ISRCTN16974329 https://doi.org/10.1186/ISRCTN16974329

Improving emotional regulation: a study on a brief focusing intervention for better mental health

Submission date
20/07/2023

Recruitment status
Suspended

Registration date
24/08/2023

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background study and aims
Affective dysregulation (impaired ability to regulate or tolerate negative emotional states) affects many people with mental disorders. Two mechanisms that have been frequently associated with emotional regulation are immersion and distancing. Focusing is a task that combines these two mechanisms of emotion regulation through the phase of creating a working distance and subsequently the phase of reassigning meaning. However, the benefit of its use for the promotion of mental health in populations without moderate to severe symptoms remains unclear. The aim of this study is to test the effectiveness of a brief intervention based on Focusing.

Who can participate?
Participants aged between 18 and 65 years who wish to improve their awareness and understanding of their emotions

What does the study involve?
Participants will be randomly allocated into two groups: the intervention group (IG) and the control group (CG; waiting list). The IG will have access to two Focusing sessions and the CG will only have access to the intervention about 4 weeks later. Both groups will be evaluated at five different times. Positive and negative affect, attitudes toward focusing (emotions and bodily sensations), the ability to perform focusing, and emotion regulation are assessed, as well as mental health and psychological well-being, depressive/anxiety symptomatology, and self-esteem.

What are the possible benefits and risks of participating?
There are no intended direct benefits of participating, besides the hypothetical benefits of the intervention for mental health and well-being. Regarding possible risks, getting too involved in the task can be emotionally challenging at times. However, it is normal to feel some discomfort during the task and emotional responses are often a necessary part of understanding and practising the task. Therapists involved in the study will be trained and experienced in supporting individuals through these difficult thoughts and emotions and will work with patients

to help them deal with these feelings. If, at the end of the intervention, someone feels they need more support, a referral will be provided.

Where is the study run from?
It will take place in the Laboratory of Psychotherapy Research, located at the University of Maia (Maia, Portugal), which is affiliated with the Center of Psychology at the University of Porto (Porto, Portugal)

When is the study starting and how long is it expected to run for?
October 2022 to August 2025

Who is funding the study?
Foundation for Science and Technology (Portugal)

Who is the main contact?
1. Dr João Salgado, jsalgado@umaia.pt
2. Dr Clara Aguiar, cpaguiar@umaia.pt

Contact information

Type(s)
Principal investigator

Contact name
Dr João Salgado

ORCID ID
https://orcid.org/0000-0003-0822-9267

Contact details
Avenida Carlos de Oliveira Campos
Maia
Portugal
4475-690
+351 (0)229 866 000
jsalgado@umaia.pt

Type(s)
Scientific

Contact name
Dr Clara Aguiar

ORCID ID
https://orcid.org/0009-0005-7055-6818

Contact details
Avenida Carlos de Oliveira Campos
Maia
Portugal
4475-690

+351 (0)229 866 000
cpaguiar@umaia.pt

Additional identifiers

Study information

Scientific Title
Effectiveness of a brief focusing intervention on emotion regulation and mental health: a randomized clinical trial in a community sample

Acronym
BFI-RCT

Study objectives
The participants who undergo the Brief Focusing Intervention (BFI) will demonstrate significant improvements in emotion regulation skills and mental health outcomes compared to the control group (waiting list):
1. The intervention group will exhibit greater improvements in emotion regulation abilities, compared to the control group by the end of the intervention;
2. The intervention group will decrease levels of clinical symptoms, including anxiety and depressive symptoms, compared to the control group by the end of the intervention;
3. The intervention group will have higher levels of subjective well-being and overall psychological well-being, compared to the control group by the end of the intervention;
4. The intervention group will have high levels of satisfaction with the intervention and perceived usefulness of focusing as an emotion regulation strategy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2023, Ethics and Deontology Council of the University of Maia (Avenida Carlos de Oliveira Campos, Maia, 4475-690, Portugal; +351 (0)22 986 6000; info@umaia.pt), ref: 105 /2023

Primary study design
Interventional

Study design
Cluster randomized trial

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Promotion of emotional regulation in adults without clinical symptoms or with mild symptoms of psychopathology

Interventions

Eligible participants will be randomized into two conditions: (1) intervention group (IG); (2) control group (CG). Both groups will complete the same online questionnaires, but the CG group will wait for approximately 4 weeks, being evaluated at 3 times during this waiting time. IG will have immediate access to the Brief Focusing Intervention, being evaluated at 5 different times. Cluster randomization will be performed by an independent researcher not involved in data collection using an automated computer-based random intergenerator.

The Brief Focusing Intervention (BFI) is based on the book by Kwatra and colleagues (2022). The BFI consists of two sessions, each lasting approximately 90 minutes, with a 1-week interval between them. These sessions are conducted online using the Microsoft Teams platform. In the initial phase of the sessions, participants are invited to connect with their internal experience through the Clear a Space (focusing preparatory task) and Focusing. Afterwards, participants will have the opportunity to share their task experience with the group. Participants will be asked to repeat the task at home between sessions, and audio and text instructions will be provided for this purpose. Throughout the intervention process, participants will undergo assessment moments by filling out questionnaires before and after each session. Additionally, 2 weeks after the second session, participants will complete some questionnaires as part of the follow-up assessment.

Intervention Type
Behavioural

Primary outcome(s)
Focusing attitudes assessed using the Focusing Manner Scale (FMS) at T1, T4, and T5

Note. T1 = Evaluation moment before session N°1; T2 = Evaluation moment at the end of session N°1; T3 = Evaluation moment before session N°2; T4 = Moment of evaluation at the end of session N°2; T5 = Assessment time 15 days after T4 (follow-up).

Key secondary outcome(s)
1. Positive and negative affect assessed using the Positive and Negative Affect Program (PANAS) at T1, T2, T3, and T4
2. Ability to focus assessed using the Post-Focusing Checklist 2 (PFC-2) at T2 and T4
3. Propensity to use six emotion regulation strategies to decrease their experience of negative emotions: a) distraction, b) rumination, c) reappraisal, d) suppression, e) engagement, and f) arousal control, assessed using the Survey on the Regulation of Emotional Systems (RESS) at T1, T4, and T5
4. Mental health and psychological well-being assessed using the Clinical Outcome Routine Evaluation – Outcome Measure (CORE-OM) at T1, T3, and T5
5. Subjective well-being assessed using the Psychological Well-Being Scale - Short Version (EBEP - VR) at T1 and T5
6. Depressive symptoms assessed using the Patient Health Questionnaire (PHQ-9) at T1, T3, and T5
7. Anxiety symptomatology assessed using the General Anxiety Disorder (GAD-7) at T1, T3, and T5
8. Self-esteem assessed using the Rosenberg Self-Esteem Scale (RSES) at T1 and T5

Note. T1 = Evaluation moment before session N°1; T2 = Evaluation moment at the end of session N°1; T3 = Evaluation moment before session N°2; T4 = Moment of evaluation at the end of session N°2; T5 = Assessment time 15 days after T4 (follow-up).

Completion date
01/08/2025

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years old
2. Having an interest in clarifying their emotions
3. Having digital literacy to use internet-based videoconference (Microsoft Teams)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Changes in their therapeutic plan with psychopharmaceuticals in the last month
2. Currently undergoing a psychological treatment
3. Moderate to severe psychopathology
4. Not having internet access and/or conditions to carry out the sessions with privacy

Date of first enrolment
01/09/2023

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Portugal

Study participating centre
University of Maia - Laboratory of Psychotherapy Research
Avenida Carlos Oliveira Campos

Maia
Portugal
4475-690

Study participating centre
Center for Psychology at University of Porto
Rua Alfredo Allen
Porto
Portugal
4200-135

Sponsor information

Organisation
University of Maia - Portugal

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Portugal

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study may be available upon reasonable request to Clara Aguiar (focusing@umaia.pt).

All information collected about the participants will be kept confidential and anonymous. The data will be kept in a pseudo-anonymized format. Specifically, participants will receive an alphanumeric code that will serve for their identification throughout the study, and it will only be known by themselves, the evaluator, and the responsible researcher. The only personal identifying information that will be kept will be the email address provided by the participant, along with their alphanumeric code. This will be kept on paper in a safe at our laboratory, with access only allowed to those responsible for contacts, and destroyed after the completion of the study, or immediately if an immediate exclusion is required.

All databases created will be stored encrypted on the OneDrive platform, according to a security protocol guaranteed by the IT services of the University of Maia. Access to the database with sociodemographic elements will be limited through a password, held by the Responsible Investigator. In this way, the identity of the person will be protected while ensuring that, if requested by the participant, their data can be deleted. After properly curating the databases created, without any identifying data, may be subject to open access for the scientific community. Sociodemographic data will be recorded in a separate database from the other data in terms of hardware and software. Additionally, weekly, during periods of new participant intake, sociodemographic data will be exported to a separate database, and the data will be deleted from the original database. Regarding data collection through questionnaires, participants will have access to detailed information about the study and an informed consent form with terms and conditions that they must agree to.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/11/2024	20/11/2024	Yes	No
Statistical Analysis Plan			24/07/2023	No	No