Evaluation of information provision about fertility sparing treatments for women with breast cancer.

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We expect that the Decision Aid will support patients in deciding about fertiliy preservation prior to their cancer treatment by decreasing decisional conflict.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26732

Bron
NTR

Verkorte titel
KEEP

Aandoening

Young premenopausal women (18-40) with breast cancer
at risk for premature ovarian failure (POF)

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Pink Ribbon, DSW Health insurance

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(Measured with a questionnaire).
Decisional conflict as measured with the decisional conflict scale (DCS, O'connor, 1995).

Toelichting onderzoek

Achtergrond van het onderzoek

Because survival chances for women with breast cancer are high, quality of life (QOL) after treatment is becoming more important. Infertility, or concerns about fertility, due to the cancer treatment have a negative influence on the QOL. Therefore, interest in possibilities for fertility preservation (FP) has risen. At this moment, options to preserve fertility prior to oncologic treatment in the Netherlands are cryopreservation of in vitro fertilized embryos, oocytes and ovarian tissue, or suppression of the ovaries. Despite an increasing number of studies and guidelines demonstrating the need of discussion of FP issues with young cancer patients, information provision about treatment-induced infertility and FP techniques is not sufficient.

Sufficient and clear information is necessary to enable informed decision making. To support informed decision making and improve information provision, we have developed a web-based Decision Aid (DA) on FP. With the availability of this DA, every patient who is eligible for counseling on FP can obtain optimal counseling at any location in the Netherlands. Aim of this RCT is to evaluate the DA for FP on its effectiveness compared to treatment as usual (TAU) regarding outcomes of decision making and decision making processes.

Doel van het onderzoek

We expect that the Decision Aid will support patients in deciding about fertiliy preservation prior to their cancer treatment by decreasing decisional conflict.

Onderzoeksopzet

T0: Baseline (after registration);

T1: 6 weeks;

T2: 6 months;

T3: 1-2 years.

Onderzoeksproduct en/of interventie

Information provision trough a Webbased decision aid (intervention) about fertility preservation compared to general patient brochures (control) about fertility preservation. The effect of the intervention will be measured by making use of self report questionnaires.

The intervention is a webbased decision aid (website) with information about the consequences of breast cancer treatment on fertility, fertility preservation options, options to fulfill a desire for children when fertility preservation is not possible, background information on normal fertility. Furthermore, the website consists of an explicit value clarification exercise by which patients can deliberate values that are important for them in the decision whether or not to undergo fertility preservation. Subsequently, patients' answers are sorted from most important (as defined by the patient) to least important. No advice is given.
Patients can decide for themselves how much time they spend on the website and what proportion they read, or use.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women;

2. 18-40 years old;

3. Diagnosed with breast cancer;

4. Will soon start their breast cancer treatment;

5. Eligible for FP;

6. Have an email address.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No sufficient knowledge of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-06-2011
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2908
NTR-old	NTR3054
Ander register	METC LUMC : P11.027
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A