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 Sir/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. Participation is voluntary. You are receiving this letter because your partner is participating in the HYGEIA trial and has been assigned to the intervention group. 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.

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 tot he researcher who provided you with this information.
- Talk to your partner, family, or friends about this research.
- Ask questions tot he 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 and their partners, 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 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.

Previous research has shown that it is easier to improve lifestyle if you do it together with your partner. Therefore, you as a partner are also invited to use the Smarter Pregnancy Plus app. You will receive advice on improving your own lifestyle. We want to investigate whether it helps if you as a partner also participate.

4. How Does the Research Proceed?

How Long Does the Research Last?

If you participate in the research, it will last for 6 months for you. 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 your partner participates in the research and receives the Smarter Pregnancy Plus app. To participate, you must be 18 years or older, be able to read and speak Dutch or English, and have a mobile phone or tablet.

Step 2: The Program

Your partner has been assigned to group 1 of this research through randomization. This group receives the Smarter Pregnancy Plus app. This app is also available to you as a partner. Therefore, we ask you to participate as well.

Step 3: Research and Measurements

You do not need to come to the hospital for the research. If you participate, you will sign (digitally) the consent form in Appendix C. After that, you will get access to the app. You will receive a short questionnaire about your lifestyle at the start of the research and after 6, 12, 18, and 26 weeks. In total, 5 times. Filling it out takes about 5 minutes each time. After that, you will receive personal advice based on your answers. You can also join the video call that your partner receives.

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 in Appendix C, you can indicate whether 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?

This research does not affect any care you may receive. You will receive help in improving your lifestyle.

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 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.

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 participate, you will receive free access to the Smarter Pregnancy Plus app. Normally, there are costs associated with this. If you manage to change your habits with the help of the program, it will benefit your health. You can also support your partner in changing her habits. In addition, by participating, you make an important contribution to research on lifestyle in pregnant women with obesity. In doing so, you can help future parents and children.

Participating can have the following potential disadvantages or consequences:

- Participating in the research takes time.
- If you do not succeed in changing certain habits, this can be considered a disadvantage.

Do you not want to participate?
It is entirely your choice whether or not to take part in the study.
If you choose not to participate, your partner will continue in the study without you.

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 collected up to the point of stopping. The entire research is completed when all participants are finished.

9. What Happens After the Research?
After 6 months, your use of the Smarter Pregnancy Plus app stops. You can still view the previously given advice, but you will no longer receive new advice.

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.

What Data Do We Store?
We store the following data:

- Your name, date of birth, address, and nationality.
- Answers tot he questionnaires about your lifestyle.
- Usage data of the app.

Why Do We Collect, Use, and Store Your Data?
We collect, use, and store your data 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 your body material a code. We only put this code on all your data. We keep the key to the code in a secure place in the hospital. When we process your data, 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. 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. 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.

May We Use Your Data 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.

Can You Withdraw Your Consent for the 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 study 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.

Do You Give Permission to Share Data with External Parties?
For this study 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?

Participation in the study costs you nothing. You can use the Smarter Pregnancy Plus program for free. You will not receive any compensation.

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. 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 your partner. If you prefer not to, contact the complaints committee of Erasmus MC. Appendix A provides information on where to find them.

14. How Do You Give Consent for the 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, fill out the consent form attached to this information letter. This is done digitally. 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.

15. 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

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-practising physician, epidemiologist, professor of Periconception Epidemiology.
Tel. 010- 703 82 54
E-mail: r.steegers@erasmusmc.nl

Co-Investigators

Dr. M. Rousian, gynecologist, 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.

Email: 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

	Start participation	After 6 weeks	After 12 weeks	After 18 weeks	After 26 weeks	After 12 months
Lifestyle Questionnaire (takes about 5 minutes)	X	X	X	X	X	X
Personal Coaching (via the app)	Throughout the period from 0 t/m 6 months					
Optional: Interviews and Group Discussions	Interview 1 hour Group Discussions 2 times 2 hours					

Appendix C: Consent Form

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. 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 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 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 subject about the mentioned study.

If information becomes known during the study that may influence the subject's consent, I will inform the subject in time.

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

Additional information provided by:

Name:……..
Function:……
Signature:…… Date: __ / __ / __

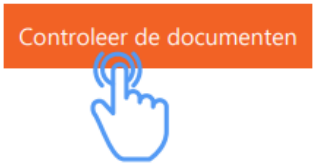
The subject receives a complete information letter along with a signed version of the consent form.

Appendix D: Digital Signature Procedure

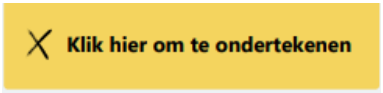
Step 1. Your partner is participating in this study and has been assigned to the group with the Smarter Pregnancy Plus app. During registration, she indicated that you might also want to participate.

Step 2. You will receive an email from ValidSign with the subject "HYGEIA signature request." Open this email on your computer, tablet, or smartphone.

Step 3. Click on "check the documents." Read this folder thoroughly.



If, after reading this information, you want to participate, 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. Now click on "finish."

Step 4. 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 5. You will get access to the Smarter Pregnancy Plus app.

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