

Impact of a psychological intervention in patients under assisted reproductive treatment (in vitro fertilisation [IVF]/intra-cytoplasmic sperm injection [ICSI])

Submission date 11/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/05/2009	Overall study status Completed	☐ Protocol
Last Edited 11/05/2009	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

Grant no.: 325100-11375411

Study information

Scientific Title

Impact of a psychological intervention in patients under assisted reproductive treatment (in vitro fertilisation [IVF]/intra-cytoplasmic sperm injection [ICSI]): a prospective (longitudinal) blinded randomised experimental intervention study

Study objectives

1. A significant difference in psychological outcome is expected between groups. Specifically, it is assumed that the group with the psychological intervention will have better outcomes in terms of psychological functioning (quality of life and depression, suffering from infertility).
2. A difference in biomedical outcome is expected between groups. As above, it is assumed that the group in the psychological intervention condition will profit in terms of a higher chance of pregnancy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cantonal Ethics Committee of Bern (Switzerland) gave approval on the 22nd March 2007 (ref: KEK-BE 005/07)

Study design

Interventional multicentre prospective (longitudinal) blinded randomised experimental intervention study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infertility

Interventions

Psychological intervention versus a waiting control group.

Psychological intervention (fertility group intervention):

A combination of clarification and mastery techniques, based primarily on principles of cognitive behavioural therapy, clarification-oriented therapy and system therapy. The intervention consists of 10 weekly sessions organised according to 10 thematic blocks: a structured group /couple setting and a combination of educational and supportive therapeutic elements.

Waiting control group:

The control group is randomised to the waiting list control patients for 6 months. After this time they could participate in the intervention if they want.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Specific stress reactions:
 - 1.1. Infertility distress questionnaire (Fragebogen zur infertilitätsbedingten Belastung [IBS]; 11 items)
 - 1.2. Cognitions in infertility questionnaire (Kognitionen bei Infertilität [KINT]); 20 items)
2. Psychological functioning:
 - 2.1. Centre for Epidemiologic Studies Depression Scale (CES-D); 20 items
 - 2.2. German Inkongruenzfragebogen (K-INK); 23 items
3. Pregnancy rate

All primary and secondary outcome measures were assessed at baseline, after 5 weeks, at post-treatment (12 weeks after baseline), and at six-month follow-up.

Key secondary outcome(s)

1. Psychosocial conditions:
 - 1.1. Demographic questionnaire (Socioeconomic Status [SES]; 14 items)
 - 1.2. Relationship Assessment Scale (RAS); 7 items
 - 1.3. Sozialer Support; 7 items
2. Coping, self-efficacy, emotion regulation:
 - 2.1. Coping Inventory for Stressful Situations (CISS) short version; 19 items
 - 2.2. Self-efficacy questionnaire (Selbstwirksamkeit [SWE]; 10 items)
 - 2.3. Emotion Regulation (EMOREG); 26 items

All primary and secondary outcome measures were assessed at baseline, after 5 weeks, at post-treatment (12 weeks after baseline), and at six-month follow-up.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Written consent for this study as well as for the IVF/ICSI treatment are on hand
2. The patient is currently not in psychological treatment
3. The patient has an indication to an IVF/ICSI treatment
4. The patient is in reproductive age (maximal age is 42 years)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Inability to communicate
2. Fundamental contraindications to an IVF/ICSI treatment:
 - 2.1. Acute/chronic infectious diseases: human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis
 - 2.2. Severe psychiatric diseases: schizophrenia, severe depressive disorders
 - 2.3. Acute/chronic addiction
 - 2.4. Carrier of a severe genetic disease
 - 2.5. Age of the female patient is greater than 42 years
3. Need of psychological or psychiatric treatment before or during the study
4. Not any more willing to participate in the study
5. Severe injuries to the protocol
6. Separation of the couple
7. Severe disease of one partner

Date of first enrolment

01/06/2007

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Switzerland

Study participating centre

Institute of Psychology

Bern

Switzerland

3012

Sponsor information

Organisation

Swiss National Science Foundation (Switzerland)

ROR

<https://ror.org/00yjd3n13>

Funder(s)

Funder type

Government

Funder Name

Swiss National Science Foundation (Switzerland) (grant ref: 325100-11375411)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary