An online fertility workup for subfertile couples

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27046

Bron
Nationaal Trial Register

Verkorte titel
OFO Online

Aandoening

subfertility

Ondersteuning

Primaire sponsor: Jeroen Bosch Ziekenhuis
Overige ondersteuning: Jeroen Bosch ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient centeredness as measured with PCQ-infertility

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Couples who suffer from involuntarily childlessness can experience a high psychological burden and treatment for their infertility has a high impact on their daily life. To modernize and optimize current fertility healthcare, a pilot study was performed to evaluate the use of video-consulting, with positive results. This trial is designed to expand the idea of video-consulting to a new group of patients, suffering from infertility
Objective: The aim of this study is to compare if an online consultation with diagnostic testing during a fertility workup, is as effective as a regular consult in terms of patient centeredness, shared decision making and costs.
Study design: single-centre randomized, non-blinded, controlled trial.
Study population: Couples, female between the age of 18-42 with their male partner with primary or secondary infertility, who have been referred for the first time, to a fertility clinic or hospital.
Intervention online fertility workup with video-consultation
Comparison regular fertility workup with appointments in an outpatient clinic.
Main study parameters/endpoints: Patient centeredness, shared decision making and costs. In addition semi-structured interviews will be held to get more in depth information about patient’s experiences and time investments.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The possible disadvantage is a lower score on patient centeredness, because couples want and need the confirmation of a physical contact by a regular appointment in a clinic. A potential benefit is the experience of a more personalised setting without the problems that belong to appointments in a hospital, for example: long waiting times, travel distances and the feeling of being a patient without control over their health issues

Doel van het onderzoek

Our hypothesis is, that this new type of fertility workup will have the same level of patient centeredness, with the benefits of less interference with their personal life and more discretion.

Onderzoeksopzet

follow-up time (from time of randomisation): 3 months

primary outcome: PCQ-infertility questionnaire: will be sent within a week after the video or regular consult, by email. If patients do not respond after two weeks, a reminder will be sent.

Secondary outcome:
Data concerning diagnosis, progression to different types of treatment and costs will all be extracted from the Landelijk Specialistisch Fertiliteits Dossier (LSFD), after follow up is complete.

Shared discision making, measured with the CollaboRATE and time investment of patients will be asked in the same questionnaire as the PCQ-infertility. This will be sent within a week after the video or regular consult, by email. If patients do not respond after two weeks, a reminder will be sent.

Onderzoeksproduct en/of interventie

Online fertillity workup with videoconsult:
The intervention arm will exist of:
- a questionnaire, which is a standard questionnaire according to the national fertility workup guidelines.
- online recommendations about diagnostic tests, via a secure network: digitale kinderwens poli. This online platform follows the Dutch quality standard ‘NEN 7510’.
- a gynaecological ultrasound on the outpatient clinic.
- a 30 minute during video-consultation on ‘Webcam consult. This system is already implemented in the JBZ and is a safe program to use during a video-consult. The platform is ISO027001 and NEN 7510 compliant.
- A letter with an overview of the consult with diagnosis and recommendations.
- The PCQ-infertility questionnaire
- Some couples will be asked for further follow up in the form of semi-structured interview.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary or secondary infertility, lasting at least 1 year
2. Referral by general practitioner
3. Female age 18-42 and their male partner from the age of 18
4. Written informed consent
5. Possibility to speak Dutch or English or to bring a translator to the conversation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A history of fertility treatment
2. Previous fertility diagnostic tests
3. No availability to a WIFI connection at home.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2020
Aantal proefpersonen:	91
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8554
Ander register	Study management Jeroen Bosch ziekenhuis : 2020.04.15.02

Resultaten