Generation R Next intervention study

Published: 12-12-2022
Last updated: 04-06-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53844

Source
ToetsingOnline

Brief title
Generation R Next

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions
- Lifestyle issues

Synonym
Perinatal morbidity and mortality / adverse birth outcomes

Health condition

stress in het dagelijks leven

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW;ministerie van VWS,Bernard van Leer Foundation;Stichting Achmea Gezondheidszorg;Volkskracht;Erasmus MC

Intervention

Keyword: Health, Lifestyle, Preconception, Pregnancy

Outcome measures

Primary outcome

The intervention study will focus on at least one of the following parameters: preterm birth (birth after < 37 weeks of gestational age); low birth weight (< 10th percentile); low Apgar score 5 minutes after birth (Apgar score < 7); high birth weight (>90th percentile). These outcomes are strongly related to perinatal morbidity and mortality and unfavorable long-term outcomes in the child. The occurrence of congenital abnormalities is also strongly related to perinatal mortality. However, given the low prevalence of perinatal death and congenital or serious birth defects, these outcomes are not included in this study. The above data will be obtained from information in medical records.

Secondary outcome

Outcomes in mother: adherence to lifestyle advice / completed lifestyle changes; facilitators / barriers to lifestyle change; sleep/wake rhythm and its improvement; social support (for example from partner); time to pregnancy; miscarriage; weight gain and glucose metabolism during pregnancy; the experienced stress during pregnancy and after childbirth; hypertension during pregnancy; diabetes during pregnancy; breast-feeding; weight maintenance at 6 months and 1 year after delivery.

Outcomes for partner: compliance with lifestyle advice / completed lifestyle adjustments; facilitators / barriers to lifestyle change; sleep/wake rhythm and its improvement; social support (for example from partner); the experienced stress.

Outcomes in child: growth of the child; obesity; behavior; health up to and including 54 months.

Study description

Background summary

Partly on the basis of findings from Generation R, new insights have been developed about the health of (future) parents, reproduction and its effect on the growth and development of the child. Those insights led to the development of consultation hours in the preconceptional phase where woman planning for pregnancy receive advice about lifestyle and health before and during pregnancy.

In line with recent research results, the importance of a healthy weight (BMI: 18.5-25 kg/m2), stopping the use of alcohol/smoking/drugs, supplementing folic acid and vitamin D, and the importance of a healthy diet (weekly fish, iron and vitamin C rich food) are discussed. Reducing feelings of stress also appears to be effective for improving (maternal) health and reducing risk behavior. Mind-body therapy, a combination of yoga exercises and mindfulness, has proven to be a popular intervention, especially among pregnant women or women of childbearing age from various ethnic backgrounds. Small-scale research shows that this form of therapy is widely accepted among this population and has low dropout rates. However, the use of these consultation hours and the given advice regarding lifestyle and health is not yet optimal. This is partly due to the difficulty of reaching (vulnerable) groups, together with the limited insight into the relevance of these recommendations within these groups, the limited scientific support and the demonstrated effectiveness.

Study objective

For this reason, we will conduct an intervention study aimed at promoting the health of (future) parents. The concrete goal of this intervention is to improve the health of (future) parents by optimizing lifestyle in the preconception period and early pregnancy to improve birth outcomes and

long-term outcomes in mother and child. The Generation R Next intervention study will be embedded in the available Generation R Next research infrastructure with data collection in line with Generation R Next (MEC-2016-589; NL57828.078.16).

Study design

We will include (future) parents in a randomized controlled trial. Inclusion is possible in the preconception period or in the first trimester of pregnancy (gestational age < 11 weeks). Follow-up will initially be planned up to and including the child's age of 54 months. The ambition is to follow the parents and children for a long time.

Intervention

After randomization, there will be two groups: the intervention group and the control group. The intervention group will attend three group sessions (online or physical, depending on the current covid-19 measures) focusing on national advice for health during preconception and early pregnancy, coping with stress and adherence to a healthy(er) lifestyle. They also receive advice regarding a diet with a focus on products with a low glycemic index. Compliance with the prescribed advice is encouraged via a digital platform. Prior to the intervention, the intervention and control group will be offered an individual lifestyle consultation in line with current national advice for preconception and early pregnancy.

Study burden and risks

Participation in the study may result in a burden in time because of the time investment (i.e. filling out large questionnaires) and inconvenience that comes with the performed measurements, such as with a blood sample. The risks of venipuncture (invasive) are negligible as it is a standard procedure that will be performed by trained staff. If participants do not agree with a vaginal ultrasound, an abdominal ultrasound will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Women and their partners:
* Planning a pregnancy or early pregnancy up to < 11 weeks;
* With the presence of at least one of the predetermined risk factors;
* Residential address in the municipality of Rotterdam and expected residential address in the municipality of Rotterdam at the birth of their child;
* Sufficient command of the Dutch language;
* Consent for participation in Generation R Next intervention study.

Exclusion criteria

* Temporary or complete withdrawal from participation;
* Gestational age >= 11+0 at study entry.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2023
Enrollment:	1750
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT05870878
CCMO	NL81446.078.22