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

Gepubliceerd: 15-04-2021 Laatst bijgewerkt: 18-08-2022

The decision aid will support couples at risk of transmitting a genetic disease to their offspring in their decision-making regarding the fulfillment of their child wish. HP1: The decision aid will lead to a statistically significant decrease of...

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

Samenvatting

ID

NL-OMON25214

Bron
Nationaal Trial Register

Verkorte titel
DS CHild Wish

Aandoening

Hereditary Diseases

Ondersteuning

Primaire sponsor: MUMC+/Maastricht University
Overige ondersteuning: ZonMw.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Decisional conflict. This will be assessed by means of the Decisional Conflict Scale (O'Connor, 1995).

Toelichting onderzoek

Achtergrond van het onderzoek

A nationwide multi-center randomized controlled trial will be implemented to investigate the immediate, short- and long term efficacy of a decision aid (DA) aimed to support couples at risk of transmitting a genetic disease in making a decision regarding reproductive options . Couples will be randomly allocated to a control group (standardized information) and an experimental group (DA).

Doel van het onderzoek

The decision aid will support couples at risk of transmitting a genetic disease to their offspring in their decision-making regarding the fulfillment of their child wish. HP1: The decision aid will lead to a statistically significant decrease of decisional conflict.
HP2: The decision aid will lead to a statistically significant increase in informed decision-making after using the decision aid

Onderzoeksopzet

Baseline (before intervention, T0), immediately after viewing the DA/standardized information intervention, (T1) after 1 month (T2) and after 6 months (T3).

Onderzoeksproduct en/of interventie

Decision aid with written and visual information, including value clarification methods (VCMs).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

One of the partners has an autosomal dominant hereditary condition, an X-linked condition, a chromosomal anomaly or both partners are carrier of an autosomal recessive condition for which all reproductive options are available in the Netherlands, participants should have an active child wish (within 5 years), and the female partner should be of reproductive age (18-41 years). Additionally, couples should have sufficient knowledge of the Dutch language and ample experience with the use of computers and internet.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Being pregnant at time of inclusion.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-05-2021
Aantal proefpersonen:	256
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-04-2021
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	NL9415
Ander register	Issueing body: Medical Ethics Committee Maastricht University Medical Centre +. : Niet-WMO METC 2019-1278

Resultaten

Samenvatting resultaten

We expect to write one publication about the RCT regarding the short- and long term effects of the decision aid on the primary and secondary outcome measures.