

De Zin en Zwanger studie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23775

Source

Nationaal Trial Register

Brief title

The CoSy trial

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam

Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Ongoing pregnancy, naturally conceived within six months after randomization

Secondary outcome

1. Time to pregnancy
2. Mean change in sexual activity
3. Mean change in each partners' sexual functioning
4. Mean change in individual wellbeing of each partner
5. Time and interactive effects on all outcomes

Study description

Background summary

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.

Study objective

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

Study design

Ongoing pregnancy, naturally conceived within six months after randomization

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	1164
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	04-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4467
NTR-old	NTR5709
Other	METC AMC (Amsterdam) NL55012.018.15 : ZonMW 843001605

Study results