Cost-effectiveness of lifestyle care tailored to pregnant women with obesity during this critical period and window of opportunity in the life course: The HYGEIA randomised controlled trial.

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

Summary

ID

NL-OMON57196

Source
ToetsingOnline

Brief title
HYGEIA RCT

Condition

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

Synonym
Gestation and obesity, pregnancy and obesity

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW Leefstijl en Zorg

Intervention

Keyword: ehealth., lifestyle, Obesity, pregnant

Outcome measures

Primary outcome

The primary composite outcome used for the effectiveness is incidence of CVMD

(hypertensive pregnancy complications, chronic hypertension, diabetes

gravidarum, type I and II diabetes) during the 12 months study period.

Secondary outcome

Secondary outcomes are maternal outcomes, neonatal outcomes, cost-effectiveness.

Tertiary outcomes are user satisfaction, reimbursement and implementation

roadmaps.

Study description

Background summary

Obesity is a chronic disease and is associated with cardiovascular and metabolic disease (CVMD) as comorbidities. (1) Pregnancy is a stressor for the cardiovascular and metabolic health of the mother in general, and in particular in obese women. Around 50% of pregnant women is overweight or obese, with 25% developing the CVMD symptoms during pregnancy, and face a 10-fold higher risk of CVMD within 10 years after pregnancy. (2) Since a poor lifestyle and a poor living environment are known risk factors for CVMD(3, 4), lifestyle care integrated in pregnancy care and involving the partner is a promising approach

for the sec-ondary prevention of CVMD and other obesity-related complications during this critical phase of life. Integration of lifestyle care in pregnancy care for obese women faces three main chal-lenges: 1) Sustainable adoption of healthy lifestyle behaviour through an intervention that is inclusive and considers the own living environment, health and digital literacy and socio-economic status (SES); 2) Implementation of the intervention in the pregnancy care system while avoiding increase of workload for healthcare providers (HCPs); and 3) Convincing evi-dence to justify reimbursement of the lifestyle intervention by national health care insurances. We present SmarterPregnancy+ (SP+), a digital lifestyle care path opti-mised for women with obesity, as a solution. SP+ supports a sustainable behavioural change through lifestyle and exercise-promoting nudging. Here, we aim to demonstrate the cost-effectiveness of this solution in the Dutch pregnancy care system and pave the way towards national reimbursement within the basic health insurance package and implementation.

Study objective

Main objective is to assess the effectiveness of SP+ in an almost real-life setting of a randomised controlled trial (RCT) in 930 women with obesity, using CVMD-score as primary outcome measurement.
Secondary aim is to assess the cost-effectiveness of SP+. Tertiary aim is to develop a roadmap for reimbursement and implementation together with stakeholders in which technological and end-user conditions for use of SP+ as a digital intervention in the Dutch pregnancy care system will be set, and the requirements, barriers and facilitators for imple-mentation, adoption and sustainability will be assessed, defined and laid down in a budget im-pact analysis.

Study design

A randomised controlled trial, conducted at a primary, secondary and tertiary pregnancy care setting.

Intervention

The intervention group receives SP+, while the control group receives Care as Usual.

Intervention: The 6-month lifestyle care path SP+ involves coaching on healthy nutrition, folic acid and vitamin D supplement use, physical activity, mental health and stop smoking and alcohol use, optimized according to the needs and values of these women with obesity and vulnerable conditions. The intervention uses the already existing program Smarter Pregnancy (SP) as starting point. SP will be transformed into a mobile application, with a complete revision and adaptation tailored for women with obesity (and their partner).This includes

adjustments in language, behavior change techniques, and content within the app. Existing modules focused on fruit, vegetable, folic acid, alcohol, and tobacco intake are being expanded to include modules on physical activity and mental health. New functionalities are also being added, such as a read-aloud feature, a habit diary for tracking personal habits, videos, exercises, and more background information on healthy habits. Furthermore, information, questions and tips will be rewritten and provided via push message and users will be given the opportunity to personalize the frequency and timing of these messages. This will be combined with one or two video coaching sessions with a research team member in which users can ask questions and receive additional advice.

Control: the control group receives standard of care, which might include information on lifestyle. This group does not receive SP+ or video coaching. Information on lifestyle (and other study out-comes) will be obtained through Castor.

Study burden and risks

Since this intervention solely consists of lifestyle coaching, the risks are negligible and the burden minimal. In addition, the intervention is based on the non-invasive, certified and publicly available website Slimmer Zwanger (www.slimmerzwanger.nl or www.smarterpregnancy.co.uk). This program has been recognized as cost-effective and safe in changing lifestyle habits by the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) in 2020 (5) based on the results of prior studies. (6-13) The current intervention is an improved, extended and adjusted version of this program for women with obesity and will focus on pregnancy outcomes.

The total duration of participation is 52 weeks. In this period, the intervention group will re-ceive 6 months of SP+. A detailed description of the content of SP+ can be found in section 5.1 in this protocol. In summary its content includes a 5-minute baseline screening on person-al conditions (e.g., gender, age, pregnancy state, gestational age, body mass index, zip code) and lifestyle (nutrition, folic acid, alcohol, smoking, physical exercise, mental health). Based on these conditions and lifestyle behaviors, the algorithm generates a personalized coaching path of 6 months which is complemented by one or two video-coaching sessions. To assess the change of the lifestyle behaviors and habits, participants receive a 5-minute monitoring questionnaire at t= 6, 12, 18 and 26 weeks and at the end of the RCT at week 52.

To assess the costs, quality of life and behavioral change, participants will receive 20 to 30-minute study questionnaires at three time points, see figure 1 and 2 for details. Furthermore, medical files will be requested. In addition, a selection of ±20 women will be followed during their patient journey and asked to participate in interviews and focus groups. For this selec-tion of women, the consumption of care and interaction with HCPs will also be timed. Health

care providers and stakeholders will also be asked to participate in interviews and focus groups.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in target group 1, a subject must meet all the following criteria. Women are eligible to participate if:
- they are above 18 years of age,
- they have a body mass index (BMI) >=30 (BMI is classified according to World Health Organization criteria for adults)
- they have a singleton pregnancy of less than 3 months,
- they have sufficient understanding of the Dutch or English language,
- they have access to a smartphone or tablet,
- they have provided informed consent for participation.

The partner of the women randomized in the intervention group be invited to participate to involve the close living environment of the woman (intrinsic and extrinsic motivation). The participation of the partner is voluntary. Partners are eligible to participate if:
- they are partner of a participating pregnant woman in the intervention group
- they are above 18 years of age,
- they have sufficient understanding of the Dutch or English language,
- they have provided informed consent for participation (PIF partners).

Health care providers for target group 2 are eligible if they are involved in the implementation of SP+ and obstetric care. Stakeholders are invited based on their expertise on SP+, technology in general and obesity care. They must provide informed consent for participation after reading the patient information folder.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- not able to give written informed consent
- insufficient understanding of the Dutch or English language.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	1435
Type:	Anticipated

Ethics review

Approved WMO Date:	19-12-2024
Application type:	First submission
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
CCMO	NL87213.078.24