

De Zin en Zwanger studie

Gepubliceerd: 04-02-2016 Laatste bijgewerkt: 18-08-2022

Online sex-counseling improves the probability of a naturally conceived pregnancy in heterosexual couples with unexplained subfertility and a good prognosis

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23775

Bron

NTR

Verkorte titel

The CoSy trial

Aandoening

1. Unexplained subfertility for at least one year
2. Chance on a spontaneous pregnancy of $\geq 30\%$ calculated by the model of Hunault
3. An advice for expectant management for at least 6 months

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy, naturally conceived within six months after randomization

Toelichting onderzoek

Achtergrond van het onderzoek

Each year, 5,000 heterosexual couples are diagnosed with unexplained subfertility and a good prognosis ($\geq 30\%$ chance on a live-born child after natural conception within 12 months). The guidelines of the Dutch Society of Obstetrics and Gynaecology (NVOG) currently advise postponing medically assisted reproduction (MAR) for six months in these couples as this is equally effective as six months of intra-uterine insemination (IUI) with controlled ovarian stimulation. Until now, expectant management simply means sending couples home for continuing to attempt natural conception without guidance on sexual activity, surveillance or support.

Expectant management proves to be challenging in clinical practice because of pressure from desperate couples who have a lack of confidence in natural conception and who overestimate success rates of MAR.

According to a small cohort study, sex counselling can increase the proportion of couples having intercourse during their fertile days and can thereby increase ongoing pregnancy rates. Whether sex counselling indeed increases ongoing pregnancy rates, however, has never been demonstrated in a randomized clinical trial.

Objective

To compare the effectiveness, expressed in terms of naturally conceived ongoing pregnancy rate, and the cost-effectiveness of six months of internet-based sex counseling to six months of expectant management without guidance on sexual activity, surveillance or support in couples with unexplained subfertility and a good prognosis.

Doel van het onderzoek

Online sex-counseling improves the probability of a naturally conceived pregnancy in heterosexual couples with unexplained subfertility and a good prognosis

Onderzoeksopzet

Ongoing pregnancy, naturally conceived within six months after randomization

Onderzoeksproduct en/of interventie

Six months of internet-based sex counselling aiming to increase the probability of natural conception of an ongoing pregnancy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Heterosexual couples with unexplained subfertility
2. $\geq 30\%$ chance of an naturally conceived ongoing pregnancy calculated (Hunault)
3. Sufficient command of the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Somatic or psychological problems interfering with the couples ability to have sexual intercourse

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	1164
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	04-02-2016
Soort:	Eerste indiening

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
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NTR-new	NL4467
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NTR-old	NTR5709
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Ander register METC AMC (Amsterdam) NL55012.018.15 : ZonMW 843001605

Resultaten