

STUDY PROTOCOL

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TITLE : Process evaluation of the effectiveness of two transdiagnostic interventions targeting emotional regulation: compassion focused program and emotional skills training program

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Objectives:

The purpose of this research is to evaluate the effectiveness of two programs - Compassion Focused Program and Emotional Skills Training - on participants' emotional regulation, well-being, compassion, emotional skills, and anxiety-depressive symptoms compared to the control group in a subclinical population and clinical population

Types of studies:

- Multiple single-case study
- Randomized controlled study in subclinical population
- Pilot study in a clinical population

Primary Objectives:

Evaluation of the effectiveness of the Compassion Focused Program and Emotional Skills Training programs on participants' emotional regulation (DERS, Gratz & Roemer, 2004) compared to the control group.

Secondary objectives and criteria:

The secondary objectives are, in comparison to the control group, to evaluate (1) the effectiveness of the interventions on emotional regulation strategies (DERS, Dan-Glauser & Scherer, 2013), well-being (BE, Ryff, 1995, anxiety and stress symptoms (DASS21, Henry & Crawford, 2005), emotional competencies (S-PEC; Mikolajczak, Brasseur, & Fantini-Hauwel, 2014), and compassion (SCS; Neff, 2003) and (2) to assess program effectiveness processes on: feeling of effectiveness of emotional regulation (Bandura, 2006) and cognitive flexibility (CFI; Dennis & Vander Wal, 2010).

Control variables:

In addition to the primary and secondary objectives, we will control for two variables: participants' expectations of the intervention prior to the start of the program (QCA, Coste et al., 2019), and participants' satisfaction with the intervention at the end of the intervention (STTS-R, Oei & green, 2008).

Inclusion criteria

- Age between 18 and 65 years inclusive
- Person who can understand, speak and read French
- Person who was orally informed and gave informed consent to participate in the study
- Subject's participation in the study noted in the medical record

Non-inclusion criteria

- Participation in positive psychology, mindfulness or stress management groups for less than 3 months

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- Change in psychotropic medication (taking, stopping, or changing dosage) within 2 months prior to study participation
- Person with a mental disability
- Person deprived of liberty by court order

Numbers of subjects to be included:

- Single case study: 10 participants, 5 participants per group
- Randomized controlled study: 123 participants: 41 participants per group
- Pilot study: 60 patients, 20 patients per group

Provisional research schedule

SINGLE CASE STUDY	
Beginning of inclusions	November 2020
Inclusion period	1 months
Duration of interventions	3 months
Duration of participation for each subject	5 months
Exclusion period (=period during which the participant will not be able to participate in any other research involving an emotional regulation intervention)	5 months
RANDOMIZED CONTROLLED STUDY	
Beginning of inclusions	Février 2021
Inclusion period	18 mois
Duration of interventions	3 mois
Duration of participation for each subject	7 mois
Exclusion period (=period during which the participant will not be able to participate in any other research involving an emotional regulation intervention)	6 mois
PILOT STUDY	
Beginning of inclusions	August 2021
Inclusion period	2 months
Duration of interventions	3 mois
Duration of participation for each subject	7 months
Exclusion period (=period during which the participant will not be able to participate in any other research involving an emotional regulation intervention)	6 months
TOTAL RESEARCH TIME	31 months
END OF THE RESEARCH	March 2022

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Benefits for participants

The two interventions will allow individuals to become familiar with their emotions, to cope more easily with the emotional difficulties encountered in their daily lives and to develop new strategies to manage their emotions. Indeed, research shows that emotions contribute to an individual's ability to adapt to his environment by guiding him in social interactions (Keltner & Kring, 1998), by facilitating the detection of danger (Ohman et al., 2001), by preparing him to face a series of situations (Frijda, 1986), by accelerating and orienting his decision making (Bechara & Damasio, 2005) and by allowing him to memorize important elements more easily (Luminet & Curci, 2008). In this sense, the individual's skills in emotional regulation seem to be essential to his well-being.