Subject Information for participation in medical-scientific Research

Digital lifestyle coaching for pregnant women with obesity: the HYGEIA-trial

Cost-effectiveness of tailored lifestyle care for pregnant women with obesity in this critical and promising period of life: The HYGEIA Randomized Trial.

Introduction

Dear Madam,

With this information letter, we would like to ask if you would like to participate in medical-scientific research for which you do not need to come to the hospital additionally. Participation is voluntary. You are receiving this letter because you are pregnant and have a body mass index (BMI) of 30 or higher.

Here you will read what the research is about, what it means for you, and what the advantages and disadvantages are. It is a lot of information. Would you like to read the information and decide if you want to participate? If you want to participate, you can fill out the form found in Appendix C. If you have registered via the website (www.slimmerzwangeronderzoek.nl/en) and/or only had telephone contact with the researchers, you will receive an invitation via email to sign this form digitally. How this works is explained in Appendix D. If you do not find this convenient, you can indicate this so that we can still make an appointment for signing.

Ask your questions

You can make your decision with the information found in this information letter. Additionally, we recommend you do the following:

- Ask questions to the researcher who provided you with this information.
- Talk to your partner, family, or friends about this research.
- Ask questions to the independent expert. For contact details, see Appendix A.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

1. General information

The Department of Obstetrics and Gynaecology of Erasmus MC has set up this research. Below, we will refer to Erasmus MC as the 'sponsor'. Researchers, who can also be doctors or research assistants, conduct the research at Erasmus MC, IJsselland Hospital, Reinier de Graaf Gasthuis, and Erasmus University.

Participants in medical-scientific research are often called subjects. Both patients and healthy people can be subjects. A total of 930 women and up to 465 partners will participate in this research. The medical-ethical review committee of Erasmus MC has approved this research.

2. What is the Purpose of the Research?

In this research, we examine whether the digital personal coaching program Smarter Pregnancy Plus (Slimmer Zwanger Plus in Dutch), hereinafter referred to as SP+, can help improve dietary and lifestyle habits in pregnant women with obesity, reduce stress, and lower the risk of problems during pregnancy. We compare the effectiveness of Smarter Pregnancy Plus with normal pregnancy care.

3. What is the Background of the Research?

Overweight and obesity are becoming more common. Obesity is defined as a body mass index (BMI) of 30 or higher. Obesity increases the risk of certain problems and diseases, including cardiovascular diseases and metabolic diseases such as diabetes. Women with obesity have an increased risk of problems during pregnancy. These can be problems for the mother, such as high blood pressure, preeclampsia, and gestational diabetes. Women with obesity also have an increased risk of problems for the baby, such as miscarriage, growth problems, or congenital abnormalities. Obesity can have multiple causes, including an unhealthy lifestyle or environment. Lifestyle improvement can help reduce the risk of problems during pregnancy and later in life, both for the mother and the baby.

In this research, we want to study whether Smarter Pregnancy Plus can help improve lifestyle and reduce the risk of problems during pregnancy.

4. How Does the Research Proceed?

How Long Does the Research Last?

If you participate in the research, it will last for a total of one year. What participation entails is explained further below.

Step 1: Are You Eligible to Participate?

We first want to know if you are eligible to participate. You can participate in the research if you are 18 years or older, less than 14 weeks pregnant with one baby, and have a body mass index (BMI) of 30 or higher. You can calculate your BMI yourself at https://www.diabetes.ca/resources/tools-resources/body-mass-index-(bmi)-calculator. Additionally, it is important that you can read and speak Dutch or English sufficiently to understand the information and that you have a mobile phone (smartphone) or tablet on which you can use the SP+ app.

Step 2: The Program

For this research, we create 2 groups:

- Group 1: The people in this group receive the Smarter Pregnancy Plus app. This group is called the intervention group.

- Group 2: The people in this group do not receive an app. This group is called the control group.

Randomization determines which group you are in. The researcher will tell you which group you are in. Your healthcare provider(s) and/or the researchers have no influence on the outcome of the randomization. After randomization, it cannot be changed which group you are in.

Step 3: Research and Measurements

You do not need to come to the hospital (extra) for the research. Everything is done digitally. After signing the consent form, you will be randomized, and the research will begin. What the research entails depends on the group you are randomized into and is explained below. In Appendix B, you will see a schematic overview of what participation entails.

Group 1, the Intervention Group with the Smarter Pregnancy Plus Program

You will receive your normal pregnancy check-ups, the Smarter Pregnancy Plus app, and lifestyle coaching. This consists of information and messages via the app and one or two video consultations with a researcher where you can ask questions or receive additional advice. The first video consultation is scheduled when you register. After this conversation, you can indicate if you want another conversation later.

You will receive a short questionnaire about your lifestyle via the app at the start of the research and after 6, 12, 18, 26, and 52 weeks. In total, 6 times. Filling it out takes about 5 minutes each time. After that, you will receive personal advice based on your answers.
You will receive a long questionnaire at the start of the research and after approximately 6 moths (at 36 weeks gestation) and 12 months. In total, 3 times. Filling it out takes about 20 to 30 minutes each time. Your partner can also participate. You can indicate at your registration if your partner wants to participate. If you are randomized into this group, we will also ask your partner to sign a consent form. After that, your partner can download their own app with advice tailored to their lifestyle. Your partner can also join the video consultation.

Group 2, the Control Group

You will receive your normal pregnancy check-ups. Your midwife and/or gynaecologist may discuss lifestyle with you. You will not receive any additional treatment or coaching (no app or video consultations). You will receive a long questionnaire at the start of the research and after approximately 6 months (at 36 weeks gestation) and 12 months. In total, 3 times. Filling it out takes about 20 to 30 minutes each time. You will receive a short questionnaire after 12 weeks. Filling it out takes about 5 minutes.
Your partner cannot participate.

Both Groups

We request the file about your pregnancy, delivery, and the period up to 1 year after delivery from your midwife and/or gynecologist and from the national organization Perined (a collaboration of organizations involved in obstetric care in the Netherlands) to collect data such as blood test results (including the sugar test), blood pressure measurements, ultrasound examinations, and the course of pregnancy and delivery. No additional measurements are done for the research. We also want to request medication data from your pharmacy.

For some participants, a small amount (about 20 milliliters) of blood will be taken at the start of the research and after 26 weeks. This is done to measure certain substances in the blood, such as sugar and cholesterol. On the consent form, you can indicate if you agree with this. If you are selected for blood draws, the researcher will schedule an appointment with you at the hospital.

Some participants will be asked to participate in interviews and group discussions. This takes a total of three to five hours. On the consent form, you can indicate if we may contact you for this. This is not a fixed part but a choice. You will receive an additional information letter if you indicate that you may be contacted for this.

What is Different from Regular Care?

There is not much different from regular care in this research. The pregnancy check-ups are done by your own midwife and/or gynaecologist. These check-ups do not change if you participate in the research. If you participate, we will send a letter to your midwife and/or gynaecologist to inform them that you are participating in this study.

5. What Agreements Do We Make with You?

We would like the research to go well. Therefore, we make the following agreements with you:

- You use the program in the way the researcher explained to you.
- You fill out the questionnaires.
- You contact the researcher in these situations:
  - You have a miscarriage or stillbirth.
  - You no longer want to participate in the research.
  - Your phone number, address, or email address changes.

6. What Side Effects, Adverse Effects, or Discomforts Might You Experience?

There are no risks associated with participating in this research for you or your unborn baby. If you participate in the blood draws, it can be painful or cause a bruise.

7. What Are the Advantages and Disadvantages of Participating in the Research?

Participating in the research can have advantages and disadvantages. Below we list them. Think carefully about this and talk about it with others.

If you are in the intervention group (group 1), the advantage of participating is that you get free access to the Smarter Pregnancy Plus program. Normally, there are costs associated with this.
If you succeed in changing your habits with the help of the program, it is a health benefit for you. The behavioural changes achieved may have a positive effect on the course and outcome of your pregnancy. However, participation in the research does not guarantee having a healthy child.

Additionally, your participation makes an important contribution to research on lifestyle in pregnant women with obesity. This can help future parents and children.

Participating can have these potential disadvantages or consequences:

- Participating in the research takes extra time.
- If you do not succeed in changing certain habits, this can be considered a disadvantage. Additionally, the extra information about risk factors and the advice you receive may cause a certain degree of tension.

Do You Not Want to Participate?
You decide whether you want to participate in the research. If you do not want to participate, you will receive the usual treatment for your pregnancy.

8. When Does the Research End?

The researcher will inform you if new information about the research becomes available that is important to you. The researcher will then ask if you want to continue participating.

The Research ends for you in these situations:

- All studies according to the schedule are completed.
- You want to stop participating in the research. You can do this at any time. Inform the researcher immediately. You do not need to explain why you want to stop.
- The researcher thinks it is better for you to stop.
- One of the following institutions decides that the research must stop:
  - Erasmus MC
  - The government, or
  - The medical-ethical committee that reviewed the research.

What Happens If You Stop Participating in the Research?
The researchers will use the data and blood collected up to the point of stopping.

The entire research is completed when all participants are finished.

9. What Happens After the Research?

If you are in the intervention group (group 1), your use of the Smarter Pregnancy Plus program will stop after 6 months. You can still view the previously given advice, but you will no longer receive new advice. Six months later, you will receive the final questionnaire.

About a year after the research is completed, the researcher will inform you of the main outcomes of the research.

10. What Do We Do with Your Data?

If you participate in the research, you also give permission to collect, use, and store your data and blood. You can give separate permission for the collection of blood on the consent form. This is **not** mandatory.

What Data Do We Store?

We store the following data:

- Your name, date of birth, address, and nationality.
- Data about your health and pregnancy.
- (Medical) data collected during the research.
- All answers to the questionnaires.
- Usage data of the app.

What Body Material Do We Store?

We collect, use, and store blood samples if you give permission for this.

Why Do We Collect, Use, and Store Your Data and Blood?

We collect, use, and store your data and possibly your blood to answer the research questions of this study and to publish the results.

How Do We Protect Your Privacy?

To protect your privacy, we give your data and body material a code. We only put this code on all your data and body material. We keep the key to the code in a secure place in the hospital. When we process your data and body material, we only use that code. In reports and publications about the research, no one can trace that it was about you.

In this research, we collaborate with other parties, the so-called HYGEIA consortium (see Appendix E). We also share the coded data with them.

Who Can See Your Data?

Some people can see your name and other personal data without a code. These can be data specifically collected for this research, but also data from your medical file. These are people who check whether the researchers are conducting the research properly and reliably. These people can access your data:

- Members of the committee that monitors the safety of the research.
- An auditor hired by the researcher.
- National supervisory authorities.

These people keep your data confidential. We ask for your permission to allow these people to access your data. The Health and Youth Care Inspectorate can access your data without your permission. The researchers are obliged to cooperate with this to ensure the safety of the research.

How Long Do We Store Your Data and Body Material?
We store your data, including the data collected with the app, for 15 years after the research ends at Erasmus MC. We store your blood at Erasmus MC. Your data is stored to allow for new determinations related to this research during the course of the study. Once this is no longer necessary, we will destroy your data and body material.

May We Use Your Data and Body Material for Other Research?
Your collected data may also be of interest for other scientific research in the field of obstetric care, lifestyle, or obesity. For this purpose, your data will be stored at Erasmus MC for 15 years after the end of the study. In the consent form, you indicate whether you agree with this. If you do not give permission, you can still participate in this study. You will receive the same care.

What Happens in Case of Unexpected Discoveries?
During the research, we may accidentally find something that is not directly relevant to the research but is important for your health or the health of your child. The researcher will then contact you or your general practitioner, midwife, or specialist. You will discuss with your general practitioner, midwife, or specialist what needs to be done. The costs of this fall under your own health insurance. By signing the form, you give permission to inform your general practitioner, midwife, or specialist.

Can You Withdraw Your Consent fort he Use of Your Data?
You can withdraw your consent for the use of your data at any time. Inform the researcher if you wish to do so. This applies to the use of your data in this research and for other research. However, please note: if you withdraw your consent and researchers have already collected data for a study, they may still use this data. For your body material, the researchers will destroy it after you withdraw your consent. However, if measurements have already been made with your body material, the researcher may continue to use the results.

Do You Give Permission to Share Data with External Parties?
For this research and future research, we may send your coded data, in addition to the HYGEIA consortium (see Appendix E), to other research institutes and commercial parties for medical-scientific research. Your privacy will be protected. We ask for your separate consent on the consent form for sending your coded data to other research institutes and commercial parties. This is not mandatory. If you do not give permission, you can still participate in this study.

For this and future research, we may also send your coded data to countries outside the European Union. In those countries, the privacy rules of the European Union do not apply.

We ask for your permission for this. This is not mandatory. If you do not give permission, you can still participate in this study.

May We Contact You Again for Follow-Up Research?
When this study is over, we may conduct follow-up research. We would like to contact you to ask if you would like to participate again. On the consent form, you can indicate whether you give us permission to contact you again.

Want to Know More About Your Privacy?

- Want to know more about your rights regarding the processing of personal data? Visit www.autoriteitpersoonsgegevens.nl.
- Have questions about your rights? Or have a complaint about the processing of your personal data? Contact the person responsible for processing your personal data. See Appendix A for contact details and website.
- If you have complaints about the processing of your personal data, we recommend discussing them first with the research team. You can also contact the Data Protection Officer of Erasmus MC. Or you can file a complaint with the Dutch Data Protection Authority.

11. Do You Receive Compensation for Participating in the Study

As a thank you for your participation, you will receive a gift voucher worth 50 euros after completing the final questionnaires. You can indicate whether you want to receive this via email or post. If you stop the study early, you will unfortunately not receive a gift voucher.

12. Are You Insured During the Study?

You are not additionally insured for this study because participating in the study does not involve any additional risks. Therefore, the researcher does not need to take out additional insurance from the medical-ethical review committee (METC) of Erasmus MC.

13. We Inform Your Midwife or Gynecologist.

The researcher will send your midwife or gynecologist a letter or email to inform them that you are participating in the research. Your file will also be requested from your midwife and/or gynecologist at the end of your participation.

14. Do You Have Questions?

You can ask the researcher any questions about the study. If you want advice from someone who has no interest in the study, contact the independent expert. For contact details, see Appendix A. They know a lot about the study but are not involved in it.

Do you have a complaint? Discuss it with the researcher, midwife, or doctor treating you. If you prefer not to, contact the complaints committee of Erasmus MC. Appendix A provides information on where to find them.

15. How Do You Give Consent fort he Study?

You can take your time to think about this study. Then tell the researcher whether you understand the information and whether you want to participate. If you want to participate, you can indicate this via the website www.slimmerzwangeronderzoek.nl/en or inform the researcher you spoke to. Then fill out the consent form attached to this information letter. This can be done on paper (with the researcher) or digitally if you register via the website. Appendix D explains how this works. Both you and the researcher will receive a signed version of this consent form.

Thank you for your time.

16. Appendices to This Information

A. Contact details Erasmus MC
B. Research procedures schedule
C. Consent form
D. Digital signature procedure
E. Parties involved in the HYGEIA project (HYGEIA consortium)

Appendix A: Contact Details Erasmus MC

General Contact Details of the Research Team

If you have any questions, you can contact a member of the research team during office hours via hygeia@erasmusmc.nl of tel. 06 - 81 17 76 05

Principal Investigator

Prof. Dr. R.P.M. Steegers-Theunissen, non-practicing physician, epidemiologist, professor of Periconception Epidemiology.
Tel. 010- 703 82 54
E-mail: r.steegers@erasmusmc.nl

Co-Investigators

Dr. M. Rousian, gynaecologist, epidemiologist Erasmus MC
m.rousian@erasmusmc.nl
Drs. R.J. de Bruin, physician-researcher Erasmus MC
r.j.debruin@erasmusmc.nl

Independent Physician

Prof. dr. Irwin Reiss, neonatologist at Erasmus MC
Tel. 010 - 703 60 77
E-mail: i.reiss@erasmusmc.nl

Complaints

If you are not satisfied with the research or treatment, you can contact the independent complaints reception/complaints officer of Erasmus MC. On the Erasmus MC website, a digital complaints form is available via https://www.erasmusmc.nl/en/patient-care/complaint-handling-and-mediation
After filling it out, the form is automatically sent to the complaints officer. If you cannot fill out the digital complaints form, you can also send your complaint by post: Erasmus MC, Secretariat Complaints Reception (GK-745), Antwoordnummer 55, 3000 WB Rotterdam. Include your name, patient number (if applicable), name of the study, and contact details in the letter. After receiving the letter, the complaints officer will contact you.

Data Protection Officer:

The Data Protection Officer of Erasmus MC can be reached via the secretariat of the Legal Affairs department.
E-mail: functionaris.gegevensbescherming@erasmusmc.nl
Tel: 010-703 4986

For More Information About Your Rights:

For more information or questions about your rights, you can contact the Data Protection Officer or the Dutch Data Protection Authority.

Appendix B: Research Procedures Schedule

Study Schedule Group 1: Intervention group with Smarter Pregnancy Plus App

	Start Participation	After 6 weeks	After 12 weeks	After 18 weeks	After 6 months	After 12 months
Lifestyle Questionnaire (takes about 5 minutes)	X	X	X	X	X	X
Personal Coaching (push messages, video consultations)	Throughout the period from 0 to 6 months					
Other Questionnaires (takes 20-30 minutes)	X				X	X
Requesting General and Medical Data						X
Optional: Blood Draw	X				X	
Optional: Interviews and Group Discussions	Interview 1 hour Group Discussions 2 times 2 hours					

Study Schedule Group 2: Control group

	Start Participation	After 6 weeks	After 12 weeks	After 18 weeks	After 6 months	After 12 months
Lifestyle Questionnaire (takes about 5 minutes)	X		X		X	X
Other Questionnaires (takes 20-30 minutes)	X				X	X
Requesting General and Medical Data						X
Optional: Blood Draw	X				X	
Optional: Interviews and Group Discussions	Interview 1 hour Group Discussions 2 times 2 hours					

Appendix C: Consent Form for Participant: Pregnant Women

Digital lifestyle coaching for pregnant women with obesity: the HYGEIA-trial

- I have read the information letter. I could also ask questions. My questions have been sufficiently answered. I had enough time to decide whether to participate.
- I know that participation is voluntary. I also know that I can decide at any time to stop participating in the study. I do not need to explain why I want to stop.
- I give the researchers permission to collect and use my data and/or body material. The researchers do this only to answer the research question of this study.
- I give permission for sharing my coded data with the HYGEIA consortium (Appendix E) if necessary to answer the research question of this study.
- I give the researcher permission to inform the midwife or gynaecologist treating me that I am participating in this study.
- I give the researcher permission to request information about me from:
    - My midwifery practice or the hospital that provided care during my pregnancy up to 1 year after delivery.
    - Stichting Perinatale Registratie Nederland (Perined) for obstetric data.
    - My pharmacy about my medication use.
- I give the researcher permission to provide my general practitioner, midwife, or specialist with information about unexpected findings that may be important for my health.
- I give permission to the members of the research team to view my medical file and copy the data needed for this research from my file.
- I know that some people can see all my data for the control of the study. These people are listed in this information letter. I give these people permission to see my data for this control.

Please check yes or no in the table below:

I give permission to store my data to use it for other research, as stated in the information letter. The data will be stored for 15 years after the end of the study.	Yes ☐	No ☐
I give permission for blood draw at the start of the research and after 26 weeks.	Yes ☐	No ☐
I want to participate in the interviews and/or group discussions as mentioned in section 4. I may be contacted for this.	Yes ☐	No ☐
I give permission to be asked after this study if I want to participate in follow-up research.	Yes ☐	No ☐
I give permission to transfer my coded data in the context of this and future research to countries outside the EU where the European data protection regulations do not apply. The data will be transferred coded, without my name.	Yes ☐	No ☐
I give permission for sharing my coded data with other research institutes and commercial parties for future research.	Yes ☐	No ☐

- I want to participate in this study.

My name is (subject): ……..

Signature: …… Date : __ / __ / __

I declare that I have fully informed this participant about the mentioned study. If information becomes known during the study that may influence the participant's consent, I will inform the participant in time.

Name of researcher (or representative):……..
Signature:…… Date: __ / __ / __

Additional information provided by:
Name:……..
Function:……
Signature:…… Date: __ / __ / __

The participant receives a complete information letter along with a signed version of the consent form.

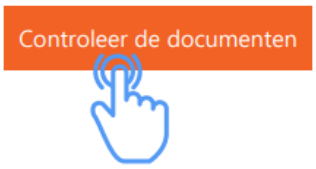
Appendix D: Digital Signature Procedure

Step 1. You read this participant information on the HYGEIA research website and indicate that you want to participate.

Step 2 You will be called by a researcher. If you do not answer, you will receive an email asking you to call back. During the phone call, you can ask questions and decide whether or not to participate.

Step 3. If you decide to participate, you will receive an email from ValidSign with the subject "HYGEIA signature request." Open this email on your computer, tablet, or smartphone.

Step 4. Click on "check the documents."



You will now see the document offered for signature (Appendix C). Check the boxes for consent and click on "click here to sign."

If you have filled out everything, click on "OK" to confirm.

The signature field will now show "accepted," and the screen will indicate that you have successfully signed. Click on "finish."

Step 5. The researcher will also receive a request to sign. After this is done, you will receive a copy of the signed form via email.

Step 6. The researcher arranges the randomization. If you are randomized into group 1, you will receive an activation email for the app, an appointment for the coaching conversation, and the first questionnaires. If you have indicated that your partner also wants to participate, your partner will now also receive a signature request.

If you are randomized into group 2, you will be informed via email and receive the first questionnaires.

Appendix E: Parties Involved in the HYGEIA Project (HYGEIA Consortium)

The research is conducted by:
Erasmus University Medical Centre Rotterdam (Erasmus MC), Rotterdam
IJsselland Ziekenhuis, Capelle aan den IJssel
Reinier de Graaf Gasthuis, Delft
Erasmus School of Health Policy & Management (ESHPM), part of Erasmus University Rotterdam, Rotterdam

Other Involved Parties:
TU Delft
Hogeschool Rotterdam
Pharos
Peercode
Zwangerenportaal
Universiteit Leiden
HELLP Stichting
PCA Zorg&ICT BV