Predictors of psychological distress in couples undergoing infertility treatment.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual function and fertility disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30901

Source
ToetsingOnline

Brief title
Psychological distress in infertility.

Condition

- Sexual function and fertility disorders

Synonym
fertility disorder, infertility

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: infertility treatment, psychological distress, risk factors

Outcome measures

Primary outcome

The questionnaire will include the following concepts:

- Medical history and treatment characteristics;

- Coping strategies will be measured with the CERQ (cognitive coping, 18 items, Garnefski, Kraaij, & Spinhoven, 2001) and four scales of the COPE (behavioral coping, 14 items, Carver, Scheier, & Weintraub, 1989);

- Goal frustration will be measured with the Goal Hindrance Instrument (GHI, 24 items, Kraaij & Garnefski, 2006);

- Coping self-efficacy will be measured with the Coping Self-Efficacy Scale (8 items, Kraaij, van der Veek, & Garnefski, 2005);

- Social support from others and from the partner will be measured with the Social Support Scale (SSI, 2 sets of 4 items, Garnefski & Kraaij, 2006);

- Illness cognitions will be measured with the Illness Perception Questionnaire (IPQ, 8 items, Weinman, Petrie, Moss-Morris, & Horne, 1996);

- Symptoms of anxiety and depression will be measured by means of the Hospital Anxiety and Depression Scale (HADS, 14 items, Zigmond & Snaith, 1983).

Secondary outcome

N.a.

Study description

Background summary

At the department of gynecology, LUMC, about 300 couples are currently being treated for infertility problems. Research shows that people undergoing infertility treatment experience higher levels of distress and psychological problems, compared to people without inferitlity problems. While there is growing evidence that the psychological distress experienced affects conception rates, there is a dearth of research exploring the factors that might contribute to this distress. Factors that will be studied in the present study are extracted from (extended) stress-coping models and will include: coping, goal frustration, coping self-efficacy, social support, spousal support and illness cognitions.

Study objective

It is important that we get insight into which of the above mentioned factors are related to psychological problems. It could give us some important starting points for designing psychological intervention programs. Such an intervention could not only contribute to lower levels of distress and a better well-being, but possibly also to better conception rates.
In the present study we will therefore study the relationships between coping, goal frustration, coping self-efficacy, social support from others and from the partner, and illness cognitions at the one hand, and symptoms of anxiety and depression at the other hand.

Study design

Design
The research will be a cross sectional research with questionnaires.

Procedure
The data collection will take place between April and September 2007. All couples in infertility treatment at the LUMC will be approached by the department of gynecology (LUMC) and will receive two written questionnaires (one for each partner) at their home addresss. The questionnaires will be accompanied by a letter informing them about the study, and an informed consent form with the request of signing it before filling in the questionnaire. The questionnaires can be returned in a pre-paid envelope. Privacy will be warranted, by separating the personal information on the informed consent form from the research information. The questionnaire will be coded by a number. After the questionnaire has been filled in, the subjects will be asked for their permission to contact them for possible further research. A reminder letter will be sent after two weeks. The key of the code will stay within the

LUMC.
Filling out the questionniare will take approximately 30 minutes.

Instruments
A written self-report questionnaire will be composed.

Study burden and risks

N.a.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All people who are undergoing infertility treatment at the LUMC, department of gynecology
Male and female
Dutch speaking

Exclusion criteria

No Dutch speaking
Couples in diagnostic phase

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL16558.058.07