Decision support for couples with hereditary diseases 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-OMON25214

Source
Nationaal Trial Register

Brief title
DS CHild Wish

Health condition

Hereditary Diseases

Sponsors and support

Primary sponsor: MUMC+/Maastricht University
Source(s) of monetary or material Support: ZonMw.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcome measures include knowledge and realistic expectations of different reproductive options (e.g. accuracy of perceived risks), deliberation (van den Berg et al., 2006), attitude , joint informed decision-making and preparation for decision making (Bennett et al., 2010). The Multidimensional Measure of Informed Choice (MMIC; Marteau et al., 2001) will be used to assess informed choice.

Study description

Background summary

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).

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

Being pregnant at time of inclusion.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	256
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

Study results

Summary results

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.