# Long term effects of using a DA for embryo transfer in IVF care: A follow up on the PITS study.

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With this follow up study we would like to find out how couples from both control- and interventiongroup look back on the decision they made regarding embryo transfer during the PITS study. Not much is known about the long term effects of using DA...

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON42554

**Source**
ToetsingOnline

**Brief title**
Long term effects of DA for embryo transfer

### Condition

- Other condition
- Family issues

**Synonym**
reproductive medicine

**Health condition**

voortplantingsgeneeskunde, IVF

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** decision aid, embryo transfer, follow up, IVF

## Outcome measures

### Primary outcome

Decisional Regret is the primary study parameter. We would like to determine to what extent couples experience a feeling of regret when it comes to the decision they made during the PITS study for SET (single embryo transfer) or DET (double embryo transfer).

### Secondary outcome

Quality of life, measured with the Mental Health Continuüm is the secundairy study parameter.

The study also has some determinants, which are:

-Choice for SET or DET during the PITS study

-Outcome of treatment during PITS study (singleton or twin pregnancy, live or still born)

-Self efficacy with the general Self Efficacy Scale

-Family situation (amount of children)

-Hopes and expectations before starting treatment

# Study description

### Background summary

Between November 2006 and July 2007 the so called PITS study was conducted among 300 couples that were on the waiting list for IVF treatment. These couples were about to receive treatment in IVF clinics in Nijmegen, Veldhoven, Ede, Apeldoorn or Eindhoven. This PITS study focussed on a multifaceted implementation strategy in IVF care, to help couples decide to either transfer 1 or 2 embryos during their treatment. An important part of this strategy was a decision aid (DA) developed in Radboudumc Nijmegen. This DA explained all the pros and cons and risks for the transfer of 1 and 2 embryos. The DA also described the chances of pregnancy for single embryo transfer and double embryo transfer.
Couples were divided into two groups, a controlgroup and an intervention group. The controlgroup received regular IVF care and the interventiongroup received regular IVF care plus the DA. Results of the PITS study showed that couples from the interventiongroup were more likely to choose single embryo transfer compaired to the controlgroup (11% difference). Another result from the PITS study is that couples from the interventiongroup felt well informed and therefore more empowered to make a decision for themselves.
Not much is known about the effects of decision aids on the long term, and with this follow up study we hope to learn more about these long term effects of decision aid use in IVF care (and possibly health care in general).

## Study objective

With this follow up study we would like to find out how couples from both control- and interventiongroup look back on the decision they made regarding embryo transfer during the PITS study. Not much is known about the long term effects of using DA's in healthcare, since previous research on DA's only follow up after 1-3 years. By using a questionnaire with questions regarding the patients' choice on embryo transfer during PITS study, their quality of life and feelings of regret we will learn more about the patients' view on their choice. This way we can learn more about the long term effects of the use of this particular DA, but results from this study might also give more insight on DA use in general healthcare, since there is no study known in literature with a follow up time that is as long as it is in this study.

## Study design

We will ask couples that participated in the PITS study and that had more than 1 embryo available for transfer to participate in this follow up study. We will collect the correct adresses by performing a GBA-check in the Radboudumc Nijmegen. If this will not give the result we hoped for we will use social media (Facebook) to find the former PITS study participants by searching for first and last names. We will create a special Facebook page of the PITS study, from which we will contact the former PITS-study participants. This will occur via private message and will therefore not be visible to others.
When we have obtained the correct home adresses, we will send these patients a

questionnaire, brochure for participants of scientific research, a consentform and an explanation letter. The patients will be contacted from the hospital they received treatment at the time of the PITS study. Patients can fill in the consentform to let us known if they want to participate in this study or not, and they can sent the consentform and questionnaire back to us.
The results of these questionnaires will be analyzed and internationally reported.

**Study burden and risks**

Filling in the questionnaire and sending it back will only take 10-15 minutes of the participants' time. Participants might have to go back in time since the treatment we are reffering to happened over 8 years ago, but that will be the only effort they have to put in in order to participate in our study. It is possible that participants feel like filling in the questionnaire is heavy and emotional, but we don't expect this to occur (since treatment is over 8 years ago, it is not 'fresh' in memory). If we do get this negative feedback we will report this and stop sending new reminders when we receive 10% negative feedback (10% of the 222 invited participants, which means 22 negative responses).

# Contacts

**Public**
Universitair Medisch Centrum Sint Radboud

Geert Groteplein zuid 10
Nijmegen 6525 GA
NL
**Scientific**
Universitair Medisch Centrum Sint Radboud

Geert Groteplein zuid 10
Nijmegen 6525 GA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Couples that participated in the PITS studie (between November 2006 and July 2007) and that were undergoing IVF treatment where they had more then 1 embryo available for transfer. If couples participated in the entire PITS study (so we have a complete follow up) and they fit this criteria they can participate.

## Exclusion criteria

Less then 2 embryo's available for transfer during PITS study, pregnant before the start of IVF, not a complete follow up

# Study design

## Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Health services research |

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 222 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 03-09-2015 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL53153.091.15 |