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

Submission date
22/07/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Completed

Last Edited
12/09/2019

Condition category
Urological and Genital Diseases

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

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
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Study website
https://efp.clinic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
EFP

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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).

Overall study start date
02/09/2019

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

Age group
Adult

Sex
Both

Target number of participants
128

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
England

Greece

Portugal

Russian Federation

Spain

United Kingdom

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
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WD6 3BS

Study participating centre
Women's Health
Kirova St. 52
Ufa
Russian Federation
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Study participating centre
Embryoclinic Private Polyclinic - Medically Assisted Reproduction Unit P.C
6 Adrianoupoleos Street
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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
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Sponsor information

Organisation

inFertile Life

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Sponsor type
Industry

Website
https://efp.clinic

Funder(s)

Funder type
Industry

Funder Name
inFertile Life (trading name for Andreia Trigo Consulting Ltd)

Results and Publications

Publication and dissemination plan
Intend to publish main results and conclusions of the study.
The study report will be completed by May 2019 and sent to all study sites.
Dissemination at congresses, including ESHRE.
Relevant publications and magazines in reproductive health.

Intention to publish date
29/05/2020

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