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# Beyond Fertility: a psychosocial intervention to promote patients' healthy adjustment to unsuccessful fertility treatment

**Submission date**
08/04/2022

**Recruitment status**
No longer recruiting

**Registration date**
14/04/2022

**Overall study status**
Completed

**Last Edited**
08/07/2024

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Around four in every ten patients end fertility treatment without achieving a pregnancy. Facing unsuccessful fertility treatment (i.e., all in vitro fertilisation/intracytoplasmic sperm injection (IVF /ICSI) cycles attempts are unsuccessful, and no new cycles are attempted) triggers an intense and protracted period of grief. European fertility guidelines (European Society of Human Reproduction and Embryology [ESHRE]) stress the need to support patients adjusting to this experience to ameliorate extreme psychosocial reactions and facilitate long-term healthy adjustment. However, there is a scarcity of evaluated interventions available to this end and a lack of provided support during this period. This study aims to evaluate whether a brief psychosocial intervention - Beyond Fertility - supports patients to healthy adjust to this experience.

Who can participate?
Fertility patients aged 18 years or older scheduled to initiate, within 1 month, their last IVF/ICSI treatment cycle reimbursed by the NHS

What does the study involve?
Participants complete an online survey and are randomly assigned to one of two groups: the intervention group or the care as usual group. Participants in the intervention group receive Beyond Fertility. Beyond Fertility is a brief face-to-face psychosocial intervention, designed to support patients adjusting to unsuccessful fertility treatment. It aims to be delivered by a mental healthcare professional, in-person or in an online format via Zoom. Beyond Fertility encompasses seven therapeutic sessions. One first session (in an individual/couple format) to be delivered within 1 month before the patient's scheduled date to start the last IVF/ICSI treatment cycle reimbursed by the NHS; and six following sessions (one individual/couple and five group sessions) starting 3 weeks after the end of this last IVF/ICSI treatment cycle reimbursed by the NHS. These latter sessions are only directed to those patients who experience an unsuccessful cycle and are not offered or do not plan to undergo an additional cycle. The care as usual group receives the mental healthcare currently offered in the clinics. All patients enrolled in the study (regardless of the treatment cycle outcome) are asked to complete four online surveys over

time, i.e., within 1 month before the patient's scheduled date to initiate the last IVF/ICSI treatment cycle reimbursed by the NHS, and 2 weeks, 3 months, and 6 months after the end of this treatment cycle.

What are the possible benefits and risks of participating?
This intervention aims to promote patients' healthy adjustment to unsuccessful fertility treatment. Although the control group does not receive the intervention and only the usual care, research has shown that, in general, people appreciate participating in research studies and evaluate this experience as beneficial and positive for their wellbeing. At the end of the study, a debrief will be sent to all the participants, and the possibility of being referred to individualised psychological support and other forms of support will also be offered. Patients who do not meet the inclusion criteria to participate, do not consent, or withdraw from the trial will also be offered this possibility.
As with any intervention in the field of psychology, during the therapeutic process, patients are expected to experience negative emotions and thoughts, which can be distressing. However, this process will be carried out in a controlled context, led by a trained clinical psychologist. Notwithstanding, those patients who experience significant discomfort, which is not manageable in the context of Beyond Fertility, will be referred to individualised psychological support and other forms of support.

Where is the study run from?
1. Cardiff University (UK)
2. Institute of Public Health of the University of Porto (ISPUP) (Portugal)

When is the study starting and how long is it expected to run for?
January 2019 to December 2023

Who is funding the study?
Portuguese Foundation for Science and Technology [Fundação para a Ciência e a Tecnologia (FCT)] (Portugal)

Who is the main contact?
1. Dr Sofia Gameiro (gameiros@cardiff.ac.uk)
2. MSc Mariana Sousa Leite (Sousaleitem@cardiff.ac.uk)

# Contact information

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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
Nil known

# Study information

**Scientific Title**

Efficacy evaluation of a psychosocial intervention - Beyond Fertility - versus care as usual, to promote fertility patients' quality of life after unsuccessful fertility treatment: a multicentre randomised controlled trial

## Acronym
Beyond Fertility: Efficacy trial

## Study objectives
1. It is expected that the quality of life of those fertility patients who are allocated to the psychosocial intervention (i.e., Beyond Fertility) will improve (moderate effect size expected) from baseline (i.e., within 1 month before the patients' scheduled date to initiate the last in vitro fertilisation/intracytoplasmic sperm injection (IVF/ICSI) treatment cycle reimbursed by the NHS) to 6 months after unsuccessful treatment, and remain stable for those allocated to receive care as usual.
2. It is also expected that the mental health and wellbeing of those fertility patients who are allocated to the psychosocial intervention (i.e., Beyond Fertility) will improve (small to moderate effect size expected) from baseline to 6 months after unsuccessful treatment, and remain stable for those allocated to receive care as usual.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Approved 18/06/2021, School of Psychology Research Ethics Committee of Cardiff University (Tower Building, 70 Park Place, Cardiff, CF10 3AT, UK; +44 (0)29 2087 0360; psychethics@cardiff.ac.uk), ref: EC.21.05.18.6351A
2. Approved 19/02/2021, University Hospital Centre of São João/Faculty of Medicine of the University of Porto [Centro Hospitalar Universitário de São João (CHUSJ)/Faculdade de Medicina da Universidade do Porto (FMUP)] Ethics Committee (Alameda Professor Hernâni Monteiro, Porto, 4200-319, PT; +351 (0)225 512 126; comissao.etica@chsj.min-saude.pt), ref: 127/2020
3. Approved 21/04/2021, University Hospital Centre of Porto/Institute of Biomedical Sciences Abel Salazar [Centro Hospitalar Universitário do Porto (CHUPorto)/Instituto de Ciências Biomédicas Abel Salazar (ICBAS)] Ethics Committee (Largo do Professor Abel Salazar, Porto, 4099-001, PT; +351 (0)222 077 500; secretariado.etica@chporto.min-saude.pt), ref: 2020.204 (161-DEFI/162-CE)
4. Approved 17/03/2022, Lisbon Academic Medical Centre [Centro Académico de Medicina de Lisboa (CAML)] Ethics Committee (Avenida Professor Egas Moniz, Lisboa, 1649-035, PT; +351 (0) 217 805 405; comissaoeticacaml@chln.min-saude.pt), ref: 398/21
5. Approved 24/08/2022, Central Lisbon University Hospital Centre [Centro Hospitalar Universitário de Lisboa Central] Ethics Committee (Rua José António Serrano, Lisboa, 1150-199, PT; +351 (0)213 514 410; comissao.etica@chlc.min-saude.pt), ref: 1244/2022

## Study design
Two-arm parallel-group non-blinded multicentre randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Fertility health problems

## Interventions
Patients who meet the eligibility criteria, consent to participate and complete the baseline assessment (i.e., an online survey via the Qualtrics platform (Qualtrics, Provo Utah, USA) targeting sociodemographic characteristics, fertility treatment history, psychosocial mediators - mechanisms of change, and outcomes) are assigned (non-blind) to one of these two groups: intervention; care as usual (1:1 ratio). For allocation of the participants, a computergenerated sequence of random numbers is used. The randomisation sequence is stratified by centre (i.e., fertility clinic) and parenthood status (childless; with children) with permuted random block sizes. A minimum sample size of 15 participants per group is required in the analysis of the primary outcome, with a twosided 5% significance level and a power of 90%. Driven by the inclusion criteria and results from a preceding feasibility study, a minimum of 540 eligible patients needs to be recruited.

The intervention group receives Beyond Fertility. Beyond Fertility is a brief face-to-face psychosocial intervention designed to support patients adjusting to unsuccessful fertility treatment. It aims to be delivered by a mental healthcare professional, in-person or in an online format via zoom (Zoom Video Communications, 2012). It is rooted in the Three Tasks Model (3TM; comprehensive guidance informed by an in-depth systematic review on how people adjust to unmet parenthood goals) and applies contextual cognitive behavioural (CCBT) therapeutic principles. Beyond Fertility encompasses preventive and early intervention care throughout seven therapeutic sessions. Preventive care comprises one first session (in an individual/couple format) to be delivered within 1 month before the patients' scheduled date to initiate the last IVF/ICSI treatment cycle reimbursed by the NHS. Early intervention care comprises the following six sessions (one individual/couple and five group sessions) starting 3 weeks after the end of this last IVF/ICSI treatment cycle reimbursed by the NHS. These sessions are only directed at those patients who experience an unsuccessful cycle and are not offered or do not plan to undergo an additional treatment cycle. Those patients who experience a successful outcome (i.e., a positive beta hCG) or decide to undergo an additional cycle do not receive the early intervention care (still, they complete the evaluation process, which encompasses four assessment timepoints - described below).

The care as usual group receives the mental healthcare currently offered in the clinics.

## Intervention Type
Behavioural

## Primary outcome(s)
Quality of life measured using the core module of the Fertility Quality of Life at the four assessment time points: (1) baseline - within 1 month before the patients' scheduled date to initiate the last IVF/ICSI treatment cycle reimbursed by the NHS; (2) 2 weeks (3) 3 months, and (4) 6 months post the end of this treatment cycle.

## Key secondary outcome(s))
1. Mental health measured using the Mental Health Inventory-5 (MHI-5)
2. Wellbeing measured using the Satisfaction with Life Scale (SWLS) and the Flourishing Scale (FS)

These outcomes are measured at (1) baseline - within 1 month before the patients' scheduled date to initiate the last IVF/ICSI treatment cycle reimbursed by the NHS; (2) 2 weeks (3) 3 months, and (4) 6 months post the end of this treatment cycle.

### Completion date
31/12/2023

## Eligibility

### Key inclusion criteria
1. Adults (aged 18 years or older)
2. Scheduled to initiate, within 1 month, the last IVF/ICSI treatment cycle reimbursed by the NHS (including the last transfer, with own [fresh or cryopreserved] or donated gametes/embryos and with or without preimplantation genetic testing [PGT])

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Having been diagnosed with a mental health problem in the last two years (e.g., bipolar disorder, schizophrenia, and other psychoses or dementia) - self-reported
2. Currently receiving therapy (psychotherapy or medication) for a clinically diagnosed mental-health problem - self-reported
3. Currently under psychological treatment by a certified psychologist or therapist, either in an individual or group format, specifically in relation to fertility issues and/or fertility treatment - self-reported
4. Unable to read and speak Portuguese - self-reported

### Date of first enrolment
28/12/2021

### Date of final enrolment
31/05/2023

## Locations

### Countries of recruitment

Portugal

**Study participating centre**
**University Hospital Centre of São João [Centro Hospitalar Universitário de São João (CHUSJ)]**
Department of Reproductive Medicine
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**Study participating centre**
**University Hospital Centre of Porto [Centro Hospitalar Universitário do Porto (CHUP)]**
Northern Maternal and Child Centre [Centro Materno Infantil do Norte (CMIN)]
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**Northern Lisbon University Hospital Centre [Centro Hospitalar Universitário de Lisboa Norte]**
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# Sponsor information

**Organisation**

Cardiff University

**ROR**
https://ror.org/03kk7td41

**Organisation**
Institute of Public Health of the University of Porto (ISPUP)

# 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 underlying the current trial will be available upon reasonable request and approval from Dr Sofia Gameiro (gameiros@cardiff.ac.uk) and MSc Mariana Sousa Leite (sousaleitem@cardiff.ac.uk). Data will be retained for a minimum period of 15 years after the end of the project or after the publication of any findings based upon the data (whichever is later). Personal data will be deleted, and the research data will be effectively anonymised. These data will be made available at the same time as the publication of the project's findings (expected date: 31/12/2024) but will only be shared for research purposes upon reasonable request and approval from Cardiff University - consent from participants was obtained.

**IPD sharing plan summary**
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Abstract results | | 03/07/2024 | 08/07/2024 | No | No |
| Participant information sheet | | | 11/04/2022 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |