DIY health monitoring and simulation of health in pregnant women: a pilot study

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Primary Objective: To determine the feasibility of DIY studies in pregnant women to detect changes in health parameters, by:a. assessing the compliance of participants with the study protocol (number of complete total datasets as well as per...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44770

Source
ToetsingOnline

Brief title
oPTiMuM (PreganT Moms Measure)

Condition

- Other condition

Synonym
healthy child-bearing; healthy pregnancy

Health condition

gezonde zwangerschap

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: do-it-yourself research, maternal health, obesity, pregnancy

Outcome measures

Primary outcome

We will evaluate the feasibility of DIY-studies with pregnant women by the percentage of complete datasets. This should be at least 80% for each participant. Besides, the percentage of useful datasets for each individual device, questionnaire or test should be at least 80% to be considered eligible for do-it-yourself studies (compliance).

Capability of and burden for participants of the use of DIY tools will be assessed with a questionnaire and potentially an extra evaluation during the closing visit with the researcher (Spaarne Hospital). This will encompass questions on how often the devices are used, the context in which the device is used, the satisfaction of the user with the device and the effects of the device on user behaviour.

Secondary outcome

We will also focus on determining differences in health parameters over time driven by overweight. This will be done by comparing the measured health parameters of lean with obese pregnant women and by comparing these data with health outcomes of mother and child (as measured by the midwife).

Additionally, we will apply a network biology approach to identify clusters of correlating maternal health parameters and oral and intestinal microbiota composition parameters.

The included health parameters are body weight (BW), physical activity (PA), food intake (FI), GPS-location, fasting plasma glucose (FPG), glucose response profile, insulin/c-peptide response profile, total cholesterol (TC) and triglycerides (TG), blood pressure (heart rate, systolic blood pressure and diastolic blood pressure), cognition, faecal and salivary microbiota composition, blood biomarkers (including but not restricted to fatty acids and HbA1c) and cortisol.

The subjects will also fill out online-questionnaires vitality (Vita-16) and sleep (Groninger Sleep Scale) and VAS Health Scale at four to five moments during the study (W16, W24, W32, W40 and optional in W52). At W40-52 women will be asked to fill out two questionnaire on acceptable and desirable health measurements on their babies (for the follow-up study).

Finally, in this study also measures by the midwife/gynaecologist during control visits will be included in the study database as reference value for healthy development of mother and child during pregnancy. Measures of the mother during the control visits (8-10 weeks, 20 weeks, 30 weeks) that will be included are weight, blood pressure, blood glucose and HbA1c.
Measures of the child that will be included are the measures done during the

echoes (20-weeks and other if applicable) by the midwife. These echo-forms include the following data: CRL (Crown, Rump, Length), BPD (Bipariëtale Diameter), HC (head circumference), TCD (Trans Cerebellair Diameter), AC (abdominal circumference), EFW (estimated fetal weight), heart and heart-action, location of the placenta, Vrw (amniotic), tractus gastro-intestinalis, tractus uro-genitalis, abdominal wall, thorax shape, CNS (central nervous system), face. Additionally, birth weight, apgar score, delivery term, length and type of labour (natural delivery or caesarean section) will be included.

Study description

Background summary

The 1,000 days from the start of a woman*s pregnancy until her child*s 2nd birthday offer a unique window of opportunity to shape healthier and more prosperous futures for the child. An important part of these first 1,000 days of life is the pregnancy itself. Impaired health states in pregnant women are associated with negative pregnancy outcomes as well as with negative health outcomes for both mother and child. It has been well established that pregnant women are motivated towards a healthy diet and lifestyle when provided appropriate advice. To optimally align advice on a healthy life style and diet and to the individual, it is key to empower the individual to monitor its own health. Smartphone apps, Quantified Self devices and self-tests give individuals the opportunity to measure several aspects of health with increasing accuracy, like food intake, body weight, blood pressure and physical activity. The data that is garnered through the use of Do-It-Yourself tools can be used to identify relations between health parameters during pregnancy on the one hand, and to empower pregnant women to make healthy life style choices on the other hand.

Study objective

Primary Objective:
To determine the feasibility of DIY studies in pregnant women to detect changes in health parameters, by:

a. assessing the compliance of participants with the study protocol (number of complete total datasets as well as per measurement)
b. assessing the capability of and burden for participants of the use of these DIY tools (user experiences)

Secondary Objective(s):
Besides assessing the feasibility of do-it-yourself research in pregnant women, we have underlying scientific objectives. Since this is a pilot study, these objectives are of a more exploratory nature:
- To identify the integrated differences in physiological development between obese (BMI * 30) and lean (BMI 18,5 - 25) pregnant women and their effects on the health status of the baby
- To gain insight in the usability of do-it-yourself monitoring for early detection of deviations in health parameters
- To test the hypothesis that the gut and saliva microbiota composition differs in obese (BMI * 30) pregnant women compared with normal-weight (BMI 18,5 - 25) pregnant women and is further associated with physiological development during pregnancy.

Study design

The study is designed as an open, parallel, do-it-yourself, explorative, two-group study. Subjects are women who are pregnant for approximately 3 months at the start of the study. Subjects will be included between week 12 and 18 of their pregnancy. Week 16-18 is the start of the study (T=0). In the first group obese pregnant women (BMI * 30) will be included; the second group will consist of lean pregnant women (BMI 18,5 - 25).
The women will be requested to assess physiological parameters at regular intervals from three months pregnancy until giving birth; and optionally until three months after giving birth (total study duration of approximately six and optionally nine months).
Health parameters are known to be subject to change in pregnant women; the self-monitoring devices should be able to show these changes. Included subjects will be provided with the do-it-yourself devices, manuals and the study protocol. During the study, the subjects will use these do-it-yourself devices to self-monitor multiple health parameters in an at-home setting. They will be reminded to perform these tests via notifications on the tablet. There are two frequency intervals defined (two week interval and eight week interval).

Intervention

The intervention in this study will consist of the use of do-it-yourself devices and sample collection kits for self-monitoring health parameters in an at-home setting.
The included devices are an activity tracker (Activ8), a blood pressure monitor (Medisana MTX), a blood glucose meter (Medisana MediTouch 2), a smart scale

(FitBit Aria), a cholesterol meter (Mission Cholesterol 3-1 meter) and a centimetre.
The do-it-yourself sample collection kits that will be used, include saliva, urine, faeces, smell identification, bitter taste, hair and dry blood spot sampling kits. The do-it-yourself questionnaires include the VAS score, POMS, Vita-16, physical performance, Sleep and Inquisit tests.
Subjects will be supplied with these devices and kits upon inclusion in the pilot study.
Devices have to be handed in again at the end of the study. Additionally, subjects will be given access to a food intake application Mijn Eetmeter.

Study burden and risks

Data collection will be primarily based on *do-it-yourself* non-invasive or minimally invasive methods. These data will be delivered by the participant to their online portal. For some health parameters, participants will send their samples to labs for analysis; in this case, the lab will be responsible for uploading the data to the portal. We do not foresee any health risks in using the do-it-yourself methods for measuring health parameters. All methods have been used in previous studies and most are commercially available, and are therefore, with normal use, considered safe. Data of the study will be uploaded to the online NRC portal by an account created for the study-participant. Personal data and research data are stored in separate databases. Research data is stored pseudonymized, such that researchers that analyze the data cannot connect data to an individual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Pregnant between 12-18 weeks at the start of the study;
2. Women must be able to speak, write and read in Dutch;
3. Healthy as assessed by the Health and Lifestyle questionnaire (P9624 F02);
4. Body mass index:
- BMI 18,5 - 25 for the lean group
- BMI * 30 for the obese group;
5. Able to use self-monitoring devices;
6. Voluntary participation;
7. Having given written informed consent;
8. Willing to comply with study procedures;
9. Willingness to share pseudonymised data on measured health parameters with external parties that provide the measuring devices (including MijnEetmeter, Moves and NRC) for reasons of synchronisation with the study database;
10. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data by TNO;
11. Have internet access at home;
12. Subjects should own a Smartphone that runs either a recent version of iOS or Android.

Exclusion criteria

1. Use of concomitant medication;
2. Having a history of medical or surgical events that may significantly affect the study outcome, including physical limitations or cardio-vascular events;
3. Having a (history of a) medical condition that might significantly affect the study outcome as judged by the principal investigator and health and life style questionnaire. This includes diabetes type 1 or 2, gastrointestinal dysfunction, diseases related to inflammation, or a psychiatric disorder;

4. Hypertension: systolic blood pressure >160 mmHg, diastolic blood pressure >90 mmHg;
5. Having a pacemaker;
6. Previous pregnancy with medical issues (e.g. pre-eclampsia);
7. Reported slimming or medically prescribed diet;
8. Physical, mental or practical limitations in using computerized systems;
9. Alcohol consumption > 14 units (drinks)/week;
10. Smoking;
11. Reported unexplained weight loss or gain of > 2 kg in the three months prior to the pre-study screening / pregnancy;
12. Recent blood donation (<1 month prior to the start of the study);
13. Not willing to give up blood donation during the study;
14. Personnel of TNO and their partner.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-09-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	20-08-2015
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	09-03-2016

Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	19-09-2017
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
CCMO	NL52707.094.15