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

Gepubliceerd: 21-10-2015 Laatst bijgewerkt: 18-08-2022

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…

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

Samenvatting

ID

NL-OMON22355

Bron
NTR

Verkorte titel
GENEA

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht UMC+
Overige ondersteuning: Alpe d HuZes/KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

01-02-2017 untill 01-09-2018

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- insufficient knowledge of the Dutch language

- pregnancy at time of inclusion

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	256
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2015
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	NL5357
NTR-old	NTR5467
Ander register	Alpe d’HuZes : UM2013-6374

Resultaten