Study Protocol

Title of Research
How do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for people with chronic pain?

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List of Abbreviations

ACT	Acceptance and Commitment Therapy
CBT	Cognitive-Behaviour Therapy
CFT	Compassion-Focused Therapy

Background: The Impact of Chronic Pain
Chronic pain is pain that lasts longer than 3 months and affects 18% of the Scottish population (NHS QIS, 2008). Unlike acute pain, it is not an indication of sinister disease processes. In the process of learning to live with chronic pain, people may have experiences of being disbelieved by family, friends and health professionals, struggle with beliefs of being a burden on their loved ones and feel disappointment at not being able to fulfil previously held roles in the family (Smith & Osborn, 2007). Chronic pain becomes a stigma and these experiences, in conjunction with debilitating physical symptoms, can have a profound impact on mood, behaviour and general wellbeing. It is not the intensity of the pain that affects quality of life; the issue is more relational, for example, the negative beliefs that someone may hold about their pain (Lamé et al., 2005). Negative cognitions and emotions are activated by pain-related difficulties and multi-disciplinary treatments for chronic pain target the management of these internal experiences and daily functioning, rather than attempting to eliminate the physical sensation of pain.

Current Treatment Models in Chronic Pain
Alongside education and physical exercise, Cognitive Behaviour Therapy (CBT) and Acceptance and Commitment Therapy (ACT) are used across multidisciplinary pain management programmes in the treatment of chronic pain. CBT is recommended by the Scottish Intercollegiate Guidelines Network (SIGN) Guideline 136 and ACT is recommended by the American Psychological Association (APA Division 12: Society of Clinical Psychology).

CBT aims to identify, examine and alter the impact of distressing, unhelpful cycles of cognition and behaviour. Techniques such as graded activation and graded exposure are also used to help achieve sustainable levels of activity and reduce avoidance (Williams et al., 2012; Bailey et al., 2010). Mediator analyses have identified self-efficacy as the mechanism of change in CBT for chronic pain (Turner et al., 2007), which is a construct targeted by many other psychotherapies, not only CBT. Acceptance and Commitment Therapy (ACT) aims to develop mindfulness, willingness to experience undesirable internal experiences and foster

distance between the self and negative thoughts. The overall process underlying the methods used in ACT can be conceptualised as 'psychological flexibility' (Hayes et al., 1999). A review by Hughes and others (2017) examined 11 trials, finding significant medium to large effect sizes for measures of acceptance and psychological flexibility.

Comparisons between individuals on an ACT and a CBT pain management programme has not uncovered significant differences across improvements sustained in pain interference, depression, anxiety, and quality of life (Wetherall et al., 2011). Gaudinano (2009) notes that more attention should be focused on the mechanisms of action as opposed to pitting separate treatments against each other and drawing conclusions about their efficacy based on differences across outcomes. Many psychotherapies share constructs and are often shown to result in similar outcomes.

Psychological Flexibility

Cross-sectional studies do not give explanation into the direction of the relationship between process and outcome variables; it is difficult to deduce if outcomes have improved because psychological flexibility has increased, or if psychological flexibility has increased because the outcomes have improved. A number of cross-sectional studies have, however, proven that psychological inflexibility is linked to anxiety, depression and wellbeing (e.g. Masuda & Tully, 2011). Vowles and others (2014) performed correlation and regression analyses and reported significant relationships between psychological flexibility and measures of disability, emotional functioning, pain acceptance and valued activity. Four key process variables of psychological flexibility were investigated by McCracken and Gutierrez-Martinez (2011): pain acceptance, values-based action, psychological acceptance and mindfulness. General acceptance was found to show the largest effect size, predicting gains in outcome more so than those accounted for by pain acceptance. The authors note that the concept itself is a tricky idea to capture accurately, because behaviour related to psychological flexibility cannot be measured until one has a concept of psychological flexibility, which affects measurement of the baseline.

Self-Compassion

Compassion-focused therapy (CFT) was developed for individuals who struggle with shame and self-criticism (Gilbert, 2009), both of which can be conceptualised as examples of distressing private experiences in the ACT model. It aims to promote a compassionate internal relationship with the self, drawing on the ability to view distressing experiences with kindness, understanding and shared humanity (Neff, 2003). Shame involves a negative evaluation of the *self*, unlike guilt, which involves a negative evaluation of *behaviour* (Lutwak et al., 2003). These complex emotions and cognitions are relevant in the context of chronic pain because of the experience in losing and adjusting to an identity. Purdie and Morley (2016) note that chronic pain is frequently invalidated by society and this constant negative social evaluation can result in a shameful appraisal of a person's sense of self. In this sense, CFT targets self-acceptance in the same way as ACT, but from a different perspective by bringing social inclusion into awareness.

The positive influence of self-compassion is beginning to be investigated across a range of long-term health conditions, such as diabetes (Friis et al., 2015) and cancer (Pinto-Gouveia et al., 2014). To date, however, there is little research on self-compassion and chronic pain.

Wren and others (2012) found that self-compassion was a significant predictor of mood, negative pain beliefs and disability related to pain. This cross-sectional study indicated that self-compassion may be significant in predicting pain adjustment, but can only comment on association and not causal relationships. The authors suggest that future research in this area could examine interventions specifically designed to promote self-compassion. Marshall and Brockman (2016) reported self-compassion to significantly correlate with processes of psychological flexibility, and self-compassion actually predicted mental wellbeing over and above psychological flexibility. This indicates that combining these therapies may result in improved treatment outcomes. This study was, however, conducted on a non-clinical population which may limit generalisability. Empirical research examining links between these two constructs is limited.

Rationale

There is a need for evidence-based answers to explain why and how psychological interventions are successful (Kazdin, 2007). Multimodal treatments are becoming the norm and breaking down these components to examine individual efficacies is not a good use of resources (Wicksell et al., 2010). CFT offers a complementary approach to be used alongside current interventions, targeting the inevitable feelings of shame and self-criticism in the process of adjusting to chronic pain. A strong correlation between self-compassion and psychological flexibility has already been established, and gaining insight into the direction of the relationship between these concepts and treatment outcome would be the next logical step. By focusing on mechanisms of change, better theories can be developed and may promote treatment efficacy (e.g. by matching to patient need). This would be a far more efficient way to develop interventions, whilst maintaining a person-centred delivery of care.

Principal Research Question

- Do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for adults with chronic pain?

Secondary Research Questions

- Which is the better predictor of change - self-compassion or psychological flexibility?

Methodology

Participants

Participants will be adults with chronic pain who attend and complete the CFT-incorporated groups at the Lothian Chronic Pain Service / Pain Management Programme.

Inclusion Criteria	*Exclusion Criteria*
- Chronic Pain lasting a minimum of 3 months - Fluency of English sufficient for participation in the group and completion of questionnaires - Aged 18+ (no upper age limit)	- Active substance misuse - Active suicidality - Terminal illness - Inability to provide informed consent (as defined by the Five Statutory Principles of the Mental

- Ability to provide informed consent as judged by the clinical team	Capacity Act, Code of Practice, 2007)

Design

This study will follow a within-group (non-randomised) effectiveness-implementation design (Curran, 2012). Five self-report measures will be completed by participants at three specified time periods (pre-, mid- and post-group; see *Procedure* below).

Recruitment

2-3 new Pain Management Programme groups start every month, each running for 11 weeks at the Astley Ainslie Hospital in Edinburgh. 6 groups run every week and each group is booked for a maximum of 15 people. These groups are run by at least two qualified members of the clinical team (Clinical Psychologists and Physiotherapists). There will be no need to advertise the research outwith normal clinical operations because clinical staff will offer all group participants the opportunity to participate in the research during their initial assessment, and data collection will overlap with existing routine outcome measures.

Procedure

Potential participants will be identified through their initial assessment upon referral to the Chronic Pain Service. Those who are deemed to be suitable for a Pain Management Programme (e.g. capacity, motivation) will be offered an introductory group session, followed by invitation to an upcoming 11-week group. Information sheets and consent forms will be given out at the start of the group (week 1), to be completed and returned the following week. The information sheets will contain details about the purpose of the research, expectations of the participant in taking part and further information about consent, potential benefits, confidentiality and details of the researchers. Participants will be given time to consider the information and direct questions to the clinical team, to go home and consider the information privately, and also given the opportunity to phone the service and ask further questions if desired. Those who can provide written informed consent will complete pre-group measures at the start of week 1. Mid-group measures will be completed at the end of week 5 and post-group measures will be completed at the end of week 11. (See section 6.4 for details of outcome measures.) The clinical team will be available if participants require support to complete the measures (e.g. literacy issues). The data for participants who do not complete the group will not be used in the final analysis.

Intervention

All groups will follow the same 11-week, structured timetable, using Compassion-Focused Therapy. As there are no current guidelines for using CFT in chronic pain, exercises have been adapted from 'Compassion Focused Therapy for Dummies' (Welford, 2016), incorporating the key elements of CFT (Gilbert, 2009).

Data Collection

Demographic information routinely collected by the service will be used for descriptive statistics (gender, age, area of residence, pain diagnoses and other relevant physical health conditions, duration of pain, employment status and recent pain-related contact with healthcare services).

The following self-report measures will be completed by participants at the beginning of week 1 (start) and at the end of week 11 (end). Questionnaires denoted with '*' will be completed by participants at these time intervals and, additionally, at week 5 (mid-point).

Anxiety and Depression*

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a 14-item measure of the symptoms of anxiety (7 items) and depression (7 items) in individuals with physical health issues. Each of the items are scored from 0 to 3, where a higher score depicts greater frequency or intensity of the described symptom over the last week (e.g. "I get sudden feelings of panic" and "I have lost interest in my appearance"). Anxiety and depression are rated separately, each allowing for a minimum score of 0 or a maximum score of 21. Bjelland et al. (2002) reviewed 747 papers using the HADS and demonstrated a two-factor structure (i.e. anxiety and depression), with a high level of internal consistency for both the anxiety (Cronbach's alpha = .83) and depression (Cronbach's alpha = .82) subscales. Michopoulos et al. (2008) reported a high test-retest reliability of .94 over a 20-day period.

Mental Wellbeing*

The shortened version of the Warwick-Edinburgh Mental Wellbeing Scale (Taggart et al., 2015) (SWEMWBS; Stewart-Brown et al., 2009) is a 7-item measure reporting on subjective positive mental wellbeing and psychological functioning over the last two weeks. It aims to cover a broad range of positive mental health concepts (e.g. "I've been feeling confident" and "I've been feeling close to other people") but does not include spirituality or socioeconomic factors. Each of the items on the measure require a response on a Likert scale, from 1 (none of the time) to 5 (all of the time). This yields a minimum score of 7 and a maximum score of 35 (higher score indicating greater well-being). The SWEMWBS has a test-retest reliability of .83 and demonstrates stability after one week (Stewart-Brown et al., 2009).

Pain

The Brief Pain Inventory (short form, BPI-SF; Cleeland & Ryan, 1994) is a 9-item measure designed to capture two aspects of pain: pain interference (with daily living) and pain severity. These two distinct dimensions have been confirmed through factor analysis. Responses to items on this measure range from 0 (does not interfere) to 10 (completely interferes) on the pain interference subscale and 0 (no pain) to 10 (pain as bad as you can imagine) on the pain severity subscale. The BPI-SF demonstrates stable test-retest reliability and high internal consistency, with Cronbach's alpha ranging from .80 to .92 (Cleeland, 2009). The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT; Dworkin et al., 2005) recommends that all chronic pain research should include outcomes in pain interference and pain severity.

Self-Compassion*

Self-Compassion Scale (short form, SCS-SF; Neff, 2003) is a 12-item measure designed to assess a person's kindness and understanding towards themselves during difficult times. The three elements of self-compassion as defined by Neff (2003) exist on a dichotomy: self-kindness vs. self-judgement; common humanity vs. isolation; and mindfulness vs. over-identification. Responses to these items are indicated on a Likert scale, ranging from 1

(almost never) to 5 (almost always). The SCS-SF has a strong correlation with the long form measure, and factor analysis has validated the six-factor model, in addition to the single higher-order factor of self-compassion (Raes et al., 2011). The SCS-SF shows high internal consistency (Cronbach's alpha = .86; Raes et al., 2011) and good test-retest reliability over three weeks (scores of at least .8 across all subscales; Neff, 2003).

Psychological Flexibility*

Multi-Dimensional Psychological Flexibility Inventory (short form, MPFI-SF; Rolffs et al., 2016) is a 24-item measure assessing the flexibility of a person's response to negative internal experiences (e.g. thoughts and feelings). Psychological flexibility allows a person to carry these negative experiences whilst living their life in a meaningful, values-directed way. Twelve dimensions have been validated in the 6-factor model of psychological flexibility (Rolffs et al., 2016), the Hexaflex model (Hayes et al., 2011). Psychological flexibility encompasses present moment awareness, values, committed action, self-as-context, defusion and acceptance. Psychological inflexibility encompasses lack of contact with the present moment, lack of contact with values, inaction, self-as-content, fusion and experiential avoidance. Response to items range from 0 (never true) to 6 (always true) of items in the context of the last two weeks. The MPFI has been shown to have higher levels of internal consistency than other measures of psychological flexibility (Rolffs et al., 2016).

Sample Size

Fritz and MacKinnon (2007) propose guidelines for recommended sample sizes in order to detect mediation effects with .8 power. These guidelines are informed by existing literature in the field. There is less robust research on self-compassion and chronic pain, therefore, this calculation is based on research in psychological flexibility and chronic pain.

McCracken and Gutierrez-Martinez (2011) conducted correlational analyses on the processes of psychological flexibility following a group intervention based on ACT. These processes included acceptance of pain, mindfulness, psychological acceptance and values-based action (r values between 0.33 and 0.55). These positive correlations indicate that the group intervention was related to higher levels of psychological flexibility.

A review by Hayes and others (2006) identified several studies that reported correlational effect sizes between acceptance, and depression/anxiety/daily functioning related to chronic pain (r = -0.58/-0.66/0.47 respectively). These negative correlations illustrate that higher levels of psychological flexibility were related to better outcomes.

Based on these correlational effect sizes, Fritz and MacKinnon's guidelines suggest that a sample size of 53-71 is required.

Analysis

The analysis will focus on the proposed mediating factors (self-compassion and psychological flexibility) and how they explain the outcome of the CFT-incorporated group intervention. In order to study the processes of change, this study will measure change in mediators and outcomes over the course of the group.

In a mediation model, the effect of the independent variable (IV; CFT group) on a dependent variable (DV; outcome/change in symptoms) is conveyed through a third mediating variable. In order to be a mediator, a variable must change during the intervention, be associated with the intervention, and have an impact on the outcome.

In this study, it is hypothesised that self-compassion and/or psychological flexibility are the mediating variables that explain the influence of the group intervention on eventual outcome, i.e. the overall change in symptoms at the end of the group. Linear regression and nonparametric bias-corrected bootstrap, which corrects for skew in the data, will be applied to the data using SPSS, using the PROCESS macro. An effect of mediation will be indicated if the confidence interval does not contain zero.

Missing data will be handled using either the maximum likelihood or multiple imputation method, as recommended in literature.

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