# Enhanced fertility programme: developing an accessible, safe and cost-effective digital solution to improve fertility

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
22/07/2019		☐ Protocol		
Registration date	Overall study status Completed  Condition category Urological and Genital Diseases	Statistical analysis plan		
06/09/2019		Results		
Last Edited		Individual participant data		
12/09/2019		<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

The purpose of the study is to look into factors that affect fertility: healthy lifestyles, ability to cope with treatment, quality of life, patient satisfaction and experience.

The study will introduce the Enhanced Fertility Programme to patients receiving treatment in several fertility centres in Europe. The programme includes access to a digital platform and one to one coaching consultations (phone or Skype). The goal is to help improve health and lifestyle over six months. We will assess the impact of the programme on patient reported outcome measures such as adherence to healthy lifestyles, ability to cope with treatment, quality of life, patient satisfaction, experience and pregnancy status.

#### Who can participate?

Patients undergoing fertility treatment at the research sites, age 20-37, English speaking.

#### What does the study involve?

The study is looking at healthy lifestyles, ability to cope with treatment, quality of life, patient satisfaction, experience and pregnancy status in two participant groups. Patients in Group A will receive normal care as suggested by their doctor and complete an online questionnaire at baseline and 6 months later. Patients in Group B will receive normal care as suggested by their doctor, have access to the Enhanced Fertility Programme (online platform and one to one coaching) and complete an online questionnaire at baseline 6 weeks, 12 weeks, 18 weeks and 24 weeks.

What are the possible benefits and risks of participating?

There are no known direct risks associated with this study. Clinical treatment will be the same whether patients participate or not in the study. Patients may experience better health and fertility. The information we get from this study may help us improve the care of future patients.

Where is the study run from?

The Enhanced Fertility Programme clinic, London, UK

When is the study starting and how long is it expected to run for? October 2019 to April 2020

Who is funding the study? inFertile Life (trading name for Andreia Trigo Consulting Ltd), UK

Who is the main contact? Andreia Trigo andreia@infertile-life.com

# Contact information

#### Type(s)

Scientific

#### Contact name

Mrs Andreia Trigo

#### **ORCID ID**

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

EFP2019 V.1

# Study information

#### Scientific Title

Enhanced Fertility Programme as digital platform for health promotion in patients undergoing fertility treatment: a multicentric controlled trial.

#### Acronym

#### **Study objectives**

Health promotion through a digital platform improves fertility patient outcomes, care and experience.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

- 1. Approved 27/08/2019, Ethics committee at IVF London (Capsian House, The Waterfront, Elstree Road, WD6 3BS; deider.harrell@ivflondon.co.uk), ref: n/a
- 2. Approved 31/08/2019, Ethics committee at Women's Health (Kirova St. 52, Ufa, 450077, Russia; e.fazlyeva@eko-rb.ru), ref: n/a
- 3. Approved 02/08/2019, Ethics committee at Embryoclinic Private Polyclinic Medically Assisted Reproduction Unit P.C. (6 Adrianoupoleos Street, Kalamaria 55133, Thessaloniki, Greece; k. bimpa@embyoclinic.eu), ref: n/a
- 4. Approved 04/09/2019, Ethics committee at Ferticentro (Praceta Robalo Cordeiro, 3020-479 Coimbra, Portugal; vladsilva@ferticentro.pt), ref: n/a
- 5. Approved 06/09/2019, Ethics committee at Reproductive Health Group (Centre for reproductive health, Daresbury Park, Daresbury, Cheshire, WA4 4GE; aeckersley@reproductivehealthgroup.co.uk), ref: n/a
- 6. Approved 09/09/2019, Ethics committee at IVF Spain (Ansaldo 13 03540 Playa De San Juan, Alicante, Spain; mj.peral@ivf-spain.com).

#### Study design

Interventional qualitative multicentric study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Primary and Secondary Infertility, ovulatory disorders, male factor and unexplained infertility

#### Interventions

The study has two phases, one after the other:

Phase 1 will be looking at standard of care, with at least 64 patients recruited in October 2019, answering a questionnaire.

Phase 2 will start after (November 2019) with 64 patients receiving standard of care and the intervention (Enhanced Fertility Programme). This includes access to a digital platform for health promotions and one to one coaching for behaviour modification. Phase 2 patients will answer a questionnaire at baseline, 6 weeks, 12 weeks, 18 weeks and 24 weeks.

Number of patients for each phase was calculated for a 95% confidence interval and 5% margin of error

#### Intervention Type

Behavioural

#### Primary outcome(s)

Measured at: baseline, 6 weeks, 12 weeks, 18 weeks and 24 weeks through online questionnaire completed by participants:

- 1. Pregnancy status: nominal scale (yes/no)
- 2. Adherence to healthy lifestyles: Likert scale (Very good, good, nor good nor bad, poor, very poor)
- 3. Ability to cope with treatment: Likert scale (completely, a great deal, moderately, not much, nor at all).
- 4. Patient satisfaction: likert scale (extremely likely, likely, neither, unlikely, extremely unlikely).
- 5. Quality of life: FertiQoL

#### Key secondary outcome(s))

Measured at 6 months through online questionnaire completed by participants:

- 1. Accessibility to health promotion strategies: Likert scale (completely, a great deal, moderately, not much, not at all).
- 2. Inequality in fertility care: Likert scale (completely, a great deal, moderately, not much, not at all).

#### Completion date

30/04/2020

# Eligibility

#### Key inclusion criteria

- 1. Heterosexual couples or women seeking fertility treatment at one of the trial participating centres
- 2. Age 20-37
- 3. English speaking
- 4. Capacity to understand and use a computer with internet access
- 5. Diagnosed with primary or secondary infertility related to unexplained infertility, ovulatory disorders or male factor infertility

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

1. Any anatomical congenital gynaecological or urological abnormalities

#### Date of first enrolment

01/10/2019

#### Date of final enrolment

30/04/2020

# **Locations**

#### Countries of recruitment

**United Kingdom** 

England

Greece

Portugal

**Russian Federation** 

Spain

# Study participating centre EFP Clinic

Part of inFertile Life 34b York Way Kings Cross London United Kingdom N1 9AB

# Study participating centre IVF London

Capsian House The Waterfront Elstree Road London United Kingdom WD6 3BS

# Study participating centre Women's Health

Kirova St. 52 Ufa Russian Federation 450077

#### Study participating centre Embryoclinic Private Polyclinic - Medically Assisted Reproduction Unit P.C

6 Adrianoupoleos Street Kalamaria Thessaloniki Greece 55133

# Study participating centre Ferticentro

Praceta Robalo Cordeiro Coimbra Portugal 3020-479

## Study participating centre Reproductive Health Group

Centre for reproductive health Daresbury Park Daresbury Warrington United Kingdom WA4 4GE

# **Sponsor information**

# Organisation

inFertile Life

# Funder(s)

# Funder type

Industry

#### **Funder Name**

inFertile Life (trading name for Andreia Trigo Consulting Ltd)

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes