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Effectiveness of a diet information website targeting young adults before parenthood

Submission date
31/01/2021

Recruitment status
No longer recruiting

Registration date
04/02/2021

Overall study status
Ongoing

Last Edited
23/05/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-communicable diseases (NCDs) such as obesity, type 2 diabetes, cardiovascular disease, cancer, and mental disorders, account for 85-90% of the disease burden in Norway. NCDs are complex diseases that are difficult and costly to treat, so identifying better strategies for primary prevention is crucial. Poor diet is a leading cause of NCDs, with a pronounced difference in diet quality across socioeconomic groups. Diet is especially important in early developmental phases, such as the first thousand days of life, but recent research indicates that diet before conception might be foundational for child development and health. There is limited information on how preconception diet is linked to health in the next generation, whether and to which degree maternal vs paternal dietary influences differ in this respect, and when preconception diet should be targeted to effectively promote long-term health. Recent publications highlight the window of opportunity that preconception phases represent for health in the next generation and specifically the importance of preconception diet. Digital interventions have the advantage of being cheap and having exceptional reach into populations hard to engage in research, and therefore a unique potential to address and reduce social inequalities in health. The aim of this study is to develop, implement and evaluate a digital intervention targeting diet aiming to promote a healthy preconception diet that may benefit subsequent pregnancies with the potential to promote newborn health and development.

Who can participate?
Men and women, aged 20-35, with no prior biological children

What does the study involve?
The participants will be randomly allocated to either the control or intervention group. The control group will not be given access to the intervention website, nor any other information, other than being asked to respond to follow-up questionnaires. The intervention group will be given access to a website providing messages on the importance of diet and how to improve diet each week for 6 months. The researchers will track participants until the birth of their first child and assess measures of maternal health. They will also assess newborn size at birth as an indicator of health.

What are the possible benefits and risks of participating?
The possible benefits include improved diet, improved quality of life and good health of prospective children. Due to the non-intrusive educational design of the intervention the researchers do not expect adverse events directly attributable to the intervention. Unintended effects could relate to participants' concern about diet, e.g., disordered eating or eating disorders. The researchers will, however, take care to communicate diet-health messages in a sober manner.

Where is the study run from?
University of Agder (Norway)

When is the study starting and how long is it expected to run for?
The pilot started August 2021 and the main study is to start October 2021 and will last to April 2041

Who is funding the study?
University of Agder (Norway)

Who is the main contact?
Prof. Nina C. Øverby
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Effectiveness of a web-based dietary intervention program targeting young adults prior to parenthood: a randomized controlled trial (PREPARED)

Acronym
PREPARED

Study objectives
H1: 6 months of access to a digital dietary learning tool will improve male and female knowledge and skills in relation to diet and lead to healthier dietary behavior compared to a control group with no such access.
H2: 6 months of access to a digital dietary learning tool will lead to larger improvements in diet and quality of life post-intervention compared to a control group with no such access.
H3: Subsequent children of men and women with preconception access to the digital dietary learning tool, will have a lower prevalence of low (< 2500 g) and high (>4500 g) birthweight and of being small- or large for gestational age (SGA or LGA, respectively) than children of parents without such access.
H4: Pregnant women with preconception access to a digital dietary learning tool will have a lower risk of excessive gestational weight gain, gestational diabetes, preeclampsia and preterm delivery compared to pregnant women without such access.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 11/08/2020, Regional Committees for Medical and Health Research Ethics (Regional Etisk komite Sør øst B, Gullhaugveien 1-3, 0484 Oslo, Norway; +47 (0)22845511; rek-sorost@medisin.uio.no), ref: 78104
2. Approved 18/09/2020, Norwegian centre for research data (Norsk senter for forskningsdata AS, Harald Hårfagres gate 29, N-5007 Bergen, Norway; +47 (0)55 58 21 17 (# 1); Oyvind.straume@nsd.no), ref: NSD: 907212
3. Approved 17/11/2020, Faculty of Health and Sport Sciences ethics committee (University of Agder, PO 422, N-4604 Kristiansand, Norway; +47 (0)38141000; anne.skisland@uia.no), ref: FEC 20/10119

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of pregnancy risk outcomes and neonatal risk outcomes in the general population aged 20-35 years

Interventions
Current interventions as of 21/09/2021:

In this project the researchers will develop, implement and evaluate a digital intervention targeting diet aiming to promote a healthy preconception diet that may benefit fetal conditions in subsequent pregnancies with the potential to promote fetal and neonatal health and development. The intervention will target both men and women individually, with a special focus on reaching men due to the less communicated relevance of male preconception diet for the health of prospective children. Participants will be randomised, according to a predefined list, after they have filled in baseline data (questionnaires and food registrations), into either the intervention or the control group. The control group will not be given access to the intervention website, nor any other information, except information on the importance of control groups for research, and that they will be asked to respond to follow up questionnaires. The intervention group will be given access to a website with information about the importance of diet in different stages of life. Every week new messages will be given of the importance of diet and how to improve diet for 6 months.

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Previous interventions:

In this project the researchers will develop, implement and evaluate a digital intervention targeting diet aiming to promote a healthy preconception diet that may benefit fetal conditions in subsequent pregnancies with the potential to promote fetal and neonatal health and development. The intervention will target both men and women, with a special focus on reaching men due to the less communicated relevance of male preconception diet for the health of prospective children. Participants will be randomised, according to a predefined list, after they have filled in baseline data (questionnaires and food registrations), into either the intervention or the control group. The control group will not be given access to the intervention website, nor any other information, other than being asked to respond to follow up questionnaires. The intervention group will be given access to a website with information about the importance of diet in different stages of life. Every week new messages will be given of the importance of diet and how to improve diet for 6 months.

Intervention Type
Behavioural

Primary outcome(s)
Preconception diet (overall diet and diet quality) measured by food and nutrient intake and diet scores at baseline, and at 6 and 12 months follow up and in a short questionnaire every year until the first child is born

Key secondary outcome(s))
Current secondary outcome measures as of 21/09/2021:

All data retrieved from the Medical Birth Registry, Norway:
1. Preconception quality of life measured by RAND 12 and Satisfaction with life scale at baseline and every follow-up
2. Pregnancy health data retrieved from the Medical Birth Registry, Norway after the future first child is born:
2.1. Gestational weight gain (GWG)
2.2. Preeclampsia
2.3. Gestational diabetes (GDM)
2.4. Preterm delivery
2.5. Hypertensive disorders in pregnancy
3. Neonatal health data retrieved from the Medical Birth Registry, Norway after the future first child is born:
3.1. Birth weight, length and head circumference
3.2. LGA/SGA
3.3. Birthweight ≥4000 g
3.4. Ponderal index (kg/cm^3)

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Previous secondary outcome measures:

All data retrieved from the Medical Birth Registry, Norway:
1. Preconception quality of life measured by SF-12 at baseline and then at every follow-up
2. Pregnancy health data retrieved from the Medical Birth Registry, Norway after the future first child is born:
2.1. Gestational weight gain (GWG)
2.2. Preeclampsia
2.3. Gestational diabetes (GDM)
2.4. Preterm delivery
2.5. Hypertensive disorders in pregnancy
3. Neonatal health data retrieved from the Medical Birth Registry, Norway after the future first child is born:
3.1. Birth weight, length and head circumference
3.2. LGA/SGA
3.3. Birthweight ≥4000 g
3.4. Ponderal index (kg/cm^3)

Completion date
30/04/2041

Eligibility

Key inclusion criteria
1. Born in the years 1986-2001
2. Have no biological children

3. Possess an 11-digit identification number
4. Literate in Norwegian
5. Have access to a smartphone or another digital device

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Biological parent already
2. Not literate in Norwegian or another Scandinavian language
3. Not in possession of a Norwegian personal identification number

Date of first enrolment
15/10/2021

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
Norway

Study participating centre
University of Agder
PO 422
Kristiansand
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4604

Sponsor information

Organisation
University of Agder

ROR

https://ror.org/03x297z98

Funder(s)

Funder type
University/education

Funder Name
Universitetet i Agder

Alternative Name(s)
University of Agder, UiA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
We plan to share anonymized data in the UiA deposit Dataverse, this will be done no later than acceptance for publication of the main findings from the final dataset. We will retain our data for 5 years after data collection has stopped (meaning that data from our baseline will be available at least in 2027 or upon publication of main findings). Standard meta-information about the data will be uploaded.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/12/2021	03/12/2021	Yes	No
Participant information sheet			01/03/2021	No	Yes