

# Internet-based Sex counseling and chances on natural conception in couples with Idiopathic Subfertility: a randomized clinical trial

Published: 28-01-2016

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Objective of the study is to investigate whether couples with unexplained subfertility and a good prognosis have a significantly higher probability of naturally conceiving an ongoing pregnancy within six months if they are offered internet-based sex...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON50500

### Source

ToetsingOnline

### Brief title

CoSy

### Condition

- Sexual function and fertility disorders

### Synonym

infertility, unfulfilled desire to have children

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## **Intervention**

**Keyword:** Fertilization, Infertility, Pregnancy, Sex Counseling

## **Outcome measures**

### **Primary outcome**

Primary outcome: ongoing pregnancy conceived naturally within six months after randomization.

### **Secondary outcome**

Secondary outcomes: time-to-pregnancy, live birth rate, costs, sexual activity, wellbeing and sexual functioning.

## **Study description**

### **Background summary**

The current policy with regard to unexplained infertile couples is six months of expectant management in which couples are advised to attempt natural conception without guidance on sexual activity, surveillance or support.

Research has shown that only 27% of these couples conceive within six months of expectant management. Second, 67% of couples return for MAR after expectant management and MAR. As MAR has many negative aspects, it is advised to prevent this.

### **Study objective**

Objective of the study is to investigate whether couples with unexplained subfertility and a good prognosis have a significantly higher probability of naturally conceiving an ongoing pregnancy within six months if they are offered internet-based sex counseling than if they are offered expectant management without guidance on sexual activity, surveillance or support.

### **Study design**

**INTERVENTION:** Six months of internet-based sex counselling relying on sensate

focus, mindfulness, couple communication

skill training and education. This will be covered by eight progressive modules including: information, exercises, a concluding moderated group chat session and the unlimited opportunity to email with the sexologist.

**USUAL CARE/COMPARISON:** Six months of expectant management in which couples are advised to attempt natural

conception without guidance on sexual activity, surveillance or support.

**OUTCOME MEASURES:** Primary outcome: ongoing pregnancy conceived naturally within six months after randomization.

Secondary outcomes: time-to-pregnancy, live birth rate, costs, sexual activity, wellbeing and sexual functioning.

## **Intervention**

**INTERVENTION:** Six months of internet-based sex counselling relying on sensate focus, mindfulness, couple communication

skill training and education. This will be covered by eight progressive modules including: information, exercises, a concluding moderated group chat session and the unlimited opportunity to email with the sexologist.

## **Study burden and risks**

There are no extra risks associated with participating to this trial as compared to couples who do not receive additional counseling.

The burden consists of participation in sex counseling. During the first three months, both participants follow 1 module every two weeks, totalling to 6 modules. After that, two modules (one per month). The modules are provided through an internet programme which is specifically designed for this study.

## **Contacts**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105AZ  
NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 9

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

1. Heterosexual couples
2. in which the woman is between 18 and 43 years of age
3. Unexplained subfertility (bilateral tubal patency, an ovulatory cycle and a normal semen analysis)
4. At least 30% chance of an ongoing pregnancy after natural conception within 12 months, estimated based on female age, duration of subfertility, type of subfertility (primary or secondary), percentage of progressively motile sperm, and referral status (self-referral, secondary or tertiary care referral)
5. Sufficient command of the Dutch or English language
6. Willingness to give informed consent

### **Exclusion criteria**

Somatic or psychological problems interfering with couples\* ability to have intercourse

## **Study design**

## Design

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

**Primary purpose:** Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2016
Enrollment:	1112
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-05-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-02-2017
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-07-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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
CCMO	NL55012.018.15

## Study results



Date completed: 25-05-2022

Actual enrolment: 700