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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26732

Source
NTR

Brief title
KEEP

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Pink Ribbon, DSW Health insurance

Intervention

Outcome measures

Primary outcome

(Measured with a questionnaire).

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

Secondary outcome

(All measured with questionnaires).

Satisfaction with decision making (subscale dcs), preparation for decision making (Bennet et al 2010), decisional regret (Brehaut et al 2003), reproductive concerns (Wenzel et al 2005), risk perception, knowledge, attitude, preference/uptake, health literacy (Chew et al 2004), anxiety and depression (Hospital Anxiety and Depression Scale), quality of life (EORTC-QLQ-C30).

Study description

Background summary

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.

Study objective

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

Study design

T0: Baseline (after registration);

T1: 6 weeks;

T2: 6 months;

T3: 1-2 years.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

No sufficient knowledge of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2011
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-08-2011
Application type:	First submission

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
NTR-new	NL2908
NTR-old	NTR3054
Other	METC LUMC : P11.027
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A