ETHICS APPLICATION FORM

OFFICIAL TITLE OF THE STUDY

Tailoring Psychological Intervention Following Termination of Pregnancy for Foetal Anomaly: A Randomized Controlled Trial

DOCUMENT DATE

29 October 2026

ISPA - Instituto Universitário

ETHICS COMMITTEE OF THE ISPA RESEARCH CENTRE

Ethics Application Form

(All fields must be completed)

IDENTIFICATION
Title of the study or project
"Full Heart, Empty Arms": Psychological Intervention in Medical Termination of Pregnancy due to Fetal Anomalies
Context of the study or project, or scope of the research (e.g. doctoral research, research project)
Doctoral research (FCT scholarship 2025.05928.BDANA)
Name of the applicant/person responsible for the study
Beatriz Regina de Oliveira Trigo
Name of the supervisor/scientific lead of the study (if different from the above)
David Dias Neto
Contact details for questions or information (e.g. email, telephone)
btrigo@ispa.pt
PREVIOUS SUBMISSIONS to Ethics Committees
Has this research protocol been submitted to an Ethics Committee? YES OPINION received Favourable
Approved by FCT – scholarship scheme for research in non-academic settings
Has this research protocol previously been approved by this Ethics Committee? NO
Are there any changes to what was previously approved? Describe the changes.
N/A
DESCRIPTION of the research project
Objectives, context and rationale (highlight aspects relevant to the ethical issues involved in the project)
The aim is to develop a psychosocial grief intervention programme for people who have undergone medical termination of pregnancy due to a fetal anomaly (not necessarily lethal) in Portugal, to prevent adverse grief reactions and prolonged grief through early screening. Relevant ethical considerations include: • Random allocation to psychological intervention or treatment as usual. • Collection of sensitive information concerning death.
Methodological design (phases, intervention and measurement procedures)
A longitudinal, quantitative, correlational study (T0 = baseline/pre-intervention at 0 months; T1 = post-intervention at 3 months; T2 = follow-up at 6 months): two groups (intervention and treatment as usual (TAU)) will be assessed before and immediately after receiving a three-month intervention, followed by a further three months before follow-up data collection. Participants may withdraw at any time, and psychological support outside the study will be available upon request. • Intervention: individual online sessions based on the ACCEPT model.

• TAU: open peer-sharing groups for patients.

Participants (characteristics, selection/exclusion criteria, recruitment and/or referral methods, etc.)

Participants must be at least 18 years old, be able to speak, read and write Portuguese, and have undergone medical termination of pregnancy due to a fetal anomaly in Portugal. People who have experienced spontaneous pregnancy loss and/or undergone the procedure outside Portugal will be excluded. Participants will be recruited using a purposive sampling strategy, with convenience-based recruitment through partner organisations. We will collaborate with Inluto – Associação Portuguesa de Cuidados Integrados no Luto, Associação Pais Coragem and Projeto Amor Para Além da Lua.

Using G*Power to calculate sample size, a total of 116 participants was established (58 in each group):

- Test family: F tests
- Statistical test: repeated-measures ANOVA, within-between interaction
- Effect size f: .15
- Significance level: .05
- Power: .95
- Number of groups: 2
- Number of measurements: 3

Procedures (timeline, phases, instructions and data collection procedures, etc.; specify only aspects that may have ethical implications for the sample concerned)

The timeline of the doctoral programme within which this correlational study is situated is available in the appendices. There are no ethically relevant aspects specific to the sample concerned.

Instruments (identification, e.g. questionnaires, observations, document analysis or physiological measures) and their rationale.

Pre-intervention (T0)

- Questions about the circumstances of the loss (14 items)
- PGS-R (33 items) – Perinatal Grief Scale Revised
- PG-13 (13 items)
- PGST (5 items) – Prolonged Grief Screening Tool
- CORE-10 (10 items)
- CBS-16 (16 items) – Continuing Bonds Scale
- PsyFlex (6 items) – Psychological Flexibility
- RAS (7 items) – Relationship Assessment Scale
- Sociodemographic questions (10 items)

Post-intervention (T1)/Follow-up (T2)

- PGS-R
- PG-13
- PGST
- CORE-10
- CBS-16
- PsyFlex
- RAS

Information provided to participants and special precautions (if not relevant, enter NR)

YES
If yes, how?

1. Participants are informed about randomisation and that this means they cannot choose their group.
2. All participants receive an intervention. It is explained that the intervention is new and its effectiveness is being tested. It is also explained that evidence regarding the effectiveness of TAU is unavailable.
3. Participants may withdraw without disadvantage. Psychological support remains available even if they withdraw.

Is the study intrusive? Special precautions? How will any harm or inequality arising from the manipulation/intervention be addressed? (if not relevant, enter NR)

YES

The study may be considered intrusive insofar as it explores experiences of loss and death, as well as medical procedures of varying extent. Given its emotionally sensitive nature, protective measures will be adopted throughout all stages of the research and will apply to both groups. Before participation begins, it will be explained that some questions and sessions may evoke difficult emotions or memories related to the loss. Participants will be informed that they may request a break, stop a session or withdraw from the study at any time, without penalty or loss of access to available support.

During assessments and sessions, the team will remain attentive to signs of significant emotional distress, such as references to self-harm or suicide. When needs exceeding the scope of the intervention under investigation are identified, particularly severe symptoms requiring specialist intervention and/or a risk to the participant or others, the participant will be referred to appropriate services. With consent, liaison may be established with InLuto or other mental health services. In situations of immediate risk, the applicable emergency procedures will be activated, including contacting SNS24, 112 or other appropriate emergency services.

All participants will receive the contact details of the principal investigator and psychological support services. These measures will apply regardless of group allocation. Participation in the study does not replace individual psychological or psychiatric care when clinically indicated.

Informed consent? YES
Voluntary participation? YES

The present study, entitled “Full Heart Empty Arms”, aims to examine the grieving process and identify risk factors for prolonged grief or other adverse reactions associated with the experience of voluntary termination of pregnancy due to fetal anomalies.

WHO CAN PARTICIPATE
Anyone aged 18 or over who has experienced the process described above is invited to participate, whether as the pregnant person or as their partner.

PROCEDURE
Participation involves being assigned to one of the following options, both free of charge:
A) receiving support guided by a new intervention model;
B) receiving the type of support normally available.

Allocation is random, meaning that you cannot choose which option you receive. If you agree to participate, you will be asked to complete a questionnaire about your experience of loss and related feelings.
The questionnaire should take approximately 21 minutes to complete. You will need to complete another questionnaire later, after receiving the intervention. For this reason, you will be asked to provide an email address voluntarily so that we can contact you directly.

INTERVENTION
Participation will last three months. Following the initial assessment, participants will be randomly assigned to one of two groups. Random allocation means that participants cannot choose which group they join.

Group A – Psychological intervention based on the ACCEPT model
Participants in this group will receive an individual psychological intervention delivered online by video call over three months (one session per week, comprising 12 sessions of one hour each). The intervention will be delivered by the principal investigator (note: if additional professionals are recruited, they must be psychologists and will receive training in the model), using a structured protocol based on the ACCEPT model. Sessions will address, flexibly and according to each participant's needs, understanding grief reactions, emotional expression and regulation, developing strategies for coping with difficult thoughts and memories, maintaining an adapted relationship with the fetus/baby/envisioned future, the impact of the loss on interpersonal relationships, and (re)organising life after the loss. The intervention does not involve hospitalisation, medical procedures, collection of biological data or recording of sessions. Participants may request breaks, decline to discuss particular topics or discontinue the intervention. If clinical needs exceeding the programme's scope are identified, referral for specialist support will be proposed.

Group B – Treatment as usual
Participants in this group will have access to the support normally provided by partner organisations, namely open sharing groups for people who have experienced similar losses. These groups are facilitated by healthcare professionals trained in perinatal bereavement, predominantly nurses. The groups provide a space for listening, mutual support, acceptance and sharing experiences. Attendance at TAU group activities will be recorded to describe participation, but their frequency will vary according to what the organisation providing them offers. Participants in this group will undergo the same assessments and have access to the same protective measures and referral options as those in Group A.

After the study is completed, if the Group A intervention produces favourable results and it is feasible to offer it, interested participants from Group B may be invited to receive it (and vice versa).

VOLUNTARY PARTICIPATION
Your participation in this study is voluntary. You have the right to withdraw at any time without penalty. At your request, all your data may be excluded from the study.

BENEFITS
Your participation is expected to benefit you through the intervention you receive. Both interventions are expected to have beneficial effects. Participants allocated to Group B (receiving treatment as usual) may subsequently receive the

intervention offered to Group A. For this purpose, they will be placed on a waiting list if the study results are positive and they express an interest in participating. The study's findings are also expected to inform better ways of supporting bereaved people. You will therefore be helping others who may have similar experiences in the future.

EXPECTED DISCOMFORT
Completing the questionnaires may bring negative emotions and memories associated with your loss to mind. It is important to know that you can take breaks (prioritise your well-being).

CONFIDENTIALITY
All information you share will be kept confidential. Your information will be permanently deleted after the study is completed. Study documents will be password-protected to keep the data secure.

CONTACT INFORMATION
If you have any questions about this study, please contact the principal investigator: btrigo@ispa.pt. You may also get in touch if you need a referral for specialist psychological support.

Does the research involve minors? If so, what consent is requested from their legal representatives? If the minor can understand and express their wishes, their assent is also required.

Not applicable.

How will confidentiality be ensured when processing data and disseminating results? How will the information collected (recordings, biological data, etc.) be preserved?

- No identifying information will be used in the analysis.
- If a participant withdraws, all their data will be excluded and deleted.
- Sessions will not be recorded, and no biological data will be collected.
- All data collected during this study will be securely stored for five years after the study is completed. After this period, the data will be destroyed using secure methods in accordance with institutional data security protocols.

The data collected will be confidential and pseudonymised, rather than fully anonymous during the follow-up phase, because it will be necessary to link responses across assessment points, contact participants and allow for possible withdrawal of consent. Longitudinal data will be matched using a unique code chosen by each participant. This code will be used in questionnaires, research databases and analysis documents instead of names or other directly identifying information. The email address used for study-related contact will be stored in a list separate from the research database.

The link between each code and email address will be kept in a separate, encrypted, password-protected file. Access to the linking list and identifiable data will be restricted to the principal investigator and, when strictly necessary for scientific supervision or study management, the scientific supervisor and authorised team members bound by a duty of confidentiality. Partner organisations will not have access to participants' individual responses unless a participant expressly authorises contact for referral purposes. The identification key

will be destroyed after the final data collection, verification of the database and the end of the period during which participants may request deletion of their data. Once the key is destroyed, the data can no longer be linked to individual participants.

For as long as the key linking the code to the participant's identity or contact details exists, the data will be considered pseudonymised and confidential. Participants may request withdrawal of consent and deletion of their data until the linking key is destroyed or the data have been irreversibly aggregated. After longitudinal data collection and data verification are completed, the linking list will be deleted, making it impossible to associate the data with a specific person. Pseudonymised data will be retained for five years after completion of the study, in accordance with institutional policies and applicable requirements. At the end of this period, they will be securely deleted. Results will be presented only in aggregate form, and no information allowing the direct or indirect identification of any participant will be disclosed.

Data will be stored on the principal investigator's personal computer, protected by a password, disk encryption and access restricted to the investigator. A backup will be maintained on an encrypted external drive, also password-protected and kept in a secure location. Data will not be stored on personal cloud services or shared through unauthorised channels.

PROCEDURES AT THE END OF THE STUDY
Will participants and communities be informed of the study results? NO **By what means? (e.g. overall results provided to the participant or focus group; individual results provided to the participant, etc.)**
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Is dissemination to the scientific community intended? YES
Through a scientific article and possible conference presentations.
CONFLICTS OF INTEREST
Does anyone involved in designing and/or conducting the research have personal interests related to the elements examined in the study (e.g. patents, trademarks or copyright)? NO **If yes, please explain**
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Beatriz Regina de Oliveira Trigo-Paulino

Signature of the person responsible for the project and date