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A single case experimental design: how do different psychological outcome measures capture the experience of a client undergoing CBT for chronic pain

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Abstract

Introduction: Reports suggest that many people who experience chronic pain also experience associated mental health difficulties. Currently the first line psychotherapeutic intervention for people who experience anxiety and depression within the context of chronic pain is Cognitive Behaviour Therapy. Anecdotal clinical reports suggest that commonly used psychological outcome measures do not truly reflect the experience and improvement of clients who experience chronic pain following CBT. The present study therefore aimed to compare the outcomes of a CBT intervention within one client's journey through CBT.

Methods: A single case experimental design (SCED) was used to evaluate generic measures of mood, pain specific measures of wellbeing and client specific cognitions.

Results: All outcome measures suggested that the CBT intervention had been at least somewhat successful. Results suggest that the more specific the measure was to the client's experience; the more improvement was demonstrated on the measure.

Keywords

CBT, chronic pain, health, psychology, outcomes

Introduction

Many people who are diagnosed with long-term health conditions (LTC) experience associated difficulties with mental health and wellbeing.[1] The experience of Chronic Pain has been classified as an LTC[2] and has been associated with anxiety and depression.[3]

In addition to the medical management of Chronic Pain, the National Institute of Health and Care Excellence (NICE) recommend that psychotherapeutic interventions such as Cognitive Behaviour Therapy (CBT) are available.[4] Further to this evidence, the British Pain Society[5] recommend that, based on contemporary evidence, multi-disciplinary Pain Management Programmes should incorporate Cognitive Behavioural principals in order to assist those who experience chronic pain.

While many studies have demonstrated the effectiveness of CBT for people who experience chronic pain,[6] there have been anecdotal accounts within pain services that routinely used outcome measures such as the Generalised Anxiety Disorder-7 (GAD-7)[7] or the Patient Health Questionnaire-9 (PHQ-9)[8] do not fully capture the experience of clients who undertake a CBT intervention. Services have expressed concern at the use of generic GAD-7 and PHQ-9 measures due to the inclusion of somatic items which aim to measure

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anxiety or depression, but which may share a semantic overlap for people who experience chronic pain. For example; items which ask about difficulties sitting still or experiencing disturbed sleep often elicit answers from clients about their pain. While health professionals can tailor the measures and ask clients to focus on their mood and anxiety this could disrupt the validity of the measures and ignores a salient element of the client's difficulties.

It is worth noting that the newly commissioned Integrated Improving Access to Psychological Therapies (IAPT) services[9] are also required to collect GAD-7 and PHQ-9 outcomes within their chronic pain pathways. There is also a requirement to collect the Brief Pain Inventory (BPI)[10] to highlight pain intensity and quality of life which suggests that there is a recognition that more condition-specific outcome measures may be useful.

Rationale and hypothesis

Due to the concerns surrounding the ability of generic outcome measures to capture the experience of someone diagnosed with chronic pain, the following report details an individual's journey through a typical CBT intervention and their outcomes. To assess how a person's experience could be captured, three levels of outcome measure were utilised; generic anxiety and depression, chronic pain-specific aspects of wellbeing and client-specific measures focusing on personal cognitions and therapy targets. The current intervention was conducted prior to the implementation of the Integrated IAPT services and their inclusion of the BPI, therefore different pain-specific psychological outcome measures were used.

Based on the use of different levels of outcome measures, one main experimental hypothesis is to be tested; The magnitude of observed improvement on outcome measures following a CBT intervention for chronic pain will differ dependent upon the outcome measures specificity to chronic pain.

Method

Design

This study was conducted as a part of the requirements for Doctorate in Clinical Psychology and ethical approval was therefore sought from the University of Sheffield Doctorate in Clinical Psychology Department.

Single case experimental design. The Single Case Experimental Design (SCED)[11] has previously assessed psychological interventions in the chronic pain population and will help to establish within-participant variance.[12] The SCED method will follow an 'A-B' design.[13] Daily ideographic measures were collected during the baseline ('A') period of 14 days and were compared against data from the intervention phase ('B') of 37 days. During the 51 days of baseline and intervention the participant attended 8 hour-long sessions, two during the assessment ('A') and 6 during the intervention ('B').

Nomothetic bookend measures (pain specific, and generic) were also collected; first, at pre-assessment, second at a point following the assessment and prior to the intervention, and third at post-intervention.

Participant information

This report outlines the case of a 51 year-old male named Chris (Pseudonym). Chris was referred to a psychology service in a major regional hospital by a specialist nurse who was concerned about 'quite marked depressive symptomology'.

Chris has experienced chronic pain since his early twenties due to an injury sustained at work which has required several bouts of surgery and has affected his employment.

Prior to his current referral, Chris had been offered a group-based intervention in January 2015; however, he felt that focusing on what he termed 'thinking it away' would not be useful for him so he disengaged. Chris repeatedly mentioned that he was unsure about therapy being for him, and despite wanting to 'give it a go' he acknowledged that identifying and appraising his thoughts was very 'alien' to him.

Intervention

We undertook two assessment sessions to orientate Chris to the CBT model and began constructing a formulation. Chris identified how his core beliefs about being a hard worker, independent and being a strong provider felt at odds with the reality of living with chronic pain. When in pain Chris needed to rely on others which led to feelings of guilt, embarrassment or frustration. He identified an avoidant coping strategy which reduced his engagement with others or activities. Following psychoeducation around the 'neuromatrix' and 'gate-control' theories of pain[14] we began a series of behavioural experiments and gradual exposure work to increase Chris' level of activity in day-to-day life. We also spent time challenging Chris' stated beliefs and thoughts using between and within session tasks.

Measures

Ideographic measures. Chris was able to identify 4 main cognitive processes to monitor using daily ideographic measures;

How much distress has my pain caused me today?

How often have I had the thought 'I can't do anything'?

How often have I felt guilty?

How often have I felt embarrassed?

Items were scored on a 7-point Likert-type scale. Scores ranged from 1 to 7, with 1 being the best score possible, and 7 being the worst.

Nomothetic measures. Standardised measures were collected to investigate other aspects of Chris' experience of living with chronic pain. These measures were collected at pre-assessment (start of baseline), post-assessment (end of baseline/ start of intervention) and post-intervention (end of intervention).

Patient Health Questionnaire (PHQ-9). The PHQ-9 is a 9-item questionnaire assessing depression.[8] Each item consists of a four-point Likert-type-scale asking about the incidence of an experience over the previous 2 weeks. An additional 10th item asks about the impact that the reported problems on the respondent's life. Kroenke and Spitzer[8] suggest that internal consistency ($\alpha = 0.89$) and test–retest reliability ($r = 0.84$) are good.

Generalised Anxiety Disorder (GAD-7). The GAD-7 is a 7-item questionnaire assessing anxiety.[7] Each item has a 4-point Likert-type-scale asking about the incidence of specific experiences over the previous 2 weeks. Internal validity is suggested to be acceptable ($\alpha = 0.89$).

Pain Catastrophising Scale (PCS). The PCS is a 13-item questionnaire designed to investigate the incidence of problematic or catastrophising thinking which is related to pain.[15] Each item is split into a 4-point Likert-type-scale asking about the presence of certain thoughts when the respondent is in pain. Internal consistency is suggested to be acceptable ($\alpha = 0.87$).

Pain Self-Efficacy Questionnaire (PSEQ). The PSEQ is a 10-item questionnaire investigating the impact of pain on an individual's levels of self-efficacy and ability to engage in everyday life.[16] Each item is a 7-point Likert-type-scale which looks at several domains of activity which could be impacted by pain. Research has suggested that the PSEQ has acceptable internal consistency (person separation index = 0.88) and factor analysis suggests unidimensionality.[17] PSEQ items have been reverse scored in this analysis so that a reduction in scores denotes improvement to allow consistency with the other measures used.

Data analysis

Ideographic data. Visual analysis techniques for SCED can be used if there isn't significant variability in the baseline, or if a baseline trend towards the hypothesised outcome is not observed.[12] In addition, it is also important to protect against serial dependency using autocorrelation.[18] Therefore, before visual analysis techniques were employed these factors were considered.

Morgan and Morgan[19] suggest that the higher the number of intervention data points falling outside of 2 standard deviations of the baseline mean, the stronger the assumption that the intervention had a significant impact, either suggesting improvement or decline. The assessment of data-points falling outside of 2 standard deviations of the baseline mean will therefore be investigated within this paper.

Measures for non-overlapping data further assessed differences between the baseline and intervention phase. Two methods are recommended as the most robust combination, the percent of all non-overlapping data (PAND) and non-overlap of all pairs (NAP).[20] Manolov et al.[21] also advocate the percentage of data points exceeding the median (PEM) as least likely to be influenced by autocorrelation. Therefore, PEM was planned for use if autocorrelation was detected within the ideographic data.

Nomothetic data. Analysis was conducted using reliable change index (RCI) scores[22] and clinical cut-off scores. Data for RCI and clinical cut-offs have been obtained from: GAD-7,[23] PHQ-9,[7] PSEQ,[24] RCI data for the PCS was obtained from Mehlsen et al.,[25] and clinical cut-offs on the PCS were from Sullivan.[15]

Results

Data from the ideographic measures during the baseline period are presented first to assess baseline stability and data suitability for further analysis. Following baseline assessment, results analysing the effectiveness of the three levels of outcome measure are presented in order of; ideographic measures, pain-specific measures and generic mood and anxiety measures.

Baseline

Baseline ideographic data showed no trend in the hypothesised direction for any of the ideographic measures (Figure 1), variability in the measures was low (Table 1) and significant autocorrelation was not detected in the baseline data alone. Baseline data analysis suggests a stable baseline allowing for further analysis to be conducted.

Hypothesis 1: The magnitude of observed improvement on outcome measures following a CBT intervention for chronic pain will differ dependent upon the outcome measures specificity to chronic pain.

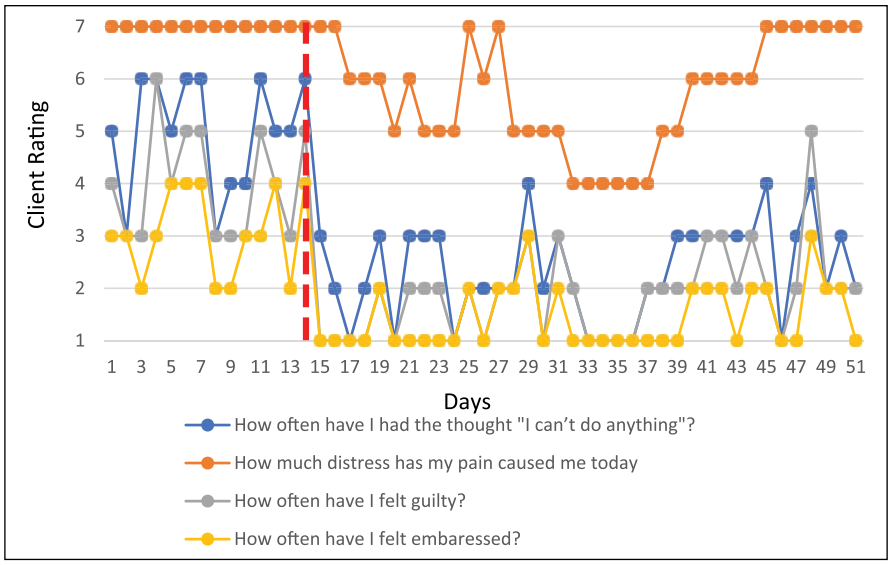

Figure 1. Daily ideographic measures.

Table 1. Means and Standard Deviations of ideographic measures.

	Mean (Standard Deviation)	
	Baseline	Intervention
How often have I had the thought 'I can't do anything'?	5.00 (1.11)	2.32 (0.91)
How often have I felt guilty?	4.00 (1.04)	1.86 (0.86)
How often have I felt embarrassed?	3.07 (0.83)	1.43 (0.6)
How much distress has my pain caused me today?	7.00 (0.00)	5.65 (1.06)

Table 2. Overlapping data analysis.

	PAND	NAP	PEM
How often have I had the thought 'I can't do anything'?	92.16%	93.44%	100%
How often have I felt guilty?	74.51%	95.27%	97.3%
How often have I felt embarrassed?	82.35%	92.86%	94.59%
How much distress has my pain caused me today?	72.55%	86.49%	72.97%

Ideographic measures

Visual inspection of ideographic measures (Figure 1) as well as their mean scores (Table 1), suggest that scores in the intervention phase were lower than the baseline. The number of data points exceeding 2 standard deviations below the baseline mean score also suggests that improvement has been observed in each of the ideographic measures during the intervention phase . "How much distress has my pain caused me today?" showed the greatest degree of change with 72.97% of data points exceeding 2 standard deviations below the baseline mean. "How often have I felt embarrassed?" was the next biggest improvement (62.16%). "How often have I had the thought "I can't do anything?""" was third (54.05%), while "How often have I felt guilty?" improved the least (35.14%). No data points reached 2 standard deviations above the baseline mean suggesting that no significant decline was observed.

In contrast to the baseline data alone, analysing the baseline and intervention together revealed significant autocorrelation ($p \leqslant 0.01$). Overlapping data was therefore assessed using PAND, NAP and PEM (Table 2). Little overlap is observed using any of the analysis types, with all effect sizes indicating medium to large beneficial intervention effects.

Pain specific outcome measures

Pain related catastrophising and Self-efficacy scores can be found in Table 3. Scores for pain related

Table 3. Nomothetic Measures pre-post change assessment.

	Pre-Assessment	Post-Assessment	Post-Intervention	Reliable Change Index	Clinical Cut-off
PCS	35	33	7	>9.6*	<30*
PSEQ**	60	59	42	>8.23*	<43.8*
GAD-7	6	10	7	>3.53	<5
PHQ-9	23	23	15	>5.2*	<5

Note. * denoted that the indicator assuming change has been met.
**PSEQ scores are reversed so that lower scores indicate improvement.

catastrophising fell from 35 down to 7 over the course of the intervention and met with criteria for reliable change as well as falling below clinical cut-off.

Pain related self-efficacy scored above clinical cut-offs at both pre-and post-assessment. Levels post-intervention fell to just below clinical cut-off and the decrease in score also met with criteria suggesting that reliable improvement had occurred.

Anxiety and depression outcome measures. Anxiety and Depression scores are shown in Table 3. Scores for anxiety started pre-assessment in the 'mild' clinical range. Following the assessment period, anxiety rose to 'moderate' clinical levels before returning to 'mild' levels post intervention. Anxiety scores were 1-point worse post intervention than pre-intervention.

Depression, scores were in the 'severe' range pre-intervention and didn't change following assessment. Post-intervention scores fell by 8 points which meets with criteria for reliable change. Depression was still in the 'severe' rating following the intervention and therefore didn't fall below clinical cut-off.

The above analysis suggests that the research hypothesis was met. Scores on all measures appeared to suggest that the greatest observed improvements were seen on client specific ideographic measures, followed by pain specific measures, with generic psychological measures showing the least improvement.

Discussion

A SCED was undertaken to test the hypothesis that different levels of outcome measures would suggest different levels of improvement following a CBT intervention for chronic pain. Following analysis of this data it would appear that this hypothesis has been met. Outcome measures which were more specific to the clients lived experience suggested a greater magnitude of improvement following the intervention.

Scores on ideographic measures showed not only medium to large effect sizes but also allowed the daily mapping of how specific events contributed to changes in the client's levels of distress or pain related cognitions. This clinically useful information was not immediately apparent with the other measures and so not only did ideographic measures suggest the greatest improvement, but they also contributed the most clinically salient information which helped to inform the ongoing intervention.

Pain-specific outcome measures, the PCS and PSEQ, both showed some improvement over the course of the intervention with scores reflecting reliable and clinically significant improvement. However, PSEQ scores only just met the cut-offs for clinical improvement by one point. This was discussed with Chris at the end of our intervention and he felt that the pain still meant that he was unable to do a lot of activities on the PSEQ; however, he said that this was not as detrimental as it used to be for him.

The third set of measures, the GAD-7 and PHQ-9, showed a mixed level of improvement. While depression did fall from 23 to 15 and met with reliable change criteria, it did not fall below clinical cut-offs. Anxiety levels rose following the intervention from 6 to 7. It is worth noting that anxiety levels were classified as clinically 'mild' at the outset of the intervention and therefore had less room to improve. It is also wort noting that in many pain specific psychological interventions, the specific aim is to allow someone to manage their experience of pain better and not necessarily to target a reduction in depression or anxiety.

Outcome measures

The use of generic outcome measures in specific populations where a physical difficulty is not amenable to change, such as in chronic pain, could be questioned. There may be concerns in terms of generic measure's meaningfulness to patient benefit and the service level implications that the true effects of psychotherapy are not being captured, especially in mass data sets. How generic measures of anxiety and depression are used could also be questioned, especially in services which calculate recovery targets based upon GAD-7 and PHQ-9 such as in IAPT or the newly commissioned Integrated IAPT services.

Based on this evidence it would be suggested that person-specific measures be used in psychotherapeutic

intervention as opposed to generic measures such as the GAD-7 or PHQ-9, and if this is not possible then condition specific outcome measures should instead be considered. The use of more specific outcome measures from this report is; however, based upon the outcomes of one client. Further research may wish to investigate if this is effect is present within a larger, more robust sample before a more formal recommendation can be made.

In addition, it is worth considering how the various forms of measures have been collected within this study. Both the generic and pain-specific measures were collected at three time points compared to the ideographic measures which were collected daily. Daily collection allowed for more detailed analysis of the ideographic measures which may have contributed to the interpretations drawn from them. The decision to not collect nomothetic measures daily was due to the additional client burden of being asked to complete an additional 39 items a day on top of the 4 items for all of the ideographic measures. Given the observed outcomes and the ease of use, the suggestion for using person-specific measures where possible is still upheld by this study.

While this report advocates the use of patient-specific measures for psychological intervention that is not to say that generic or pain specific measures cannot be used to inform wider treatment options. Based on this report a further recommendation would be to consider the context of the measure and how it is being used. For example, considering the somatic items in the total scores of the GAD-7 and PHQ-9 without considering the context of chronic pain could lead to a client accessing inappropriate care for their experience.

Critique

An important element to consider is that the present study did not formally measure the clients quality of life (QoL) using a validated measure. Research suggests that Chronic Pain can have a significant impact on QoL[26] and how this correlates with the client's ideographic measures is a question that could be addressed by further research.

This SCED did not employ data smoothing methods on ideographic data to reduce erroneous signal noise and prevent random fluctuations from overly influencing the SCED outcomes.[27] The main reason that data smoothing was not employed is that random daily fluctuations in pain intensity are inherent in Chris' life, therefore smoothed data would not accurately portray Chris' changeable lived experience.

An important aspect of the A-B SCED method is that the baseline is inactive compared to the active intervention phase. Establishing a therapeutic relationship and being given a safe space to talk about his experience may have had some psychological benefit that wouldn't have occurred had the baseline been collected while Chris was not seeing a Clinical Psychologist. While this was unavoidable due to the ethical issues of delaying treatment or asking clients to monitor distressing thoughts without having a therapeutic context to discuss them in, the point of a truly inactive baseline needs to be considered, especially considering the improvement observed following the assessment and formulation sessions during baseline.

The current study occurred within the context of a regional Chronic Pain service and therefore the model of care differs slightly from, for example, primary care IAPT services. While the CBT intervention itself would not be different, the effects of attending sessions in a hospital setting may be different from primary care settings and therefore the recommendations for the collection of data within IAPT services needs to be considered within this context.

Conclusion

This study suggests that the use of CBT for chronic pain was successful. It appeared that the more specific the outcome measure used, the more improvement was suggested. Ideographic measures yielded client-specific and clinically useful information which could be used in conjunction with, or in place of, pre-established nomothetic measures to inform clinical outcomes and therapeutic decisions. Where it may not be possible for daily patient-specific measures to be collected, it may be more appropriate to collect condition specific-measures to maintain a balance between client burden and specificity of outcome measures. Clinicians are recommended to maintain an awareness of the context of their clients experience in relation to the questions asked on the outcome measures they use.

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Conflict of interest

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Ethical approval

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Informed Consent

Informed consent for the collection of this data and its writing up was gained at the outset in accordance with ethical approval.

Trial Registration

This study did not require trial registration as this manuscript describes and evaluation of outcomes measures in a single client.

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