Empty chair task for interpersonal emotional injury

Submission date	Recruitment status	[X] Prospectively registered
15/11/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
14/12/2023	Completed	Results
Last Edited	Condition category	Individual participant data
24/11/2023	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Background and study aims

After the pilot study conducted by this project author, this project will study the Empty Chair Task (EC) application through online interventions for the resolution of emotional injuries perpetrated by significant others, among non-clinical populations/mild symptoms of psychopathology, with two purposes: evaluate the efficacy of the intervention in this context and promote understanding of its impact on emotional processing of such injury. The aim of this study is to test the effectiveness of a brief intervention based on the Empty-Chair Task.

Who can participate?

All participants must (1) identify the presence of emotional injury caused by a significant personal relationship in the past, influencing present functionality and mental well-being, (2) availability to work on the emotional injury, (3) be between 18-64 years old, (4) have adequate computer literacy and, (5) access to the internet.

What does the study involve?

Admitted participants will be randomly allocated, with a cluster randomization protocol, into two conditions: experimental and wait-list conditions.

The randomization protocol will be determined by an external member of the research team. Participants in the experimental condition will receive the Empty-Chair Task, self-administered and guided through pre-recorded audio instructions, in two 90-minute online group sessions with a weekly interval to ensure greater privacy and eliminate challenges of in-person group intervention. Participants admitted to the experimental condition will be evaluated at the following moments: T1 - immediately before the first session, T2 - immediately after the first session, T3 - immediately before the second session, T4 - immediately after the second session, T5 - 2 weeks after T4

Wait-list condition participants will be evaluated at analogous moments (T1, T3, T5) and receive the same intervention 4 weeks after admission.

What are the possible benefits and risks of participating?

Benefits: working towards the resolution of the emotional injury perpetuated by a significant other, experiencing improvement in symptomatology associated with this emotional injury and contributing to an ongoing study and investigation, assisting with the research.

Risks: Experiencing worsening of the symptoms associated with the emotional injury due to exposure to the empty chair task in online sessions. This will be addressed with immediate support from a psychologist present in the sessions.

Where is the study run from? University of Maia (Portugal)

When is the study starting and how long is it expected to run for? December 2022 to December 2024

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

Who is the main contact?
João Salgado, jsalgado@umaia.pt (Portugal)

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers

Nil Known

Study information

Scientific Title

Empty chair task for interpersonal emotional injury: randomized study of a brief online group intervention

Acronym

ECTIEI

Study objectives

This study, based on the work of Kwatra et al. (2023) and on the pilot study conducted in our lab, aims to evaluate the results of guided self-application of the Empty-Chair Task on:

- 1. Resolution of interpersonal emotional injury
- 2. Reduction of negative emotions associated with a significant other
- 3. Reduction of clinical symptoms of mental health problems

The hypotheses are that the intervention group will show greater resolution of interpersonal emotional injury, lower levels of clinical symptoms, and higher levels of well-being after the intervention, compared to the control group (waitlist condition).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/04/2023, University of Maia Ethics and Deontology Committee (Avenida Carlos de Oliveira Campos, Maia, Porto, 4475-690, Portugal; +351 229 866 000; info@umaia.pt), ref: 131/2023

Study design

Interventional randomized controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual, University/medical school/dental school

Study type(s)

Quality of life, Efficacy

Participant information sheet

Patient information material can be found at https://docs.google.com/forms/d/1F4pl61sJJ4VJ2H2Ric1OYfuW5YFT_KhcXDV43fPfQOU/edit

Health condition(s) or problem(s) studied

Non-clinical population/mild symptoms of psychopathology

Interventions

This is an interventional study. The participant pool will be recruited online using a quota sampling method. Based on the Census 2021, the sampling process will consider three variables: gender, age (divided into three age groups:18-34, 35-54, and 55-64 years), and education level (including two categories: primary/secondary education; and higher education). Statistical Power (SP) Analysis for the multivariate latent change score models to be used revealed that 80 participants are needed to ensure an SP of at least .8 (a = .05), considering a low-moderate rate of change.

Participants' levels of anxiety (GAD7), depression (PHQ9), and overall mental health/well-being (CORE-10) will be evaluated at admission (T0) to verify inclusion/exclusion criteria. Admitted participants will be randomly allocated, with a cluster randomization protocol, into two conditions: experimental and wait-list conditions.

The randomization protocol will be determined by an external member of the research team. Participants in the experimental condition will receive the Empty-Chair Task, self-administered and guided through pre-recorded audio instructions, in two 90-minute online group sessions with a weekly interval to ensure greater privacy and eliminate challenges of in-person group intervention. Participants admitted to the experimental condition will be evaluated at the following moments:

- T1: immediately before the first session (UFBRS, PANAS, GAD7, PHQ9, CORE-OM, MHC-SF).
- T2: immediately after the first session (Session Final Questionnaire, UFBRS, PANAS).
- T3: immediately before the second session (UFBRS, PANAS, GAD7, PHQ9, CORE-OM).
- T4: immediately after the second session (Final Session Questionnaire, UFBRS, PANAS).
- T5: 2 weeks after T4 (Process Final Questionnaire, UFBRS, PANAS, GAD7, PHQ9, CORE-OM, MHC-SF).

Wait-list condition participants will be evaluated at analogous moments (T1, T3, T5) and receive the same intervention 4 weeks after admission.

Intervention Type

Behavioural

Primary outcome measure

Unfinished business resolution/affects associated with a significant other measured using the Unfinished Business Resolution Scale (UFBRS) and the Positive and Negative Affects Schedule (PANAS) at T1, 2, 3 and 4

T0: evaluated at admission

T1: immediately before the first session

T2: immediately after the first session

T3: immediately before the second session

T4: immediately after the second session

T5: 2 weeks after T4

Secondary outcome measures

- 1. Sociodemographic Questionnaire measured using an Admission Questionnaire at T0
- 2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD7) at T0, 1, 3, and 5
- 3. Depression measured using the Patient Health Questionnaire-9 (PHQ9) at T0, 1, 3, and 5
- 4. General mental health and general psychological well-being measured using the Clinical Outcome Routine Evaluation-10 (CORE-OM) at T0, 1, 3, and 5
- 5. Self-reported mental health measured using the Mental Health Continuum-Short Form (MHC-SF) at T1 and 5

6. Intervention satisfaction/usefulness from participants' perspective measured using the Final Session Questionnaire at T4 and Process Final Questionnaire at T5

T0: evaluated at admission

T1: immediately before the first session

T2: immediately after the first session

T3: immediately before the second session

T4: immediately after the second session

T5: 2 weeks after T4

Overall study start date

01/12/2022

Completion date

01/12/2024

Eligibility

Key inclusion criteria

- 1. Presence of emotional injury caused by a significant personal relationship in the past (at least 2 years ago), influencing present functionality/mental well-being
- 2. Availability to work on the emotional injury
- 3. Aged 18-64 years old
- 4. Adequate computer literacy
- 5. Internet access

Participant type(s)

Population

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

55

Key exclusion criteria

- 1. Moderate to severe psychopathology
- 2. Have had changes in the therapeutic plan with psychotropic medication in the last month, if currently taking psychotropic medication
- 3. Receiving psychological treatment.

Date of first enrolment

01/01/2024

Date of final enrolment

01/05/2024

Locations

Countries of recruitment

Portugal

Study participating centre

University of Maia

Avenida Carlos de Oliveira Campos Maia Portugal 4475-690

Sponsor information

Organisation

Universidade da Maia

Sponsor details

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Sponsor type

University/education

Website

https://www.umaia.pt/pt

Organisation

University of Porto

Sponsor details

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Sponsor type

University/education

Website

https://cpup.fpce.up.pt/

ROR

https://ror.org/043pwc612

Funder(s)

Funder type

Government

Funder Name

Fundação para a Ciência e a Tecnologia

Alternative Name(s)

Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Portugal

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The recruitment of participants for the current project's studies will involve advertising on social media platforms such as Facebook and Instagram to reach a wider audience and increase the chances of obtaining the necessary participants.

In case an insufficient number of participants is observed, multiple advertisements will be posted at different times of the year, and institutional contacts with the University of Maia and the University of Porto will be strengthened. As a last resort, compensatory Bayesian statistical methods will be employed to address the potential insufficiency of participants instead of the methods outlined in the work plan.

The only piece of personal identification data that will be retained is the email address provided by the participant, along with their alphanumeric code. These codes will be securely held by the research team and destroyed either upon the study's completion or immediately if an immediate deletion is requested. Additionally, on a weekly basis, during periods of new participant enrollment, sociodemographic data will be exported to a separate database, and the data will be deleted from the original database (automatically obtained in LimeSurvey).

The created databases will be stored in encrypted form in the "cloud" using the OneDrive platform, following a security protocol ensured by the IT services of the University of Maia /Maiêutica. Access to the database containing sociodemographic elements will be restricted via a password, held by the Principal Investigator and the contact management responsible person. This ensures the protection of the individual's identity while allowing for data destruction if requested by the participant at a later time. After appropriate anonymization, the created databases, stripped of any identification data (email, age, gender, occupation), may be made available for open access to the scientific community.

The informed consent process will specify conditions of confidentiality, the right to withdraw, and the right to object. This ensures that participants can withdraw at any time and request the destruction of their data at any point, as outlined in the informed consent. It also guarantees that they can request the study's results.

In the event that participants exhibit signs or symptoms indicative of moderate to severe mental health issues, they will be asked for a telephone contact for subsequent referral to appropriate speciality services and will be excluded from the study. If they are already receiving psychological or medical care, they will also be excluded and informed of this via email. In the case of other exclusion reasons, an email will be sent explaining the specific reason (e.g., lack of computer resources).

Additionally, participants will be informed that confidentiality may, exceptionally, be breached during the assessment and/or treatment phase if there is a situation of risk to the participant or others, especially when a high risk of self-harm or harm to others is determined. These situations will always be discussed and managed in collaboration with the participants. In such cases, individuals will be referred to mental health emergency services.

IPD sharing plan summary

Published as a supplement to the results publication