**Abstract**

**Background:** Understanding successful and unsuccessful behavioural treatment for pain is essential. **Aim**: We carried out a retrospective survey of 130 people who had undergone pain rehabilitation based on Acceptance and Commitment Therapy, aiming to identify factors associated with non-response. **Method**: The sample was selected using reliable change index to define ‘responders’ and ‘non-responders’ to key outcome measures. We surveyed a range of treatment-related, systemic, practical and personal factors that may have affected their treatment, and then compared ‘non-responders’ to ‘responders’, controlling for factors that might not be causal or specific to non-response. **Results:** Logistic regression analysis showed two themes that distinguished the groups, ‘People outside programme’ and ‘Emotional state’. **Discussion:** These data have clinical implications, as such factors can be addressed directly or incorporated into an assessment of treatment ‘readiness’. This study introduced a novel methodology for the investigation of pain treatment response, which allowed a broad study of clinically relevant variables, but with greater rigour than conventional self-reports of ‘helpful factors’ in treatment.

**Keywords**

Cognitive-behavioural therapy; Acceptance and Commitment Therapy; Treatment Process; Outcome; Pain Management; Treatment Failure

**Introduction**

The need to understand the therapeutic processes underpinning successful psychological treatment for pain is paramount. Historically, psychological therapy research has generally focused on validating ‘packages’ of treatment with little understanding of the ‘active ingredients’ of positive outcome (Medical Research Council [MRC], 2008). However, without such an understanding, the community of applied researchers is unlikely to be able to generate treatments of increasing effect size. Also, unanticipated findings, such as the failure of well-conceived treatments (Williams et al., 2014) are likely to go unexplained.

To truly understand successful treatment, a better understanding of its counterpart is necessary. Psychological treatment studies for pain typically report significant group mean improvements, yet these groups will include many participants who had no improvement. A review of psychological treatment research in the chronic pain literature advised the use of responder analyses and attention to adverse events (Morley, Williams & Eccleston, 2013), where the classification of individual patients as treatment responders, or non-responders, allows researchers to go beyond mean scores in the search for predictors of treatment response. Currently, it remains unclear why some patients do not benefit.

Eliot (2010) identified three key methodological approaches in therapy process research, all of which can potentially be applied to pain treatment. ‘Process-outcome’ research is usually quantitative, using in-therapy variables to predict outcome; this includes examining mediators of treatment outcome in RCTs. ‘Sequential process’ designs analyse the events within and between therapy sessions in order to establish dependencies between therapist and client responses. Finally, the ‘helpful factors’ design directly asks recipients of treatment about their opinion of effective therapeutic factors.

The ‘helpful factors’ design is attractive as it stays close to the patient’s experience, can be done in routine treatment settings, and it does not restrict patient responses to the researcher’s pre-ordained variables. Recent examples of research in this tradition include careful qualitative interviews (e.g. Bendelin et al., 2011) or qualitative analysis of diary entries (e.g. Kristjánsdóttir et al., 2011). However, the potential power of this design is restricted by the limitations of self-report. Humans are frequently inaccurate about the causes for their own actions and reactions; decades of research on this phenomenon suggest that patients may not necessarily be experts on the causes for their own therapeutic response.

Results from ‘helpful factors’ research will depend on which participants are asked; to gain information about helpful therapeutic factors, it makes little sense to ask individuals who did not benefit from therapy. Conversely, barriers to treatment are best explored in those who have most evidently encountered them (i.e. non-responders). However, ‘helpful factors’ studies usually sample an unselected group of patients who have experienced a treatment, ignoring whether these individuals benefited from the treatment or not.

In this study, we deployed a method that may extend the usefulness of the ‘helpful factors’ design by controlling for difficulties in self-report. We used this design in the context of intensive, residential, group-based Acceptance and Commitment Therapy (ACT) treatment for chronic pain that is, on average, effective (Veehof, Oskam, Schreurs & Bohlmeijer, 2011). Exploring the reasons for treatment non-response, we asked a series of patients, defined as non-responders by statistical criteria, about a range of individual, systemic and therapy-related factors that may have affected their treatment outcome. We asked about a wide range of factors that reflected patients’ report and therapist formulations for potential treatment success or failure, rather than focusing purely on theory-driven psychological processes Then, to check that their opinions were related to outcome, we compared their responses to a group of patients who were statistically defined ‘responders’. We hypothesised that we would find clear differences between responders’ and non-responders’ views of helpful and unhelpful factors in treatment. However, we also noted that this novel approach would be most clearly vindicated if we found that non-responders cited some ‘unhelpful factors’ that were also cited as unhelpful by responders.

**Method**

*Participants*

We sent a retrospective questionnaire to 130 people with chronic, non-malignant pain who had consecutively attended psychologically-based treatment and follow up at a national specialist service. This group included 65 treatment non-responders (69% female) and 65 responders (83% female). Seventy-five of those who were successfully contacted (62%, see below) returned data. Mean age was 44.0 years, 67% were female, and mean pain duration was 140.6 months. They had relatively high levels of pain (6.9/10), low mood, and high levels of functional disability (10% in full time work). Their core problems were a heterogeneous group of musculoskeletal pain diagnoses, including Fibromyalgia, Lower Back Pain, and Failed Back Surgery Syndrome. Patients had been clinically selected for treatment, such that they had sufficient spoken English and cognitive capacity to engage in group treatment. We did not apply inclusion or exclusion criteria beyond this.

All participants had completed intensive, residential, psychologically-based pain rehabilitation treatment (3 or 4 weeks) between 5 and 43 months prior to the study (*Mdn* = 29). This treatment was based on ACT, including substantial physiotherapy using ACT techniques (treatment and outcomes from this clinical setting have previously been described in McCracken & Gutiérrez-Martínez, 2011). Treatment was delivered by a team of Clinical Psychologists, Physiotherapists and Occupational Therapists, all conversant with ACT and specialists in pain rehabilitation. Participants completed standard outcome measures around depression, disability and pain-related fear at pre- and post-treatment intervals, and at the three-month follow up period. This data was inspected for recruitment to the study.

*Procedure*

The study received Ethical approval from the relevant NHS (REC reference: 14/EE/0213; IRAS project ID: 146652) and University Research Ethics Committees (reference number: 14-050), and the local Hospital R&D Committee. We surveyed a sample of participants defined as clinically reliable treatment responders or non-responders. To identify participants, we reviewed consecutive cases in a treatment outcome database. We only considered those cases with data from pre-treatment to three-month follow up period, to be confident that we were observing somewhat durable treatment outcomes. We defined ‘responders’ and ‘non-responders’ by statistical criteria described below. We then added cases to the ‘non-responder’ and ‘responder’ groups (definitions below) until we had 65 in each group, for an overall sample of 130 patients included in the questionnaire survey. The sample size was decided pragmatically, based on the size of our source database and anticipated return rates. We sent a retrospective questionnaire about helpful and unhelpful factors in treatment to this group of 65 responders and 65 non-responders. The questionnaire package included a £10 voucher, which the participant was free to keep whether they completed the questionnaire or not. A reminder letter was sent out after two weeks.

*Definition of non-responders and responders*

This study required the classification of individuals as ‘non-responders’ or ‘responders’. To achieve this, we inspected three clinical outcome domains in our definition of non-response: overall disability, depression, or pain-related fear. ‘Non-responders’ were those who did not achieve reliable change in all domains; ‘responders’ achieved a reliable change in one or more domains. Clinically reliable change was defined using the method described by Vowles and McCracken (2008; full formulae are included in their paper). This method calculates a reliable change index (RCI), which indicates the practical importance of observed change (Jacobson, Roberts, Berns & McGlinchey, 1999). Though it is important to note that clinically significant change is not captured by this metric, as it requires normative data. In chronic pain a complete recovery may not be expected (Morley et al., 2013), limiting the availability of normative scores. Thus responder analyses are typically concerned with RCI.

*Measures used to detect response / non-response*

Participants completed the following measures as part of their standard clinical treatment; scores from these scales were used in the definition of ‘non-response’.

*Disability - Sickness Impact Profile (SIP)*

The SIP (Bergner, Bobbitt, Carter & Gilson, 1981) was used as a measure of physical and psychosocial disability. This validated measure is comprised of 136 items that can be used to assess three dimensions of disability (physical disability, psychosocial disability and “other” disability) or be combined to give a Total score, which we used in this study test-retest is good, at .87 (Bergner et al., 1981; Vowles & McCracken, 2008).

*Pain-related fear -* *Pain Anxiety Symptoms Scale (PASS)*

The PASS (McCracken & Dhingra, 2002) was used as a measure for pain-related anxiety and avoidance. It is a validated 20-item measure with good psychometric properties. The measure uses a 6-point scale ranging from “0” (never) to “5” (always). A total score was used for this study, with a test-retest coefficient cited at .86 (Vowles & McCracken, 2008)

*Depression*

Due to changes in administered measures over time, participants received one of two indices of depression. Reliable change scores were calculated for both; the same calculation was used to define ‘response’ thresholds for both scales, and these calculations are not dependent on the nature or format of the original scale.

*British Columbia Major Depression Inventory (BCMDI)*

The BCMDI (Iverson & Remick, 2004) is a 20-item measure is based on the diagnostic criteria for major depressive disorder as given by the DSM-IV (Iverson & Remick, 2004). The BCMDI assesses depressive symptom severity and their impact on various aspects of daily functioning on a 6-point scale ranging from “0” (absent) to “5” (very severe symptom). This study used the symptom severity subscale. The BCMDI is a validated measure, with Cronbach Alpha reported at .83 (Iverson, 2001).

*Patient Health Questionnaire* (PHQ-9)

The PHQ-9 (Kroenke, Spitzer & Williams, 2001) is comprised of nine items that assess the diagnostic criteria for depression as given by the DSM-IV, with a test-retest coefficient of .84 (Kroenke et al., 2001). The questionnaire uses a 4-point scale ranging from “0” (not at all) to “3” (almost every day).

*Novel ‘treatment factors’ item set*

Our intent was to create an item set that included a wide range of treatment-influencing factors that might be seen as relevant by patients and therapists. Thus, we intended to survey factors related to the individual, their context, and the therapy itself. We were aware of no existing instrument that covers these domains. The process of design aimed at creating items that closely reflected patient and therapist concerns, and that also might be grouped into scales and later subjected to quantitative analysis.

An initial item set was generated, based on the authors’ clinical experience and the results of a clinical case note audit examining treatment response, or non-response, in a sample of 30 severely disabled patients with chronic pain. We then reviewed 50 ‘patient satisfaction’ forms from the host clinical service which include sections, in free text format, where patients are invited to report what was helpful and unhelpful about the service. After including further items derived from these comments, the proposed item set was circulated to the clinical team of the host service, including 18 clinicians working at a national specialist level in pain rehabilitation.

The final item set included 80 items. The differing focus of the items and the concepts sampled necessitated different response formats for certain sets of items. For example, a 7-point scale ranging from “1” (very unhelpful) to “7” (very helpful) was used for items such as “being away from my normal routine”. In contrast, a scale from “1” (very untrue of me) to “7” (very true of me) was used for items such as “I was personally motivated to engage in treatment”. We grouped these items into six subscales; (1) Change in routine; (2) Communication and Trust, (3) Emotional State, (4) Group climate; (5) Medical interference; (6) People outside programme.

*Data Analysis*

Our primary analysis was to compare how responders and non-responders scored on the Treatment Factors item set. Thus, our first step was to compare the groups’ baseline characteristics (at the pre-treatment point) so that we understood how similar they were before intervention. Turning to the main analysis, we inspected responses to individual Treatment Factors items in order to get a detailed, descriptive understanding of the difference between groups. We also wished to examine broader themes by examining our groups of thematically related Items. We considered the internal consistency of items within our pre-defined ‘subscales’. Items were deleted if they contributed to an unsatisfactory alpha for the subscale. The remaining items resulted in internally consistent subscales (Cronbach’s α .79-.94) that were used as independent variables in a logistic regression analysis, with ‘group’ (responder or non-responder) as the dependent variable. The data were screened and checked to ensure that it satisfied the assumptions of logistic regression.

**Results**

*Responder analysis*

The responder analysis indicated that a reliable change was observed in at least one domain for 56.8% of cases. Split by outcome measure, a reliable change was found for 34.2% of patients on the BCMDI, 22.0% on the PHQ9, 30.9% on the PASS and 43.9% on the SIP.

Of 130 questionnaires sent, nine were returned due to incorrect addresses; of the correctly mailed questionnaires, 75 were returned (62%). This included 40 non-responders (53.3%; 26 female; *M* age 42.85*; Mdn* pain 114 months), and 35 responders (24 female; *M* age 45.38; *Mdn* pain 71 months). Groups were similar on baseline demographics, although responders reported higher disability (*p*<.01) and pain-related fear (*p*<.05).

*Individual items from Treatment Factors questionnaire*

We inspected responses to individual items on the Treatment Factors questionnaire, as it is of clinical interest to see the greatest, and most minimal, points of divergence between the non-responders and the responders. Table 1 shows the six individual items with the largest, and the smallest, mean differences between responders and non-responders. The largest differences were seen in items relating to the perceived demands of the treatment format, and in perceived threat and disruption from others. The items with the least between-group differences show a broader range in content.

**\*\*\*\* Table 1 about here please \*\*\*\***

We also examined individual items in order to control for a specific methodological risk, that is, that non-responders might endorse specific treatment factors as negative, where in fact they were simply unpleasant, and not actually a barrier to good outcome. If this were true, responders might also rate the same items as negative, endorsing their unpleasantness but demonstrating that these factors were not related to outcome. We found no variables that the non-response group rated as unequivocally negative towards treatment outcome. However, some of their least positive ratings were on items sampling financial pressure, insufficient individual time and drowsiness caused by medication (means 3.8 – 4.2, where 4 = ‘neutral’, 5 = somewhat true, 3 = somewhat untrue). We examined scores for responders on the same items, and they were almost identical (3.9 – 4.4), indicating that these may be more generic difficulties in treatment, rather than being linked to outcome.

*Refinement of subscales*

Inspection of Table 1 indicates that many items appear to group together; half of the six items with the largest between-group difference relate to perceived or actual adversity from others. To advance our analysis of the large number of remaining individual items, we analysed our ‘subscales’ from the Treatment Factors questionnaire, discarding items that contributed to an unacceptably low alpha. This resulted in the ejection of between 0% and 33.3% items from different subscales; the final six subscales had an internal consistency of between α .79-.94 (see Table 2).

**\*\*\*\* Table 2 about here please \*\*\*\***

*Logistic regression*

A logistic regression analysis was conducted with the six subscales entered as potential predictors of the dependent variable, ‘group’ (responder or non-responder). Logistic regression models are viable where there are at least 10 cases per variable (Vittinghoff & McCulloch, 2006). The assumptions of logistic regression analysis were satisfied.

The regression model accounted for a significant amount of variance (*p*<.01), successfully classifying 70% of the cases overall (60% of responders and 80% of non-responders). Coefficients are displayed in Table 3. Two variables emerged as independent predictors at p < .05 in the regression model: Emotional State and People Outside of Programme. Being a non-responder was associated with greater reported interference from people outside of the programme, and with lower reports of bothersome emotional states such as guilt and frustration.

**\*\*\*\* Table 3 about here please \*\*\*\***

**Discussion**

We retrospectively surveyed a group of patients who did not respond to pain rehabilitation treatment, asking them about a range of factors that may have contributed to this. We compared their responses to a group of patients who showed clear treatment benefits, in order to check that the non-responders’ results were specifically related to outcome, rather than generic factors affecting all of those in treatment. Non-responders reported that their treatment was negatively affected by people outside of treatment, and paradoxically that they were experiencing fewer distressing emotional states at the time of the programme; each of these factors was endorsed more strongly than by the ‘responder’ control group.

In order to investigate treatment process, researchers have historically investigated process variables in mediation designs or carried out qualitative studies on unselected groups (i.e. mixtures of responders and non-responders). Treatment-relevant factors are often also investigated locally in audit or patient satisfaction designs. All of these designs are useful, but are limited either by scope or rigour. RCT-based designs address individual psychological process variables without investigating systemic, practical or external psychosocial barriers to treatment response. Qualitative or audit designs are not limited in the same way, but can lack rigour, and are vulnerable to the inaccuracies of human self-report or recall bias. The design of this study permitted examination of a range of clinically relevant factors potentially related to non-response, and introduced the rigour of a comparison group. Some factors that non-responders cited as not clearly ‘helpful’ in treatment were endorsed equally by responders, indicating the value of the controlled comparison. Also this design produced a clear and counterintuitive result; the finding that non-responders reported less distress during treatment could not have been derived reliably from any other ‘helpful factors’ design. The methodological design of this study responds to recent calls for research using responder analysis in the pain literature (Morley et al., 2013) and for practitioner-oriented research in the cognitive behavioural therapy literature (McMain, Newman, Segal & DeRubeis, 2015)

Non-responders described their treatment as disrupted by ‘people outside of the programme’ and reported fewer distressing ‘emotional states’ at the time of the programme. Although single items around the length and demands of the programme day seemed to separate responders and non-responders, the subscale including these items did not emerge as an independent predictor of group membership in the logistic regression analysis. Non-responders more clearly reported that others outside of the programme were physically or emotionally abusive, or that they were worried about such abuse. They reported more difficult communications with others. It might seem obvious that ongoing interpersonal adversity would affect treatment, but this is seldom discussed in the more theoretically-oriented treatment process literature. This finding echoes the contemporary emphasis on social contextual and communication factors in chronic pain (Cano et al., 2013).

Non-responders also, in contrast to the finding above, reported lower levels of emotions such as guilt, frustration and sadness at the time of treatment. This result is counterintuitive and requires careful interpretation. At baseline, non-responders reported lower levels of pain-related fear; it could be argued that this accounts for this unusual result. However, the broader picture argues against this notion. At baseline, non-responders did not show lower levels of depression, or pain-related distress. Thus, it cannot be argued that non-responders were less generically ‘distressed’ at baseline. Also, the Emotional State subscale sampled a range of different emotions (including sadness, guilt, anger) and no item sampled pain-related fear; thus the findings for Emotional State subscale were independent of the ‘pain-related fear’ variable that was lower at baseline. It seems that the non-responders were genuinely less distressed by the treatment experience, and this is in fact a finding that echoes other research in ACT-based pain rehabilitation. It has been shown that positive treatment outcomes are related to patients’ ability to openly accept, and avoid suppression of, emotions in general (e.g. McCracken and Gutierrez-Martinez, 2011). Thus, the current study lends weight to previous findings indicating that enhanced emotional openness during ACT treatment (and thus increased experience of distress) can be associated with positive treatment response.

These findings have clear clinical implications – for example, psychosocial adversity might either be episodic or open to intervention, and assessing clinicians can benefit from knowing that high reported distress is not necessarily a barrier to successful treatment. Thus, there may be an argument for focusing treatment efforts on the social and family environment, as is now commonplace in interventions for psychotic conditions (Okpokoro, Adams & Sampson, 2014). Also, clinicians often intuitively assess whether it is ‘the right time’ for a patient to undertake treatment, given the patient’s overall state and circumstances, and understanding that some episodic stressors may improve simply with the passage of time. For example, it is common for a surgeon to postpone an operation until a patient is medically stable enough to benefit optimally from it. The results from this study add credence to the clinical assessment of ‘psychosocial stability’, but add the counterintuitive observation that reporting intense negative emotional states need be no necessary barrier to successful ACT treatment. It is also valuable to note the factors that were not related to non-response in this study. Where there were difficult group dynamics, communication, and the personal disruptions of entering intensive treatment, these did not emerge as causally related to outcome in the current study.

This study was preliminary and has several limitations. Our method of combining single items into ‘scales’ was improvisational, rather than principled. However, in the absence of measures that reflected the wide range of factors cited by patients and clinicians, this approach was warranted. We wished to start the study using a wide range of factors cited by patients and clinicians; these seemed naturally to group into some themes, but doubtless future studies may find a more elegant way of doing this. Similarly, we were unable look at clinically significant change, as normative scores are not available and return to sub-clinical levels is not expected for this population. Our findings may also be limited by the retrospective nature of participants’ report – most were more than one year after the end of their treatment. Results from a treatment setting seeing a higher volume of patients would allow this study to be repeated on patients who were less distant from their treatment experience. Prospectively employing this method and recruiting a larger sample is needed to elaborate on the current study, enabling exploration of factors related to specific outcome domains. Finally, we only sampled patients who had attended their three-month follow-up review. Positively, this allowed us to study only those where non-response, or response, was relatively enduring. However, we are unable to account for those non-responders who did not attend follow-up.

In summary, we surveyed treatment non-responders and asked them about factors that may have impacted their treatment. Comparison of their responses to responders was a methodological innovation that arguably allowed the study of a wide range of treatment factors with the rigour of a controlled design. The results included theoretically relevant and counterintuitive findings that seemed to vindicate the use of the design. They direct attention towards psychosocial factors that may be modifiable, and indicate that endorsement of strong negative emotions is no necessary barrier to successful ACT treatment.

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**Declaration of Interest**

None.

**Ethical Statement**

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, and its most recent revision.

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