Project Title: Exploration of responses to compassion in a clinical population

NCT number: TBC

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Project executive summary

This project focuses on exploring responses to compasionate imagery, a technique from Compassion Focused Therapy (CFT; Gilbert, 2014). Evidence has documented that CFT decreases depression, shame, self-criticism and increases self-esteem (Kirby, 2016).
Compassion-focused imagery (CFI) is a key technique in CFT, which involves visualizing compassion towards others, or imagining people, places or objects directing compassion towards oneself. Single trials of CFI have shown a reduction of negative affect and physiological changes associated with the attenuation of threat-focused behaviors (e.g. Rockliff et al., 2008). Regular CFI practice has increased self-compassion and reduced negative affect in both clinical and non-clinical populations (Gilbert & Irons, 2004; McEwan & Gilbert, 2016). Unfortunately, CFI can create threat-focused responses in some individuals. However, these findings have been based on tasks involving receiving compassion from others.
The present study therefore aimed to explore participants' responses to imagery exercises involving self-compassion, in comparison to a relaxation task (to control for certain task demands but without the compassion element), and a control task (reading a magazine).

GENERAL OBJECTIVE

To explore responses to self-compassionate imagery in comparison to relaxation and a control task, in a clinical population.

SPECIFIC OBJECTIVES

1. How do clinical participants initially respond to *self*-compassionate imagery in an initial trial, compared to relaxation and a control task? (using self-report and HRV measures)
2. Do any threat responses reduce following repeated trials of self-compassionate imagery?

METHODS

Participants and process of recruitment:

We plan to recruit a sample of 25 participants for this study, based upon other studies of compassionate imagery with similar designs (Rockliff et al., 2008; Duarte et al., 2015).

Inclusion criteria are:

1.Clinical level of anxiety or depression (defined for this study ≥ 8 on the OASIS or ODSIS)

2. High self-criticism (we selected a cut-off of 0.5 standard deviations above the mean in self-inadequacy or self-hatred on the FSCRS). Based upon a validation in Colombia of the FSCRS by Naismith, Duran Ferro, Ingram, & Jiménez Leal (Submitted), this represents ≥ 24 in self-inadequacy or ≥ 8 in self-hatred.

These criteria were selected because these interventions are designed to help a clinical population presenting with high self-criticism. Offering this to a non-clinical population (i) reduces the likelihood of observing significant changes, and (ii) will not allow us to help those who present with higher needs.

Nonetheless, those who complete the initial screening and do not meet inclusion criteria will be invited to a group session to learn compassion techniques. They will also receive compassion materials via email at the end of the study.

For recruitment, posters will be hung inside the campus of the University of the Andes. The same information will be published in university social media pages.

Design:

Participants will be randomized to complete 3 or 4 trials (see details below) using a 2:1 ratio, using a randomization sequence drawn up prior to the study start. This will allow us to explore in a small subgroup whether a fourth trial impacts results. We are also running a related study, which will explore the effects of psychotherapy that will be offered following these 3-4 trials, and we anticipate that a fourth trial will increase probability of dropout from the second study, therefore we will not assign all participants to do the fourth trial.

Measures:

See Appendix 2 for copies of the questionnaires that we intend to use that are not validated.

1. **Demographics**
2. **Self-report form – Physiological variation**
3. **Overall Depression Severity and Impairment Scale (ODSIS)**
4. **Overall Anxiety Severity and Impairment Scale (OASIS)**
5. **Forms of Self-Criticism/Attacking and Self-Reassuring Scale (FSCRS)**
6. **Positive and negative affect generated**

7. **Heart Rate Variability (HRV).** Heart rate variability (HRV) is a physiological measure that allows us to quantify small changes in anxiety moment by moment, that a questionnaire cannot quantify. In this study it will allow us to measure whether participants respond to compassion with a threat-based response or a relaxed response (we expect that after 3-4 trials, all participants will respond with relaxation or a neutral response, but we predict that at the start, some will respond with threat-based responses).

We will use the BioPac system to collect HRV data. Electrodes will be placed using the Lund guidance which is considered the most stable, least invasive, and with high diagnostic accuracy. Using the program Acqknowledge, we will analyse beats per minute (BPM) and ratios of sympathetic and parasympathetic activity. Specifically, we will use the Root Mean Square of the Successive Differences (RMSSD) of RR intervals (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996). RMSSD was selected because there is no agreed clinically-significant change value for anlysing HF HRV data (see Data analysis section).

Procedure

Participants will complete an initial screening questionnaire online including: an informed consent (see Appendix 1), demographics questions, ODSIS, OASIS and FSCRS. Eligible participants will be invited to attend in-person sessions. In each session, HRV will be measured by a research assistant whilst the participant engages in three 4-minute tasks in the following order:

- **Control task:** participants will read a magazine with neutral content for 4 minutes
- **Relaxation imagery** (see appendix 3): participants will complete a relaxation exercise of beach or forest imagery for 4 minutes.
- **Compassion-focused imagery:** participants will complete a compassion-focused imagery for 4 minutes (see appendix 3).

Data analysis

Paired *t*-tests will be run (i) to estimate differences in HRV during the self-compassion imagery, relaxation imagery and the control task, (ii) to examine changes in self-reported positive and negative affect from pre-CFI to post-CFI, (iii) to explore whether changes in positive and negative affect during CFI are greater or smaller from Trial 1 to Trial 3.

To complement group-level analyses, we will use reliable and clinically-significant change analyses. We will firstly report how many participants show a reliable change (Jacobson & Truax, 1991) in positive or negative affect following CFI.

We will also calculate how many individuals show a clinically-significant HRV response (≥ 5ms change in RMSSD within one individual between two different tasks).

Finally, we will report the number of positive and negative clinically-significant responses for both relaxation and compassion in each trial, in order to (i) compare effects of compassion versus relaxation at trial 1, and (ii) explore whether repeated trials improved response to each task.

References

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