Effect evaluation of a Decision Aid for Fertility Preservation in Women with Breast cancer; a Randomized Controlled Trial in the Netherlands

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Aim of the hereby proposed study 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. Primary outcome is decisional coflict.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON36509

Source
ToetsingOnline

Brief title
KEEP - Decision aid effect evaluation fertility Preservation

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Reproductive tract disorders NEC

Synonym
breast cancer, chemo-therapy induced infertility, mammacarcinoma, premature ovarian failure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: DSW Zorgverzekering ,Pink Ribbon & DSW zorgverzekering

Intervention

Keyword: Breast cancer, Decision aid, Decisional conflict, Fertility preservation

Outcome measures

Primary outcome

decisional conflict

Secondary outcome

preparation for decision making, informed decision making, value congruence,

knowledge, satisfaction with the decision made, and decisional regret,

reproductive concerns, quality of life

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 (in)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. To our knowledge, this is the first Dutch initiative of developing a DA for FP. In Australia people have developed a DA-booklet. Pilot testing of this booklet as decision aid has provided some initial evidence about the efficacy of the DA in facilitating

informed choices about fertility-treatments. However our DA will be the first webbased decision aid for FP worldwide.
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.

Study objective

Aim of the hereby proposed study 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. Primary outcome is decisional coflict.

Study design

The effectiveness of the DA for FP will be evaluated in a prospective, randomized controlled multi center trial with two follow-up moments within 6 months, and one additional follow-up moment 1-2 years later.
Patients who visit the participating centers will be randomly assigned to one of the two conditions (control vs intervention). Randomization will be done by making use of random allocation software. Randomization will take place after respondents have completed the baseline questionnaire. All respondents receive a respondent number existing of a letter followed by a number. Each center has it own letter. This letter will be randomly assigned to the participating centers. The number indicates the order of the patients; the first eligible patient receives a 01, the second a 02, the tenth a 10 etc.

Study burden and risks

Participating in this study will not cause any (physical) harm for the participants.
Participants will be asked to participate in an emotional and difficult period, after receiving the diagnosis breast cancer. This may be of some discomfort for the participants. However, it is thought that the participants will have benefit of the intervention and no harm from the control condition because this is usual care.
Participants will be asked to fill out questionnaires three times, this may cause some discomfort because of the time investments they have to make.
Participants will not receive a financial compensation for participating.

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

Women
Diagnosis: breast cancer, ductal
18-40 years old
will soon start treatment for breast cancer
eligible for fertility preservation (probability of POF > 50%, 5-years survival rate >50%, probability of metastasis to the ovaries <0.2%, ductal carcinoma, no previous treatment with chemotherapy, signed informed consent)
Willing to contribute
Internet access at home
In possession of an email address

Exclusion criteria

no access to the internet
recurrent or metastatic tumor
have other cancers than breast cancer
not eligible for fertility preservation

do not have sufficient knowledge of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	19-12-2011
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	22-01-2013
Application type:	Amendment
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	NL32155.058.11