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Further development and (cost-)effectiveness of the Smarter Pregnancy lifestyle program tailored for pregnant women with obesity (HYGEIA trial)

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Abstract

Background Maternal obesity affects approximately 16% of pregnancies worldwide and is a major concern for public health. This condition is associated with elevated risks of adverse outcomes, such as gestational diabetes, hypertensive disorders of pregnancy, and cardiovascular and metabolic disease (CVMD) during the life course. Our long-term experience with the (cost-)effective web-based Smarter Pregnancy coaching program is promising to mitigate these risks and improve lifestyle behaviours as well as maternal and neonatal health outcomes.
Here our aim is to describe the rationale and study protocol for a randomised controlled trial (RCT) to investigate the clinical and cost-effectiveness, and implementation potential of Smarter Pregnancy Plus (SP+) from early pregnancy onwards in women with obesity.

Methods The HYGEIA study is designed as a multicentre, two-armed RCT. A total of 930 women with a body mass index ≥30 kg/m^2 and a singleton pregnancy of ≤14 weeks gestation will be recruited and randomised 1:1 to the intervention (n=465) and control group (n=465). The intervention group will receive six months of digital lifestyle coaching via the SP+ application, supported by at least one video consultation. SP+ is an extended, co-designed and tailored app version for pregnant women with obesity based on the validated SP program. It provides evidence-based coaching on nutrition, physical activity, mental health, folic acid and vitamin D supplement use, and smoking and alcohol cessation. The control group will receive usual care. Data will be collected through validated questionnaires, electronic medical records, financial records, and qualitative stakeholder sessions, guided by the Non adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS)-framework.

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The primary outcome is the incidence of maternal CVMD during pregnancy, assessed using a composite measure that includes gestational diabetes, hypertensive disorders of pregnancy, and worsening of pre-existing hypertension or diabetes. Secondary outcomes include changes in lifestyle behaviours, maternal and neonatal outcomes, quality of life, and cost-effectiveness. Tertiary outcomes involve patient satisfaction, provider feasibility and a roadmap for nationwide implementation.

Discussion The HYGEIA study will provide evidence on the clinical impact, cost-effectiveness, and implementation potential of SP+ as a digital lifestyle intervention for pregnant women with obesity. If successful, SP+ could further enhance routine obstetric care and contribute to improving maternal and neonatal health while reducing healthcare costs.

Trial registration Dutch Trial Registration number NL-OMON57196 (URL: https://onderzoekmetmensen.nl/nl/node/57196/pdf), date of registration 19-12-2024.

Keywords Pregnancy, Obesity, Lifestyle, Intervention, Cardiovascular, Nutrition, Physical activity, Mental Health, Smarter Pregnancy, mHealth

Background

Maternal obesity presents a growing public health challenge, affecting approximately 16% of all pregnancies worldwide, equivalent to an estimated 39 million pregnancies annually [1]. Obesity during pregnancy is associated with significantly increased risks of adverse maternal and neonatal outcomes, including gestational diabetes (GDM), hypertensive disorders of pregnancy (HDP) and long-term cardiovascular and metabolic diseases (CVMD) in both mothers and children [2–6]. Physiological adaptations during pregnancy, such as increased blood volume and heart rate, act as a cardiovascular stress test and may amplify existing risk factors like obesity. As a result, one in four women with obesity develops at least one CVMD-related complication during pregnancy [4]. These complications contribute not only to maternal morbidity and lifelong increased risk of non-communicable diseases – with a two- to tenfold higher risk of developing chronic CVMD within ten years after pregnancy – but also place a considerable burden on healthcare and society [4, 7, 8]. Given the substantial societal costs of obesity and cardiovascular diseases, estimated at €79 billion and €8.3 billion, respectively, annually in the Netherlands, there is an urgent need for effective preventative interventions to improve pregnancy outcomes and long-term health trajectories [9].

Unhealthy lifestyles and adverse living environment are important risk factors for obesity and CVMD, making tailored lifestyle interventions a promising strategy to reduce risks before and during pregnancy. However, implementing personalised lifestyle care into routine obstetric practice remains limited and challenging [10]. Effective interventions must be known, evidence-based, tailored and accessible to women with varying levels of health and digital literacy, and seamlessly incorporated into existing care pathways without increasing the workload of healthcare providers (HCPs). Furthermore, sustainable adoption requires early involvement of HCPs, insurers, and policymakers, along with evidence of cost-effectiveness and implementation feasibility.

Digital solutions, particularly mobile applications, offer unique potential for accessible and tailored lifestyle support on a large scale. Mobile apps can provide personalised, scalable, and continuous coaching, support self-management, and help overcome time and resource constraints in clinical practice. Since 2011 Steegers-Theunissen and colleagues have gained extensive experience with Smarter Pregnancy, a web-based lifestyle coaching program that has been developed and used by thousands of (pre)pregnant women (and partner) [11–21]. Internal and external validity have been demonstrated using cohort and randomised controlled trial designs in different patient groups and general populations both in The Netherlands and United Kingdom. These studies have shown significant improvements ranging from 30 to 70% in vegetable and fruit intake and folic acid supplement use. Clinical effectiveness has been shown for higher pregnancy rates in both natural and Assisted Reproductive Technology pregnancies, embryonic growth, and a slightly lower maternal blood pressure. The program has been recognised in one of the highest categories with regard to clinical and cost-effectiveness by the Dutch National Health Care Institute [11, 13, 15, 16, 22]. So far the effects on other pregnancy outcomes have not yet been studied and subgroup analyses showed lower effectiveness in (pre)pregnant women with obesity [11, 15]. Moreover, its broader impact on healthcare costs, quality of life, and the feasibility of large-scale implementation requires further investigation.

To address these limitations, the web-based Smarter Pregnancy 4.0 has been further developed into the Smarter Pregnancy Plus (SP+) app tailored for pregnant women with obesity. The mobile app format was selected to improve accessibility, usability, and sustained engagement throughout pregnancy.

We hypothesise that SP+ will support sustainable lifestyle behavioural changes that contribute to the secondary prevention of CVMD and other obesity-related pregnancy complications. It will demonstrate good value for money as well as high acceptability and implementation among both pregnant women with obesity and their HCPs. The HYGEIA-trial, named after the Greek goddess of health and prevention, aims to evaluate the clinical and cost-effectiveness, and implementation potential of SP + in a real-world healthcare context. In this article, we describe the study protocol of HYGEIA, in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2025 guideline [23].

Methods/design

Aim

The primary aim of this randomised controlled trial (RCT) is to evaluate the effectiveness of SP+ in reducing the incidence of cardiovascular and metabolic complications or diseases (CVMD).

Secondary aims are: first, to determine the effectiveness on other adverse maternal and neonatal health outcomes; second, to evaluate the cost-effectiveness of SP+; and third, to develop a scalable framework for nationwide implementation and reimbursement of SP+.

Study design

The HYGEIA-study is a multicentre, two-arm RCT amongst 930 pregnant women with obesity. Participants will be randomised 1:1 to either the intervention ($n = 465$) or control ($n = 465$) group.

Study population

To be eligible to participate, women must meet the following criteria:

- Pre-pregnancy or first trimester body mass index (BMI) of ≥ 30 kg/m2, as classified by the World Health Organization criteria for adults [24];
- Singleton pregnancy up to 14 + 0 weeks of gestation at study entry;
- Aged 18 years or older;
- Sufficient understanding of the Dutch or English language;
- Access to a smartphone and/or tablet.

Women will be excluded in case of a non-viable pregnancy, inability to provide informed consent or insufficient understanding of the Dutch or English language.

Partners of women randomised to the intervention group will be offered the opportunity to use SP + as well, to support the women's intrinsic and extrinsic motivation through involvement of their close living environment. Partner participation is voluntary and limited to app use; they will not be actively studied or required to complete study questionnaires. To be eligible, partners must be at least 18 years of age, have sufficient understanding of the Dutch or English language and provide written informed consent.

Recruitment and randomisation

Eligible participants will be recruited from March 2025 onwards within primary, secondary and tertiary obstetric care settings. Participants receiving care in the primary care setting will be recruited through midwifery practices across the country and by a private information platform called www.zwangerenportaal.nl. This platform is connected to the digital medical system of > 50% of the midwifery practices in The Netherlands, enabling to reach women in a large part of the country. Participants receiving care in the secondary care setting, will be recruited in collaboration with the participating hospitals IJsselland Hospital in Capelle aan den IJssel, and Reinier de Graaf Gasthuis in Delft, The Netherlands. Other secondary care setting hospitals in the country will contribute by handing out leaflets. Finally, participants receiving care in tertiary care setting will be recruited through the initiating academic hospital, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands. HCPs of participants will receive confirmation of participation after their patient gets enrolled.

Eligible participants will receive a study leaflet either in person or by email, containing detailed information about the study. They will be asked for permission to be contacted by a member of the research team and offered the option to self-register via the study website [25]. If permission is granted or if participants self-register, they will be contacted by phone and be counselled by a member of the research team in accordance with the 'Good Clinical Practice' guidelines [26]. After oral consent, digital written informed consent will be obtained through Validsign. Following consent, participants will be enrolled and randomised in an electronic data capture system (Castor) using block randomization stratified by site (block sizes 4, 6, 8). This online randomization software is always available. Due to the nature of the intervention, this will not be a blinded study.

Study procedures

Participation lasts 12 months (52 weeks). Within this period, the control group will receive 12 months of standard obstetric care, which should include standard information on lifestyle provided by their HCP. The intervention group will receive 6 months of the intervention on top of standard obstetric care, followed by 6 months of standard obstetric care. Figure 1 shows an overview of the study design.

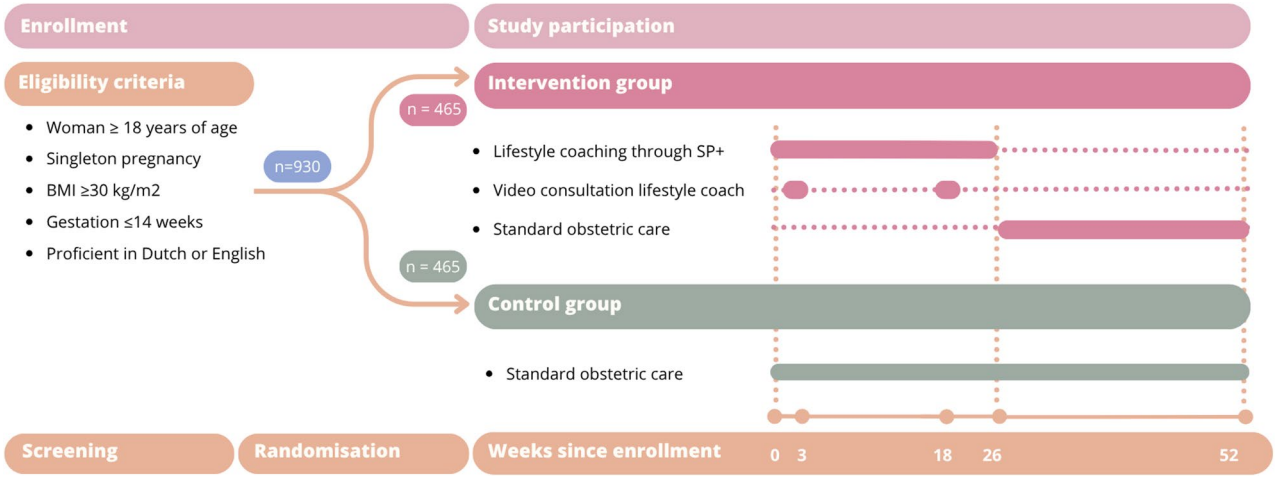

Fig. 1 Overview of the study design, including enrolment and study participation

The intervention

The intervention consists of access to the SP+ mobile application for 6 months and one or two video consultations with a lifestyle coach, depending on the participants' preference. SP + is available in Dutch and English for both Apple and Android users and was developed in co-creation with pregnant women with obesity and HCPs using focus groups and interviews, addressing their specific needs and preferences. SP+ incorporates key enhancements: supportive and non-stigmatizing language; a customisable interface; a read-aloud functionality; and new modules on mental health, physical activity, and behaviour change support. Results of these sessions will be published separately. SP+ provides personalised lifestyle coaching on the most important lifestyle domains – healthy nutrition (fruits, vegetables, fish, whole-wheat products, snacks, meals, and sugar-sweetened beverages), physical activity, mental health (stress and sleep), folic acid and vitamin D supplement use, alcohol abstinence, smoking cessation, and obesity-related risks. The coaching provided in SP + is based on Prochaska and Diclemente's transtheoretical model, Bandura's social cognitive theory for self-efficacy and Fogg's behaviour model [27–29]. In addition, for nutrition, physical activity, and mental health intervention techniques to foster habit formation were implemented, including goal setting, increasing knowledge, and implementation intentions [30]. The content of the personalised coaching is based on a baseline screening on personal conditions, nutrition and lifestyle and monitoring questionnaires at 6, 12, 18, and 26 weeks. At these time points, participants are invited to complete a short questionnaire to monitor the change in their nutrition and lifestyle. Results from the questionnaires are compared with previous responses and visualised to show progress. Participants receive tailored feedback adapted to their answers. In between these questionnaires, the tailored coaching includes a maximum of three push messages per week containing tips, recommendations, motivational messages, recipes, and additional questions addressing behaviour. The application provides the option to personalise these push messages with regards to frequency, timing and content. The application is subdivided into several lifestyle modules, all offering additional functionalities and support such as a habit tracker (to set and track personal goals and implementation intentions), physical exercises, a pedometer, mental health exercises and a mood diary tracker, as shown in Fig. 2. The interface is customizable according to the participants' wishes and personal goals. Furthermore, SP+ offers a read-aloud feature to ensure accessibility for individuals with lower language proficiency.

Finally, coaching through the mobile application will be supplemented by one or two video consultations with a lifestyle coach, during which additional coaching is provided, and potential questions are answered. The first video consultation will be planned shortly after inclusion, at T = 3 weeks. A second consultation is optional and will be planned according to the participant's wishes at T = 18 weeks. Participating partners receive a separate app, personalised according to their lifestyle and goals.

Outcome measurements

An overview of all assessed outcomes can be found in Table 1 (Additional file 1). The primary composite outcome used for the effectiveness is the incidence of CVMD during the 12 months study period, including gestational diabetes, HDP (pregnancy induced hypertension, preeclampsia, HELLP syndrome), and the aggravation of pre-existing chronic hypertension or type I or II diabetes. Pregnancy-induced hypertension, preeclampsia and HELLP syndrome will be defined according to the American College of Obstetricians and Gynaecologists (ACOG) definitions [31]. Aggravation of chronic hypertension is defined as progression to superimposed preeclampsia

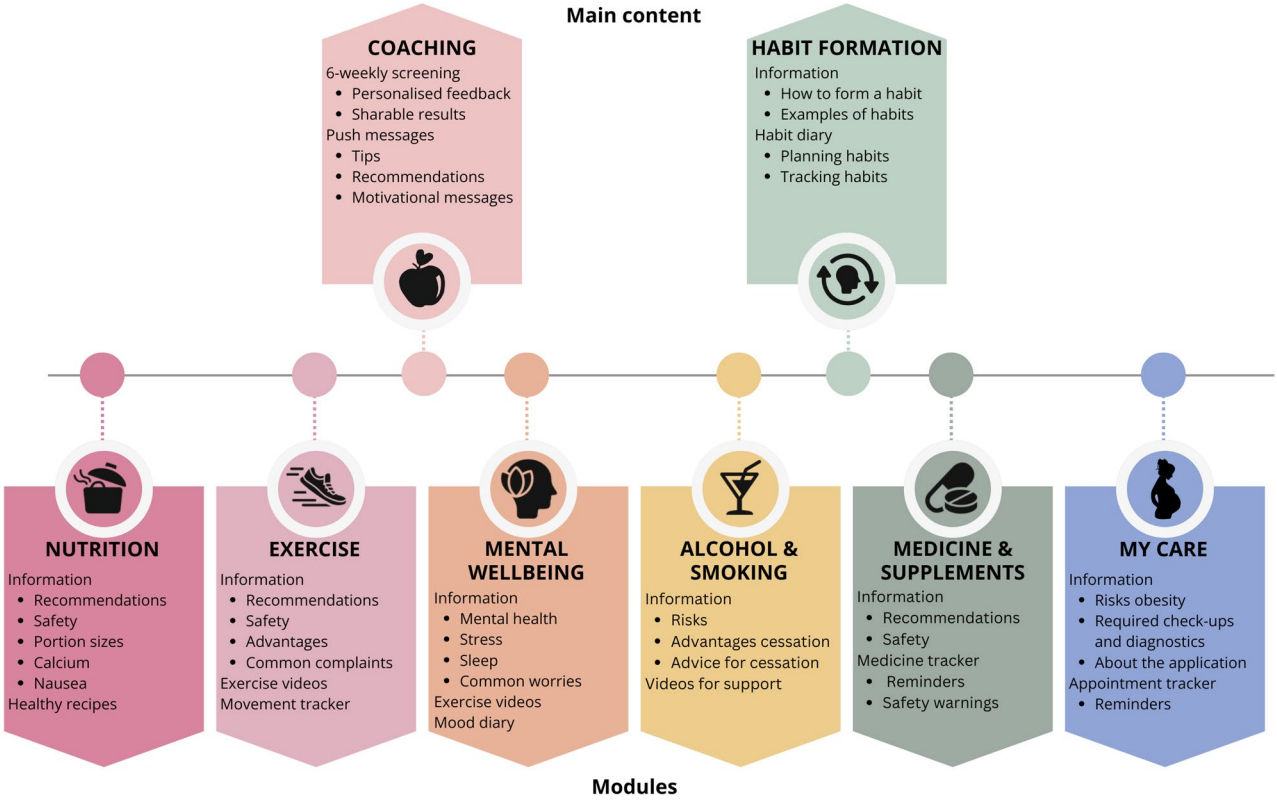

Fig. 2 Overview of the Smarter Pregnancy Plus mobile application

or hypertension without medication evolving to requirement of medication. Gestational diabetes is defined as an abnormal 75 g oral glucose tolerance test (OGTT) (fasting glucose > 6.0 mmol/L, 2-hour post intake glucose > 7.8 mmol/L) [32]. Aggravation of chronic diabetes mellitus is defined as diabetes without medication progressing to requirement of medication.

Secondary outcomes include maternal and neonatal outcomes and cost-effectiveness. Maternal outcomes that will be assessed include lifestyle risk score (LRS) change at 6 and 12 months, gestational weight gain, mode of delivery, induction of labour, premature rupture of membranes, perineal trauma, postpartum haemorrhage, blood pressure patterns, quality of life, mental health and patient reported outcome- and experience measures (PROMs and PREMs) [14, 15]. All complications assessed in the primary outcome will also be assessed individually regarding the incidence, severity and need for medication. The cardiovascular health risk will be assessed using the life's simple 7 or life's essential 8, health metrics developed by the American Heart Association to help people understand and improve their cardiovascular health, and provide a practical framework for preventing heart disease, stroke and other chronic illness [33]. As an additional secondary outcome, we will assess the extent to which specific behaviours become habitual, as this will provide important insights on the sustainability of the intervention effects beyond the scope of the intervention.

Neonatal outcomes that will be assessed include large for gestational age (>p90), small for gestational age (<p10), foetal growth restriction (<p10), congenital anomalies (detected until 6 months after delivery), preterm birth (<37 weeks gestational age), gestational age at delivery, perinatal mortality, shoulder dystocia, Apgar scores and NICU admission (up to 6 months after delivery).

The cost-effectiveness analysis will be conducted from a societal perspective. The evaluation will make a comparison between the intervention and control group by identifying, measuring and valuing the costs and patient outcomes of both treatment strategies. The time horizon of the analysis will be the 12-months study period. Established methods for economic evaluations in healthcare will be applied [34–36]. The following costs will be calculated, covering both medical and non-medical costs:

- Medical costs, collected from electronic hospital files, patient files and the iMTA Medical Consumption Questionnaire (MCQ) [37]. This includes the costs of hospital admissions, medications, laboratory costs, diagnostic imaging, outpatient visits, maternity care, home care use, visits to the general practitioner, etcetera.

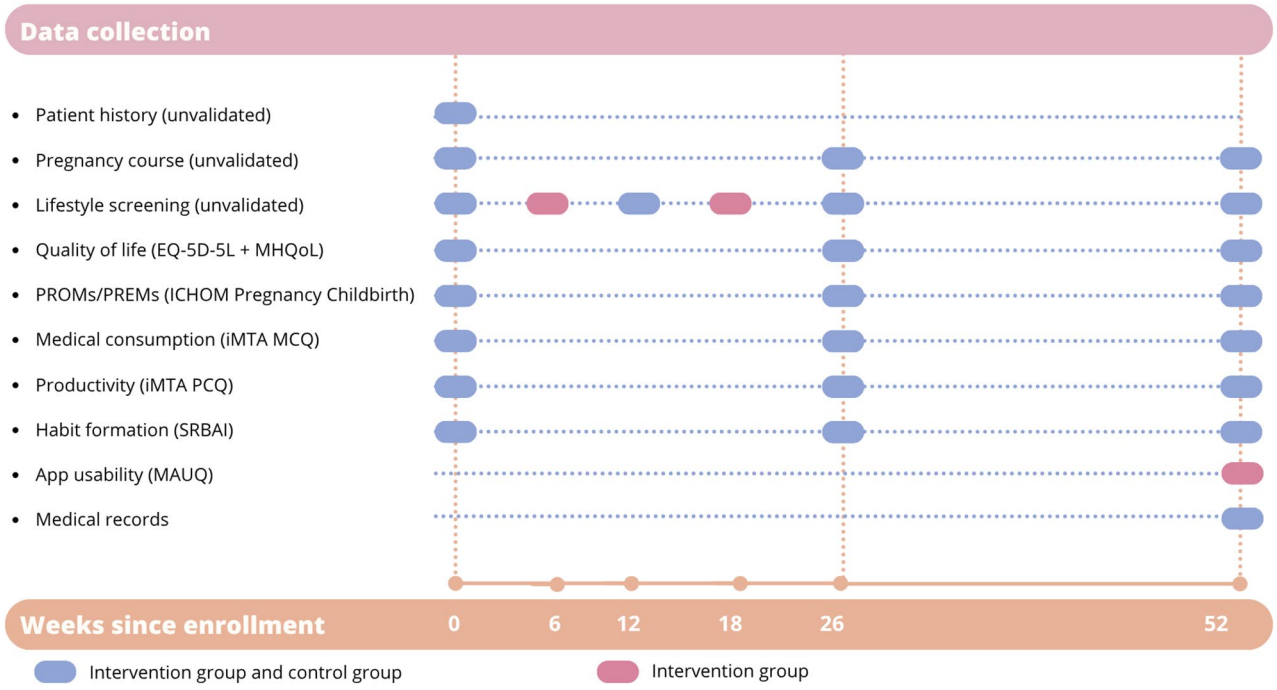

Fig. 3 Overview of data collection.

- Productivity costs related to both paid and unpaid work, collected from the iMTA Productivity Cost Questionnaire (PCQ) [38].
- Intervention costs associated with delivering the SP+ intervention (i.e., all costs made for guiding and coaching the women), partly obtained through interviews and/or observations.

Regarding the patient outcomes, the cost-effectiveness analysis will look at the occurrence of CVMD within 12 months, health-related quality of life (comprising both physical and mental health dimensions), and quality-adjusted life years (QALYs). The calculation of QALYs will be based on the EQ-5D-5 L questionnaire [39, 40]. This is a generic, preference-based quality of life measure, comprising 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), that allows for the calculation of QALYs.

Tertiary outcomes involve user satisfaction, provider feasibility and a roadmap for reimbursement and implementation. Provider feasibility will be assessed using the Measurement Instrument for Determinants of Innovation (MIDI) and Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS)-Framework. Roadmaps for reimbursement and implementation will be developed together with the HYGEIA consortium, healthcare insurers, policy makers, HCPs, and patients using qualitative focus groups and interviews.

Data collection

Questionnaires

Participants of both groups will receive several questionnaires, as listed below and in Fig. 3. Lifestyle behaviours will be assessed in both groups at T = 0 weeks, T = 12 weeks, T = 26 weeks and T = 52 weeks, by calculating and comparing the extensively validated and recognised LRS of Smarter Pregnancy [15] (see Additional file 2 for the questionnaire).

Information on background characteristics, vulnerability, medical history, obstetric history and current pregnancy will be collected through a baseline survey (T = 0 weeks). Information on pregnancy course will be collected at 36 weeks of pregnancy (approximately T = 26 weeks) and follow-up (T = 52 weeks). Information on delivery outcomes will be collected at follow-up (T = 52 weeks) (see Additional file 3 for the questionnaires).

Validated questionnaires will be used to collect information on mental health quality of life (MHQoL) [41], PROMs and PREMs (ICHOM Pregnancy and Childbirth) [42], and habit formation (SRBAI) [43]. Together with the questionnaire used for the cost-effectiveness analysis, these questionnaires will be administered at baseline (T = 0 weeks), 36 weeks of pregnancy (approximately T = 26 weeks) and end of follow-up (T = 52 weeks). App usability and satisfaction will be assessed at 36 weeks pregnancy (approximately T = 26 weeks) within the intervention group, using the validated mHealth App Usability Questionnaire (MAUQ) [44]. The total duration

for completing the questionnaires is estimated at 20 min at T = 0, T = 26 and T = 52 weeks and 5 min at T = 12.

Follow-up

Baseline characteristics and clinical outcomes will be extracted from electronic medical records or charts at T = 52 weeks. HCPs will be asked to collect at least the following key data:

- OGTT (mmol/L) between 24- and 28-weeks' gestation.
- HbA1C levels (mmol/mol) in the first trimester and recurrent if participant develops gestational diabetes or has chronic diabetes mellitus.
- Blood pressure measurements (mmHg) at every antenatal and postpartum visit, measured on the left arm.
- Weight (kilograms) at the first antenatal visit, between 20 and 24 weeks, between 30 and 32 weeks and around the estimated due date.
- Foetal biometry parameters (biparietal diameter, head circumference, abdominal circumference, femur length, estimated foetal weight) at 30- and 34-weeks' gestation *or* 32- and 36-weeks' gestation.

Other key data to be collected from medical records and charts include medical history, obstetric history, information on current pregnancy, pregnancy course and delivery, adverse pregnancy outcomes, laboratory results, prenatal screening results, and healthcare consumption and utilisation and associated costs.

Statistics

Sample size

The sample size calculation is based on our primary outcome, the prevalence of CVMD during the study period of 12 months. Assuming a 25% cumulative incidence of CMVD, we aim to achieve a 40% reduction in the intervention group (to 15%), and a 4% reduction in the control group (to 24%). Using a Chi-square test with continuity correction at a 0.05 significance level, 465 participants per group (total of 930) are required to achieve 80% power, accounting for a 30% dropout rate. This dropout estimate aligns with previous Smarter Pregnancy studies [11, 15]. The expected reduction of CVMD is supported by a meta-analysis from our group, showing lifestyle interventions reduce HDP by nearly 50% [45].

Data-analysis

The effectiveness of the intervention will be analysed using the intention-to-treat principle. Data will be analysed using IBM SPSS Statistics for Windows and R for Windows. General and baseline characteristics will be compared between groups. A post-hoc analysis will assess whether BMI differs significantly between groups at baseline. Participant flow, including group sizes and attrition at each time point, will be illustrated in a flowchart.

The primary composite outcome measure will be evaluated using multiple linear regression. For CVMD incidence, two participant groups will be defined: CVMD absent or stable, and CVMD occurrence or worsening. To assess intervention effects over time, repeated measurements and constrained longitudinal analysis will be used to evaluate interactions with key variables (e.g., age, vulnerability, ethnicity, socioeconomic status). Additionally, Generalised Estimating Equations (GEE) will be applied to examine time-based effects and their interaction with the intervention.

Potential confounders include age, education level, geographic origin, vulnerability, and parity.

Secondary maternal and neonatal outcomes will be analysed using linear regression for continuous variables and logistic regression for dichotomous variables. For blood pressure patterns, longitudinal analysis will be conducted using linear mixed modelling. A subgroup analysis within the intervention group will assess the impact of participating with versus without a partner. A subgroup analysis may compare participants with high versus low satisfaction scores.

Budget impact and cost-effectiveness outcomes will be analysed for the entire pathway, and where relevant according to subgroups of participants (based on diversity criteria). Budget impact and cost-effectiveness outcomes will be analysed for each participant, subgroup of participants (based on diversity criteria), and for the entire pathway. For the budget impact analysis, total costs will be calculated, followed by two analyses: (1) The cost difference between care as usual (control group) and the digital lifestyle healthcare path (intervention group) and (2) the proportion of costs funded by different reimbursement schemes that are used in The Netherlands. To determine cost-effectiveness, incremental cost-effectiveness ratios (ICERs) will be calculated, expressing the cost per unit of health benefit gained. These will be reported as incremental costs per case of CVMD prevented and incremental gained. Otherwise, the evaluation will focus on dominance of one strategy over the other with respect to lower cost and greater effect. Sensitivity analyses will be performed, where relevant, to assess the robustness of the results to key assumptions.

To support sustainable implementation, data from interviews and focus groups will be systematically analysed using the dimensions of the NASSS-framework. This will enable the identification of key barriers, facilitators, and contextual conditions that influence the successful implementation and long-term adoption of the intervention.

Discussion

The HYGEIA study seeks to address the urgent need for accessible, scalable and sustainable strategies to support pregnant women with obesity in adopting healthier lifestyle behaviours. This is critical in reducing the increasing prevalence of maternal obesity and its associated risks, including gestational diabetes, HDP, and long-term non-communicable diseases affecting both mother and child [2–6, 46, 47]. SP+ offers a promising approach to achieve such changes through personalised digital lifestyle support that empowers both women and their partners to make long-term lifestyle improvements.

Despite the evidence on (cost-)effectiveness, structured lifestyle care remains limited in routine obstetric care. Time constraints, inconsistent counselling, lack of continuity, fear of stigma, and limited tailoring for high-risk populations such as women with obesity often hamper implementation [48–50]. In recent years, digital interventions have emerged as a promising approach to overcome these barriers. However, previous studies investigating digital lifestyle interventions during pregnancy have shown mixed results. While some trials have demonstrated improvements in dietary quality, physical activity, and gestational weight gain, others have failed to show meaningful effects [51–53]. These inconsistencies may be due to variability in study design (including small sample sizes), population characteristics, intervention intensity, theoretical underpinning, and user engagement. Additionally, interventions often face challenges with real-world implementation and scalability.

Smarter Pregnancy Plus is a further development of Smarter Pregnancy 4.0 to address these issues. It has been tailored to the lived experience, preferences, and literacy levels of the target group, including features such as read-aloud functionality, visual support, and multi-language availability. Furthermore, SP+ incorporates features to support inclusive, sustained, and theory-based behaviour change. It targets a broader set of health behaviours and is guided by multiple behaviour change theories [27–30], including a specific focus on habit formation, as habits are widely recognised as a promising pathway for not only the initiation but also long-term maintenance of health behaviour change [54]. This theoretical foundation is operationalised in SP+ through personalised digital coaching, goal setting, education on habits, and implementation intentions to support habit formation and self-management.

A key aspect of SP + is that conform the other Smarter Pregnancy programmes the focus is not on reducing body weight as a primary target, but instead to promote healthy lifestyle changes, that benefit body weight and subsequent health of both mothers and children. This aligns with international guidelines that discourage weight loss during pregnancy due to potential risks [55, 56]. Overemphasising weight can also lead to stigma and negative affect engagement and psychological wellbeing [57]. By focusing on lifestyle behaviours, rather than weight, the study follows behaviour change frameworks [58, 59] and evidence showing that such interventions can improve metabolic outcomes, reduce gestational diabetes and hypertensive disorders, and support both maternal and neonatal health, all while offering non-stigmatizing care [60–63].

A major strength of the HYGEIA study is its comprehensive design. In addition to evaluating clinical effectiveness, the study includes an economic evaluation from a societal perspective. This is essential, given the high and rising healthcare and societal costs associated with maternal obesity and its long-term consequences [9]. By generating evidence on both health outcomes and cost-effectiveness, the study aims to support potential reimbursement of SP+ within the Dutch basic health insurance package and its integration into national obstetric care pathways. Moreover, assessing habit formation on certain lifestyle behaviours as a secondary outcome will provide important insights on the sustainability of the intervention effects beyond the scope of the intervention.

The RCT design allows us to establish causal relationships between the intervention and health outcomes, providing a robust and reliable assessment of its effectiveness. To enhance generalisability, participants will be recruited across primary, secondary, and tertiary care settings. Digital data collection methods, including validated questionnaires and linkage with routine clinical and national registry data, will ensure high data quality while reducing information bias.

Implementation is a central objective of the HYGEIA study. Alongside evaluating (cost-)effectiveness, we actively collaborate with key stakeholders, including patients, HCPs, insurers, policymakers, the Ministry of Health, and others to lay the groundwork for sustainable implementation in routine care.

Nonetheless, the HYGEIA study faces several challenges. Recruiting and retaining a sufficiently large and diverse sample of pregnant women with obesity may be difficult due to time constraints, pregnancy-related discomfort, and potential stigma. Although multiple recruitment settings improve generalisability, selective participation and attrition remain possible. The extensive set of outcomes, while essential for a comprehensive evaluation, may increase participant burden; digital reminders and user-friendly materials are included to support engagement.

Reliance on routine medical and registry data may introduce variability in data completeness, and the multifaceted nature of SP+ will limit identification of which specific components drive effects. The study is therefore

designed to evaluate the overall effectiveness and feasibility of an integrated digital lifestyle intervention rather than individual mechanisms.

Finally, successful implementation depends on HCP engagement, workflow integration, and users' digital access and literacy. Co-creation with end users, HCPs, and policymakers aims to mitigate these barriers.

Conclusion

By using available expertise and knowledge from the web-based Smarter Pregnancy programmes, we further developed the SP+app as a co-designed, theory-informed, and digitally delivered lifestyle coaching program, an intervention tailored to pregnant women with obesity. The HYGEIA trial aims to generate robust evidence on its clinical and (cost-)effectiveness, and implementation potential. In doing so, it addresses key knowledge gaps and implementation barriers identified in earlier research. If effective, SP + has the potential to be a scalable and sustainable component of routine obstetric care, contributing to improved maternal and child health outcomes and a reduction in the long-term burden of obesity-related disease.

Abbreviations

BMI	Body mass index
CVMD	Cardiovascular and metabolic diseases
EQ-5D-5L	EuroQol-5D-5 L questionnaire
GDM	Gestational diabetes mellitus
GEE	Generalised Estimating Equations
HCPs	Healthcare providers
HDP	Hypertensive disorders of pregnancy
ICER	Incremental cost-effectiveness ratios
ICHOM	International consortium for health outcomes measurement
LRS	Lifestyle risk score
MAUQ	mHealth app usability questionnaire
MCQ	Medical costs questionnaire
MIDI	Measurement Instrument for Determinants of Innovation
MhQoL	Mental health quality of life questionnaire
NASSS	Non-adoption, Abandonment, Scale-up, Spread, and Sustainability
NICU	Neonatal intensive care unit
OGTT	Oral glucose tolerance test
PCQ	Productivity costs questionnaire
PREM	Patient-reported experience measurements
PROM	Patient-reported outcome measurements
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
SP+	Smarter Pregnancy Plus

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12884-026-09196-w.

Supplementary Material 1: 1. Outcome measurements assessed within the HYGEIA study. 2. Lifestyle screening survey. 3. Baseline and follow-up survey.

Supplementary Material 2. SPIRIT Checklist

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Authors' contributions

MR, workpackage leader of the trial, contributed to the design and initiated writing of the protocol of the trial. RB also contributed to the design of the trial. MR and RB together wrote the first version of this manuscript. RST initiated and is principle investigator of the HYGEIA project, contributed to SP+ also as developer of the web-based Smarter Pregnancy applications, design of the trial, and revised multiple versions of the manuscript. IF and MP designed the cost-effectiveness analysis and budget impact analysis and drafted that section of the manuscript. EA, ASR, CF, PB, PJ contributed to designing the trial and revised the manuscript. All authors read and approved the final version of the manuscript. Melek Rousian (MR) and Rianne J de Bruin (RB) contributed equally to this work.

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Data availability

The study protocol, statistical analysis plan, data management and monitoring procedures are available upon request. The full dataset generated and analysed during the study will be made available upon reasonable request after publication of the main results.

Declarations

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of the Erasmus MC, University Medical Centre, Rotterdam, the Netherlands under reference number NL87213.078.24. Approval by the boards of management for the participating hospitals was obtained. All participants will provide informed consent prior to enrolment.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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