Decision-support for couples with hereditary cancer and child wish: weighing pros and cons of reproductive options regarding transmission of gene mutations.

No registrations found.

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

Summary

ID

NL-OMON22355

Source
NTR

Brief title
GENEA

Health condition

Hereditary cancer, child wish, decision making, risk communication, prenatal diagnosis, preimplantation genetic diagnosis

Sponsors and support

Primary sponsor: Maastricht UMC+
Source(s) of monetary or material Support: Alpe d HuZes/KWF

Intervention

Outcome measures

Primary outcome

Levels of decisional conflict will be assessed by means of the Decisional Conflict Scale (DCS; O¡¯Connor, 1995). The DCS contains 16 items divided into three subscales, measuring uncertainty about selection of alternatives, specific factors contributing to uncertainty, and perceived effectiveness of decision making.

Secondary outcome

Secondary outcomes include knowledge of different reproductive options, accuracy of perceived risks, satisfaction with the decision and the decision making process (e.g., Satisfaction with Decision Scale; Holmes-Rovner et al., 1996), and decision self-efficacy (Decision Self-efficacy Scale; Bunn & O¡¯Connor, 1996). The Multidimensional Measure of Informed Choice (MMIC; Marteau et al., 2001) will be used to assess informed choice. It should be noted that using the MMIC, an informed choice is based on relevant knowledge, is consistent with a person¡¯s values and is behaviourally implemented. As behavioural implementation or adherence to the decision (i.e. uptake of the test or treatment) is unlikely to have occurred for many couples during the study period, only subscales will be used for full analysis. Furthermore, acceptability of the brochures and DA will be assessed by recording whether women used the resource, the time taken to use the resource and how helpful they thought the resource was. For the DA, objective recordings of DA use will be available.

Study description

Study objective

This project will deliver a user-centred evidence-based patient decision aid, supporting couples with hereditary cancer in their decision making regarding fulfilment of their child wish. The decision aid will facilitate couples with an hereditary elevated cancer risk and an active child wish in choosing the most personally suitable reproductive option. As a result, we aim to relieve the exceptional psychological burden regarding reproductive decision making in affected families.

Study design

01-02-2017 untill 01-09-2018

Intervention

A multi-centre randomized controlled trial will be implemented to investigate the efficacy of

the DA. Couples will be randomly allocated to a control group (standard information) and an experimental group (DA). Randomization will take place at the couple level by means of separate randomization schedules for each of the nine participating genetic centres. All randomization schedules will be created using a computer random number generator.

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed genetic mutation for a hereditary cancer syndrome for which PND and PGD are available in the Netherlands. This includes, but is not limited to, the following types of hereditary cancer:

o Hereditary breast and ovarian cancer (HBOC)

o Hereditary colon cancer, e.g. Familial Adenomatous Polyposis (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC/Lynch Syndrome)

o Peutz-Jeghers Syndrome

o Multiple endocrine neoplasia (MEN1/2)

o Retinoblastoma

o Von Hippel Lindau disease

o Li-Fraumeni Syndrome

o Familial Atypical Multiple Mole/Melanoma Syndrome (FAMMM)

- woman in reproductive age (18-40 years)

- active child wish (¡Ü 2 years)

- access to the Internet

Exclusion criteria

- insufficient knowledge of the Dutch language

- pregnancy at time of inclusion

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2017
Enrollment:	256
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-10-2015
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	NL5357
NTR-old	NTR5467
Other	Alpe d'HuZes : UM2013-6374

Study results