Figure 2: Mean programme and follow-up scores towards individual goals set in the programme where 0 = no progress and 10 = goal attained.

External events.

Participants utilised the external events questions to varying degrees which did provide indicators of personal issues that might help to interpret some of the participants reported scores on assessments. P1 and P5 accounted for the majority of input (see appendix 13 for table of participant data).

Qualitative Data

The change interview. All seven participants were interviewed using the revised version of the change interview (Elliot et al., 2001). The resulting thematic analysis produced four themes and associated sub themes relating to the process of change. The four themes were (1) components of the programme that had helped; (2) the process elements of the group e.g. therapeutic alliance, venue issues; (3) differing modes of support outside the programme; (4) conditions that participants reported had either hindered or helped them. Each theme is discussed here using extracts from participants' transcribed interviews (see table 5).

Table 4.

Mean and range scores for aggregated participant Working Alliance Inventory per question

	Mid Intervention		Post Intervention	
Question *(mean scale scores where 1=never, 7=always*	Participant mean score *(Range)*	Therapist mean score *(Range)*	Participant mean score *(Range)*	Therapist mean score *(Range)*
Q1. Usefulness/Confidence	**5.75** *(5-6)*	**5.75** *(5-6)*	**6.25** *(5-7)*	**5** *(4-6)*
Q2. Likes me	**6** *(5-7)*	**5.5** *(5-6)*	**6.5** *(6-7)*	**4.75** *(4-6)*
Q3. Don't agree	**4.25** *(3-6)*	**5.25** *(5-6)*	**4.75** *(4-5)*	**4.75** *(4-5)*
Q4. Confident in ability to help	**2.25** *(1-4)*	**2.25** *(2-3)*	**1.75** *(1-2)*	**2** *(2)*
Q5. Mutually agreed goals	**5.75** *(4-7)*	**5.5** *(5-6)*	**6.5** *(6-7)*	**5.5** *(5-6)*
Q6. Appreciates me/them	**6.25** *(5-7)*	**5.5** *(5-6)*	**6** *(5-7)*	**5** *(4-6)*
Q7. Agree on what is important	**3.75** *(3-5)*	**6.75** *(6-7)*	**4.5** *(4-5)*	**5.75** *(5-7)*
Q8. Mutual trust	**5.75** *(5-6)*	**5.5** *(4-6)*	**6** *(5-7)*	**5.5** *(4-7)*
Q9. Different ideas of problem	**5.25** *(4-6)*	**5.25** *(5-6)*	**5.5** *(5-7)*	**5.25** *(4-6)*
Q10. Good understanding problems	**2.5** *(1-4)*	**2.75** *(2-3)*	**2** *(1-3)*	**2.75** *(2-4)*
Q11. Working with problem correct	**5.25** *(4-6)*	**5.5** *(5-6)*	**6.25** *(5-7)*	**4.75** *(4-6)*
Q12. Agree improvement	**6** *(5-7)*	**5.25** *(5-6)*	**6** *(5-7)*	**5** *(4-6)*

Programme Components

a) Challenging negative thoughts and feelings. Without exception, participants felt that there had been a shift in their thinking or in their reactions to their thoughts, to varying degrees following the programme. They talked about it helping them to think differently about their pain and recognise potential thinking traps. This maps on to the specific sessions covered in the programme using examples of common thinking errors or common traps that patients with chronic pain can fall into:

P2: *well not beating yourself up so much, trying to change your thought patterns so that you don't get into the traps of feeling so bad about yourself that it just makes you feel really low*

P5: *I think the CBT stuff was most useful for me…. you're having a thought or you're feeling grumpy because, you know, all this kind of stuff - I just think oh yeh I'm having that thought – well, forget about that, I'll do something else instead - dealing with it logically I suppose.*

b) Biology of pain/pain mechanisms. More than half of the participants reported feeling that they understood the physiology of their pain, helping them to better come to terms with its onset and subsequent trajectory. Participants talked about never having been given a proper explanation by their consultants or GPs. There were also some motivators for increasing activity gained from understanding why hurt does not always equal harm. Participants also felt better able to more effectively explain their pain to others, and in a way that helped others know how they could help them. Two sessions in the programmes taught the biology of pain and pain mechanisms:

P6: *It was the physiology stuff you know the explanation of you know the pathways and you know the mechanisms of pain I found really interesting and really useful.*

P2: *..it's just that the whole experience was enlightening and gave me a new outlook but also very very importantly it helped me understand what my condition was and why I was in pain which for 16 years nobody has given me a definite of why even after my operation you don't really know what's happening doctors just talk to you as if you're Einstein or something that you understand everything so just understanding*

why I am in pain it was a very very big thing for me to be able to move on to the next level.

Table 5

Thematic analysis

Themes and subthemes	*Number of patients contributing*
1. Programme components	
a) Challenging thoughts and feelings	7
b) Biology of pain/Pain mechanisms	5
c) Pacing	5
d) Communication with others	4
2. Process Elements	
a) Therapeutic alliance/Respect for professionals	6
b) Common or shared experiences	3
c) Communicating changes/Suitability of changes	2
3. Feeling supported	
a) Peer support	7
b) Support of significant other	3
c) Family support	3
4. Indirect moderators of change	
a) Therapeutic effect of attendance	3

c) Pacing. Pacing is a main component of the programme and something that was a catalyst for change with over half of the participants. They talked about making changes in their approach to activity that they would not have considered before the programme. The consensus was that it helped them to build up their activity and avoid doing too much or too little especially when in pain or dealing with a flare-up:

P2: *Yeh I think the erm it all came from me erm being open and be willing to try out new things even if they sounded you know completely ridiculous erm you know like the hoovering just a quarter of the room it you wouldn't do it it's not something that would enter your head oh I'll just tidy that little bit up and then I'll go and sit down again for five minutes it's not something you trying to do you know you whether do it or you don't and I think that just that middle ground finding the middle ground has been very very helpful.*

P3: *in doing things but at the same time I'm also aware of the need on some occasions to sort of restrict what I do so not to sort of go hell for leather all of the time*

P4: *I don't feel I have to empty the dishwasher and do the laundry and do the ironing all in on evening you know it's okay not to finish a task in a certain amount of time that's probably the biggest change to be honest just accepting that and being okay with it yeh*

d) Communication with others. Participants talked about how hard they found it to talk to others about their pain - a problem that often worsened their pain or mood. Communication and explaining their pain experience to others was addressed in the programme. Patients described how a lack of communication can present barriers in daily life, for example, stopping them from enjoying a holiday or struggling with their pain rather than asking for assistance:

P3: *I think the biggest problem with communications that I had was that I didn't tell my wife when things were bad and then she would notice that my mood had changed and so she would be the one who was asking me how I was rather than me being the one who told her how I was and I think it is very important to try and take the lead and*

be the one who is not sort of making your partner have to sort of guess how you are which leads to me being more up front and communicating.

Process Elements

a) Therapeutic alliance. Participants talked about their previous negative experiences with professionals and how differently the therapists on the programme treated them. Participants talked about the programme therapists being more understanding of their pain and less dismissive:

P2: *and the way they run the group is absolutely fantastic they speak to you like you are a human being and they understand you …and that helps a lot to have somebody - a professional actually -understand and show that they care and that they wanna help.*

b) Common or shared experiences. Some participants reported using the different pain experiences and motivation of the group to motivate themselves or challenge their perspectives of their own pain:

P3: *But it was also having a course where a lot of people are strongly motivated makes it good because people sort of want to make it a success and they contribute more and generally people who've done that must have some sort of motivation at the start otherwise they wouldn't have done that if you know what I mean?*

Others talked about how others experiences had a negative effect on the group, so that although they cited the same common bond and moving forward together as being important, they found particular group members presented a barrier to that.

P4: *they personality wise were quite difficult: each week we'd be talking and trying to think about how to progress and to work towards our goals, and then they would just say something along the lines of "well, I'm really glad that I'm going to die soon so I don't have to put up with it anymore".*

c) Communicating changes/suitability of changes. Participants commented about the way logistical issues had been handled and the resulting impact on their experience, eroding their respect and trust for the clinicians involved and their sense that staff were working in their best interests. Only two participants commented but both in strong terms.

P4: *think I was frustrated because they had scheduled two 'family and friends' days initially and they sent all the paperwork out to say that they want my family and friends, and then when we got there they changed the group so it wasn't - there was only one family and friends day but they sent my mum away, which was frustrating, and then all the evaluation forms kept asking "how were the family and friends days".*

Feeling Supported

A common feature of the interviews was how much participants talked about support from inside and outside the therapeutic frame of the group, and how much of that was forthcoming as they went through the programme.

a) Peer support. Without exception participants talked about how refreshing it was to meet other people with the same problems and share experiences. Not only did they learn from each other but also they reported that they had something to offer the group in terms of their experience and knowledge from their pain journey, and offering this was, in itself, therapeutic:

P3: *..it is a difficult condition and not something you can easily discuss even with loved ones let alone with other people so it's been very good from that point of view in terms of the group being there.*

P4: *... that's been the powerful thing about the group as well just to have a condition where you've never met anybody else with it to be in a room with five other people who are also upset and who also look absolutely fine you know but don't yeh but don't feel absolutely fine was a really a really powerful thing.*

b) Support of significant other. Partners, wives or husbands of participants were valued where they had also been involved in, or taken on board, the self-management ethos of the programme. Participants talked about finding partners, wives or husbands a source of support that had a different approach or meaning than the therapists or programme members and seemed to help participants' communication, especially if there were any problems:

P4: *…and you know I find that if I'm in a mood or saying certain things he will look at me and say if you were your patient what would you say you know or what would they say on the programme.*

c) Family support. Reports of family support were mixed in terms of family members understanding of what participants were trying to achieve on the programme. Participants talked about how increased understanding or even official letters from the hospital made a difference to how family supported them. Some also mentioned existing communication barriers or ways of interacting making support more difficult:

P1: *I showed the letter to GP to my Mother and daughter and she had not realised how much pain I was in they both then responded positively and it has changed the way they are around me.*

Indirect Influences on Change

Some participants mentioned effects of the programme contributing to changes they had made, but indirectly in the sense that they were not intentional on the part of therapists.

a) Therapeutic effect of attendance. Participants talked about the therapeutic effect of travelling to the course each week, because it built their confidence to do more travelling, demonstrated to themselves how much they could do, or provided a break from a stressful job and time to reflect:

P1: *…Encouraged me to get out and given me more confidence to travel on train and get out and about.*

Other items not included in analysis

Two people felt that the programme had imposed particular burdens, one in travel costs, hotel costs, and guilt over spending money on that (P1), and the other on completing assessments that s/he found tiring and that tended to lower his/her mood (P6). One participant reported that s/he had attended a similar course for their diabetes simultaneously and cited this as perhaps a factor in his/her being able to fully focus on the programme (P7).

Discussion

Summary of Results

The effectiveness of a multi-disciplinary pain management programme was evaluated using single case methods. Clinical outcome measures for catastrophic thinking, mood, self-efficacy, and goal attainment, and for process measures of programme adherence and therapeutic alliance, were collected from eight participants bi-weekly during baseline, intervention and follow-up phases. Seven participants provided a full set of data. Only one participant showed a reliable change in all four measures and only two participants showed significant change for self-efficacy. Three participants deteriorated significantly in self-efficacy single items with most others showing no change across the board. The overall pattern of results, therefore, was not indicative of the effectiveness of the intervention.

Other results of note were that all participants made progress on at least one of their programme goals with one participant able to stop pain medication completely. There were also high levels of concordance in working alliance between therapists and participants across all domains. Working alliance was also highly rated in the interview analysis with six of the seven participants describing ‘feeling understood’ or ‘treated like a human being’. Working alliance is an important measure of process and, in a meta-analysis of the existing literature, was identified as a moderate predictor of outcome in psychotherapy (Martin et al., 2000). One could suggest, therefore, that the reported high rating of concordance in working alliance suggests ‘ideal conditions’ for therapeutic change were present. As mentioned earlier, this is a strength of single case design in that it can monitor process variables alongside efficacy.

There were some observed relationships between adherence and participant change. For example, P2 reported increased mobility and confidence in walking without a stick whilst adherence to exercise, pacing and stretching were consistently

high throughout the programme. However, in developing this adherence measure, Curran et al. (2009) warned about the limitations of self-reported adherence data that could encounter social desirability and over estimation effects. Indeed, when one considers the mechanism of reporting how often a cognitive technique is utilised, retrospectively, it does seem vulnerable to under- or over- reporting. As a result, this study was careful not to make too many inferences using this data and would suggest combining alternative measures of adherence, such as pedometers for pacing.

Some of the fundamental elements of the PMP group were rated highly as factors for change with participants in their interviews, i.e. challenging thoughts, teaching about the biology/mechanisms of pain, and pacing. Many patients seek to understand their pain or why it happened, so facilitating a better understanding helped to change patients' perspectives on pain and also helped them communicate their pain experience to others more effectively. Group cohesion and peer support were also rated as important by participants and have been highlighted as having significant effects on outcomes in PMP groups (Williams & Potts, 2010). The universality and shared experiences helped participants feel that they were not alone in their pain and had something to offer the group. Like working alliance, peer support is a useful contextual factor for change. Where therapeutic cohesion can influence outcome it appears that peer support may have the same effects and merits further exploration. Other sources of support such as significant others or family members where available were also valued and offered something different to the group or therapist support. The observable effects of changes in their activity and psychological approach to their pain motivated the significant others of some participants to change too.

PMPs have been shown to have positive effects on mood, catastrophising and self-efficacy and were selected for this reason, so that change could be observed and explored using single case design. Much of the pain treatment outcome research

involves analysis of group means or group measurement, which have confirmed efficacy of CBT in these domains (Williams, Eccleston & Morley, 2012). Hopefully, this study has shown that these methods can complement larger trials by taking the investigation a step further to explore why or how it is effective.

This methodology is still novel in terms of its use in this patient group. However, single case methods have had some success in psychological research in terms of locating discontinuous and non-linear trends. Examples of this include the aforementioned patterns of early rapid response in depressed clients, where symptoms significantly decrease by session four and then level off (Ilardi & Craighead, 1999), and the *sudden gains* theory of Tang and DeRubeis (1999), who noticed a large improvement in a between-session interval that does not reverse. Any similarities to these studies are not immediately obvious in this study data. Perhaps one might interpret a participant's comments regarding his or her biggest change as 'being taken seriously from day one' as *sudden gain,* but this was not observed in his/her scores.

Implications for Practice

If the aim is to move away from sub-grouping patients using non-psychological properties such as diagnosis clinicians could adopt more tailored outcome measures based on their assessment findings. Using automated data collection techniques as shown in this study makes this process more efficient as multiple replications of specific outcome measures would have minimal impact on cost or effort. Collected data can be interrogated and analysed session by session and meaningful time spent with the patient discussing specific areas for improvement or tackling treatment-resistant problems. The data could also help facilitate clinical strategy in team meetings or when planning programme sessions by reviewing the real time data in meetings. Materials can then be adapted for specific patients or targeted for planning

in vivo behavioural work. In this way, single case design can complement the natural focus and concern of the clinician (i.e. how can I help this client?) rather than just making inferences at a group level (Morley, 2007). As a result, it perhaps stands a better chance than many other designs of being carried out in standard clinical practice.

Implications for Research

Single case design gives an enriched understanding of fluctuation in scores. For example, the graphical representation provides a good illustration of how the trajectory of the mean scores belies the fluctuation between bi-weekly time points. Use of the mean as the measure of central tendency by its very nature does not represent the variability in some of the data. It smoothes the line of trajectory and yet it is this variability that is at the heart of single case design that helps us to understand what it is like for the patient as they battle with their pain on a daily basis. Therefore supporting the data with graphical representation seems essential.

Participant retention was a concern in planning this study, yet seven were retained out of 8 that started and all seven provided a full set of data. Attrition is something that can have a negative impact on research outcomes. In a study of attrition, Hellard, Sinclair, Forbes & Fairley (2001) found that retention was increased where multiple strategies were employed. Two that resonate with this study's findings were increased regular contact and ensuring participants were kept well informed and encouraged. There are, of course, resource costs that can be attached to this, which perhaps explains why they are not routinely done. However, this is a useful by-product of the methodology and should be recognised. All participants were sent bi-weekly emails, informed when the phases were changing or the assessments were changing, called by phone for their opinions at the end of the study and individually thanked by letter. They also had access to the researcher should they have any difficulties or

questions. Most participants cite involvement in research as valued work and not just personal gain, so being treated well and respected for their time and effort was important to them.

The data collection software (Opinio) was a useful tool and very reliable. Those participants who chose email assessment were hardly troubled by format or technical issues. There were only two examples of emails not being received and these tended to be at participant or researcher's interface where they were blocked by email filters. The captured data was available in many useful formats e.g., Microsoft Excel, SPSS, or in a formatted report. However, Opinio is by design a survey tool so the reporting function would only allow frequency data that, for most of these measures, were not useful. Templates are available in formats that can enable data to be copied and pasted from Opinio to give quicker turnaround so would not impact on efficiency.

In terms of measurement, future studies might want to utilise more non-standardised measures to avoid the reliability issues of repeating measures that were designed for pre and post application only. These could be applied as measures of peer support or group affiliation effects which have been reported here by participants as important factors in change. Improvement in the quality of adherence might benefit from more practical measures like pedometers for pacing or diary methods collected over shorter periods (Curran et al., 2009). Reliable change often sets steep criteria where standard deviations (variance) are large, and are only applicable if people start out with scores in the range of clinical concern. As was observed in this study, certain participants' scores were very low at baseline and would never show reliable improvement, but need to be monitored to detect deterioration should it occur.

Increasing the number of data points would allow for the introduction of more robust statistical measures. However, most of these methods involve withdrawing, withholding or changing the order of therapy and so would be deemed unethical in

this patient group. For that reason, AB design was selected as the most suitable but it is also considered the weakest of the single case designs due to its vulnerability to threats to internal validity (where change is due to the passing of time, regression to the mean, or the occurrence of another event). This study has endeavoured to control for this by conducting the change interview and including a question about external issues which highlighted other factors outside the participants' control that were experienced as barriers to change.

In their study of pain-related fears, Vlaeyen, de Jong, Geilen, Heuts and van Breukelen (2001) recommend using multiple baseline design to infer effects when ethically it is impossible to withdraw treatment (albeit that the effects of treatment don't automatically reverse when treatment is withdrawn). Similar to AB design it involves repeated measurement of the same outcomes in different participants over a pre intervention outline, with the exception that the length of measurement is varied. The advantage of this design is it demonstrates that change only occurs when the intervention is directed at the behaviour, setting, or individual in question (Rizvi & Nock, 2008). It may also extend the number of data points measured.

Limitations

The desired n for this study was 12, but delays in R&D approval caused a set of assessments to be missed which would have given access to at least 4 other group assessments so potentially a substantial increase in participants. Without the delays, better selection at assessment would have been possible and the associated time pressures of starting late and adhering to study deadlines would have been reduced. One participant suggested that the bi-weekly assessments were a burden and, as this did seem to impact his scores, would also need consideration in future research.

As mentioned previously this study used the same measures multiple times and over a number of weeks, so there were risks of completion fatigue and recency

effects in completion. This is unavoidable in the methodology so controls were put in place, such as the change interview and a question about external events to counteract these effects. Whilst there is evidence that self-report data is reliable the optimum recall is 2-3 days.

It is also difficult to ascertain the effect on the results of the differing intensity and duration of each programme as they catered for the individual pain sites or types. Whilst the content of each programme was the same, just shortened or intensified, the orofacial patients did perform less well (other than P4 reducing his/her medication). Whether one could hypothesise causality to the reduced length of the programme or their specific type of pain would require further investigation. Ideally, this study would have sampled more participants and recruited equal numbers across all programmes. The orofacial patients also were the only participants that were together in their intervention and there were some comments in the qualitative interviews about others thoughts or discussion about the burden of the study measures.

Some of the measures (e.g. PCS) were not designed for such frequent use and it is difficult to assess the impact this may have had on this study. The development and use of non-standardised methods is recommended (Barlow, Nock & Herson, 2008), these being more tailored to each client and individualised at assessment. However, these are unpublished measures with no reliability data, so resulting data and analysis would need to be treated with caution. This may also conflict with the research goals of the programme in terms of data from proven standardised measures allowing generalisability to populations. Also longer term measurement, perhaps utilising the programme's 6-12 month follow-up, would have been desirable but was not possible in the timescales of this study. Observed levels of change over such a relatively short intervention and follow-up period without more evidence are difficult to generalise as typical or sustainable over a longer period.

This study also recognises that further steps could have been taken to guard against potential researcher bias in the qualitative methodology. Whilst the final selection of themes and sub-themes were audited by the research supervisor, other credibility checks could have also been performed to ensure the integrity of the data such as: 'consensus checking' where several people analyse transcripts to establish inter-rater reliability: or 'member checks' where participants themselves are asked to validate conclusions made (Elliot, Fischer & Rennie, 1999).

Conclusion

This study has demonstrated the potential strengths of single case design in trying to understand the trajectory of change in a pain management programme. The use of repeated measurement prior to, and over the course of, the intervention illustrated the distinct variability of scores on mood, catastrophic thought and self-efficacy reflecting the participant's lived weekly experience of their symptoms. The assessment of the process variables allowed monitoring of contextual factors proven to play a part in change, although adherence was less clear. By including a change interview offered a participants' view of the research experience and contributed some useful data on specific treatment ingredients, contextual and indirect factors.

Morgan and Morgan (2001) describe single case design as 'unashamedly inductive' (p124), allowing 'instant exploration of even the most serendipitous of results'. Exploration of contextual as well as clinical variables can help researchers to generate hypothesis as to the what, when and how of change whilst complementing efficacy studies. The effectiveness of CBT with chronic pain is well documented and if we can then understand why it works then this helps the clinician answer questions they face every day, such as why is treatment not working for this client (Morley, 2007).

One participant attempted to explain in the interview what it was that the programme had imparted that accounted for his/her change. However, as s/he grappled for the words it was obvious that s/he knew something had changed and that the programme was the catalyst. S/he attempted to explain it as “the whole being greater than the sum of its parts” in that it was not just one thing but the interaction of all of the programme elements. Yet we have seen here that there have been some moderate gains in some areas for different participants at different points. In order to further apply empirical methods to these findings perhaps our research question should be - are the parts greater than the sum of the whole?

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Part 3: Critical Appraisal

Introduction

This critical appraisal will reflect on my experiences in conducting two diverse pieces of work from the context of the types of research assessed i.e. randomised controlled trials (RCT) for the systematic review, and single case design for the empirical paper. It will discuss positive and negative experiences of both in undertaking this research and discuss the wider implications and learning points I can take with me into clinical practice.

Researcher Background

I was drawn to health psychology, and particularly chronic pain, as a thesis topic due to the time I spent as an assistant psychologist co-facilitating a pain management programme. The prospect of working with my current supervisor, a leader of research in this field, was also a good learning opportunity. I am also interested in entering health psychology as a service area for future practice. Chronic and acute illness sometimes belies the fact that people had a life before and so the challenge is to help them regain some of that “normality”.

Both research tasks were challenging in different ways. For example, I preferred the more personable approach of the single case design and felt in my comfort zone. Whereas the meta-analysis was getting to grips with the new, rigorous and time consuming methodology. I reflect on my experiences here.

Meta-analysis

Pettigrew and Gilbody (2004) recognize the inconsistent nature of research whereby trials studies can be measuring the same thing yet report different outcomes. Discerning empirically who is right can seem impossible. Systematic review counters bias, uncertainty and small effect sizes by synthesizing studies and testing them scientifically and transparently. Cochrane reviews and health researchers such as

National Institution of Clinical Excellence (NICE) regularly adopt this as a useful method to ascertain efficacy and advocate appropriate methods of treatment at a population level.

However, they are time consuming not just because of the rigor of the methods, but partly due to the lack of standardized reporting of clinical outcome data and adherence to methodology. As I started to review 10s of RCTs, I was surprised at the diversity of quality considering their elevated status as the gold standard in research efficacy. Despite well documented protocols of reporting i.e. CONSORT (Consolidated Standards of Reporting Trials), IMPAACT (Initiative on Methods, Measurement, & Pain Assessment in Clinical Trials) few studies were compliant in reporting findings. I considered that some of the studies perhaps pre-dated CONSORT although it was formed in 1996 and so has been in existence for nearly twenty years.

Initiatives such as CONSORT have sought to unify practice across trial reporting with checklists and list of approved measures of outcome. This then helps researchers or health providers compare standardized outcomes within populations and across trials. Potentially, simply adhering to protocol could reduce a significant burden of work involved in meta-analysis. The very nature of CONSORT being an 'initiative' deems compliance optional it seems, although some journals have made it a criteria for publication. Only one of 16 trials from my meta-analysis reached all 5 criteria for low risk of bias which are deemed protocol items for running an RCT. I contacted 13 authors for more data as they had indicated in their methods that they had captured the required data and seven did not respond (although this mean cited method of communication had changed). Granted this was not their main outcome of interest in most of the trials but if it is mentioned in the method then it is surely worth reporting, even if cited as an observation.

I realise that caution should be exercised in interpreting quality just from bias rating alone. Higgins (2011) warns that over-reliance on measures of risk of bias (we used the Yates Scale, 2005) are subject to the influence of the raters e.g methodological experience and perhaps skews understanding of quality. This was my experience as there was an obvious disparity of my knowledge compared to my supervisor who has been immersed in the pain research for many years. I did observe most studies adopt the flow of participants and attrition chart. However exclusion of details of randomization, use of the words RCT in the title, reporting all the results they measured were regular features of each trial.

There was also an issue with the data that was reported as being in various formats that made it hard to compare like for like. There was a mixture of continuous and dichotomous variables and so trials were paired together where possible or calculations made to calculate a summary statistic for aggregation. I therefore adopted risk ratio as a way of converting data to comparable formats for analysis. This did not work in every case but did allow more studies to be included in the analysis. In health research this is actually a favoured reporting method and they suggest that even SMD can be converted post analysis to observe effects on patient risk which is useful for health care providers.

Single Case Design

Undertaking single case design was like operating at the opposite end of the research spectrum. Having reviewed so many studies of sizeable populations that had taken many years to plan and complete this felt like a much more personal study. Participants could almost be described as co-researchers, especially listening to them formulate their own impressions of what has changed. I feel they responded to this too. I mention in the empirical paper that invariably people do not volunteer for research with a view of personal gain but generally feel it will bring value or want to

give something back for the treatment they are getting. This approach felt like it respected that decision.

The final data showed a lot variability and my first reaction was to compare means as there was so much data. Finding a way to attribute meaning to this amount of data points across the different measures initially felt slightly daunting. The strength of graphical analysis in single case design is, to use the statistical analysis parlance, “eyeballing” ones data. This made it immediately obvious what each participants’ level and trajectory of change was. Mean values helped to plot a line of trajectory to see trends across the three phases, but also served to illustrate the variability in scores for some participants over the weeks of measurement. It offered a realistic appraisal of what it must be like to live with chronic pain every day. Combined with external factors data it was very enlightening. It was also rewarding to see and hear participants improve in areas of difficulty.

The post research interview was an opportunity to get to hear their experiences of the group in a way that might usually be written in a feedback forms or pre and post mean scores. It helped them also to understand what they had been through. It felt like they were not just an anonymised number on a data sheet but real people who had real issues. Morley (2007) suggests one of the strengths of single case methods is the way it taps into what it is to be a clinician and help people. This resonates with my experience from that point of view.

The data collection software (Opinio) was very user friendly and, where most participants’ had opted for email assessment, could be automated in advance. I was able to agree dates for all participants and warn them in advance. I could also see whether emails had actually been sent and received as well as check daily if they had been completed. This would then prompt me to remind them if necessary. This study relied on repeated measurement and so having a reliable secure system in place that offers real-time data was essential. As I mentioned in the empirical paper there were

very few technical issues. Participants who chose email assessment (seven of the eight recruited) were hardly troubled by format or technical issues. Being able to download the data into multiple formats was also useful as I could start to format results as they came in which saved a lot of time at the end of the study. Especially as there were four different groups starting at different times. The software coped admirably with the complexity.

The professionalism of the pain management centre as well should be mentioned. All participants' commented on their warm, knowledgeable and professional approach to their pain. Working alliance concordance was high and never came into question. The interaction between researchers and the team was also supportive, timely and professional. Especially at the assessment phase where, at one point, it looked unlikely that we would recruit the required number of participants. Their outcomes are usually very consistent in terms of improvement and so along with the selected measures we were confident we would see some change even if it was mild or moderate.

Conclusion

My purpose here is not to belittle or bemoan RCT's as they have an important job to do in addressing population-based questions relating to public safety, health, education, social policy psychological and other research. Indeed they have provided reliable data on efficacy as the background to both studies. I learnt a lot from reviewing so many in a small space of time. Pettigrew and Gilbody (2004) cite approximately 6000 studies a year are added to databases for smoking and so methods of synthesizing and analyzing such big data sets are essential. Meta-analysis fits this brief nicely. Closer adherence to the well-established protocols for reporting in RCTs will hopefully make meta-analysis more accessible. The more time it takes to undertake the less likely health care professionals are to adopt it in practice.

Single case design is not designed to replace larger studies and indeed cannot offer the same results. Its strength is in its ability to look at the underlying clinical, contextual and external factors that affect change in interventions that already have proven or observed efficacy. The long term goal being to be able to tailor treatment to definite patient populations. Single case design is still a very novel methodology in chronic pain research and so hopefully this study will help inform future research.

As a soon to be newly qualified clinical psychologist, I was surprised to hear how little research is undertaken post training. Part of this research experience has been to explore research methodology that I can realistically take with me into practice. I could adopt successfully and within the time restrictions of practice but still be meaningful. Both meta-analysis and single case I think fit with practice based evidence models. Session by session monitoring of clients is already common practice and going one-step further and developing measures to assess anomalies in therapy feels very manageable.

References

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Morley, S.J, (2007) Single Case Methodology in Psychological Therapy. *In:* Lindsay SJE; Powell GE *A Handbook of Clinical Adult Psychology*, Hove: Psychology Press & Brunner-Routledge, pp. 822-844.

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Appendix 1: Sample Search Strategy

(PsycINFO)

1. exp pain/
2. (chronic* adj6 pain*).mp.
3. 1 and 2
4. (chronic* adj6 (discomfort or ache*)).mp.
5. (chronic* adj6 (fibromyalgia or neuralgi* or dysmenorrhea or dysmennorrhoea)).ti,ab.
6. 1 or 2 or 3 or 4 or 5
7. exp Psychotherapy/
8. Cognitive Therapy/
9. exp Behavior Therapy/
10. Biofeedback/
11. ((behaviour* or cognitive) adj (therapy or therapies)).mp.
12. (relax* adj6 (technique* or therapy or therapies)).mp.
13. (meditat* or psychotherap*).mp.
14. ((psychological or group) adj (treatment or therapy or therapies)).mp.
15. (self-regulation adj training).mp.
16. (coping adj skill*).mp.
17. (pain-related adj thought*).mp.
18. (behaviour* adj6 rehabilitat*).mp.
19. ((psychoeducation or psycho-education) adj (group or groups)).mp.
20. (mind and ((body adj relaxation) or (relaxation adj technique))).mp.
21. exp dualism/ or exp relaxation/ or exp relaxation therapy/
22. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. 6 and 22
24. (2007* or 2008* or 2009* or 2010* or 2011* or 2012* or 2013*).up.
25. 23 and 24
26. limit 25 to yr="2011 - 2013"

Appendix 2: Yates Scale for Risk of Bias Assessment

Quality Rating Scale – Scoring Sheet

Rater: _____

Author/Year: _____

Title: _____

TREATMENT QUALITY

Please circle the appropriate score

Item #	Question	Item	Response
1	Has a clear rationale for the treatment been given and an adequate description of its content?	Treatment content / setting	**0 1 2**
2	Has the total treatment duration been reported? If so: No. sessions_____ Duration _____ Total (hrs)____	Treatment duration	**0 1**
3 2 parts	Is there a treatment manual that describes the active components of treatment?	Manualisation	**0 1 2**
		Adherence to manual	**0 1**
4	Have the therapists been appropriately trained in the relevant procedures for this trial?	Therapist training	**0 1 2**
5	Is there evidence that the patients have actively engaged in the treatment?	Patient engagement	**0 1**

Total score for section: _____

Item #	Question	Item	Response
1 2 parts	Are the inclusion and exclusion criteria clearly specified?	Sample criteria	**0 1**
		Evidence criteria met	**0 1**
2 2 parts	Is there evidence that CONSORT guidelines for reporting attrition have been followed?	Attrition	**0 1 2**
		Rates of attrition	**0 1**
3 2 parts	Is there a good description of the sample in the trial?	Sample characteristics	**0 1**
		Group equivalence	**0 1**
4 4 parts	Have adequate steps been taken to minimise biases?	Randomisation	**0 1 2**
		Allocation Bias	**0 1**
		Measurement Bias	**0 1**
		Treatment expectations	**0 1**
5 3 parts	Are the outcomes that have been chosen justified, valid and reliable?	Justification of outcomes	**0 1 2**
		Validity of outcomes for context	**0 1 2**
		Reliability and sensitivity to change	**0 1 2**
6	Has there been a measure of any sustainable chance between the treatment and control groups?	Follow up	**0 1**
7 5 parts	Are the statistical analyses adequate for the trial?	Power calculation	**0 1**
		Sufficient sample size	**0 1**
		Planned data analysis	**0 1**
		Statistics reporting	**0 1**
		Intention to treat analysis	**0 1**
8	Has a good, well-matched alternative treatment group been used?	Control Group	**0 1 2**

Total score for section: _____

Total Score: _____

Comments:

Appendix 3: Characteristics and risk of bias tables for included studies

Characteristics of studies

Characteristics of included studies

Alaranta 1994

Methods	RCT; 2 arms;assessed at pretreatment, 3 months follow-up. 1 year follow-up
Participants	3 month follow-up n = 286 Start of treatment n = 293 Sex: 160 F, 133 M Mean age = 40.5 (SD 4.5) Source = patients referred for inpatient rehabilitation Diagnosis = chronic low back pain
Interventions	"progressive intervention of intensive physical training and psychosocial activation AK- SELI" "control: less intensive physical training and passive physical therapies"
Outcomes	number of visits to doctors (12-month follow-up) number of physical therapy outpatient visits (12-month follow-up) WHO occupational handicap 0 to 5 sick days
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"patients stratified according to age ... and sex and randomly divided into intervention and control groups"
Allocation concealment (selection bias)	High risk	No information but post-randomisation exclusion of patients "not fit" for intervention group
Blinding of outcome assessment (detection bias)	High risk	Self report and examination by psychiatrist and physiotherapist at baseline and follow- up. No statement about blinding
Incomplete outcome data (attrition bias)	High risk	Attrition implied not reported; no reporting of differences
Selective reporting (reporting bias)	High risk	Many outcomes not reported

Busch, 2011

Methods	RCT: 4 arms: assessed at pre-treatment. post-treatment. 6 months, 18 months, 3 years. 10 years
Participants	End of treatment n = 181 Start of treatment n = 214 Sex: 117 F. 93 M Mean age = 43.3 (SD 10.4) Source = pain or rehabilitation clinic Diagnosis = mixed (mostly chronic low back pain) Mean years of pain = 2.7
Interventions	"CBT" "Behavioural medicine rehabilitation"(BM) "Behaviourally orientated physical therapy" (BET) "Treatment as usual"(CG)

Outcomes	Sick days from official records Rehabilitation economy
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Shuffled sealed envelopes
Allocation concealment (selection bias)	Low risk	Sealed envelopes: procedure by researchers blind to participant screening
Blinding of outcome assessment (detection bias)	Unclear risk	Data gathered by research team
Incomplete outcome data (attrition bias)	High risk	Partially reported: differential attrition; no test of differences
Selective reporting (reporting bias)	Low risk	Fully reported

Flor 1993

Methods	RCT: 3 arms: assessed at pre-treatment, post-treatment, 6 month and 2 year follow-up
Participants	End of treatment = 68. Start of treatment = 78 Gender = 60% female Mean age = 42.43 yrs SD = 9.68 Ave pain duration 9.4 yrs (SD = 7.57) Diagnosis = CBP or chronic TMDP Referred from local orthopedic practices
Interventions	EM + Biofeedback CBT Med
Outcomes	Pain related healthcare visits in 3 months prior to tx and at 6 & 24 month follow-up
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported. Appears that wanted equal numbers of CBP and TMD patients in each group and so appears clinician selection?
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported

Incomplete outcome data (attrition bias)	Low risk	Attrition data provided for treatment and follow-up and analysis of impact on results and independent telephone follow-up for reasons for attrition
Selective reporting (reporting bias)	Low risk	results tables report all specified measures

Geraets 2005

Methods	RCT: 2 arms: assessed at pre-treatment. post-treatment. 1 year
Participants	End of treatment n = 158 Start of treatment n = 176 Sex: 109 F. 83 M (at start of treatment) Mean age = 52.5 (SD 12.4) Source = mixed community and volunteer Diagnosis = shoulder pain Mean years of pain = not given
Interventions	"Graded exercise" "Primary care TAU"
Outcomes	General Practitioner visits Physician visits Physiotherapy visits Number of drug prescriptions Number of days work absence Total cost of health care (Euros)
Notes	BT versus TAU: analyses 7.1, 7.2. 7.4. 8.2

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation according to random number table
Allocation concealment (selection bias)	Low risk	Random number table generated by per- son not involved in study; opaque sealed envelopes; "Blinding for patients .... of al- located treatment was not possible" but treatment preferences
Blinding of outcome assessment (detection bias)	Low risk	Researchers not involved in randomisation collect data
Incomplete outcome data (attrition bias)	Low risk	Attrition fully reported; dropouts different in pain characteristics but not outcome measures at baseline
Selective reporting (reporting bias)	Low risk	Fully reported

Jensen 1997

Methods	RCT; 2 arms; assessed pre-treatment. post-treatment. 6 months. 18 months
Participants	End of treatment n = 59 Start of treatment n = 63 Sex: 63 F. 0 M (at start of treatment) Mean age = 43.4 (SD 8.4) Source = pain or rehabilitation clinic

	Diagnosis = non-specific back or neck pain Mean years of pain = 4.2
Interventions	"Woman-specific CBT" "Regular CBT"
Outcomes	Sick leave verified by NI records 1 year prior to treatment and up to 18 months following. Only periods of absence greater than 14 days reported due to restrictions of recording system and does not qualify which are pain related sickness absence.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Central randomisation using random numbers table
Allocation concealment (selection bias)	High risk	Not reported
Blinding of outcome assessment (detection bias)	Low risk	Assessors blind to treatment condition
Incomplete outcome data (attrition bias)	High risk	Attrition partially reported: no test for differences
Selective reporting (reporting bias)	High risk	Partially reported

Jensen 2001

Methods	RCT; 4 arms: assessed at pre-treatment, post-treatment, 6 months, 18 months, 3 years
Participants	End of treatment n = 186 Start of treatment n = 214 Sex: 117 F, 93 M Mean age = 43.3 (SD 10.4) Source = pain or rehabilitation clinic Diagnosis = mixed (mostly chronic low back pain) Mean years of pain = 2.7
Interventions	"CBT" "Behavioural medicine rehabilitation" "Behaviourally orientated physical therapy" (BT) "Treatment as usual"
Outcomes	2005 FUP reports healthcare utilisation (yes or no response) at 5 time points over 3 year follow-up period Sick days over same period
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Shuffled sealed envelopes
Allocation concealment (selection bias)	Low risk	Sealed envelopes: procedure by researchers blind to participant screening

Blinding of outcome assessment (detection bias)	Unclear risk	Data gathered by research team
Incomplete outcome data (attrition bias)	High risk	Partially reported; differential attrition; no test of differences
Selective reporting (reporting bias)	Low risk	Fully reported

Johansson 1998

Methods	RCT. Two arms. Assessed pre-treatment, post-treatment, one month
Participants	End of treatment n = 36 Start of treatment n = 42 Sex: 28F, 8M (at end of treatment) Mean age = 43.5 (s.d. 7.6) Source = Pain or Rehabilitation clinic Diagnosis = chronic musculoskeletal pain Mean years of pain = 11
Interventions	"CBT" "WLC"
Outcomes	Primary Pain Outcome: VAS pain intensity Primary Disability Outcome: MPI Activity Primary Mood Outcome: none available Visual Analogue Scale: pain intensity Visual Analogue Scale: pain interference Sick leave % Hours of occupational training per day Multidimensional Pain Index
Notes	Yates quality scale: total quality = 17/35. design quality = 11/26, treatment quality = 6/ 9

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomly assigned"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of outcome assessment (detection bias)	Unclear risk	Mostly self-report so not blindable but ? occupational status
Incomplete outcome data (attrition bias)	High risk	14% dropout: data dropped
Selective reporting (reporting bias)	Low risk	Fully reported

Kaapa 2006

Methods	RCT; 2 arms: assessed at pre-treatment, post-treatment, 6 months, 1 year. 2 years
Participants	End of treatment n = 120 Start of treatment n = 132 Sex: 120 F. 12 M (start of treatment) Mean age = 46.3 (SD 7.5) Source = community Diagnosis = chronic low back pain Mean years of pain = 1.3
Interventions	"semi-intensive multidisciplinary rehabilitation" "individual physiotherapy"
Outcomes	Subjective work capacity 0 to 10 Recent sick leave due to back pain Beliefs re working (2-year follow-up) 0 to 10 Health care consumption 12 months
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes; numbers generated by independent statistician
Blinding of outcome assessment (detection bias)	High risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Fully reported; no test for difference
Selective reporting (reporting bias)	Low risk	Fully reported

Lindell 2008

Methods	RCT: 2 arms: assessed at pre-treatment, post-treatment, 18-month follow-up
Participants	End of treatment n = 123 Start of treatment n = 125 Sex: 68 F, 57 M Mean age = 42.6 (SD not given) Source = primary care Diagnosis = non-specific back or neck pain Mean years of pain = not given but had to be sick listed for more than 6 weeks up to 2 years; mean over 7 months sick listed
Interventions	"Cognitive-behavioural rehabilitation" "Primary care"
Outcomes	Sick listed days Healthcare visits
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerised block randomisation procedure
Allocation concealment (selection bias)	Low risk	Randomisation generated by independent statistician; in opaque envelopes
Blinding of outcome assessment (detection bias)	High risk	Assessors not blind to treatment condition, except for sick listing outcome
Incomplete outcome data (attrition bias)	Unclear risk	Fully reported; no test for differences
Selective reporting (reporting bias)	Low risk	Fully reported

Marhold 2001

Methods	RCT. Two arms. Assessed at pre-treatment, post-treatment, two-four months. four-six months
Participants	End of treatment n= 70 Start of treatment n = 72 Sex: 72F, 0M Mean age = 46.0 (s.d. 9.0) Source = national sick leave register Diagnosis = mixed chronic pain. 58% neck Mean years of pain = not given. but half had been on sick leave 3 months. and half for 26 months
Interventions	"Cognitive Behaviour Therapy for return to work" "Treatment as usual"
Outcomes	Primary Pain Outcome: no data available Primary Disability Outcome: no data available Primary Mood Outcome: no data available Days on sick leave Multidimensional Pain Index Coping Strategies Questionnaire Beck Depression Index Disability Rating Index Pain and impairment rating scale (PAIRS)
Notes	Yates quality scale: total quality = 20/35, design quality = 15/26. treatment quality = 5/ 9

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of outcome assessment (detection bias)	Unclear risk	Some data from external sources. and says psychology student did posttreatment assessments but unclear if blind to allocation

Incomplete outcome data (attrition bias)	Unclear risk	3% dropout: data dropped
Selective reporting (reporting bias)	Low risk	All outcomes reported

Moore 1985

Methods	RCT; 3 arms: Couple, individual therapy compared to WLC. Post treatment assessment and follow-up (3-8 months as collecting med record data)
Participants	End of treatment = 34 Start of treatment = 43 Mean age 49.3 (SD = 13.2) Sex = 42 M 1 F Diagnosis = "experienced pain for at least 6 months" Mean pain duration = 16.5 yrs (Sd = 12.6) CP patients from veterans hospital.
Interventions	Couple tx Ind Tx WLC
Outcomes	Use of out patient medical resources from medical records with no distinction between pain and non-pain related appointments. Medication usage (although the study goes on to mention that this proved to be very unreliable due to subjective self report and inaccessible pharmacy records)
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Does mention in table notes why some data was missing but does not report or analyse attrition
Selective reporting (reporting bias)	Low risk	Fully reported in table and text in results section

Schmidt 2011

Methods	RCT; 3 arms: mindfulness-based stress reduction. active relaxation control. waiting list: post-treatment. 2-month follow-up
Participants	End of treatment n = 148 Start of treatment n = 177 Sex: 177 F: 0 M Mean age = 52.5 (SD 9.6) Source = newspapers, GP and specialist referrals, patient self help

	groups Diagnosis = fibromyalgia
Interventions	Mindfulness-based stress reduction; active control (relaxation, support and education); waiting list
Outcomes	Ongoing therapies, medical visits and medication Medication diary
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	randomised in blocks by a computer algorithm"
Allocation concealment (selection bias)	Low risk	Patients and personnel blinded to treatment allocation
Blinding of outcome assessment (detection bias)	Low risk	Assessors blinded
Incomplete outcome data (attrition bias)	Unclear risk	Attrition fully reported; no test for differences
Selective reporting (reporting bias)	Low risk	Fuly reported

Thieme 2003

Methods	RCT: 2 arms: assessed at pre-treatment, post-treatment, 6 months, 15 months
Participants	End of treatment n = 61 Start of treatment n = 83 Sex: 61 F, 0 M Mean age = 47.3 (SD 8.3) Source = hospital for rheumatic disorders Diagnosis = fibromyalgia
Interventions	"operant treatment" "standard physical treatment"
Outcomes	Doctor visits (from medical records) Hospital days (from medical records) Medication diary
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"randomly assigned"
Allocation concealment (selection bias)	High risk	Not reported
Blinding of outcome assessment (detection bias)	High risk	Not reported

Incomplete outcome data (attrition bias)	Unclear risk	Attrition reported; no test for differences
Selective reporting (reporting bias)	Low risk	Fully reported

Turk 1996

Methods	RCT; 2 arms; Intradental app+stress mng with Biofeed+supportive counselling vs same but with Cog Tx for depression instead of counselling; Post treatment and 6 month follow-up.
Participants	End of treatment = Start of treatment = Diagnosis = TMD patients > 3 month duration Mean duration of pain = 4.2yrs Sex; 90%F; 10%M Mean age = 33.6 (sd 9.4) 48 consecutive referrals from TMD University outpatient clinic
Interventions	"IA+SM+SC" "IA+SM+CT"
Outcomes	Self reported use of medication and self reported use of consultants for TMJ pain
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"patients were randomly assigned": no details of method
Allocation concealment (selection bias)	Low risk	Allocation could not be concealed by credibility ratings taken in each condition and did not differ at baseline
Blinding of outcome assessment (detection bias)	Unclear risk	Some dental measures made by observer but unclear whether observers were blind to allocation
Incomplete outcome data (attrition bias)	High risk	Attrition reported; little difference between groups. Only completers analysed.
Selective reporting (reporting bias)	Low risk	Fully reported

Van Eijk-Hustings 2013

Methods	RCT; 3 arms; Multi-Disc pain tx vs Aerobic exercise vs TAU; post treatment and 18 month follow-up.
Participants	End of Treatment = 203 Start of treatment = 203 Diagnosis; FM diagnosed in last 3 months Mean duration of FM = 7 years Sex: 94%F MDT: 100%F AE; 97.9%F UC Recruited from 3 outpatient Rheum clinics
Interventions	"MD" "AE" "UC"

Outcomes	Two monthly cost questionnaire measuring FM related healthcare resources GPs, Specialists, PTs and Psychs.
Notes	"unclear who delivers MDT intervention and content described as sociotherapy, physiotherapy, psychotherapy and creative art"

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated random numbers in opaque sealed envelopes, following the order of consent"
Allocation concealment (selection bias)	Unclear risk	No information and not possible to blind patients or therapists to allocation
Blinding of outcome assessment (detection bias)	Unclear risk	All self report
Incomplete outcome data (attrition bias)	Low risk	High levels of dropout both groups but particularly exercise control. Authors tested for differences and said dropout was random and analysed
Selective reporting (reporting bias)	Low risk	All outcomes reported

Williams 1996

Methods	RCT; 3 arms; assessed at pre-treatment, post-treatment, 6 months, 1 year
Participants	End of treatment n = 99 Start of treatment n = 121 Sex: 68 F, 53 M Mean age = 50.0 (SD 11.5) Source = pain clinic Diagnosis = mixed chronic pain, low back commonest Mean years of pain = 7.8
Interventions	"inpatient CBT" "outpatient CBT" "waiting list"
Outcomes	Primary pain outcome: VAS pain Primary disability outcome: SIP patient-rated Primary mood outcome: BDI depression Catastrophising outcome: CSQ catastrophising Visual analogue scale (VAS): pain intensity Visual analogue scale (VAS): pain distress Sickness Impact Profile (SIP): patient-rated Beck Depression Inventory (BDI) State-Trait Anxiety Inventory (STAI) Coping Strategies Questionnaire (CSQ): catastrophising Pain Self-Efficacy Questionnaire (PSEQ) Pain Cognitions Questionnaire (PCQ) Walk distance Arm endurance Stair climb Stand ups Medication use Health care use

Notes	CBT versus TAU, post-treatment (waiting list not followed up): analyses 3.1, 3.2, 3.3 Yates quality scale: total quality = 22/35, design quality = 15/26, treatment quality = 7/ 9

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomly assigned by throw of a die"
Allocation concealment (selection bias)	High risk	Not reported
Blinding of outcome assessment (detection bias)	Low risk	"interviewers and assistants blind to the patients' treatment"
Incomplete outcome data (attrition bias)	Low risk	Attrition reported
Selective reporting (reporting bias)	High risk	Partially reported

Footnotes

Appendix 4: Ethical Approval

NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Fulham
HRA NRES Centre Manchester
Barlow House
3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7821
Facsimile: 0161 625 7299

11 June 2013

Dr Amanda C de C Williams
Reader
University College London
Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street, London
WC1E 6BT

Dear Dr C de C Williams

Study title:	**What changes for whom? Exploring the process of change in a pain management programme using single case design**
REC reference:	**13/LO/0940**
IRAS project ID:	**124279**

The Proportionate Review Sub-committee of the NRES Committee London - Fulham reviewed the above application on 10 June 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator, Miss Shehnaz Ishaq, nrescommittee.london-fulham@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions specified by the REC

1. Insert the following standard mandatory statement 'I understand that relevant data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.'

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of insurance or indemnity		01 August 2012
Investigator CV	Amanda Williams - 2	03 May 2013
Investigator CV	Andrew Pike - 2	06 May 2013
Investigator CV	Dr Clare Daniel - 1	06 May 2013
Participant Consent Form	3	06 May 2013
Participant Information Sheet	4.0	15 May 2013
Protocol	6.0	17 May 2013
Questionnaire: PCS	6.0	17 May 2013
Questionnaire: The Working Alliance Inventory - Short Form (Therapist)	6.0	17 May 2013
Questionnaire: The Working Alliance Inventory - Short Form	6.0	17 May 2013

(Client)		
REC application	3.5	03 June 2013
Referees or other scientific critique report		19 October 2012
Summary/Synopsis	1.0	06 May 2013

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

13/LO/0940	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Signed on behalf of:
Dr Charles Mackworth-Young
Chairman

Email: nrescommittee.london-fulham@nhs.net

A Research Ethics Committee established by the Health Research Authority

Appendix 5: Patient Information Sheet

University College London Hospitals NHS
NHS Foundation Trust

Patient Information Sheet

"What changes for whom? Exploring the process of change in a pain management programme using single case study design"

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully. Ask us if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

What is the purpose of the research study?

There are many studies showing Cognitive Behavioural Therapy (CBT) for persistent and chronic pain to be effective in improving activity levels, mood and, to some extent, reducing pain. The pain management programmes at the Pain Management Centre of the National Hospital, Queen Square, are well established and run by an experienced team of psychologists, physiotherapists and nurses. Routine evaluation shows that overall, patients improve in pain, disability and mood.

We need to understand in more detail the changes made by patients before, during, and after the programme This may help us to deliver treatment more effectively in future. .

Why have I been chosen?

We have chosen you because you have chronic pain and are being assessed for a pain programme. We would like to include you in our research if you decide to do the programme.

Do I have to take part?

It is up to you to decide whether or not to take part in this research. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. This does not affect your right in the future to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

In order to monitor in more detail the changes over the course, of treatment, you will be asked to complete a questionnaire twice each week before, during and after the programme. The questionnaire should take no more than 20 minutes. It asks about problems associated with pain that are targeted by the programme.

We realise that it is quite a lot of effort to complete these questionnaires so often. So other than the times when you attend the programme, we suggest that you might prefer to use e-mail, telephone, or SMS (mobile phone text) to give us your answers. Of course, if you prefer to use pen and paper and to post it to us, that is fine. This would apply on the days you don't attend during the programme, and in the weeks before the programme starts, and the month up to follow-up. We hope that this minimises the demands and gives some flexibility around your lifestyle. There is also an interview of up to half an hour, by phone, at a time that suits you, at the end of the research.

What are the possible benefits of taking part?

At this stage of the research there are no additional or intended clinical benefits to you from taking part in this study. However, the information you give us during this research can be supplied to you as graphs or tables at the end of the study if you wish. By way of recognition of the demands of completing the brief questionnaire multiple times and as an incentive to take part, we offer £15 to each participant who completes the monitoring and submits a full set of answers.

Will my taking part in this study be kept confidential?

All information that is collected or recorded will be kept strictly confidential and be accessed and stored for up to 12 months after the study has ended. All participants will be identified by a code and not include any personally identifiable information (such as name or address). Your personal information will not be used in any reports as a result of your participation. We will not access your medical records. Any participant data not identifiable to the research team may be retained for future use.

What will happen to the results of the research study?

The results of this study will form part of a doctoral thesis. We also intend to publish the study in peer-reviewed journals and/or report it at conferences, but all data will be anonymised and no participant will be identifiable.

Who is organising and funding the research?

The study is being organised and funded by University College London as part of a Doctoral thesis project in Clinical Psychology.

Who has reviewed the study?

This study has been reviewed by the London Fulham NHS Research Ethics Committee.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask programme staff if you would like more information on this.

What happens if something goes wrong?

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the Hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Amanda C de C Williams who is the Chief Investigator for the research and is based at University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Complaints Procedure

The normal NHS complaints mechanism is available to you if you wish to complain about any aspect of the way you are approached or treated during the course of this study. Independent information and advice is available from the PALS office. Please contact:

Patient Advice & Liaison Service

University College Hospital

Hospitals NHS Foundation Trust

Ground Floor

University College Hospital

235, Euston Road

London

NW1 2PQ

Tel No: 0207 380 9975

Contacts for Further Information:

Chief Investigator & Academic Supervisor:

Dr Amanda C de C Williams

Reader

Research Department of Clinical, Educational and Health Psychology

University College London

Gower Street

London

WC1E 6BT
Email: Amanda.williams@ucl.ac.uk
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Andy Pike
Trainee Clinical Psychologist
Research Department of Clinical, Educational and Health Psychology
University College London
Gower St
London
WC1E 6BT
E*mail:* [redacted]
Telephone: [redacted]

Thank you for your time and consideration of participation in this study

Appendix 6: Patient Consent Form

University College London Hospitals NHS
NHS Foundation Trust

Centre Number:

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **What changes for whom? Exploring the process of change in a pain management programme using single case study design.**

Name of Researcher: **Dr Amanda C de C Williams**

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **30/07/13** (version **4**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the personal information I provide will only be used for the purposes of this project and not transferred to an organisation outside of UCL. The information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998. ☐

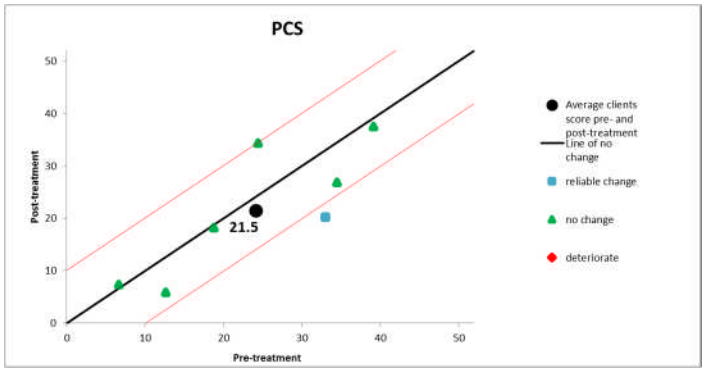
4. I understand that relevant data collected during the study may be looked at by individuals from UCL, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data. ☐

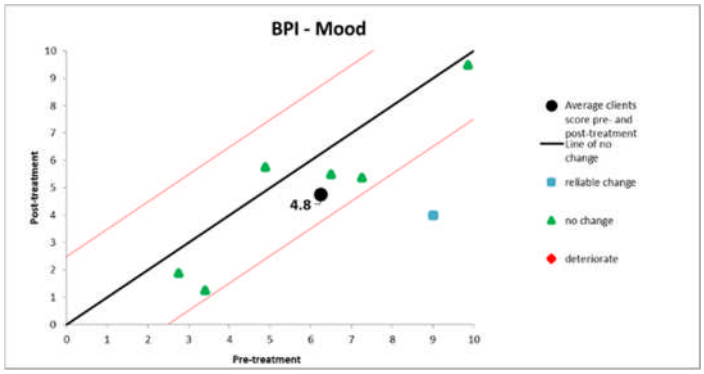
5. I agree to take part in the above study. ☐

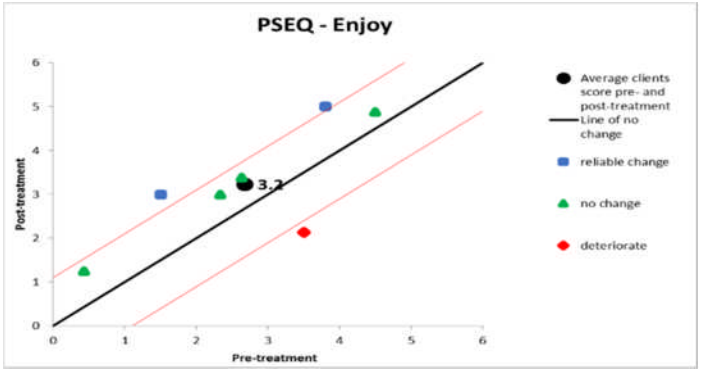
_____	_____	_____
Name of Participant	Date	Signature

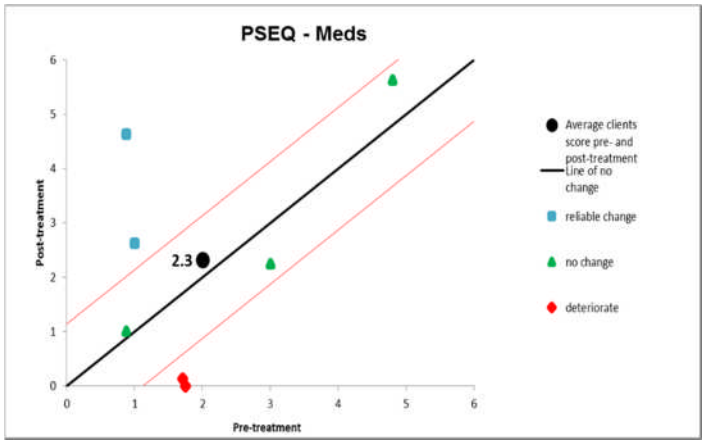
_____	_____	_____
Name of Person taking consent.	Date	Signature

Appendix 7: Graphical representation of reliable change for each measure









Appendix 8: Graphical representation of pain catastrophising scale

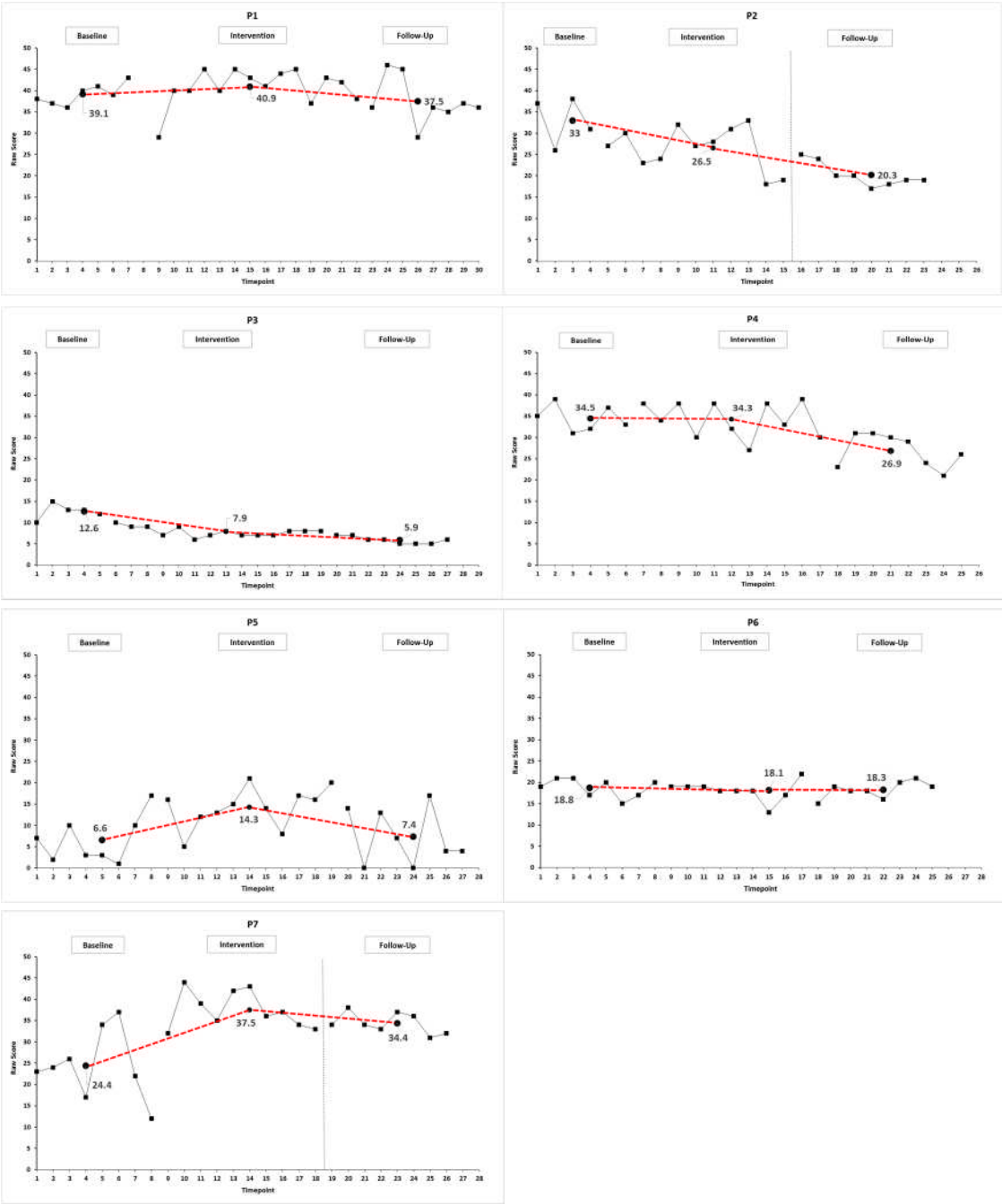


Figure 3 - PCS raw scores and associated mean value for baseline, intervention and follow-up

Appendix 9: Graphical representation of mood raw scores per participant

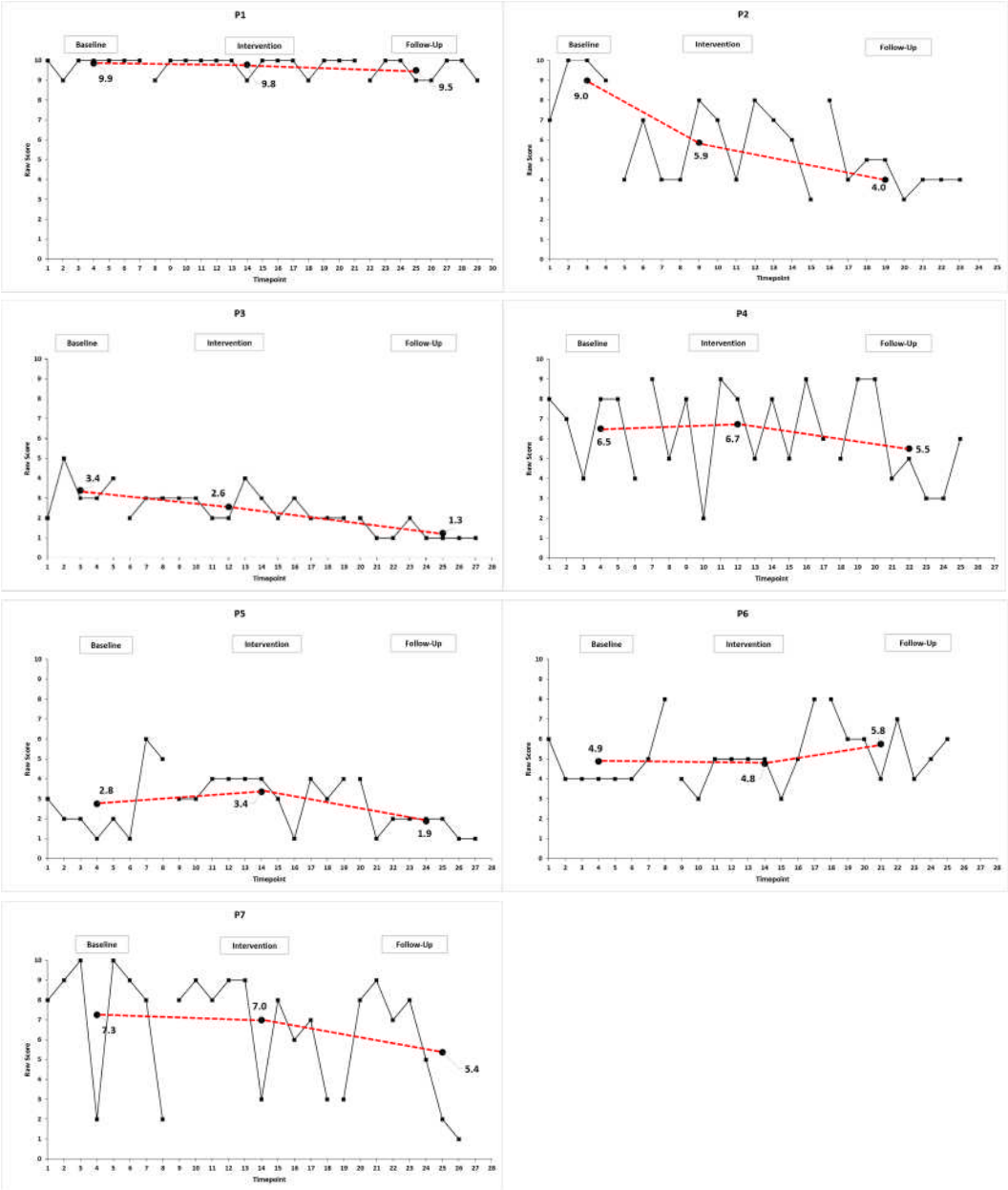


Figure 4 – Single item question raw data for mood and associated mean values for baseline, intervention and follow-up

Appendix 10: Graphical representation of PSEQ raw scores for being able to enjoy life despite the pain per participant

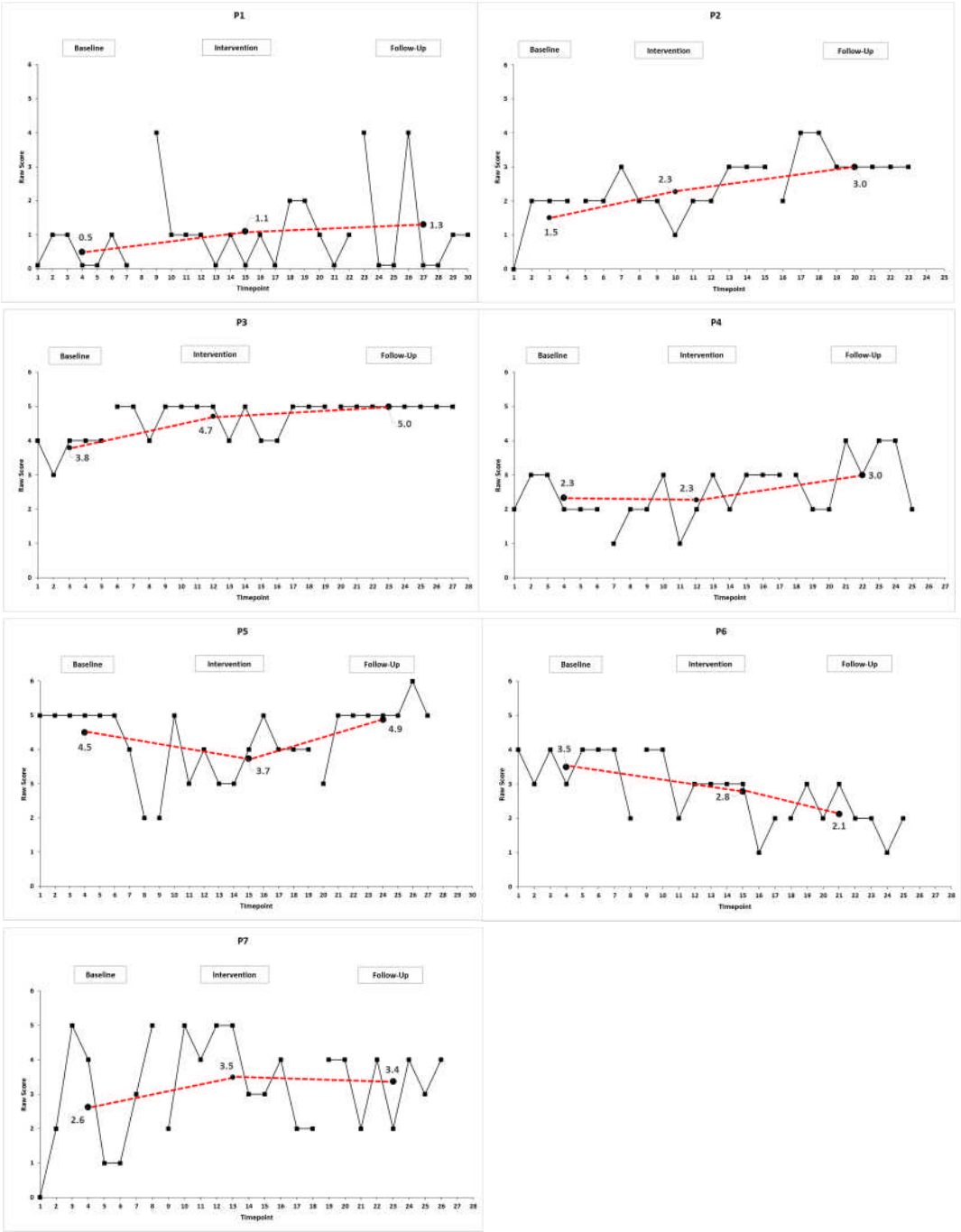


Figure 5 – Plotted PSEQ single item raw scores per participant for "enjoying things despite the pain" and associated mean value for baseline, intervention and follow-up

Appendix 11: Graphical representation of PSEQ raw scores for being able to cope with pain without medication per participant

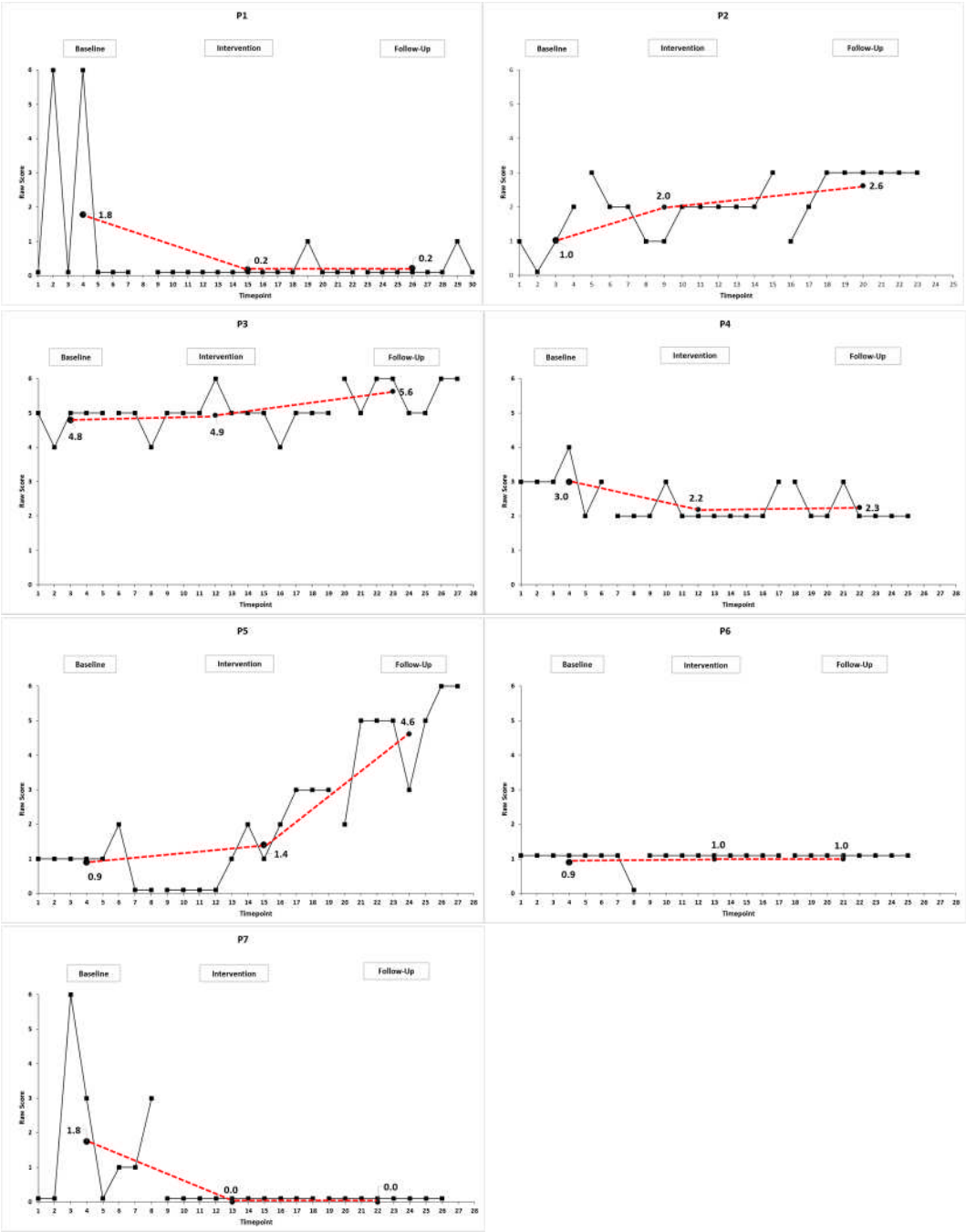
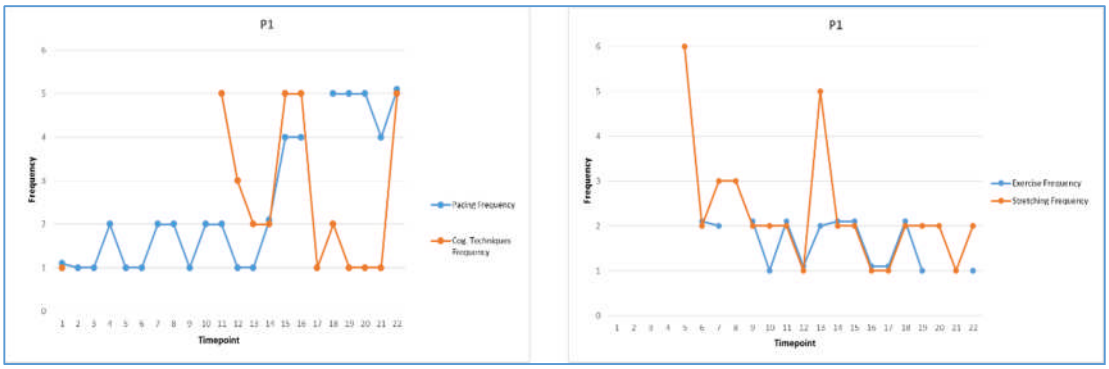
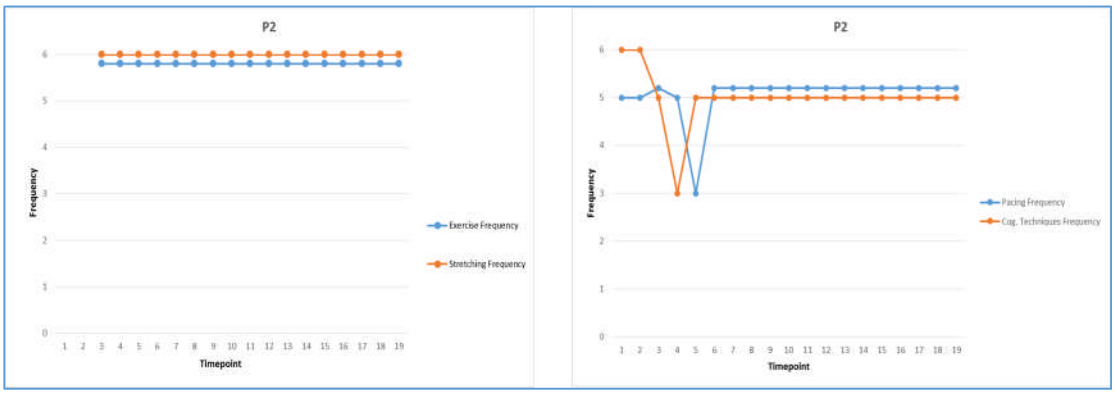
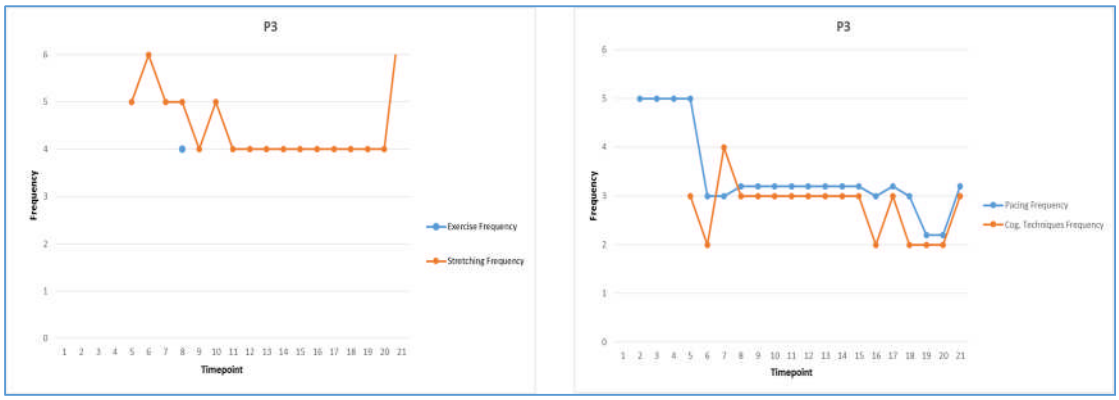


Figure 6 – Plotted PSEQ single item raw scores per participant for "coping with my pain without medication" and associated mean value for baseline, intervention and follow-up

Appendix 12: Graphical representation of adherence frequency and occasion scores per participant







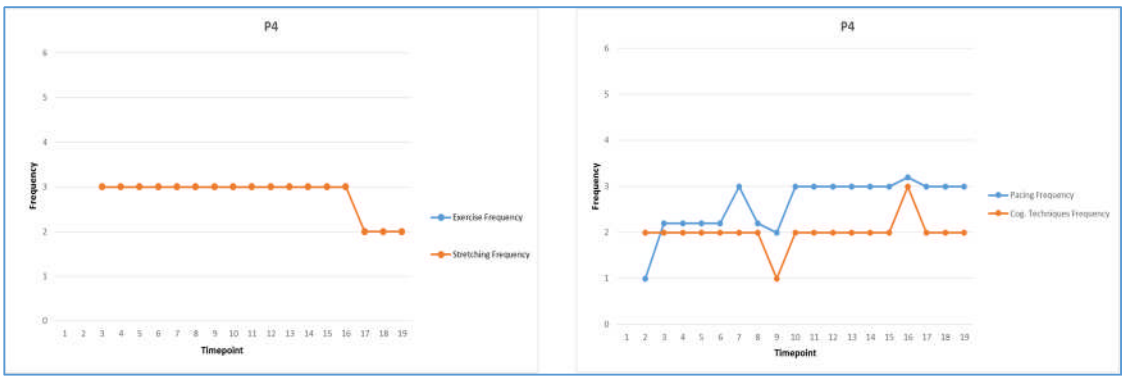


Figure 6 - Exercise Frequency/Stretching Frequency – 1=stopped completely, 2= less than once per week, 3=once or twice/week, 4=three to four times/week, 5=five to six times/week, 6=at least once per day, 7=n/a

Pacing Frequency/Cog.Techniques Frequency - 1=not at all, 2=once or twice/week, 3=three to four times/week, 4=five to six times/week, 5=at least once per day, 6=n/a

Appendix 13: Table of data of external factors

Have any other factors outside treatment affected how you are today?

Participant ID	Response	Rating (1=not at all, 5=completely)
P1	*I have a Mum,86 who will not answer the phone when I ring. We take her food every other day but she is leaving it and putting a lot of pressure on us both physically and mentally. Very self centered.*	5
	I get stressed very easily and have a short fuse. Used to be in a high pressure job and could cope with whatever was thrown at me. Find it hard to cope with how I am now.	5
	In a lot of pain yesterday, course day and the seats really uncomfortable and I cannot sit on the floor. The long drive to and from London is not helping	5
	Mother in hospital so have to visit her everyday. Car in garage so have to use wheelchair - good exercise!!	5
	Travelling to and from the course. Will try coming by train next week but I do use a mobility scooter or wheelchair, so lots of arrangements have had to be made.	
	The course makes you think about pain which is something I try to put behind me. The travelling makes me very tired. My Mum is in hospital	5
	Train journey back. Great 'till MAN. ramps up and out of virgin trains. ramp put up at MAN -'no card for your scooter' 'in the post - on morphine & need ramp already there' ramp pulled away & had to struggle up huge step etc.lot of pain.	5
	Been so tired due to the trips to London and back. Something always seems to happen to make my pain worse and I lose sleep over this.	5
	The Link course involves a lot of travel and the seats at the venue are not good when in pain. Pain really bad Mon/Tue/Wed	5
	The long journey to and from the Link programme is hard work and the chairs are very hard.	5
	Am doubly incontinent & had an accident on the train on the way to London - twice- so very nervous about trip back. Christmas coming too soon.	5
	Travel to and from London is very exhausting and painful.	5
	Travelling too and from London for the course has been very tiring and painful. Would have been better if been fortnightly for anyone travelling	4
	Mum now back at home and even though EVERYONE is telling her/me that she has to rely on Carers for anything physical and I must not go to see her everyday, it is hard for me to let go and her not to 'wind me up'.	3
	Having to double check EVERYTHING. The next meeting is being held at a different location. I rang venue and I cannot access the meeting room on my scooter…	3
	I awoke at 4.00 am in chronic pain, could not move. This is the first time I have been in chronic pain when I have been resting and I am very frightened. Been in bed all day.	5
	Very disappointed in response from Link when I found out that venue was not appropriate for me and to be honest felt I got more out of meeting other Ladies with pelvic pain.	5
	Relief that the trips to Link are over for the time being. The last one was extremely stressful. We are penciling in small goals everyday to improve quality of life. Only managed one day as spent most of the last few in bed in pain.	5
	Had a lot of pain these last few days which meant I have not been out of the house. Find this depressing.	5
	Pain has been bad and been in bed a lot. Cannot do things I want to and have been bad tempered. Close relationships have suffered.	4
	My therapist from Link rightly suggested that I reduce the amount of morphine. Started a reduced dose on Monday. Pain worse and feel poorly but determined to persevere.	5
	Reducing the morphine at the beginning of the week has increased the pain. A Family meal had to be cancelled and going out with friends ditto. Getting better slowly so feel more positive today.	5
P2	*I feel slightly more confident that I can do things on my own because of traveling to and from COPE.*	3
	I have used public transport a lot this week and am drained	3
P3	*I have done more than usual and this has mad ethe pain somewhat worse*	2
P4	*I moved house at the weekend and have been unwell with suspected glandular fever for the last four weeks*	4
	Moved a week ago so still unpacking	2
	On annual leave from work	3
	Been on annual leave from work	2
P5	*Difficulty with grumpy work colleagues*	4
	period pain	2
	having hassle at work	3
	hassle at work, feeling tired	4
	A very busy week at work. Today I fell asleep at 3pm!	3
	Had an evening out in London followed by 6hrs nonstop teaching and now I feel knackered!	3
	Bit of stress from an exploding fishtank! Otherwise quite a good few days.	2
	Manic at work. Feel tired a lot.	3
	Another manic day at work and 2 children bickering when I collected them from school.	2
	Feeling cheerful. Paid off the mortgage this week!	4
	menstruation; feeling very irate!	4
	Been crying a lot. Just can't seem to help it. Have to hide in the loo when it happens at work.	
	Squabbling children sent me into a rage yesterday.	3
	I keep spending hours crying. Having to hide in the loo to avoid being seen. Maybe missing the meds. But teeth are fine!	4
	Can't get off the treadmill. Just feel constantly tired	3
	Have had a fun weekend paving the driveway and feel totally tired but proud of it!	5
	Easter hols imminent. Looking forward to a break from teaching.	4
P6	*Not really sure what this question means. The pain is very dependent on my general stress and fatigue levels, which vary day to day.*	1
P7	*No reason given*	2
	No reason given	2
	No reason given	2
	No reason given	2
	No reason given	2
	No reason given	2
	No reason given	2
	No reason given	2
	No reason given	3
	No reason given	2
	No reason given	2
	No reason given	2