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HEALTHYMOMS – A SMARTPHONE APPLICATION TO PROMOTE HEALTHY WEIGHT GAIN, DIET AND PHYSICAL ACTIVITY DURING PREGNANCY: A RANDOMIZED CONTROLLED TRIAL

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Cover illustration: A photo of me when I was pregnant with our first child Mina, using the HealthyMoms app. The photo is taken by Viktor my partner and edited by me.

HealthyMoms – a smartphone application to promote healthy weight gain, diet and physical activity during pregnancy: a randomized controlled trial
THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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To the shining and guiding stars in my life –

my loving partner Viktor and our two beautiful daughters

POPULAR SCIENCE SUMMARY OF THE THESIS

Background

Weight gain in pregnancy is closely related to the health of both mother and child. For instance, gaining too much weight during pregnancy increases the risk of gestational diabetes, and later obesity for both mother and child. On the other end of the spectra, an insufficient weight gain increases the risk of e.g., preterm birth. Alarmingly, few women gain weight in accordance with current recommendations. In fact, one in two pregnant women in the Western world, including Sweden, gain excessive weight in pregnancy. Lifestyle factors such as diet and physical activity play an important role in supporting a healthy weight gain and have been the focus of many previous lifestyle interventions in pregnancy. Fortunately, these have been shown to successfully decrease the risk of excessive weight gain; however, traditionally, they have relied on face-to-face counselling which requires extensive resources. In this digital era the use of technology such as smartphone apps to deliver lifestyle interventions has emerged and compared to traditional delivery modes, require less resources while simultaneously provide wider reach and possibilities to provide more individually tailored interventions. To date, few studies have investigated the usability and effectiveness of a lifestyle intervention in pregnancy solely delivered through a smartphone app. Finally, pregnancy is characterized by physiological changes which impact the ability to maintain the same level of physical activity and few pregnant women reach the recommended levels of physical activity. Current knowledge on how physical activity levels in pregnancy change, especially taking all movement behaviors (i.e., physical activity of different intensities, sedentary behavior, and sleep) into consideration is insufficient. Thus, to further understand the impact of physical activity in pregnancy and improve future interventions and guidelines research on this topic is needed.

Research approach

A randomized controlled trial was conducted to investigate the effectiveness of a 6-month digital pregnancy and lifestyle intervention (the HealthyMoms app) on weight gain, diet, physical activity, and glycemia in pregnancy and infant body size and composition (i.e., fat- and fat free mass). Three hundred and five women were recruited in early pregnancy at maternity clinics in the county of Östergötland and completed baseline assessments in early pregnancy (gestational week 14). These included measurements of weight, body composition, diet, physical activity, and cardiometabolic health indicators (i.e., blood pressure, blood lipids). After completion of these measurements, women were randomized to either the intervention (i.e., standard maternity care and the HealthyMoms app) or control group (i.e., standard maternity care). Women then returned for a follow up measurement in late pregnancy (gestational week 37) to repeat the same assessments. Furthermore, at this time point usage and satisfaction with the app was also examined by exit interviews with nineteen women from the intervention group. Lastly, the women returned for a third measurement 1-2 weeks after birth at which their infant's weight, length, and body composition were assessed to investigate potential effects of the intervention on the child as well. Finally, the data on physical activity collected in pregnancy were used to investigate associations between physical activity of different intensities, sedentary behavior, and sleep with body composition and cardiometabolic health indicators (e.g., metabolic syndrome score, blood sugar levels and insulin resistance) in early and late pregnancy.

Results

Overall, the results showed no effect on gestational weight gain, in the whole group; however, women in the intervention group with overweight or obesity prior to pregnancy gained almost 1.7 kg less weight compared to their counterparts in the control group. The women in the intervention group also reported a healthier dietary index score (i.e., taking intakes of fruit and vegetables, fat quality, red meat, wholegrain and added sugar into consideration). No interventional effect on maternal physical activity nor infant weight, length, or body composition were observed. As for the women's usage and satisfaction with the HealthyMoms app, the results revealed that the app was considered easy to use, trustworthy and appreciated and that it can inspire a healthy lifestyle in pregnancy. Regular updates and feedback from the app were perceived to motivate both healthy habits and usage of the app. Moreover, personal interests, motivation and need of behavior change and curiosity about the app were described to motivate app usage while pregnancy-related complications and lack of time were described as limiting. Additionally, aspects such as high trustworthiness of the app, increased knowledge, and awareness from using the app were described as important and motivated the women to improve or maintain healthy habits in pregnancy. Regarding the role of physical activity in pregnancy the results showed that reallocating time to physical activity of higher intensity was associated with better metabolic syndrome score while higher levels of light physical activity (e.g., walking) was associated with lower body weight and better insulin resistance in early pregnancy. Finally, spending more time in light physical activity relative to sedentary behavior and sleep was associated with more favorable body composition (i.e., less fat mass), blood sugar levels, insulin resistance and metabolic syndrome score in late pregnancy.

Conclusions

In conclusion, the results demonstrate that a digital lifestyle intervention (the HealthyMoms app) has potential to promote healthy dietary habits overall as well as decrease weight gain in pregnancy in women with overweight and obesity, without influencing offspring growth. Moreover, the HealthyMoms app was appreciated and used to a high extent which further shows its potential to be implemented in healthcare to promote a healthy lifestyle in pregnancy. Furthermore, physical activity of lower intensities might be enough to improve maternal body composition and cardiometabolic health indicators and could be a key focus in future health promotion in pregnancy.

ABSTRACT

Background: The prevalence of overweight and obesity is a major public health concern, also among pregnant women. Alarmingly, around half of pregnant women in high income countries exceed the recommendations for an optimal gestational weight gain (GWG). Clearly, scalable interventions are needed, and digital interventions have the potential to reach many women and promote healthy GWG. In addition to intervention effectiveness, it is also important to investigate user engagement and satisfaction with the intervention as well as potential intervention effects on the infant (e.g., infant growth and body composition). Finally, although it is clear that lifestyle factors such as low levels of physical activity may contribute to excessive GWG, levels of physical activity tend to decrease during pregnancy. However, current knowledge on how time spent in different physical activity intensities as well as sedentary behavior and sleep (i.e., movement behaviors) in pregnancy is scarce. Thus, to further understand the impact of physical activity during pregnancy and improve future interventions and guidelines research on this topic is needed.

Aims: The overall and primary aim of this thesis was to investigate the effectiveness and usability of a 6-month digital lifestyle intervention (the HealthyMoms app) intended to promote a healthy weight gain, diet, and physical activity during pregnancy. Furthermore, as a secondary aim, I explored how time spent on different movement behaviors (i.e., sleep, sedentary behavior, light physical activity [LPA], and moderate-to-vigorous physical activity [MVPA]) changed from early to late pregnancy, and how such changes were associated with maternal weight and body composition (i.e., fat- and fat free mass) as well as cardiometabolic health indicators. This may be important for future development of the HealthyMoms app as well as for other researchers when developing lifestyle interventions in this field. The specific aims of the included papers were:

Paper I: To investigate the effectiveness of the HealthyMoms app on i) GWG (primary outcome), and ii) body fatness, dietary habits, MVPA, glycemia, and insulin resistance (secondary outcomes) in comparison to standard maternity care.

Paper II: To explore participants' engagement and satisfaction with the 6-month usage of the HealthyMoms app.

Paper III: To investigate i) the effects of the HealthyMoms app on infant body composition 1-2 weeks postpartum, and ii) whether a potential intervention effect on infant body composition is mediated through maternal GWG.

Paper IV: To examine cross-sectional and longitudinal associations of 24-hour movement behaviors (i.e., sleep, sedentary behavior, LPA, and MVPA) with GWG, maternal body composition and cardiometabolic health in i) early- (gestational week 14), and ii) late pregnancy (gestational week 37).

Methods:

Paper I: A 2-arm parallel randomized controlled trial including 305 pregnant women. Women were randomized in a 1:1 ratio to either the intervention (n=152) or control group (n=153) upon completion of baseline measures in gestational week 14. The control group received standard care while the intervention group also received the HealthyMoms app for six months. Outcome measures were assessed at baseline and follow up in gestational week 37. The primary outcome was GWG, and secondary outcomes included body fatness (air-displacement plethysmography using Bod Pod), dietary habits (Swedish Healthy Eating Index) and MVPA (ActiGraph wGT3x-BT accelerometer), glycemia and insulin resistance. Linear regression was used to examine differences in primary and secondary outcomes between the intervention and control group.

Paper II: A qualitative study including 19 women from the intervention group in the HealthyMoms trial. Semi-structured exit interviews were performed. The interviews were audio-recorded and fully transcribed, coded and analyzed using thematic analysis with an inductive approach.

Paper III: A secondary outcome analysis including 305 healthy full-term infants from the HealthyMoms trial. Body composition was measured using air-displacement plethysmography (Pea Pod) at 1-2 weeks of age. Linear regression was used to examine the effect of intervention allocation (intervention vs control) on infant outcomes.

Paper IV: An observational study utilizing both cross-sectional (n=273) and longitudinal data (n=242) from the HealthyMoms trial. Exposure (movement behaviors [ActiGraph wGT3x-BT accelerometer]) and outcome measures (body composition [Bod Pod] and cardiometabolic health [metabolic syndrome score, MetS score; homeostatic model assessment for insulin resistance, HOMA-IR]) were assessed in gestational weeks 14 and 37. To investigate associations between different combinations of movement behaviors with body composition and cardiometabolic health compositional data analysis was used.

Results

Paper I: Overall, no statistically significant effect on GWG (*P*=0.62) was found; however, the results from both the imputed and completers-only analyses indicate that women in the intervention group with a pre-pregnancy BMI ≥25 kg/m^2 gained less weight compared to their counterparts in the control group (-1.33 kg; 95% CI -2.92 to 0.26; *P*=0.10, and -1.67 kg; 95% CI -3.26 to -0.09; *P*=0.031, respectively). Among women with overweight and obesity Bayesian analyses showed that there was a 99% probability of any intervention effect on GWG, and an 81% probability that this effect was over 1 kg. The intervention group had higher scores for the Swedish Healthy Eating Index at follow up than the control group (0.27; 95% CI 0.05-0.50; *P*=0.02). No statistically significant differences in the other outcomes (i.e., body fatness, MVPA, glycemia, and insulin resistance) between the intervention and control groups at follow up were observed (*P*≥0.21).

Paper II: One main theme ('One could suit many – a multi-functional tool to strengthen women's health during pregnancy') and two subthemes ('Factors within and beyond the app influence app engagement' and 'Trust, knowledge, and awareness – aspects that can motivate healthy habits') were revealed from the thematic analysis. These illustrated that a health and pregnancy app that is easy to use, trustworthy and appreciated can inspire a healthy lifestyle during pregnancy. Factors within the app (e.g., regular updates and feedback) were perceived to motivate both healthy habits and app engagement, while factors beyond the app were described to both motivate (e.g., interest, motivation, and curiosity) and limit (e.g., pregnancy-related complications, lack of time) app engagement (first subtheme). Aspects such as high trustworthiness of the app, increased knowledge, and awareness from using the app were described as important and motivated participants to improve or maintain healthy habits during pregnancy (second subtheme).

Paper III: No statistically significant effect on infant weight (β=-0.004, *P*=0.94), length (β=-0.19, *P*=0.46), body fat percentage (β=0.17, *P*=0.72) or any of the other body composition variables in the multiple regression models (all *P* ≥ 0.27) were observed at 1.8 (SD 0.4) weeks of age. Moreover, no mediation effect through GWG on infant outcomes were found.

Paper IV: Reallocating time to MVPA in favor of the other behaviors was associated with lower MetS score (all γ≤0.343, all *P*≤0.002), while higher levels of LPA were associated with lower body weight (adj. γ=-5.959, *P*=0.047) and HOMA-IR (all γ≤-0.495, *P*≤0.047) in early pregnancy. Increasing LPA relative to the other behaviors in early pregnancy was associated with lower fat mass index (adj.: γ=-0.668, *P*=0.028), glucose levels (all γ≤-0.219, all

$P \leq 0.043$), HOMA-IR (all $\gamma \leq -0.619$, all $P \leq 0.016$) and MetS score (all $\gamma \leq -0.410$, all $P \leq 0.040$) in late pregnancy.

Conclusions: The results from this thesis demonstrate that a digital lifestyle intervention (the HealthyMoms app) has potential to promote healthy dietary habits in women representing all BMI-categories and decrease weight gain during pregnancy in women with overweight and obesity without compromising offspring growth. Moreover, the HealthyMoms app was appreciated and used to a high extent which further shows its potential to be implemented in healthcare to promote a healthy lifestyle during pregnancy. Furthermore, the results indicate that LPA might be a stimulus of enough intensity to improve body composition and cardiometabolic health indicators and could be a key focus in future health promotion initiatives during pregnancy.

LIST OF SCIENTIFIC PAPERS

I. **Sandborg J**, Söderström E, Henriksson P, Bendtsen M, Henström M, Leppänen MH, Maddison R, Migueles JH, Blomberg M, Löf M. Effectiveness of a Smartphone App to Promote Healthy Weight Gain, Diet and Physical Activity During Pregnancy (HealthyMoms): Randomized Controlled Trial. *JMIR mHealth and uHealth.* 2021 Mar 11;9(3):e26091.

II. **Sandborg J**, Henriksson P, Larsen E, Lindqvist AK, Rutberg S, Söderström E, Maddison R, Löf M. Participant's Engagement and Satisfaction With a Smartphone App Intended to Support Healthy Weight Gain, Diet and Physical Activity During Pregnancy: Qualitative Study Within the HealthyMoms trial. *JMIR mHealth and uHealth.* 2021; Mar 5;9(3):e26159.

III. **Sandborg J**, Henriksson P, Söderström E, Migueles JH, Bendtsen M, Blomberg M, Löf M. The effects of a lifestyle intervention (the HealthyMoms app) during pregnancy on infant body composition: secondary outcome analysis from a randomized controlled trial. *Pediatric Obesity.* 2022;e12894.

IV. **Sandborg J**, Migueles JH, Söderström E, Blomberg M, Henriksson P, Löf M. Physical activity, body composition and cardiometabolic health during pregnancy: a compositional data approach. *Manuscript submitted*

SCIENTIFIC PAPERS NOT INCLUDED IN THE THESIS

Below is a list of other papers published or submitted thus far from the HealthyMoms trial including the study protocol (*Appendix 1*).

I. Henriksson P, **Sandborg J**, Blomberg M, Alexandrou C, Maddison R, Silfvernagel K, Henriksson H, Leppänen MH, Migueles JH, Widman L, Thomas K, Trolle Lagerros Y, Löf M. A Smartphone App to Promote Healthy Weight Gain, Diet, and Physical Activity During Pregnancy (HealthyMoms): Protocol for a Randomized Controlled Trial. JMIR Res Protoc. 2019 Mar 1;8(3):e13011.

II. Henriksson P, **Sandborg J**, Söderström E, Leppänen MH, Snekkenes V, Blomberg M, Ortega FB, Löf M. Associations of body composition and physical fitness with gestational diabetes and cardiovascular health in pregnancy: Results from the HealthyMoms trial. *Nutr Diabetes*. 2021 Jun 7;11(1):16.

III. Henström M, Leppänen MH, Henriksson P, Söderström E, **Sandborg J**, Ortega FB, Löf M. Self-reported (IFIS) versus measured physical fitness, and their associations to cardiometabolic risk factors in early pregnancy. *Sci Rep*. 2021 Nov 22;11(1):22719.

IV. Henriksson P, Migueles JH, Söderström E, **Sandborg J**, Maddison R, Löf M. User engagement in relation to effectiveness of a smartphone app to promote healthy weight gain, diet and physical activity in pregnancy: Results from the HealthyMoms trial (*Manuscript submitted*)

CONTENTS

LIST OF ABBREVIATIONS

ADP	Air-displacement plethysmography
App	Mobile application
BMI	Body mass index
CI	Confidence interval
DBP	Diastolic blood pressure
eHealth	Electronic health
FFMI	Fat free mass index
FMI	Fat mass index
GWG	Gestational weight gain
HDL	High-density lipoprotein
HOMA-IR	Homeostatic model assessment for insulin resistance
LDL	Low-density lipoprotein
LPA	Light physical activity
MetS	Metabolic syndrome
mHealth	Mobile Health
MUFA	Monounsaturated fatty acids
MVPA	Moderate-to-vigorous physical activity
NAM	National Academy of Medicine
PUFA	Polyunsaturated fatty acids
RCT	Randomized controlled trial
SB	Sedentary behavior
SBP	Systolic blood pressure
SD	Standard deviation
SFA	Saturated fatty acids
SHEI	Swedish healthy eating index

1 INTRODUCTION

1.1 OBESITY AND UNHEALTHY WEIGHT GAIN IN PREGNANCY – LARGE PUBLIC HEALTH ISSUES

Overweight and obesity is a major public health issue with high prevalence in the general population [1] as well as among pregnant women in Sweden and other developed countries [2]. According to a recent report from the Swedish National Board of Health and Welfare the number of women with overweight (BMI: 25.0-29.9 kg/m^2) and obesity (BMI ≥ 30.0 kg/m^2) have increased the last years, and in 2020, 44% of pregnant women in Sweden had overweight or obesity at the first visit in maternity care [3]. Additionally, the majority of pregnant women do not meet the recommendations for gestational weight gain (GWG) [4]. A review by Goldstein et al. [4] showed that in the US and Europe, around 50% exceed the recommended GWG and approximately 20% gain less than the commonly applied recommendations provided by the National Academy of Medicine (**Table 1**) [5]. Similarly, data from Sweden indicate that almost 50% of Swedish women exceed the recommendation [6,7]. This is concerning since both overweight/obesity and excessive GWG are associated with negative health outcomes in both mother and child [8,9]. Excessive GWG increases the risk of e.g. cesarean delivery, gestational diabetes, preeclampsia, and later obesity in both mother and child [8,10]. In addition, pregnancy complications (e.g., gestational diabetes) have been found to increase the risk of future cardiometabolic disease [11,12]. Notably as many as 30-40% of normal weight women have been shown to gain excessive weight in pregnancy [6,13], indicating that support to counteract excessive GWG is important not only for those with overweight or obesity. Thus, it is important to promote a healthy GWG across different BMI-categories, and in that aspect lifestyle factors such as diet and physical activity are important targets.

Table 1. Recommendations for gestational weight gain according to the 2009 National Academy of Medicine’s recommendations.

Pre-pregnancy BMI [a]	GWG recommendations (kg) [b]
Underweight	12.5-18
Normal weight	11.5-16
Overweight	7-11.5
Obesity	5-9

BMI: body mass index; GWG, gestational weight gain.

[a] Underweight, BMI < 18.5 kg/m^2; Normal weight, BMI = 18.5-24.9 kg/m^2; Overweight, BMI = 25.0-29.9 kg/m^2; Obesity, BMI ≥ 30 kg/m^2.

[b] GWG recommendations according to the National Academy of Medicine (previously Institute of Medicine) [5].

1.2 INTERVENTIONS TO PROMOTE A HEALTHY GESTATIONAL WEIGHT GAIN - PROMISING BUT RESOURCEFUL

Considering the risks associated with excessive GWG and the high prevalence of pregnant women not fulfilling the recommendations, effective and evidence-based strategies to promote a healthy GWG is of great importance. Traditional interventions (e.g. face-to-face counselling individually or in group, supervised exercise sessions) to reduce the risk of excessive GWG have been reported to be successful [14–16]. A Cochrane review from 2015 found that traditional interventions focusing on diet, exercise or both can reduce the risk of excessive weight gain during pregnancy by 20% [15]. Similarly, more recent systematic reviews and meta-analyses have found that lifestyle interventions focusing on diet and/or physical activity have a positive effect on GWG [17–19]. More specifically, lifestyle interventions in pregnancy reduced GWG with 1.15 kg (95% CI: -1.40 to -0.91; 117 RCT studies, n=34,546) [19]. However, results from individual intervention studies are mixed and not all applied interventions have been effective. For instance, even though a randomized controlled trial (RCT) in 374 Swedish healthy pregnant women (BMI ≥ 19 kg/m^2) with a comprehensive intervention (education on recommended GWG, a personalized weight graph, prescription of exercise and regular GWG monitoring) had an effect on average GWG (intervention group: 14.2 [SD 4.4] kg; control group: 15.3 [SD 5.4] kg) the intervention did not manage to reduce the proportion of women exceeding the recommendations [20]. In addition, an RCT study in pregnant Australian women with normal weight that evaluated the effect of a dietitian-led dietary and exercise advice intervention observed no effect on GWG or other pregnancy outcomes despite improvements in diet [21]. Additionally, an RCT study [22] (n=2286) found no effect of the intervention (consisting of lifestyle advice given by trained healthcare providers) on GWG and similar to previous findings e.g. [4,6], 45% of the women in the study exceeded the GWG recommendations. In contrast, Morison et al. [18] found that a patient-centered intervention reduced GWG when compared with standard prenatal care. The effectiveness of GWG interventions does indeed vary and in addition, data on the cost-effectiveness of interventions to reduce GWG is scarce and existing results are inconsistent [23]. It could; however, be stated that traditional interventions often are resource heavy and rely considerably on healthcare staff. These examples also highlight the need of individual evaluation of interventions since each intervention is unique. Furthermore, it is challenging to assess adherence in traditional interventions (e.g., dietary counselling using personalized dietary plans) as study participants are not monitored between counselling sessions.

1.3 MHEALTH - POTENTIAL TO PROVIDE SCALABLE TOOLS TO PROMOTE HEALTHIER LIFESTYLE AND GWG IN PREGNANT WOMEN

In the last decade, the use of digital technologies (e.g., electronic Health [eHealth] and mobile Health [mHealth]) to deliver interventions has increased. These terms refer to healthcare services provided with the support of information and communication technology (e.g., computers, mobile phones) and the use of e.g., smartphones for health services and information, respectively [24]. In comparison to traditional interventions, eHealth and mHealth interventions have the potential of being more cost-effective as they can be made available to a larger number of people [25]. In addition, as digital solutions can be delivered anywhere and at any time it may relieve the burden on healthcare staff and thus serve as a valuable resource. Moreover, mHealth solutions (e.g. mobile applications [apps]) can be tailored to fit individual needs which may increase engagement in an intervention program [26]. In addition, many women in developed countries use e.g. commercial pregnancy-related apps for gathering information (e.g. information on maternal and fetal health, pregnancy tracking) and support (e.g. personalized tools to assess nutrition and weight) [27–29]. Pregnancy apps are also the most commonly used medical app [27–29]. However, previous data on pregnant women's app usage have shown that uncertainty of the correctness of information in such apps can cause feelings of anxiety [27,29]. The importance of accurate information and support for a healthy GWG have been stressed previously [30], indicating a need of evidence-based pregnancy apps.

Interestingly, the request for digitization of maternity care services in general has recently been enforced for another reason as well, i.e., the COVID-19 pandemic [31]. Such changes include reduced number of in-person appointments and extended use of virtual care. Although this cautionary approach to decrease the risk of infection has been appreciated by pregnant women, the introduction of digital services has also been reported to cause negative emotions such as fear of essential clinical care being missed and confusion over advice [32–34]. In addition, the pandemic has been described to reduce physical activity and increase unhealthy eating among pregnant women due to the restrictions [35]. Nevertheless, web-based resources have been increasingly used and digital support tools (e.g., apps) have also been described to help compensate for the loss of face-to-face advice and support [35]. Moreover, already prior to the COVID-19 pandemic, pregnant women have expressed positive views regarding mHealth for the promotion of a healthy lifestyle in maternity care [36]. Altogether, there is a need of evidence-based pregnancy apps with reliable information covering both pregnancy related information and healthy lifestyle advice, and the enforced digitalization of other maternity healthcare services due to the pandemic may actually have paved some way in this development.

Moreover, previous studies in non-pregnant populations have demonstrated the potential of digital interventions to improve dietary habits, physical activity and weight management [37]. Interventions using digital components have also been evaluated in pregnant women; however, thus far the number of studies is quite few and results inconsistent. For instance, one pilot study in women with overweight/obesity reported promising results with a lower proportion of women in the intervention group exceeding the recommended GWG compared to usual care (58% vs. 85%) [38]. Furthermore, a review by Hussain et al. [39] reported that three out of four individual studies showed an intervention effect on GWG. In contrast, a meta-analysis from 2020 including three digital interventions during pregnancy found no effect on GWG (-0.28 kg; 95% CI: -1.43 to 0.87, n=3 studies); however, the included studies were primarily pilot RCTs with insufficient power to detect an effect [40]. Moreover, previous studies in this research field have had high heterogeneity in terms of modes of intervention delivery which complicates comparisons of intervention effectiveness. Some studies have combined digital intervention components with face-to-face or telephone contact e.g. [41,42], others have used text messages e.g. [41], or combinations of text messages, websites or other components e.g. [43–45], and few studies have utilized a smartphone app only e.g. [38]. To conclude, the full potential of digital interventions in pregnancy is still to be explored since most studies thus far have been pilot studies with small sample size, and none of them have included women from all BMI categories.

1.4 KEY OUTCOMES TO MEASURE IN LIFESTYLE INTERVENTIONS

1.4.1 Diet

An important aspect when designing interventions is the choice of accurate and feasible methods to assess intervention outcomes, such as diet and physical activity which are two important factors that may contribute to an unhealthy GWG. Accurate and precise assessments of intake of foods, drinks and energy are challenging and although there are many different methods they rely on self-report and are associated with different sources of bias (e.g., recall bias: 24-hour recall, food frequency questionnaire; interviewer bias: 24-hour recall; social desirability bias: all methods including weighed food record). These methods are also often resource-intensive and expensive (e.g., weighed food records). A landmark in nutritional physiology research was the introduction of the doubly labelled water method in humans in the 1980's which provided for the first time accurate estimates of total energy expenditure [46]. It also provided new possibilities to evaluate reports of energy intake and then it became evident that underreporting of food intake was common in adults irrespectively of dietary method used [46]. A recent systematic review by Burrows et al. [47] compiling evidence on the evaluation of dietary methods (e.g., food records, 24-hour recalls, food frequency questionnaire) confirmed that the majority of the included methods significantly underestimated energy intake compared with doubly labelled water. Also, studies in pregnant women have identified underreporting of energy intake as a problem [48,49]. It is also relevant to note that the review by Burrows et al. [47] concluded that the problem of underreporting was less pronounced for 24-hour recalls.

In recent years, the use of technology-based solutions (e.g., computer/web assisted recalls) to assess diet has increased. Even though studies using a technology component reported under-reporting of energy intake (by 6-24%) it showed similar accuracy when compared to traditional 24-hour recalls which underestimated energy intake by 8-30% [47]. In addition, using technology/web-based methods to collect dietary data is feasible [50] and has been used to assess diet in pregnant women [51]. Moreover, web-based methods to assess diet simplifies data processing and data collection by providing the opportunity to automatically link diet records with food databases. For instance, the Swedish National Food Agency validated and used a new web-based method which utilizes repeated 24-hour recalls to assess dietary intake in adolescents [52–54]. Although, there is yet no golden standard method with high accuracy and precision to assess diet, web-based solutions provide some advantages as it is less burdensome for both participants and researchers. Furthermore, if possible, it is important to validate dietary methods for the population under investigation in an intervention study to be able to quantify and identify errors and their implications on the actual research questions.

1.4.2 Physical activity

Similar to assessment of diet, self-reported methods to assess physical activity (e.g., questionnaires) may be biased due to e.g., misreporting. The importance of using objective methods in research in pregnant women has also been highlighted in a commentary by

Guérin et al. [55]. For instance, an Australian study in pregnant women with overweight and obesity found that self-reported questionnaires overestimated moderate-to-vigorous physical activity (MVPA) [56]. Although, the study had a small sample size it exemplifies what has been seen in several previous studies as demonstrated by Guérin et al. [55]. In addition, questionnaires have also been found to be a poor measure of sedentary behavior in pregnant women [57]. Thus, objective measures (such as accelerometers) to assess movement behaviors (i.e., different physical activity intensities, sedentary behavior, and sleep) can be considered more accurate [58]. Accelerometers such as the ActiGraph GT3X+ have also been validated in pregnant women showing moderate to strong reliability and moderate validity when compared to indirect calorimetry [59]. Moreover, a study by Hesketh et al. [60] compared compliance of wrist- and hip worn accelerometers, and concluded that the first mentioned may be preferable to assess physical activity during pregnancy as the compliance was higher for wrist-worn accelerometers.

Furthermore, this is also an interesting field with a rapid development in the past years in terms of data processing and analysis. For instance, packages i.e. GGIR [61], for accelerometer data processing in the software program R (http://www.R-project.org/) have enabled more comprehensive analyses as well as enhanced reproducibility and transparency of data analyses. Additionally, the 24-hour continuum which considers movement behaviors as co-dependent has become more recognized [62]. This approach (using compositional data analysis) enables more nuanced analyses in which the effect of reallocating time spent in one movement behavior to the others can be examined at the same time as it lowers the risk of multicollinearity [62,63]. This is of special interest as most women evidently alter their movement behaviors in pregnancy. In that aspect, it is important to identify what type of changes that can still offer health benefits, and more research in this area is needed [64].

1.4.3 Body composition

Another key outcome to measure in interventions to promote healthier GWG is of course body weight which should be measured under standardized conditions (i.e., fasting, in light clothing, using the same equipment). However, preferably, for a full evaluation of the trial effect, body weight measures should be complemented with data on the composition of the weight gain (i.e., fat- and fat free mass). Previous studies have mainly used measures such as length and body weight or BMI to assess maternal outcomes e.g. [65]. BMI has however, been found to be a poor marker of the proportion of body fat, also in pregnant women and using it as a proxy for fat mass does not account for potential confounding effects of the amount of lean mass on health outcomes [66]. Potential methods to assess body composition in pregnancy with sufficient accuracy are underwater weighing and isotope dilution [67]; however, these methods are rather time consuming and not feasible in all women and in larger studies. Another comprehensive method that is safe but also more user-friendly as it is non-invasive and fast is air-displacement plethysmography (by means of Bod Pod) which uses gestational-age specific densities to correct for the changes in fat free mass hydration and density in pregnancy [68,69]. The method measures body weight and volume from which body density can be derived (weight divided by volume). Body fatness is then calculated by using gestational-age specific densities for fat- and fat free mass [70,71] which have been shown to be appropriate estimates during pregnancy [68,69]. However, few studies have investigated the effects of a lifestyle intervention in pregnancy on maternal body composition using air-displacement plethysmography.

1.4.4 Infant outcomes

As previously described, both excessive and inadequate GWG are associated with negative health outcomes for the child [8,9,72], and the prenatal period, which is characterized by rapid development, has been shown to have persisting influence on obesity risk [73,74]. Moreover, GWG and maternal lifestyle factors (e.g., diet and physical activity) in pregnancy have been shown to influence health and disease risk in the infant [8,10], and factors such as high birthweight and rapid growth in infancy have been identified as risk factors for elevated BMI in childhood and later in life [75,76]. Thus, interventions intended to promote a healthy lifestyle and weight gain in pregnancy also has potential to impact infant outcomes. Therefore, it is important to investigate the effects of lifestyle interventions targeting pregnant women also on the child (e.g., body size and composition) to identify potential benefits and ensure the safety of the intervention. Fortunately, interventions aimed at reducing excessive GWG have been found to reduce birthweight, risk of macrosomia and large for gestational age [77], indicating beneficial effects of lifestyle interventions in pregnancy also for the infant. Moreover, body composition has been hypothesized to mediate the link between fetal nutrition experience and later disease [78]. Thus, in addition to assessment of weight alone, measurements of body composition provide a more comprehensive assessment of infant growth. In that aspect, air-displacement plethysmography (by means of Pea Pod) is a safe and user-friendly method that has been shown to provide accurate estimates of the proportion of fat- and fat free mass also in infancy [79–82]. However, to date only a few full-scale studies have investigated the effects of a lifestyle intervention in pregnancy on infant body composition, and although the effect on GWG were similar in these two studies (approximately -1.7 kg) their results on infant outcomes were inconsistent [83,84].

1.4.5 User engagement and satisfaction

Another important aspect in assessment of intervention effectiveness is adherence to the intervention. Indeed, user engagement has been described as a precondition for intervention effectiveness also in digital interventions [85]. Compared to more traditional lifestyle interventions, the use of mHealth enables more comprehensive investigation into participant behavior and engagement with the intervention, for instance by using in-built tools to track usage. This facilitates comprehensive evaluation of the relationship between participants' adherence and usage with intervention effectiveness, which is information that can provide important knowledge on intervention strengths and weaknesses. In addition to this type of objective and quantitative measures of adherence, qualitative research (e.g., interviews) can provide more in-depth and richer information on participant engagement and satisfaction with the intervention which further facilitate evaluation as well as future intervention development, tailoring and improvements. Indeed, qualitative research aims to provide a greater understanding of a phenomenon [86]. In comparison to e.g., questionnaires, qualitative research methods (e.g., focus groups, interviews) are often far more time consuming while also engaging less people. To illustrate, semi-structured interviews only engage one participant at a time and often lasts up to an hour [87]. However, an advantage of this type of method (which employs a prespecified interview guide accompanied by follow up questions) is that it is more flexible in terms of questions being asked and can thereby provide insights into unforeseen issues which questionnaires cannot [87]. Altogether, both quantitative and qualitative methods to assess participant engagement can provide important insights that are crucial for intervention evaluation, as well as implementation and adaption of interventions into e.g., routine practice. Further, it can serve as an important basis for future intervention development.

1.5 POTENTIAL TO IMPROVE KNOWLEDGE ON MOVEMENT BEHAVIORS IN PREGNANCY USING OBJECTIVE METHODOLOGY

Higher levels of physical activity have been associated with lower risks of excessive GWG as well as pregnancy complications (e.g., pre-eclampsia, gestational hypertension and gestational diabetes), and thus optimize maternal and fetal health [64,88,89]. In 2020, the World Health Organization published new global guidelines for physical activity and sedentary behavior [64], which were followed by national guidelines for Sweden in June 2021 [90]. This is the first time these guidelines have included specific recommendations for pregnant women. Unfortunately, levels of physical activity tends to decrease in pregnancy, and studies have shown low adherence to the recommendations [88,91–93]. For instance, only 27% of the women in a Swedish study reported reaching the recommendations in the third trimester [88]. Clearly, it is important to promote physical activity in pregnancy to help prevent excessive GWG [94], and it is also a strategy which is often incorporated in GWG interventions e.g. [20,21,65,95]. Moreover, exercise interventions during pregnancy have also been shown to positively affect the proportion of women meeting the recommendations [96]. In addition, it is well-established that physical activity, sedentary behavior, and sleep are all associated with physical and mental health [64,97,98]. These three behaviors are part of a 24-hour movement continuum as the proportion of time allocated to sleep, sedentary behavior, and physical activity is co-dependent [99]. Thus, increasing time spent in one movement behavior (i.e., sleep, sedentary behavior, and physical activity) automatically result in a proportional decrease in the other behaviors. Nevertheless, little is known on the associations of dosage and levels of movement behaviors and pregnancy outcomes (e.g., cardiometabolic health indicators) and more research in this area has been requested [64]. In that aspect, risk scores e.g., the metabolic syndrome (MetS) score, which is comprised of a cluster of risk factors (i.e., central adiposity, blood pressure, triglycerides, high-density lipoprotein [HDL] cholesterol and fasting glucose), provide a potential opportunity to identify individuals at risk and also follow progress over time [100]. Moreover, using a composite score instead of individual scores provides a better reflection of cardiometabolic risk and may also compensate for day-to-day variations in the single risk factors [101].

1.6 BRIEF SUMMARY

In summary, although traditional lifestyle intervention studies in pregnant women have shown promise, many studies have had a short intervention period, does not include all BMI categories (e.g., only women with normal weight [21], normal weight and above

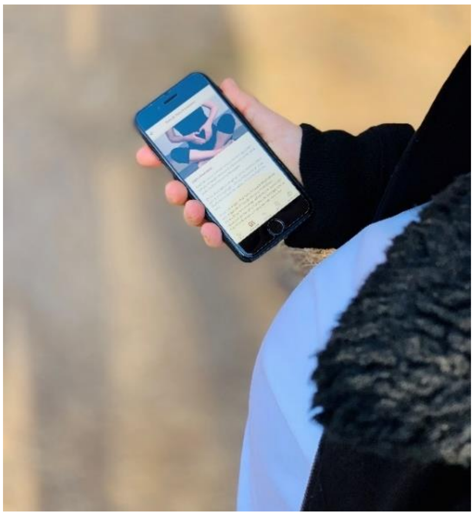
[65,102,103], or women with overweight/obesity [104]), and have mainly used subjective measures to assess physical activity (e.g. questionnaires) e.g. [21]. Also, few studies have examined body composition (in addition to GWG) and intervention effects on infant body composition using accurate methodology such as air-displacement plethysmography (e.g., [83,84,105,106]). Furthermore, as demonstrated above many traditional interventions rely heavily on healthcare staff which limits scalability and reach. mHealth solutions on the other hand have the advantage of greater accessibility; however, to date, most mHealth studies have been pilot studies with small sample size (e.g. [38,107]) and few have investigated the effects of an intervention solely delivered through an app on GWG. Thus, RCTs with larger sample size, and robust methods to assess outcome measures to evaluate the effectiveness of apps targeting pregnant women are warranted. Moreover, as stated previously each intervention is unique and individual evaluation of interventions intended to promote a healthy GWG is necessary to determine effectiveness and usefulness, as well as safety and potential beneficial effects on infant body composition and growth. Furthermore, diet and physical activity are often the focus of GWG interventions and their importance for a healthy pregnancy is well-acknowledged; however, little is known on the associations of dosage and levels of physical activity in pregnancy and pregnancy outcomes. Subsequently, more research in this area has been called for [64]. This is of importance for future development of GWG interventions as well as physical activity guidelines in pregnancy.

2 RESEARCH AIMS

The overall and primary aim of this thesis was to investigate the effectiveness and usability of a 6-month digital lifestyle intervention (the HealthyMoms app) intended to promote a healthy weight gain, diet, and physical activity in pregnancy. Furthermore, as a secondary aim, I explored how time spent on different movement behaviors were associated with maternal body weight and composition as well as cardiometabolic health indicators in early and late pregnancy. This may be important for future refinements and modifications of the HealthyMoms app as well as for other researchers when developing lifestyle interventions in this field.

The specific aims of my PhD project were:

1) to investigate the effectiveness of the HealthyMoms app on i) GWG (primary outcome), and ii) body fatness, dietary habits, MVPA, glycemia and insulin resistance (secondary outcomes) in comparison to standard maternity care (***Paper I***)
2) to explore participants' engagement and satisfaction with the 6-month usage of the HealthyMoms app (***Paper II***)
3) to investigate i) the effects of the HealthyMoms app on infant weight and body composition 1-2 weeks postpartum, and ii) whether a potential intervention effect on infant body composition is mediated through maternal GWG (***Paper III***)
4) to examine cross-sectional and longitudinal associations of 24-hour movement behaviors (i.e., sleep, sedentary behavior, light physical activity [LPA], and MVPA) with GWG, maternal body composition and cardiometabolic health in i) early- (gestational week 14), and ii) late pregnancy (gestational week 37) (***Paper IV***)



3 MATERIALS AND METHODS

3.1 STUDY DESIGN AND POPULATION

3.1.1 The HealthyMoms trial

The HealthyMoms trial was a 2-arm parallel RCT conducted in Östergötland, Sweden (October 2017-November 2020). Outcomes were measured at baseline (gestational week 14) and follow ups (gestational week 37 and 1-2 weeks postpartum). The primary outcome was GWG, and secondary outcomes included maternal body fatness, dietary habits, MVPA, glycemia and insulin resistance, and infant body composition (i.e., weight, fat- and fat free mass). After completion of baseline measures women were randomized to either the intervention or control group. Women allocated to the control group received standard care while women in the intervention group also received the HealthyMoms app for 6-months (both described in more detail below). A study protocol for the HealthyMoms trial (ClinicalTrials.gov NCT03298555) was published in 2019 (*Appendix 1*) [108]. The reporting of the trial and associated papers followed the subsequent statements: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online Telehealth statement [109] (*Paper I*), the Consolidated Criteria for Reporting Qualitative Research [110] (*Paper II*), the Consolidated Standards of Reporting Trials statement [111] (*Paper III*), and the Strengthening The Reporting of Observational Studies in Epidemiology checklist [112] (*Paper IV*).

3.1.2 Participants and recruitment

Figure 1 presents an overview of the HealthyMoms trial from recruitment to the second follow up 1-2 weeks postpartum and **Table 2** describes the studies included in this thesis [113–116]. Participants were recruited from maternity clinics in Linköping, Norrköping and Motala in early pregnancy. During the study period approximately 4000 pregnant women in the first trimester attended these clinics and a total of 399 reported interest in participating in the study. Out of these, 94 were excluded due to the following reasons: did not meet the inclusion criteria (n=21), declined to participate due to personal reasons (n=27), experienced a spontaneous abortion (n=25), or unknown reasons/no contact (n=21). Inclusion criteria were age of 18 years or older, carrying a singleton fetus, and sufficient literacy in Swedish in order to understand the content of the app. Women with a previously diagnosed eating disorder, diabetes type 1 or 2, or other medical conditions with possible effects on body weight were excluded. Thus, a total of 305 women completed baseline measures and were randomized in a 1:1 ratio using restricted randomization generated using STATA (version 13; StataCorp), leading to 152 women being allocated to the intervention group and 153 to the control group. Opaque envelopes were used to ensure allocation concealment, and these were opened by the assessor after completion of all baseline measures. Participants were then informed of their allocation and women allocated to the intervention group received information on how to access the HealthyMoms app, an introduction to the features in the app and they were instructed to use it as much as they preferred. Due to the nature of the intervention, participants and assessors were not blinded to the allocation. At the follow up measurement in gestational week 37 and follow up 1-2 weeks postpartum, 271 (271/305, 89%) and 257 (257/305, 84%) women returned to complete outcome measures, respectively, with equally high completion rate in the intervention and control group (Figure 1). Recruitment for *Paper II* occurred upon intervention completion at the follow up assessment in gestational week 37 (August 2018 to February 2019). A total of 20 participants in the intervention group were consecutively asked to participate and all agreed; however, one participant later withdraw her participation due to have given birth prior to the scheduled interview. Thus, the final sample in the interview study consisted of 19 women. For *Paper III*, 10 mother-infant pairs were excluded due to infant hip dislocation (n=2), other medical conditions (n=2), or that the measurement was not performed according to the Pea Pod protocol (n=6) for the complete-case analyses. Thus, the final sample for *Paper III* was 247 mother-infant pairs. For *Paper IV,* women with complete data on physical activity (wrist-worn accelerometry) at the two time points were included. Thus, the study sample for *Paper IV* consisted of 273 women in the cross-sectional analyses and 242 women in the longitudinal analyses.

3.1.3 Ethics

The HealthyMoms trial was approved by the Regional Ethical Review Board in Linköping, Sweden, on April 24, 2017 (ref No. 2017/112-31), with an amendment on May 4, 2018 (ref No. 2018/262-31). All participants provided written informed consent before study commencement and both parents provided written informed consent for the participation of their newborn child.

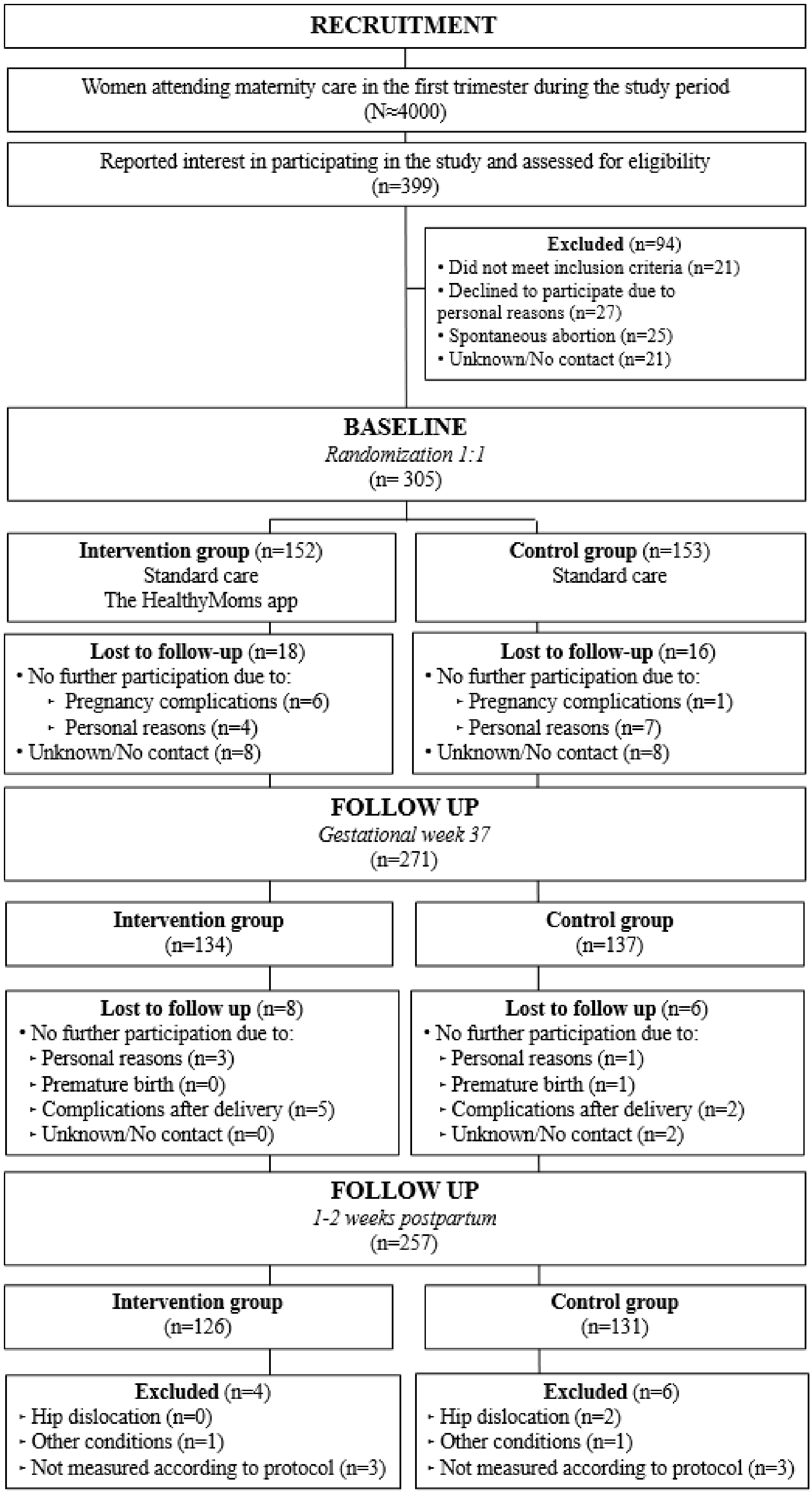


Figure 1. Flowchart of the HealthyMoms trial from recruitment to the follow up measurement 1-2 weeks postpartum.

Table 2. Overview of the included studies in this thesis.

	Paper I	***Paper II***	***Paper III***	***Paper IV***
Aim(s)	To investigate the effectiveness of a 6-month intervention (the HealthyMoms app) on GWG, body fatness, dietary habits, MVPA, glycemia and insulin resistance in comparison to standard maternity care	To explore participants' engagement and satisfaction with the 6-month usage of the HealthyMoms app	To i) investigate the effects of the HealthyMoms app on body composition in healthy full-term infants 1-2 weeks postpartum, and ii) investigate whether a potential intervention effect on infant body composition is mediated through maternal GWG	To examine associations of 24-hour movement behaviors (i.e., sleep, sedentary behavior, LPA, MVPA) in early pregnancy with maternal body weight and composition and cardiometabolic health in i) early and ii) late pregnancy
Design	Randomized controlled trial	Qualitative interview study	Randomized controlled trial	Cross-sectional and longitudinal analyses within the HealthyMoms trial
Participants	305 pregnant women	19 pregnant women from the intervention group	305 pregnant women and their healthy full-term infants	273 pregnant women in gestational week 14 and 242 pregnant women in gestational week 37
Methods & variables	GWG and body composition (ADP), diet (24-hour dietary recall), MVPA (ActiGraph), glycemia and insulin resistance (blood samples)	Participants' engagement and satisfaction with the Healthy-Moms app (semi-structured interviews)	Infant anthropometrics and body composition (ADP), GWG	Movement behaviors (ActiGraph), body weight and composition (ADP), and cardiometabolic health (MetS score, HOMA-IR)

ADP, air-displacement plethysmography; GWG, gestational weight gain; LPA, light physical activity; MVPA, moderate-to-vigorous physical activity; MetS score, Metabolic Syndrome score; HOMA-IR, homeostatic model assessment for insulin resistance.

3.2 INTERVENTION

Upon completion of baseline measures women were randomized in a 1:1 ratio to either the intervention or control group (described below). In addition to standard care, women in the intervention group received access to the HealthyMoms app for six months.

Development and content

The HealthyMoms app is based on the same technical platform (ScientificMed Tech AB) and similar structure used in a previous trial targeting parents with a preschool-aged child by our research group (the MINISTOP trial, PI: Professor Marie Löf) [117]. As described in the study protocol [118], a multidisciplinary team with expertise in nutrition, behavioral science, obstetrics, psychology, physiotherapy, physical activity and app development were involved in the development of the HealthyMoms app. The app content is based in social cognitive theory [119], uses behavior change techniques (e.g., shaping knowledge, self-monitoring, feedback) [120] and includes both gradually introduced, static and interactive features. Social cognitive theory is a theory of human behavior in which human agency is in focus, i.e., individuals are agents of their own lives and intentionally influence their own functions and life circumstances [119]. Some important constructs for behavior maintenance and change includes self-efficacy, observational learning, expectations, and reinforcement [119]. Behavior change techniques are commonly used in interventions intended to stimulate behavior change [121], and behavior change techniques such as shaping knowledge (e.g., general information on healthy diet, physical activity and GWG), goals and planning (e.g., goal setting and identification of barriers), and feedback and monitoring (e.g., self-monitoring and feedback on behavior) were incorporated in the app. Prior to finalizing the app, semi-structured interviews with a convenience sample of pregnant women and women who had recently given birth (n=10) were conducted to pre-test the content and features, confirm selected and add additional themes, and obtain other relevant information. Additionally, midwives at Kvinnohälsan in Östergötland and experts at the National Food Agency, Sweden reviewed the content related to maternal and fetal development, and dietary recommendations, respectively.

Gradually introduced features

The app is built around twelve themes (**Figure 2a** shows the fourth theme) with a new theme being introduced every other week; thus, all information is not available at once. The themes include information and practical tips concerning healthy foods, healthy weight gain, physical activity and exercise, how to change habits, sweets and cravings, fruit and vegetables, nutrition for both mother and child, the last trimester, why we eat, physical activity and exercise in the last trimester, how to maintain new habits, and the time after delivery. The app also includes a pregnancy calendar (weekly updates following the pregnancy progression) with information on the development of the fetus, physiological changes for the mother and texts aimed at the partner (e.g., information on how to support the pregnant woman in maintaining a healthy lifestyle). Finally, women receive push notifications from the app 3-4 times per week with encouragement, practical tips, and reminders to use the self-monitoring features (described below).

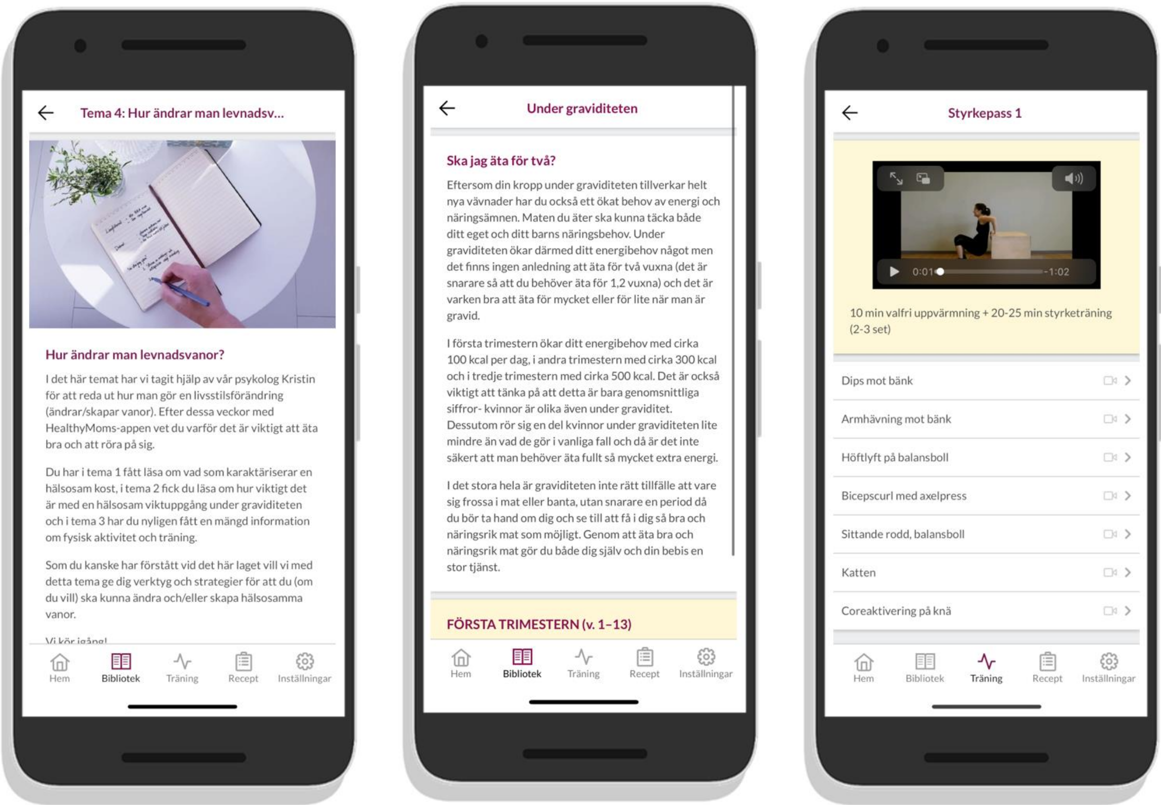


Figure 2. Three screenshots from the HealthyMoms app illustrating a) the fourth theme (to the left), b) frequently asked questions during pregnancy (in the middle), and c) an exercise program with videos and instructions in text (to the right).

Static features

The app also includes information that is available throughout the entire intervention period, and these include a library, an exercise- and a recipe feature. The library includes frequently asked questions (e.g., can I eat everything during pregnancy, how much weight should I gain, questions regarding exercise and physical activity during pregnancy) (Figure 2b), practical tips (e.g., portion sizes and hunger, how to read a nutrition label, practical tips to be more physically active, how to change a habit), and useful links (e.g., webpages to the local maternity healthcare, the Swedish National Food Agency, 1177 Vårdguiden). The exercise feature includes exercise programs and videos suitable for the different trimesters (Figure 2c), information on exercise during pregnancy (e.g., when it is not advisable to exercise, physiological changes during pregnancy and how to modify training exercises to avoid risk of injuries/when experiencing pelvic girdle pain, frequently asked questions related to exercise, how to exercise the pelvic floor muscles, information and tips related to stress and mindfulness. Finally, the recipe feature consists of weekly menus (suitable for meat- and fish eaters as well as vegetarians), recipes for healthy breakfast and snacks, healthier alternatives to candy and savory snacks, and tips on how to improve typical Swedish dishes (e.g., meatballs and mashed potatoes).

Interactive features

Additionally, the app includes three self-monitoring features with accompanying feedback for weight, diet, and physical activity (shown in **Figure 3**). The participants are reminded and encouraged to use the self-monitoring features once per week (i.e., weekly weight, diet, and physical activity) via a push-notification. Self-monitoring of weight (Figure 3a) involves reporting current weight and the feedback is presented graphically as a green field showing the recommended weight gain (individually tailored and based on the participant's pre-pregnancy BMI) from gestational week 22 until the end of pregnancy. Thus, participants receive no feedback following the weight registration prior to gestational week 22. In contrast, self-monitoring of diet and physical activity (Figure 3b-c) is followed by instant feedback in the form of graphical illustration and text. Self-monitoring of diet involves answering five questions on the intake of fruits, vegetables, sweets, and sugary drinks consumed over the past week. The participant then receives feedback presented in a graph (illustrating a total score [purple line], a score for sweets and sugary drinks [pink line], and a score for fruit and vegetables [grey line]) and in text with a traffic light (for the total score). A green traffic light represents reaching the recommendation, yellow represents almost reaching the recommendation and red represents being far from reaching the recommendation. Moreover, the graphical feedback enables the participant to identify which area that is in need of improvement (e.g., eating more fruits and vegetables or less sweets and sugary drinks). Self-monitoring of physical activity includes setting a physical activity goal (activity minutes per week) and reporting physical activity. The reported physical activity data is illustrated graphically as a bar chart summarizing the accumulated physical activity during the past week in relation to the recommendation for physical activity (150 min/week) (green line) as well as the participant's own goal (blue line). Similar to the self-monitoring of diet, the participant also receives feedback in the form of the traffic light as described above.

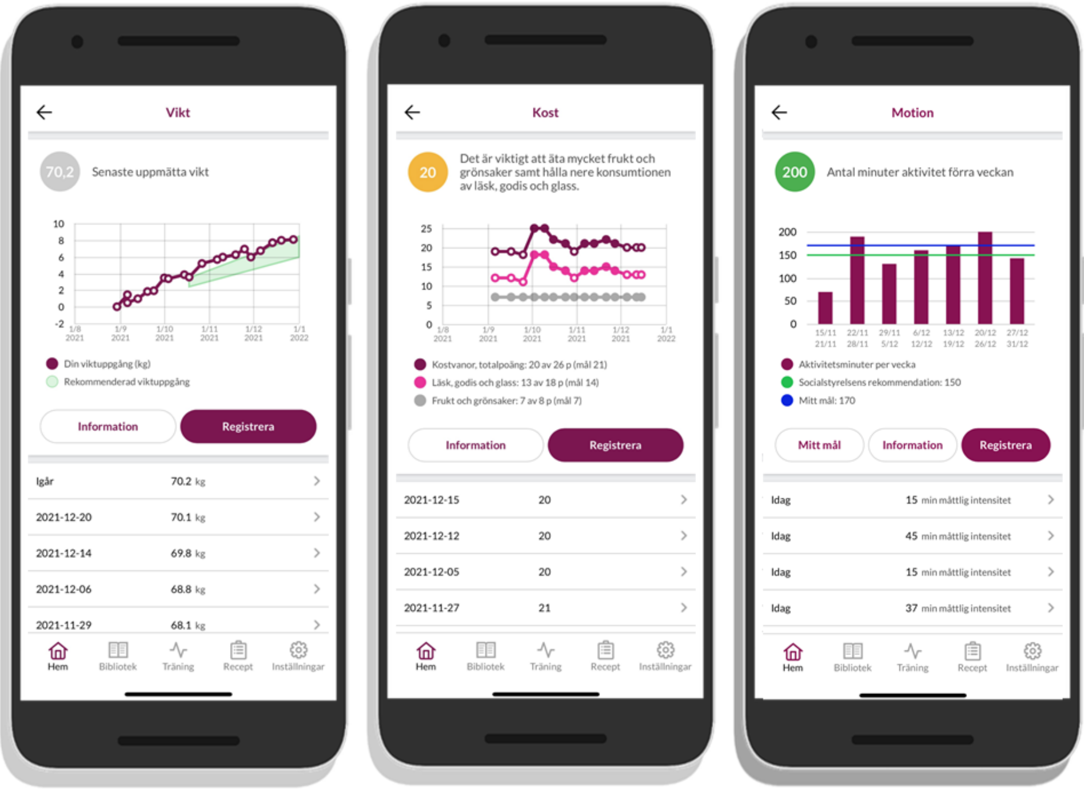


Figure 3. Three screenshots from the HealthyMoms app illustrating the self-monitoring feature for a) weight gain (to the left), b) diet (in the middle), and c) physical activity (to the right). The green field indicates the recommended weight gain based on the participant's pre-pregnancy BMI according to the National Academy of Medicine's recommendations [5]. For the self-monitoring of diet, the yellow circle with accompanying feedback in text format indicate inadequate compliance with dietary recommendations for fruit and vegetables and sodas, candy and ice cream. For the self-monitoring of physical activity and exercise, the blue line indicates the participant's own weekly goal (min/week) while the green line represents the recommended level of 150 min of physical activity per week [90]. The green circle in the self-monitoring for physical activity indicates compliance with the recommended 150 min of physical activity per week (in this case 200 min of physical activity accumulated during the past week).

3.3 CONTROL

The control group received standard care which consisted of regular midwife appointments (including e.g., measurement of weight, blood samples to assess iron- and glucose levels, blood pressure measurements, and monitoring of the fetus heartbeat) as well as an optional lecture on healthy habits and pregnancy related health in early pregnancy.

3.4 MEASURES

An overview of the outcome measures and other variables in the HealthyMoms trial that are included in this thesis (*Paper I-IV*) are shown in **Table 3**. Baseline assessments were conducted in gestational week 14 (13.9 [SD 0.7]) and follow up assessments in gestational week 37 (36.4 [SD 0.4] weeks) and approximately 1-2 weeks postpartum (range 0.9-3.0 weeks, mean weeks 1.8 [SD 0.4]). All assessments have been described previously [113–116] and are described in more detail below.

Table 3. Overview of outcome measures and other variables from the HealthyMoms trial included in this thesis (*Paper I-IV*).

	Gestational week 14	**Gestational week 37**	**1-2 weeks postpartum**
Maternal anthropometric variables and body composition	Height, weight, BMI, body fat %, fat mass, fat free mass, FMI, FFMI	Weight, BMI, body fat %, fat mass, fat free mass, FMI, FFMI, GWG	-
Diet	Dietary intake (24-hour recall), diet quality (SHEI score)	Dietary intake (24-hour recall), diet quality (SHEI score)	-
Physical activity	MVPA, LPA, SB, and sleep	MVPA, LPA, SB, and sleep	-
Cardiometabolic health	Glucose, insulin, blood lipids, blood pressure, insulin resistance (i.e., HOMA-IR), MetS score	Glucose, insulin, blood lipids, blood pressure, insulin resistance (i.e., HOMA-IR), MetS score	-
Usage and satisfaction with the HealthyMoms app	-	Questionnaire, semi-structured interviews, app adherence (i.e., total number of registrations)	-
Infant outcomes	-	-	Weight, length, BMI, body fat %, FMI, FFMI
Demographics and self-reported measures	Age, education level, birth country, parity, pre-pregnancy weight	Diagnosed gestational diabetes or pre-eclampsia	Last weight prior to delivery, birth mode, gestational age at birth, infant sex, birthweight, birth length, feeding, age at measurement

BMI, body mass index; FMI, fat mass index; FFMI, fat free mass index; SHEI score, Swedish healthy eating index score [53]; MVPA, moderate-to-vigorous physical activity; LPA, light physical activity; SB, sedentary behavior; HOMA-IR, homeostatic model assessment for insulin resistance; MetS score, metabolic syndrome score (i.e., the standardized sum of the z scores of triglycerides, inverted high-density lipoprotein, glucose, the average of systolic and diastolic blood pressure, and FMI).

3.4.1 Maternal anthropometric variables and body composition (Papers I, III and IV)

Height was measured using a wall-stadiometer (Tillquist, Spånga, Sweden) when the participant was not wearing shoes and body weight (kg) was measured after an overnight fast when the participant was only wearing underwear (Bod Pod, COSMED). GWG was calculated as the difference in body weight between the follow up measurement in (gestational week 37) and baseline (gestational week 14). To analyze the proportion of women exceeding, meeting and not reaching the GWG recommendations by the National Academy of Medicine [5], GWG between gestational weeks 14 and 37 was calculated (expressed as kg/week) and compared to the recommendations for the second and third trimester which vary according to pre-pregnancy BMI (**Table 4**).

Table 4. Recommendations for weekly gestational weight gain in the second and third trimester according to the 2009 National Academy of Medicine's (NAM) recommendations.

Pre-pregnancy BMI [a]	Recommended GWG (kg/week) [b]
Underweight	0.44-0.58
Normal weight	0.35-0.50
Overweight	0.23-0.33
Obese	0.17-0.27

BMI: body mass index; GWG, gestational weight gain
[a] Underweight, BMI < 18.5 kg/m^2; Normal weight, BMI = 18.5-24.9 kg/m^2; Overweight, BMI = 25.0-29.9 kg/m^2; Obesity, BMI ≥ 30 kg/m^2.
[b] GWG recommendations for the second and third trimester in kg/week according to the National Academy of Medicine (NAM) (previously Institute of Medicine) [5].

Maternal body composition (i.e., fat- and fat free mass) was assessed using air-displacement plethysmography (Bod Pod, COSMED) as previously described [79]. This method accurately measures body volume and body weight which enables calculation of body density after adjusting for thoracic gas volume. Predicted values for thoracic gas volume was used as measurement of thoracic gas volume can be difficult and only a small difference has been observed between predicted and measured thoracic gas volume in pregnancy in the third trimester [122]. By using appropriate densities for fat- and fat free mass, body composition can then be calculated using the so-called two-compartment model (i.e., dividing the body into fat mass and fat free mass) [69,71]. This method has been shown to produce accurate estimates of body composition in pregnancy provided that the increase in hydration of the fat free mass (and consequently lower fat free mass density) is accounted for [69,71]. Therefore, densities for fat mass and fat free mass by Most et al. [71] (which are based on the work by van Raaij et al. [70]) appropriate for gestational week 14 (0.900 cm^3 and 1.098 cm^3, respectively) and 37 (0.900 cm^3 and 1.089 cm^3, respectively) were used to calculate body fat percentage. BMI was calculated as weight (kg) divided by height squared (m^2), while fat mass index (FMI) and fat free mass index (FFMI) were calculated as fat mass (kg) or fat free mass (kg) divided by height squared (m^2), respectively.

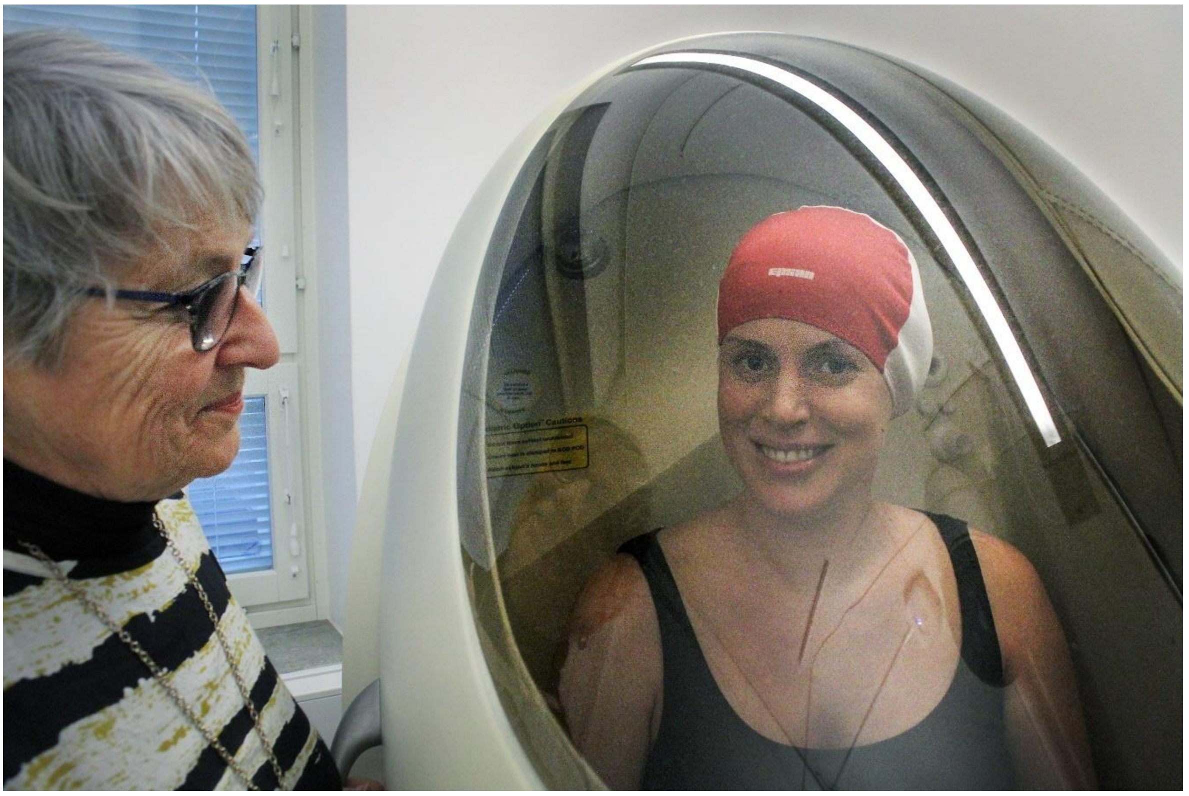


Figure 4. This picture shows an on-going Bod Pod measurement of a participant in the HealthyMoms trial. The person to the left in the picture is Eva Flinke who played an essential role in the data collection in HealthyMoms during the entire study period. Photo by: Ulrik Svedin, Östgöta Correspondenten.

3.4.2 Diet (Paper I and IV)

The web-based dietary recall method Riksmaten FLEX which was developed by the Swedish National Food Agency [52], and adapted to pregnant women was used to assess dietary habits. In summary, the method uses a repeated 24-hour recall approach over three days (covering both weekdays and weekend days). Participants received instructions (including the date when to log in) and login details (link, username, and password) to Riksmaten FLEX approximately 1-2 weeks prior to the assessments at baseline and in gestational week 37. After the first log-in, participants were instructed to register their dietary intake for that day as well as the previous day. The third day was automatically generated to occur within seven days of the first registration, either on a weekday or weekend day [52]. The registrations had to occur within 72 hours for each day or a new day had to be generated by the administrator of Riksmaten FLEX at the Swedish National Food Agency (Eva Warensjö-Lemming). When registering food intake, participants were first asked to specify the approximate time of the meal as well as type of meal (e.g., breakfast, lunch, or snack). Whereupon they could choose from food items and pre-specified dishes. After selecting a food item or dish, participants were asked to define portion size by choosing among pictures demonstrating different amounts of foods and other measurement aids depending on the food. Upon completion of registration, prompts (e.g., are you sure you have registered everything you have eaten today? Did you have something to drink with your meal?) were used to increase the likelihood of capturing all intakes of foods and drinks. Intakes of energy, macronutrients and micronutrients were then derived by linking the registrations to the Swedish national food composition database [52]. Finally, as described by Moraeus et al. [52] daily dietary intakes of ≤ 800 kcal or ≥ 3500 kcal were checked in detail by other members of the research group to rule out inaccurate energy intakes. Four days (one at baseline, three at follow up) were deemed implausible and excluded based on these criteria. Intakes for macronutrients and the following food groups were summarized and averaged for each participant and day: fruits, vegetables, red meat, fish and shellfish. Diet quality was then assessed by calculating the Swedish Healthy Eating Index (SHEI) score [53] for each participant. The components of the score and advice behind each component are shown in **Table 5**. The score is based on the Nordic Nutrition Recommendations [123], and consists of nine components: fruits and vegetables (g/day), fish and shellfish (g/day), red meat (g/week), fiber (g/MJ), wholegrain (g/10 MJ), polyunsaturated fat (E%), monounsaturated fat (E%), saturated fat (E%) and sucrose (E%). Each item can have a score from 0-1 (values below zero or above one were recorded as one and zero, respectively) and the total score ranges from 0-9, with a higher score indicating better compliance with the dietary guidelines [53].

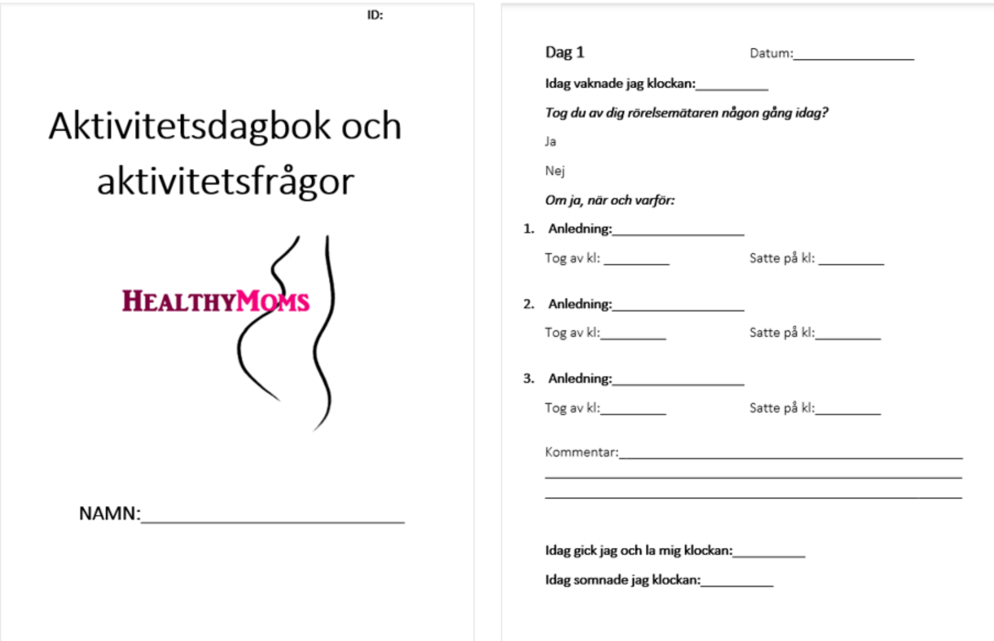
Table 5. The components of the Swedish Healthy Eating Index score and the advice behind each component as well as a theoretical example.

SHEI component	Recommendation [a]	Calculation	Example
Fruit & vegetables (g/day)	≥500 g/day	Intake/500	450/500 = 0.90
Fish & shellfish (g/day)	45 g fish & shellfish/day [b]	Intake/45	20/45 = 0.44
Red meat (g/week)	≤500 g red meat/week	1-((intake/500)/500)	1-((300-500)/500) = 1
Fiber (g/MJ)	2.5 g fiber/MJ	Intake/2.5	1.2/2.5 = 0.48
Wholegrain (g/10 MJ)	≥75 g wholegrain/10 MJ	Intake/75	30/75= 0.40
Polyunsaturated fat (E%)	≥7.5 E%	E%/7.5	8/7.5= 1.07 → 1.0
Monounsaturated fat (E%)	≥ 15 E%	E%/15	20/15= 1.33 → 1.0
Saturated fat (E%)	≤10 E%	1-((E%-10)/10)	1-((8-10)/10) = 1.2 → 1.0
Sucrose (E%)	≤10 E%	1-((E%-10)/10)	1-((12-10)/10) = 0.8
Total score [c]			**7.02**

E%, percent of total energy intake; SHEI, Swedish Healthy Eating Index [53]
[a] Based on the Nordic Nutrient Recommendations [123]
[b] Frequency 2-3 times/week and portion size 125 g
[c] Total score ranging from 0-9, with higher score indicating higher compliance with the recommendations

3.4.3 Movement behaviors (Paper I and IV)

Movement behaviors (i.e., physical activity [LPA and MVPA], and sedentary behavior) were assessed using the wrist-worn triaxial ActiGraph wGT3x-BT (ActiGraph, Pensacola, FL). Participants were sent out an accelerometer and a diary (to capture non-wear and sleep time, shown in **Figure 5**) approximately two weeks prior to the baseline measurement in gestational week 14 and follow up measurement in gestational week 37. The accelerometer was programmed to collect data at 100 Hz and participants were instructed to wear it on the non-dominant wrist for seven consecutive 24-hour periods and only removing it when engaging in water activities (e.g., showering or swimming). Due to sanitary restrictions in the workplace (i.e., healthcare), a small number of participants were unable to wear the accelerometer on the wrist and thus wore it on the hip instead (baseline, n=23; follow up, n=18). These women were similar in terms of baseline characteristics to the whole sample, with equal proportion of women wearing it on the hip in both groups, and the intervention effect was very comparable when excluding these women (*Paper I*). Thus, they were included in *Paper I*; however, they were excluded in the analyses for *Paper IV* in which associations between movement behaviors and body composition and cardiometabolic health were studied since time spent on such behaviors may differ depending on monitor placement [124,125]. Appropriate thresholds to identify MVPA were used (100 m*g* for wrist; 70 m*g* for hip) [126]. Data processing was conducted using the software program R and the package GGIR [61].


ID:

Aktivitetsdagbok och aktivitetsfrågor

HEALTHYMOMS

NAMN:__________

Dag 1 Datum:__________

Idag vaknade jag klockan:__________

Tog du av dig rörelsemätaren någon gång idag?

Ja

Nej

Om ja, när och varför:

1. Anledning:__________
   Tog av kl: ________ Satte på kl: ________
2. Anledning:__________
   Tog av kl:________ Satte på kl:________
3. Anledning:__________
   Tog av kl:________ Satte på kl:________

Kommentar:__________

Idag gick jag och la mig klockan:__________

Idag somnade jag klockan:__________

Figure 5. A picture of the accompanying diary to enable verification of non-wear time and sleep which was filled in by the participants. The picture to the left shows the front page and the picture to the right shows a page in the diary where the participant is instructed to fill in date, when she woke up, if she removed the accelerometer during the day (if yes, why and during what time was it off), and when she went to bed and fell asleep.

3.4.4 Cardiometabolic health (Paper I and IV)

During the baseline assessment and the follow up in gestational week 37, the following measurements were conducted to assess cardiometabolic health (e.g., insulin resistance, glycemia, Metabolic Syndrome [MetS] score). First, a venous blood sample was drawn after an overnight fast to assess levels of glucose, insulin, and blood lipids (i.e., high-density lipoprotein [HDL], and low-density lipoprotein [LDL], triglycerides). These were taken at Linköping University Hospital and all samples were analyzed at the Department of Clinical Chemistry, Linköping University, Sweden (ISO/IEC 17025). The glucose hexokinase method and the Elecsys electrochemiluminescene immunoassay (using a Cobas 602, Roche Diagnostics Scandinavia AB, Bromma, Sweden) were used to analyze glucose and insulin, respectively. The fasting values for insulin and glucose were then used to calculate the homeostatic model assessment for insulin resistance (HOMA-IR) as follows: (fasting insulin [μU/L] × fasting glucose [mmol/L])/22.5) [127]. For the statistical analyses, HOMA-IR was transformed using the natural logarithm (ln) because of its skewness. As for blood lipids, plasma concentrations of total cholesterol, HDL and triglycerides were measured directly using the enzymatic, colorimetric method (using a Cobas c 701 module, Roche Diagnostics Scandinavia AB, Bromma, Sweden), while the Friedewald equation [128] was used to calculate LDL. Second, two measurements of systolic and diastolic blood pressure were taken in an upright sitting position after a five-minute rest using an electronic sphygmomanometer (ProBP 3400 series, WelchAllyn, NY, USA). If the two measurements differed more than 10mmHg for either the systolic or diastolic blood pressure, a third measurement was performed, and the averages of the systolic and diastolic blood pressure were used in the statistical analyses. Finally, a MetS score was calculated as previously described [129] but including FMI instead of waist circumference as the women were pregnant. Thus, the MetS score was calculated as the standardized sum of the z scores of triglycerides, inverted HDL cholesterol, glucose, the average of systolic and diastolic blood pressure and FMI. A z score (also called a standard score) is a measure of how many standard deviations below or above the population mean a raw score is. Thus, it provides information on how far a data point is from the mean.

3.4.5 Usage and satisfaction with the HealthyMoms app (Paper I-III)

At the follow up measurement in gestational week 37, all participants in the intervention group were asked to fill in a questionnaire on their usage and satisfaction of the HealthyMoms app (Multimedia Appendix 2, *Paper I* [113]). Additionally, objective measures on usage of the self-monitoring features (i.e., weight, diet, and physical activity) was automatically retrieved from the app. This data was used as an objective measure of usage (*Paper I*) and to define app adherence (i.e., total number of registrations) (*Paper III*). Qualitative data on usage and satisfaction with the HealthyMoms app (i.e., semi-structured interviews) was also gathered (*Paper II*). In conjunction with the follow up measurement in gestational week 37, during the time period August 2018 to February 2019, all participants in the intervention group were invited to participate in semi-structured interviews. All interviews were conducted individually and face-to-face by J Sandborg in a separate room at Linköping University, Linköping, Sweden. A semi-structured design was used with a set of main questions (i.e., the interview guide) (Multimedia Appendix 1, *Paper II* [114]). The interview guide was developed by the research team behind *Paper II* which has expertise in pregnancy, nutrition, physical activity, qualitative methodology and mHealth and revolved around the following topics: layout and function of the app, as well as usage, experiences, and satisfaction of using the features in the app. These main questions were then followed by questions tailored to individual responses. All interviews were audio recorded and transcribed verbatim after which they were anonymized and kept stored unavailable to unauthorized.

Figure 6. Two pictures from a Pea Pod measurement in the HealthyMoms trial. The picture to the left shows the infant resting on the Pea Pod tray prior to measurement start. The picture to the right shows the infant in the Pea Pod chamber during the measurement.

3.4.6 Infant outcomes (Paper III)

Infant length (to the nearest of 0.5 cm) was measured when the infant was resting on a measuring board with a movable foot plate placed by the child's heels. Body weight and body composition were measured without clothes (the infant was only wearing a tight cap) using the Pea Pod (COSMED). Air-displacement plethysmography by means of Pea Pod measures body weight and body volume to calculate body density. This enables calculation of body fatness by using body density and densities for fat- and fat free mass appropriate in infancy

[80–82,130]. **Figure 6** shows two pictures from the Pea Pod measurement in the HealthyMoms trial. In practice, basic information (e.g., infant sex, length, date- and gestational age at birth) is entered in the software program, and the infant is first weighed (only wearing a tight cap) on the scale which is embedded in the unit before he/she is placed in the Pea Pod test chamber tray and enters the warm test chamber for the measurement (duration of 2 minutes).

3.4.7 Demographics and self-reported measures (Papers I-IV)

At baseline, participants were asked to fill in a questionnaire regarding e.g., age, birth country, parity, education level, and pre-pregnancy weight. The latter was used to calculate pre-pregnancy BMI (self-reported weight prior to pregnancy [kg] divided by measured height [m^2]). Information on diagnosed gestational diabetes and preeclampsia was gathered via a questionnaire at the follow up measurement in gestational week 37. At the final measurement 1-2 weeks postpartum, participants were asked to fill in a questionnaire with information on e.g., last weight prior to delivery, mode of delivery (i.e., vaginal, caesarean, or instrumental), gestational age at birth, infant sex, weight and length at birth, feeding (i.e., breastfeeding, formula or a combination), as well as infant age (days) at the time of the measurement.

3.5 STATISTICS, POWER CONSIDERATIONS AND DATA ANALYSES

3.5.1 Overview of methods and power

Table 6 provides an overview of the analyses used in *Paper I-IV*. All statistical tests were two-sided and *P*-values of <0.05 were considered statistically significant. SPSS version 26 (IMB, Armonk, NY, USA) (*Paper III*) and R version 3.6.3 (*Paper I*) and version 4.0.3 (*Paper III* and *Paper IV*) were used to analyze the quantitative data. The trial was powered for the primary outcome (GWG), and 226 women (113 in each group) would provide 80% power (two-tailed, $\alpha = 0.05$) to detect a difference of 1.5 kg between the groups (*Paper I*). For intervention effects on infant outcomes (*Paper III*), the sample size in the HealthyMoms trial would provide 80% power (two-tailed, $\alpha = 0.05$) to detect an effect of Cohen's *d* of 0.36 (medium to strong effect sizes) which corresponds to a difference in body fat of 1.4%. In the analysis for *Paper IV* the sample size (n=242) would provide 80% power (two-tailed, $\alpha = 0.05$) to detect a standardized regression coefficient of 0.18.

Table 6. Overview of the methods used to analyze the quantitative data in this thesis (*Paper I*, *II* and *IV*).

	Paper I	***Paper III***	***Paper IV***
Outcomes	GWG (primary), body fatness, dietary habits (SHEI), physical activity (MVPA), glycemia and insulin resistance (secondary)	Infant weight, length, BMI, body fat%, FMI and FFMI	Maternal weight, BMI, FMI, FFMI, glucose, HOMA-IR, SBP, DBP, MetS score
Exposure	Intervention allocation (i.e., intervention vs control)	Intervention allocation (i.e., intervention vs control)	Time spent in MVPA, LPA, SB, and sleep
Statistical method(s)	Linear regression (*complete case and multiple imputations*)	Linear regression (*complete case and multiple imputations*)	Compositional data analysis (*cross-sectional* and *longitudinal*)
Unadjusted/ crude model	Baseline value of the outcome	Unadjusted	Unadjusted (*cross-sectional*) Movement behavior (i.e., MVPA, LPA, SB, and sleep) and outcome at baseline and follow up (*longitudinal*)
Adjusted model	Pre-pregnancy BMI (underweight/normal weight vs overweight/obesity), parity (0 vs ≥1), education level (university degree vs no university degree)	Pre-pregnancy BMI (underweight/normal weight vs overweight/obesity), parity (0 vs ≥1), and height (m)	Age, parity (0 vs ≥1), and education level (university degree vs no university degree) (*cross-sectional*), and movement behavior (i.e., MVPA, LPA, SB, and sleep) and outcome at baseline and follow up, and group allocation (*longitudinal*)
Complementary and sensitivity analyses	Bayesian analysis for the primary outcome Excluding participants diagnosed with gestational diabetes or pre-eclampsia before the follow up measurement	Mediation analysis (group allocation on infant body composition through maternal GWG) Interaction term (group × BMI category) Influence of app adherence on infant outcomes	Adjusted for SHEI score in gestational week 14 and 37 (*cross-sectional*, *longitudinal*) Excluding participants with < 4 valid days of accelerometer data (*cross-sectional*, *longitudinal*)

BMI, body mass index; DBP, diastolic blood pressure; FFMI, fat free mass index; FMI, fat mass index; HOMA-IR, homeostatic model assessment for insulin resistance; LPA, light physical activity; MetS score, metabolic syndrome score (i.e., the standardized sum of the z scores of triglycerides, inverted high-density lipoprotein, glucose, the average of systolic and diastolic blood pressure, and FMI); MVPA, moderate-to-vigorous physical activity; SB, sedentary behavior; SBP, systolic blood pressure; SHEI score, Swedish healthy eating index score.

3.5.2 Main analyses

3.5.2.1 Paper I

To investigate differences in primary (GWG) and secondary (SHEI score, MVPA, body fatness, glycemia and HOMA-IR) outcomes between the intervention and control group multiple linear regression was used. Multiple imputations with chained equations (50 iterations) was used to handle missing data [131], and analyses were pooled using Rubin's rules [132]. Complete case analyses were also performed for all outcomes. Since all women except one had used the app at least once (criteria for per-protocol), only one participant was removed in the per-protocol analyses and findings were unchanged. Therefore, only multiple imputations and complete case analyses were reported. To account for regression towards the mean [133], a crude model was fitted for all outcomes in which the model was adjusted for the baseline value of the outcome. For instance, for the primary outcome (GWG), follow up weight in gestational week 37 was regressed on group allocation and adjusted for baseline weight. Further, a second regression model adjusting for pre-pregnancy BMI (underweight and normal weight vs overweight and obesity), parity (0 vs ≥1), and educational attainment (university degree vs no university degree) was fitted for all outcomes (adjusted model). To estimate effect modifications of the intervention on GWG, the regression model was extended with interactions between group allocation and pre-pregnancy BMI, parity, and educational attainment, respectively. Sensitivity and complementary analyses were also performed. First, women diagnosed with gestational diabetes or pre-eclampsia (n=7) before the follow up measurement in gestational week 37 was excluded (results were comparable). Finally, for the primary outcome, the interaction effect between group allocation and pre-pregnancy BMI was also analyzed using Bayesian analysis [134]. This approach provides calculation of posterior probability of an interaction effect despite the null hypothesis being rejected [135,136]. Thus, an estimation of the probability of different effect sizes is provided. In this case, the probability that the intervention would have an effect size of 0 kg, < 1 kg, <1.5 kg or < 2 kg.

3.5.2.2 Paper II

Thematic analysis as described by Braun and Clarke [137] was used to analyze the semi-structured interviews. To minimize the risk of the analysis being influenced by the preconceptions of the researchers, data were analyzed using an inductive (data-driven) approach at a semantic level (not looking beyond what the participant has said) [137]. The audio recorded interviews were first transcribed verbatim whereupon the transcripts were actively read and reread several times by the author (female nutritionist and PhD student) and a female medical student (Erica Larsen) to obtain an overall sense of the data. Next, initial codes (data of interest and related to the aim) were generated separately by the author and Larsen, and then analyzed and sorted into groups. Prior to setting preliminary themes, disagreements in the coding or grouping were discussed, and the themes were then defined and agreed upon through thorough discussions between the authors of this paper.

3.5.2.3 Paper III

The analyses in this paper follow the same analysis plan as the maternal outcomes in gestational week 37 and missing data was handled in the same way (*Paper I*). Thus, multiple regression models were used to examine the effect of intervention allocation (intervention vs control) on infant outcomes (both multiple imputations and complete case analysis). An unadjusted and adjusted model (adjusting for maternal pre-pregnancy BMI [underweight and normal weight vs overweight and obesity], parity [0 vs ≥1], and maternal height [m]) were fitted for all outcomes. To investigate whether the intervention effect was different depending on pre-pregnancy BMI (underweight and normal weight vs overweight and obesity) an interaction term (group × BMI category) was added to the model. A sensitivity analysis was performed to assess the influence of app adherence on infant outcomes. In more detail, app adherence was defined as high (above the median) and low (below the median) usage of all three registration features (weight, diet, and physical activity) during the intervention period, with the median of total registrations being 37.5 (*Paper I* [113]). The regression models (imputed and complete case analyses) were re-run to assess the associations of high (n=61) and low (n=61) usage with infant outcomes using the control group (n=125) as reference. Finally, mediation analysis (PROCESS macro version 3.5 with 5000 bias-corrected bootstrap samples and 95% confidence intervals) was performed to explore potential mediation effects of maternal GWG on infant outcomes. More specifically, mediation was assessed by the indirect effect of group allocation (independent variable) on infant body composition (dependent variable) through maternal GWG (**Figure 7**).

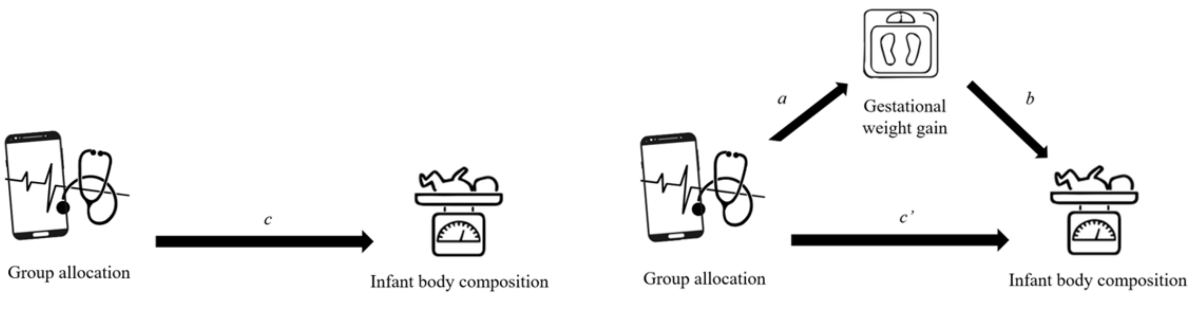


Figure 7. Illustration of the mediation analysis from *Paper III* [115]. The association between independent (group allocation) and dependent variable (infant body composition) is shown in pathway *c*, while the indirect pathway follows *a* × *b*, and the direct pathway is *c'*.

3.5.2.4 Paper IV

Compositional data analysis investigates the reallocation of time across behaviors over a specified continuum (i.e., 24-hours) while lowering the risk of multicollinearity [62,63], and was used to investigate associations between different compositions of movement behaviors with body composition and cardiometabolic health. One time-use composition including sleep, sedentary behavior, LPA and MVPA was used. As previously described [62] isometric log ratios were calculated in sequential binary partition and included as explanatory variables. The gamma (γ) coefficient represents the strength and direction of the association of each behavior relative to another (e.g., LPA relative to MVPA) with an outcome (e.g., fat mass). To predict the effect of reallocating time proportionally across behaviors (e.g., increasing LPA while reducing the other behaviors) and pairwise (e.g., increasing LPA while reducing sedentary behavior) on the outcomes the models' coefficients were used. Pairwise time reallocation plots which show the outcomes associated with reallocating time from one behavior to another (e.g., reallocating 30 min/day to MVPA from LPA) were used to present the results. The results can be interpretated as demonstrating the outcome associated with reallocating time between behaviors for a hypothetical average participant in the study sample as all outcomes are relative to the mean behavior composition in the sample. For the cross-sectional analyses an unadjusted and adjusted model (i.e., adjusted for age, parity [0 vs ≥1] and education level [university degree vs no university degree]) were fitted. Similarly, a crude and an adjusted model were fitted for the longitudinal analysis. In the crude model, the change in the outcome from gestational week 14 to 37 (dependent variable), and the isometric log ratios for the movement behaviors at gestational week 14 (i.e., sleep, sedentary behavior, LPA and MVPA) together with the change in these isometric log ratios from gestational week 14 to 37 and the outcome at gestational week 14 (independent variables) was included. In addition, the adjusted models were also adjusted for age, parity [0 vs ≥1], education level [university vs no university degree] and group allocation [intervention vs control]. Moreover, sensitivity analyses to assess the influence of diet (SHEI score), number of valid days of accelerometer data as well as group allocation on the estimates were performed. In more detail, the SHEI score in gestational week 14 and 37 was added to the adjusted model in the cross-sectional and longitudinal analyses, respectively. Further, the models were re-run excluding women with less than 4 valid days of accelerometer data (n=8 in gestational week 14, n=10 in gestational week 37) and only including women in the control group (n=123), and results remained similar (data not shown).

4 RESULTS

4.1 HEALTHYMOMS STUDY POPULATION (PAPER I-IV)

Characteristics of the participating women (*Papers I-IV*) and infants (*Paper III*) are presented in **Table 7** and **Table 8**, respectively. At baseline (gestational age: 13.9 [0.7] weeks), women were on average 31 (SD 4) years old, 88% (270/305) were Swedish born, 57 % (175/305) nulliparous and 78% (237/305) had a university degree. The majority had normal weight (70%, 212/305), 22% (67/305) had overweight, 7% (20/305) had obesity and 2% (6/305) had underweight. As also shown in Table 7, no differences were observed for the pre-pregnancy characteristics and measured variables at baseline between the intervention and control group, and the women included in the different papers. As for infant characteristics (Table 8), weight and length at birth were on average 3.5 (SD 0.5) kg and 50 (SD 2) cm, respectively. The average gestational age at birth was 40 (SD 1) weeks, 54% (134/247) were boys, and 85% (208/247) experienced a non-instrumental vaginal delivery. At the time of the measurement, the average age was 1.8 (SD 0.4) weeks. No differences were observed between the infants in the intervention and control group in terms of birth characteristics and outcome measures (Table 8).

Table 7. Baseline characteristics of the women in the HealthyMoms trial.

		Intervention (n=152)	**Control (n=153)**	***Paper I* (all, n=305)**	***Paper II* (n=19[a])**	***Paper III* (n=247[b])**	***Paper IV* (n=273[c])**
Pre-pregnancy characteristics	Age (years)	31.4 (4.3)	31.3 (3.8)	31.3 (4.0)	31.7 (4.4)	31.4 (4.1)	31.4 (4.1)
	Swedish born (n, %)	136 (89.5)	134 (87.6)	270 (88.5)	19 (100)	219 (88.7)	239 (87.9)
	Nulliparous (n, %)	86 (56.6)	89 (58.2)	175 (57.4)	11 (57.9)	139 (56.3)	153 (56.3)
	University degree (n, %)	115 (75.7)	122 (79.7)	237 (77.7)	13 (68.4)	194 (78.5)	209 (76.8)
	Pre-pregnancy BMI categories (n, %)						
	Underweight (<18.5 kg/m^2)	1 (0.7)	5 (3.3)	6 (2.0)	0 (0.0)	5 (2.0)	4 (1.5)
	Normal weight (18.5-24.9 kg/m^2)	103 (67.8)	109 (71.2)	212 (69.5)	12 (63.2)	176 (71.3)	195 (71.3)
	Overweight (25.0-29.9 kg/m^2)	34 (22.4)	33 (21.6)	67 (22.0)	6 (31.6)	53 (21.5)	58 (21.0)
	Obesity (>30 kg/m^2)	14 (9.2)	6 (3.9)	20 (6.6)	1 (5.3)	13 (5.3)	16 (5.9)
Measured variables at baseline	Gestational age (weeks)	13.8 (0.6)	14.0 (0.7)	13.9 (0.7)	13.9 (0.7)	13.9 (0.7)	13.9 (0.7)
	Weight (kg)	68.3 (12.8)	67.0 (10.2)	67.7 (11.5)	68.1 (10.9)	67.5 (11.1)	67.3 (11.3)
	Height (m)	1.66 (0.06)	1.68 (0.06)	1.67 (0.06)	1.66 (0.06)	1.67 (0.06)	1.67 (0.06)
	BMI (kg/m^2)	24.7 (4.3)	23.8 (3.2)	24.2 (3.8)	24.6 (3.4)	24.1 (3.6)	24.1 (3.8)
	Fat mass index (kg/m^2)	8.4 (3.6)	7.6 (2.6)	8.0 (3.2)	8.5 (2.6)	7.9 (3.0)	7.9 (3.1)
	Fat free mass index (kg/m^2)	16.2 (1.4)	16.2 (1.3)	16.2 (1.3)	16.1 (1.2)	16.2 (1.3)	16.2 (1.3)
	Swedish healthy eating index score	6.54 (0.98)	6.79 (0.97)	6.66 (0.98)	6.42 (1.08)	6.65 (1.00)	6.67 (0.99)
	Moderate-to-vigorous physical activity (min/day)	38 (25)	40 (24)	39 (24)	51 (32) [d]	39 (23)	39 (24)
	Glycemia (mmol/l)	4.8 (0.3)	4.8 (0.3)	4.8 (0.3)	4.9 (0.3)	4.8 (0.3)	4.8 (0.3)
	HOMA-IR	1.4 (0.8)	1.4 (0.7)	1.4 (0.7)	1.5 (0.7)	1.4 (0.7)	1.4 (0.7)

Data is presented as mean (SD) unless otherwise stated. BMI, body mass index; HOMA-IR, homeostatic model assessment for insulin resistance.
[a] Study sample included in *Paper II* (intervention group, n=19). [b] Study sample included in *Paper III* (intervention group, n= 122; control group, n= 125). [c] Study sample included in *Paper IV* (intervention group, n= 134; control group, n= 139). [d] Median= 42 min/day; quartile 1= 23; quartile 3=87

Table 8. Characteristics of the infants in the HealthyMoms trial (*Paper III*).

		All (n=247)	Intervention (n=122)	Control (n=125)
Birth characteristics	Gestational age at birth (weeks)	40.2 (1.2)	40.1 (1.1)	40.2 (1.2)
	Infant sex (n, %)			
	Female	113 (45.7)	60 (49.2)	53 (42.4)
	Male	134 (54.3)	62 (50.8)	72 (57.6)
	Birthweight (kg)	3.53 (0.46)	3.52 (0.47)	3.53 (0.44)
	Birth length (cm)	50.4 (2.0)	50.3 (2.1)	50.4 (1.8)
	Birth mode (n, %)			
	Non-instrumental vaginal delivery	208 (84.9)	102 (85.0)	106 (84.8)
	Instrumental	14 (5.7)	5 (4.2)	9 (7.2)
	Caesarean section	23 (9.4)	13 (10.8)	10 (8.0)
Measured variables 1-2 weeks postpartum	Age at measurement (weeks)	1.8 (0.4)	1.7 (0.4)	1.8 (0.4)
	Weight (kg)	3.69 (0.46)	3.66 (0.46)	3.71 (0.46)
	Length (cm)	52.3 (2.0)	52.1 (2.1)	52.5 (1.8)
	BMI (kg/m^2)	13.4 (1.1)	13.4 (1.0)	13.4 (1.1)
	Body fat (%)	13.2 (4.0)	13.3 (4.3)	13.2 (3.8)
	Fat mass index (kg/m^2)	1.8 (0.6)	1.8 (0.7)	1.8 (0.6)
	Fat free mass index (kg/m^2)	11.6 (1.0)	11.6 (0.8)	11.5 (1.2)
	Feeding (n, %)			
	Breastfeeding	207 (84.1)	102 (83.6)	105 (84.7)
	Formula	6 (2.4)	4 (3.3)	2 (1.6)
	Combination	33 (13.4)	16 (13.1)	17 (13.7)

Data is presented as mean (SD) unless otherwise stated. BMI, body mass index.

4.2 EFFECTIVENESS OF HEALTHYMOMS ON GWG, DIET AND PHYSICAL ACTIVITY (PAPER I)

Table 9 presents the GWG in the intervention and control group for the whole sample and according to pre-pregnancy BMI, and the intervention effects for the adjusted models for the primary outcome GWG (imputed and complete case analysis) is presented in **Table 10**. The results showed no statistically significant difference between the intervention and control group on GWG in either the crude (-0.20; 95% CI -0.98 to 0.59, *P*=0.62) nor adjusted model (-0.20 kg; 95% CI 1.00 to 0.60, *P*=0.62). In regard to adherence to the GWG guidelines, there was no difference between the intervention and control group for all comparisons (all *P*≥0.29). However, data indicated an interaction between pre-pregnancy BMI and group allocation with the intervention being more effective in women with overweight and obesity compared to those with underweight and normal weight. In more detail, in the multiple imputation analysis, for women with overweight or obesity in the intervention group GWG was 1.33 kg (95% CI -2.92 to 0.26, *P*=0.10) lower compared to the control when also accounting for parity and education level. The interaction effect was stronger and statistically significant in the complete case analysis (-1.67 kg; 95% CI -3.26 to -0.09; *P*=0.031, n=271). Moreover, the complementary analysis using Bayesian analysis (**Figure 8**) further supported these results as it showed that the probability that the expected GWG in the intervention group was less than in the control group was 27% among women with underweight and normal weight. In comparison, this probability was 99% among women with overweight and obesity and the probability that this effect was over 1 kg and 1.5 kg was 81% and 57%, respectively. Finally, no statistically significant interaction effect for parity or educational attainment was observed (results not shown).

Table 9. Gestational weight gain in the intervention and control group for the whole sample and according to pre-pregnancy BMI.

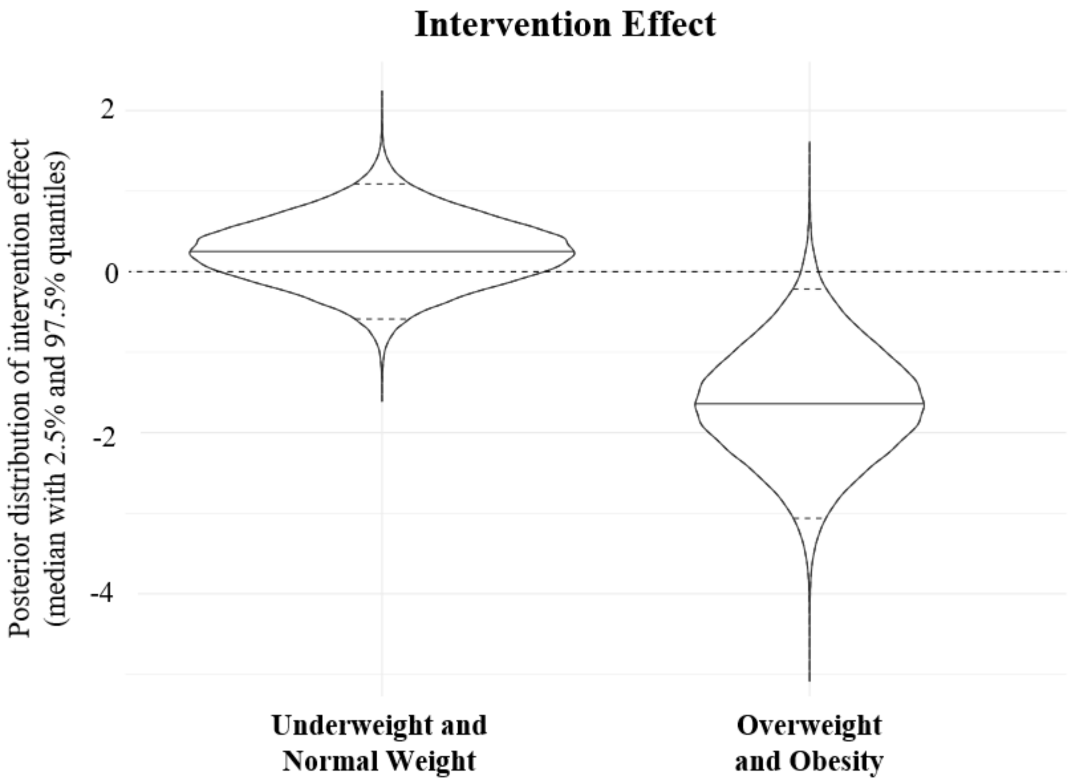
	Gestational weight gain (kg) [a]		
	All	Intervention	Control
Whole group [b]	10.7 (3.2)	10.6 (3.3)	10.8 (3.2)
Pre-pregnancy BMI [c]			
Underweight/normal weight [c,d]	10.7 (3.0)	10.9 (2.9)	10.6 (3.0)
Overweight/obesity [c, e]	10.6 (4.0)	11.4 (3.7)	10.0 (4.1)

Data presented as mean (SD). BMI, body mass index.
[a] Gestational weight gain calculated as the difference between measured weight in gestational weeks 37 and 14
[b] n=271 (intervention=134, control=137)
[c] Underweight, BMI < 18.5 kg/m^2; Normal weight, BMI = 18.5-24.9 kg/m^2; Overweight, BMI = 25.0-29.9 kg/m^2; Obesity, BMI ≥ 30 kg/m^2.
[d] n=200 (intervention=93, control=107)
[e] n=71 (intervention=41, control=30)

Table 10. Intervention effect on the primary outcome.

Outcome	Intervention effect using regression analysis [a]			
	Imputed data analysis		Complete case analysis	
	Coefficient (95% CI)	*P*	Coefficient (95% CI)	*P*
GWG (kg) [b]	-0.20 (-1.00 to 0.60)	0.62	-0.24 (-1.01 to 0.54)	0.55
GWG according to NAM guidelines [b, c, d]				
Excessive	0.75 (0.43 to 1.32)	0.31	0.75 (0.43 to 1.32)	0.32
Adequate	Reference		Reference	
Inadequate	0.66 (0.30 to 1.43)	0.29	0.66 (0.30 to 1.44)	0.29

CI, confidence interval; GWG, gestational weight gain; NAM, National Academy of Medicine
[a] Regression analysis of follow up measure of outcome on group allocation. The coefficient is interpreted as the estimated effect of the intervention compared with the control adjusted for baseline value of the outcome, pre-pregnancy BMI (underweight and normal weight vs overweight and obesity), parity (0 vs ≥1) and educational attainment (university degree vs no university degree). Imputed data analysis included data for all 305 women and the complete case analysis data for 263-271 women.
[b] Baseline, n=305 (152 intervention, 153 control); Follow up, n=271 (134 intervention, 137 control)
[c] The coefficient is expressed as odds ratio.
[d] GWG was calculated as the difference between weight at follow up and baseline. To obtain GWG expressed as kg/week. To classify GWG as excessive, adequate, or inadequate, this GWG (kg/week) was divided by gestational weeks and compared to the weekly recommendations for GWG by the National Academy of Medicine for the second and third trimesters [5].



Pre-pregnancy BMI-category	Effect estimate[a]	Posterior probability of estimate[a] being lower than 0 kg, -1 kg, -1.5 kg, and -2 kg			
	Median (kg) (2.5%; 97.5%)	< 0 kg	< -1 kg	< -1.5 kg	< -2 kg
Underweight or normal weight before pregnancy	0.25 (-0.58; 1.09)	27%	< 0.01%	< 0.01%	< 0.01%
Overweight or obesity before pregnancy	-1.63 (-3.05; -0.21)	99%	81%	57%	31%

[a] The regression model included follow up weight regressed on group allocation, pre-pregnancy BMI category and the interaction of group allocation × BMI category (underweight and normal weight vs overweight and obesity), baseline weight, parity (0 vs ≥1), and educational attainment (university degree vs no university degree).

Figure 8. Intervention effect on gestational weight gain according to pre-pregnancy BMI analyzed using Bayesian analysis (with imputation, n=305) from *Paper I* [113].

As for the secondary outcomes (**Table 11**), no significant differences between the intervention and control group for MVPA, fat mass, fat free mass, glycemia or HOMA-IR were seen (all $P \geq 0.21$). However, at follow up, the intervention group had higher total score for the SHEI score compared to the control group (0.27; 95% CI 0.05 to 0.50, $P=0.017$). This difference was driven by slightly higher scores in 7 out of 9 components (indicating a healthier diet), and with a statistically significant reduction in the intake of red meat ($P=0.03$).

Table 11. Intervention effect on the secondary outcomes.

Outcome	Intervention effect using regression analysis [a]			
	Imputed data analysis		Complete case analysis	
	Coefficient (95% CI)	*P*	Coefficient (95% CI)	*P*
Swedish Healthy Eating Index Score [b]				
Total score (points)	0.27 (0.05; 0.50)	0.02	0.27 (0.05; 0.50)	0.02
Fruit and vegetables (g/day)	29.3 (-12.2; 70.8)	0.17	26.8 (-15.8; 69.5)	0.22
Fibre (g/MJ)	0.03 (-0.12; 0.19)	0.66	0.03 (-0.12; 0.19)	0.66
Wholegrain (g/10 MJ)	0.20 (-0.48; 0.89)	0.56	0.20 (-0.49; 0.89)	0.58
Fish and shellfish (g/day)	2.8 (-4.8; 10.4)	0.47	2.3 (-5.4; 10.0)	0.56
PUFA (E%)	0.06 (-0.30; 0.42)	0.74	0.09 (-0.28; 0.47)	0.62
MUFA (E%)	-0.06 (-0.75; 0.63)	0.87	-0.06 (-0.76; 0.64)	0.87
SFA (E%)	0.27 (-0.39; 0.93)	0.42	0.19 (-0.47; 0.85)	0.56
Red meat (g/week)	-86.5 (-163.2; -9.90)	0.03	-86.8 (-164.5; -9.20)	0.03
Sucrose (E%)	-0.18 (-1.00; 0.63)	0.66	-0.19 (-1.01; 0.63)	0.64
MVPA (min/day) [c]	-0.76 (-5.34; 3.80)	0.74	-1.01 (-5.66; 3.62)	0.67
Fat mass (kg) [d]	0.05 (-0.65; 0.76)	0.88	-0.03 (-0.71; 0.64)	0.92
Fat free mass (kg) [d]	-0.09 (-0.46; 0.28)	0.64	-0.07 (-0.45; 0.30)	0.70
Glycemia (mmol/l) [e]	0.06 (-0.03; 0.15)	0.21	0.06 (-0.03; 0.14)	0.18
HOMA-IR [e]	0.10 (-0.13; 0.34)	0.39	0.12 (-0.11; 0.36)	0.31

CI, confidence interval; HOMA-IR, homeostatic model assessment for insulin resistance: MVPA, moderate to vigorous physical activity; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; SFA, saturated fatty acids.
[a] Regression analysis of follow up measure of outcome on group allocation. The coefficient is interpreted as the estimated effect of the intervention compared with the control adjusted for baseline value of the outcome, pre-pregnancy BMI (underweight and normal weight vs overweight and obesity), parity (0 vs ≥1) and educational attainment (university degree vs no university degree). Imputed data analysis included data for all 305 women and the complete case analysis data for 263-269 women.
[b] Baseline, n=302 (151 intervention, 151 control); Follow up, n=269 (135 intervention, 134 control)
[c] Baseline, n= 296 (146 intervention, 150 control); Follow up, n=267 (132 intervention, 135 control)
[d] Baseline, n=305 (152 intervention, 153 control); Follow up, n=268 (133 intervention, 135 control)
[e] Baseline, n=304 (151 intervention, 153 control); Follow up, n=263 (130 intervention, 133 control)

4.3 PARTICIPANT USAGE AND SATISFACTION (PAPER I-III)

4.3.1 Self-reported and objectively measured usage of the HealthyMoms app

Self-reported and objectively measured usage of the HealthyMoms app is presented in **Table 12**. Overall, the majority of participants in the intervention group (83%, 111/134) reported using the app once per week or more often (*Paper I*) with comparable usage among the women included in *Paper II* and *Paper III* (79% [15/19] and 82% [100/122], respectively). Correspondingly, objective data on app usage showed that the self-monitoring for physical activity was used the most, followed by self-monitoring for weight and lastly diet (Table 12). Moreover, the median usage of the self-monitoring features over the entire intervention period (i.e., 24 weeks) was 37.5 times (quartile 1: 13; quartile 3: 106; range 0-270, n=134) (*Paper I*) which is equivalent to approximately 1.6 times/week (37.5 divided by 24 weeks), with similar usage among the women included in *Paper II* and *Paper III* (data not shown).

Table 12. Objectively measured and self-reported usage of the HealthyMoms app (n=19-134).

App usage	*Paper I* [a]	*Paper II* [b]	*Paper III* [c]
Self-reported usage (n, %)			
More than 3 times/week	20 (14.9)	3 (15.8)	16 (13.1)
2-3 times/week	46 (34.3)	5 (26.3)	43 (35.2)
Once a week	45 (33.6)	7 (36.8)	41 (33.6)
2-3 times/month	15 (11.2)	2 (10.5)	14 (11.5)
Once a month	2 (1.5)	1 (5.3)	2 (1.6)
Less than once per month or never	6 (4.5)	1 (5.3)	6 (4.9)
Objectively measured usage of the self-monitoring features			
Physical activity (registrations/week)	1.6 (2.1)	2.0 (2.3)	1.6 (2.1)
Weight (registrations/week)	0.7 (0.8)	0.6 (0.4)	0.8 (0.8)
Diet (registrations/week)	0.2 (0.3)	0.3 (0.4)	0.2 (0.3)

Data presented as mean (SD) unless otherwise stated.
[a] n=134
[b] n=19
[c] n=122

4.3.2 Self-reported satisfaction with the HealthyMoms app

The self-reported satisfaction with the HealthyMoms app is presented in **Table 13**. The majority of women in the intervention group strongly or fully agreed with the statement that they were satisfied with the HealthyMoms app (78%, 104/134) and that they would recommend the app to other pregnant women (76%, 102/134) (*Paper I*), with similar responses (79% [15/19] and 63% [12/19], respectively) among the women in the interview study (*Paper II*).

Table 13. Self-reported satisfaction with the HealthyMoms app at the follow up measurement (n=19-134). Participants responded to the following statements with the six alternatives shown.

	Strongly disagree	Agree to a small extent	Agree to some extent	Strongly agree	Fully agree	Do not know
I am satisfied with the app						
Paper I [a]	2 (1.5)	5 (3.7)	18 (13.4)	66 (49.3)	38 (28.4)	5 (3.7)
Paper II [b]	0 (0.0)	0 (0.0)	3 (15.8)	9 (47.4)	6 (31.6)	1 (5.3)
The app has been a good support for a healthy weight gain during pregnancy						
Paper I [a]	9 (6.7)	18 (13.4)	39 (29.1)	32 (23.9)	20 (14.9)	16 (11.9)
Paper II [b]	0 (0.0)	6 (31.6)	5 (26.3)	4 (21.1)	2 (10.5)	2 (10.5)
The app has been a good support for healthy food habits						
Paper I [a]	12 (9.0)	16 (11.9)	42 (31.3)	41 (30.6)	11 (8.2)	12 (9.0)
Paper II [b]	0 (0.0)	2 (10.5)	10 (52.6)	3 (15.8)	2 (10.5)	2 (10.5)
The app has been a good support for exercise habits						
Paper I [a]	15 (11.2)	16 (11.9)	29 (21.6)	44 (32.8)	20 (14.9)	10 (7.5)
Paper II [b]	0 (0.0)	3 (15.8)	5 (26.3)	8 (42.1)	2 (10.5)	1 (5.3)
The app has given me insight regarding my food habits						
Paper I [a]	26 (19.4)	16 (11.9)	39 (29.1)	31 (23.1)	9 (6.7)	13 (9.7)
Paper II [b]	3 (15.8)	2 (10.5)	9 (47.4)	4 (21.1)	1 (5.3)	0 (0.0)
The app has given me insight regarding how physically active I am						
Paper I [a]	28 (20.9)	16 (11.9)	32 (23.9)	36 (26.9)	13 (9.7)	9 (6.7)
Paper II [b]	3 (15.8)	0 (0.0)	8 (42.1)	6 (31.6)	2 (10.5)	0 (0.0)
I think that the HealthyMoms app is better than other similar apps						
Paper I [a]	3 (2.2)	10 (7.5)	31 (23.1)	24 (17.9)	9 (6.7)	57 (42.5)
Paper II [b]	0 (0.0)	0 (0.0)	4 (21.1)	2 (10.5)	1 (5.3)	12 (63.2)
I would recommend other pregnant women to use the HealthyMoms app						
Paper I [a]	3 (2.2)	7 (5.2)	16 (11.9)	45 (33.6)	57 (42.5)	6 (4.5)
Paper II [b]	0 (0.0)	0 (0.0)	5 (26.3)	8 (42.1)	4 (21.1)	2 (10.5)

Data is reported as n (%).
[a] n=134
[b] n=19

4.3.3 Engagement and satisfaction with the HealthyMoms app

The thematic analysis revealed one main theme and two subthemes (**Figure 9**). These illustrated that the HealthyMoms app was appreciated, used in different ways, easy to use, perceived as trustworthy and could inspire healthy habits in pregnancy and are presented below. For supporting quotations please see *Paper II* [114].

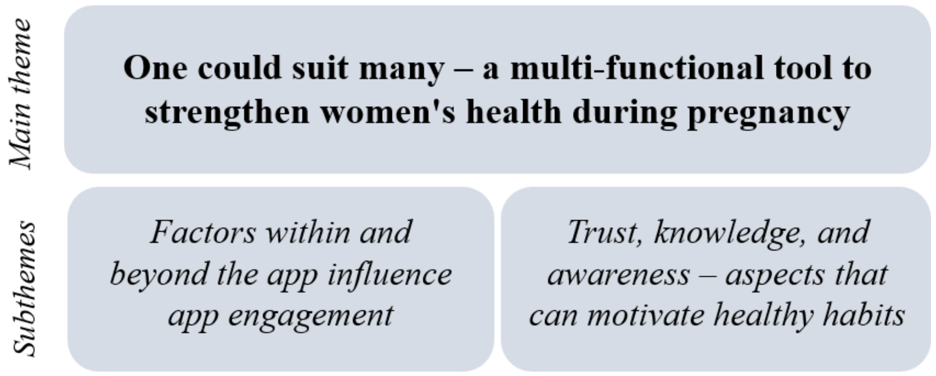


Figure 9. The resulting themes from the thematic analysis from *Paper II* [114].

4.3.3.1 Subtheme 1: Factors within and beyond the app influence app engagement

The first subtheme described factors within and beyond the app that influence engagement. Engagement varied and different features affected usage in different ways. For instance, the regular updates and push notifications sparked interest and reminded of usage and thus positively affected app usage. The design and feedback from the self-monitoring feature for diet and physical activity on the other hand were described to negatively influence usage. Although, the feedback could be perceived as encouraging, repeatedly reaching the goal for diet was described to decrease motivation to use that feature while constructive feedback could cause feelings of guilt and result in discontinued registration. Moreover, the risk of becoming too fixated with weight and diet was described as a reason for not using these self-monitoring features. Similarly, difficulties remembering food intake and estimating physical activity intensity was described as possible reasons for lower usage of the self-monitoring for diet and physical activity. An option to choose activity instead of intensity level, an in-built pedometer, or the possibility of transferring data from other apps were suggested as improvements. Engagement was also described to be influenced by factors beyond the app, such as lifestyle, prior knowledge, personal interests, and experienced need of the features in the app. To illustrate, lack of need or motivation to make dietary changes could explain low or nonexistent usage of the self-monitoring feature for diet while a personal interest in physical activity could explain higher usage of this self-monitoring feature. Motivation and a need of behavior change was described to influence the usefulness of the app as well as previous experience (e.g., excessive GWG during a previous pregnancy). Both primiparous and multiparous women found the app to be useful; however, women expecting their second child described having less need of the pregnancy-related features and number of children could also impact engagement as it restricted the time available to spend on an app. Curiosity about the app was higher in the beginning which positively influenced usage initially, while the pregnancy (e.g., course of pregnancy and pregnancy complications) also had an impact on engagement and usage was described to decline in late pregnancy. Higher initial usage was also explained by more energy and motivation to maintain healthy habits, and larger need of pregnancy-related information in early- and mid-pregnancy. Establishment of new habits, a sense of security following the progression of pregnancy as well as inability and lack of motivation to maintain a healthy lifestyle due to pregnancy complications (e.g., pelvic pain) were described as reasons for reduced usage (i.e., mainly the self-monitoring features). In contrast, engaging in healthy habits could feel more important in late pregnancy as pregnancy initially could feel more surreal.

4.3.3.2 Subtheme 2: Trust, knowledge and awareness: aspects that can motivate healthy habits

The HealthyMoms app was described as appreciated due to its appealing layout, being easy to use, having no technical issues, that the content was in line with Swedish maternity care, that it was developed by experts and was non-commercial which made it a trustworthy and credible source of information. Participants also valued the information in the app (i.e., pregnancy calendar and themes) as it was perceived as relevant and comprehensive, thus participants felt no need to search for information elsewhere. The content of the app with multiple features, broad focus covering both general and pregnancy-related health, and wide range of features was appreciated, increased its usefulness, and described as rare in other pregnancy apps. Moreover, the app was found to positively impact knowledge and awareness about weight gain, diet, and physical activity in pregnancy as well as how lifestyle impact both mother and child, which in turn was described as motivating. The self-monitoring features were described to enable self-evaluation, positively impact diet and physical activity regardless of prior habits and increase awareness of GWG, dietary and exercise habits. Additionally, the app was a good support for changing or maintaining habits as well as supporting a healthy weight gain. Although, the information on the importance of a healthy GWG was appreciated, the recommended GWG in the app was described as inconsistent with the information received from the midwife and exceeding the recommendations could give rise to anxiety, frustration, and discouragement. Another feature described as both positive (i.e., reminded of usage and made the app feel personal) as well as causing negative emotions (i.e., feeling annoyed when received at a bad time) were the push notifications. More personalized features (e.g., calendar), tailored push notifications, challenges, larger focus on mental health, a sharing- and network function, and including the partner more were described as suggested improvements. Moreover, additional suggested improvements were earlier access and a continuation postpartum.

4.4 INTERVENTION EFFECT ON INFANT OUTCOMES (PAPER III)

The intervention effect on infant body composition for the multiple imputation (n=305) and complete case analyses (n=247) are shown in **Table 14**. No statistically significant differences in any of the infant body composition variables between the intervention and control group were found (all $P \geq 0.13$). Moreover, the results from the mediation analyses investigating GWG as a mediator in the association of group allocation and infant body composition (shown in **Table 15**) showed no statistically significant effects. Finally, no evidence of differences in intervention effect depending on pre-pregnancy BMI (**Table 16**) nor associations between app adherence and infant outcomes were found (**Table 17**).

Table 14. Intervention effects on infant body composition.

Outcome	**Intervention effect using regression analysis** [a]			
	Imputed analysis (n=305)		**Complete case analysis (n=247)**	
	Unstandardized Coefficients beta (95% CI)	*P*	Unstandardized Coefficients beta (95% CI)	*P*
Weight (kg)				
Unadjusted	-0.03 (-0.14, 0.08)	0.60	-0.04 (-0.16, 0.07)	0.45
Adjusted	-0.004 (-0.11, 0.11)	0.94	-0.01 (-0.12, 0.10)	0.88
Length (cm)				
Unadjusted	-0.28 (-0.78, 0.22)	0.27	-0.39 (-0.89, 0.11)	0.13
Adjusted	-0.19 (-0.69, 0.31)	0.46	-0.27 (-0.75, 0.22)	0.28
BMI (kg/m^2)				
Unadjusted	0.03 (-0.26, 0.32)	0.84	0.03 (-0.24, 0.30)	0.81
Adjusted	0.08 (-0.21, 0.36)	0.60	0.10 (-0.16, 0.36)	0.45
Body fat (%)				
Unadjusted	0.10 (-0.86, 1.06)	0.83	0.12 (-0.89, 1.13)	0.82
Adjusted	0.17 (-0.79, 1.13)	0.72	0.25 (-0.76, 1.25)	0.63
FMI (kg/m^2)				
Unadjusted	0.01 (-0.14, 0.16)	0.89	0.01 (-0.15, 0.17)	0.88
Adjusted	0.03 (-0.12, 0.18)	0.73	0.04 (-0.12, 0.20)	0.63
FFMI (kg/m^2)				
Unadjusted	0.10 (-0.16, 0.37)	0.44	0.11 (-0.15, 0.36)	0.42
Adjusted	0.12 (-0.15, 0.38)	0.40	0.13 (-0.13, 0.38)	0.32

SD: standard deviation, CI: confidence interval, BMI: body mass index, FMI: fat mass index, FFMI: fat free mass index.
[a] Intervention effect on infant outcomes compared to the control adjusted for maternal pre-pregnancy BMI (underweight and normal weight vs overweight and obese), parity (0 vs ≥1), and height.

Table 15. Total, direct, and indirect effects of the simple mediation analyses investigating gestational weight gain as a mediator in the association of group allocation (intervention vs control) and infant body composition (n=247).

Outcome	Total effect (*c*)	Direct effect (*c'*)	Path *a*	Path *b*	Indirect effect (*ab*)	BC 95% CI (lower, upper)
Weight (kg)	-0.01 (0.06)	-0.01 (0.06)	-0.03 (0.41)	0.01 (0.01)	0.00 (0.01)	-0.01, 0.01
Length (cm)	-0.27 (0.25)	-0.26 (0.25)	-0.03 (0.41)	0.06 (0.04)	0.00 (0.03)	-0.06, 0.06
BMI (kg/m^2)	0.10 (0.13)	0.10 (0.13)	-0.03 (0.41)	0.02 (0.02)	0.00 (0.01)	-0.02, 0.02
Body fat (%)	0.25 (0.51)	0.25 (0.51)	-0.03 (0.41)	0.03 (0.08)	0.00 (0.03)	-0.07, 0.08
FMI (kg/m^2)	0.04 (0.08)	0.04 (0.08)	-0.03 (0.41)	0.01 (0.01)	0.00 (0.01)	-0.01, 0.01
FFMI (kg/m^2)	0.13 (0.13)	0.13 (0.13)	-0.03 (0.41)	0.03 (0.02)	0.00 (0.02)	-0.04, 0.03

BC: bias corrected (the calculated confidence interval for the indirect effect); BMI: body mass index; CI: confidence interval, FMI: fat mass index, FFMI: fat free mass index.
Data presented as absolute beta values (standard error) and BC 95% CI based on 5000 bootstraps. All analyses were adjusted for maternal pre-pregnancy BMI (underweight and normal weight vs overweight and obese), parity (0 vs ≥1), and height.

Table 16. Sensitivity analysis using regression analysis to assess intervention effect on infant body composition according to pre-pregnancy BMI [a].

Outcome	Imputed analysis (n=305)	Complete case analysis (n=247)
	Unstandardized Coefficients Beta (95% CI)	Unstandardized Coefficients Beta (95% CI)
Underweight or normal weight before pregnancy [b]		
Weight (kg)	-0.05 (-0.17, 0.08)	-0.06 (-0.18, 0.07)
Length (cm)	-0.43 (-1.00, 0.14)	-0.55 (-1.11, 0.01)
BMI (kg/m^2)	0.06 (-0.26, 0.39)	0.09 (-0.21, 0.38)
Body fat (%)	0.62 (-0.49, 1.74)	0.74 (-0.41, 1.90)
FMI (kg/m^2)	0.09 (-0.09, 0.26)	0.11 (-0.08, 0.29)
FFMI (kg/m^2)	0.07 (-0.24, 0.38)	0.08 (-0.21, 0.38)
Overweight or obesity before pregnancy [c]		
Weight (kg)	0.11 (-0.10, 0.32)	0.13 (-0.09, 0.34)
Length (cm)	0.46 (-0.49, 1.40)	0.54 (-0.39, 1.48)
BMI (kg/m^2)	0.12 (-0.42, 0.66)	0.14 (-0.36, 0.64)
Body fat (%)	-0.95 (-2.75, 0.85)	-1.15 (-3.08, 0.78)
FMI (kg/m^2)	-0.12 (-0.40, 0.16)	-0.15 (-0.45, 0.15)
FFMI (kg/m^2)	0.24 (-0.29, 0.76)	0.26 (-0.24, 0.75)

SD: standard deviation, CI: confidence interval, BMI: body mass index, FMI: fat mass index, FFMI: fat free mass index.
[a] Intervention effect on infant outcomes compared to the control adjusted for parity (0 vs ≥1), and height with an interaction for pre-pregnancy BMI-category.
[b] n=181 (intervention group, n=85; control group, n=96)
[c] n=66 (intervention group, n=37; control group, n=29)

Table 17. Sensitivity analysis using regression analysis to assess associations of engagement (high- and low adherence vs control) and intervention effect on infant body composition [a].

Outcome	Imputed analysis (n=305)		Complete case analysis (n=247)	
	Unstandardized Coefficients Beta (95% CI)	*P*	Unstandardized Coefficients Beta (95% CI)	*P*
Weight (kg)				
High usage	-0.007 (-0.141, 0.127)	0.916	-0.023 (-0.157, 0.110)	0.731
Low usage	0.000 (-0.134, 0.134)	0.999	0.007 (-0.129, 0.142)	0.923
Length (cm)				
High usage	-0.184 (-0.783, 0.414)	0.544	-0.306 (-0.901, 0.288)	0.311
Low usage	-0.183 (-0.795, 0.429)	0.556	-0.224 (-0.825, 0.378)	0.465
BMI (kg/m^2)				
High usage	0.066 (-0.275, 0.407)	0.704	0.069 (-0.244, 0.383)	0.664
Low usage	0.087 (-0.261, 0.435)	0.623	0.130 (-0.187, 0.447)	0.421
Body fat (%)				
High usage	0.448 (-0.733, 1.628)	0.456	0.498 (-0.725, 1.722)	0.423
Low usage	-0.080 (-1.264, 1.105)	0.895	-0.014 (-1.252, 1.224)	0.983
FMI (kg/m^2)				
High usage	0.052 (-0.131, 0.236)	0.576	0.059 (-0.133, 0.251)	0.545
Low usage	0.003 (-0.179, 0.185)	0.974	0.018 (-0.176, 0.213)	0.854
FFMI (kg/m^2)				
High usage	0.090 (-0.235, 0.415)	0.586	0.088 (-0.222, 0.397)	0.576
Low usage	0.141 (-0.194, 0.475)	0.408	0.169 (-0.144, 0.482)	0.289

CI: confidence interval, BMI: body mass index, FMI: fat mass index, FFMI: fat free mass index.
[a] Associations of high- (n=61) and low (n=61) app adherence with the control group (n=125) as reference. High- and low app adherence was defined as usage of the HealthyMoms app (defined as total number of registrations) above or below the median (37.5) of total number of registration (i.e., for diet, physical activity, and weight), respectively. The model was adjusted for maternal pre-pregnancy BMI (underweight and normal weight vs overweight and obese), parity (0 vs ≥1), and height.

4.5 PHYSICAL ACTIVITY, BODY COMPOSITION AND CARDIOMETABOLIC HEALTH (PAPER IV)

As expected, maternal body composition (e.g., weight, fat- and fat free mass) and cardiometabolic health indicators were generally higher in gestational week 37 ($P<0.001$) (**Table 18**). The distribution of movement behaviors (i.e., sleep, sedentary behavior, LPA and MVPA) in gestational weeks 14 and 37 as well as the change in the individual behaviors are shown in **Figure 10a-c**. The composition of movement behaviors was similar at the two time points but with greater variation in gestational week 37 (Figure 10b) than in gestational week 14 (Figure 10a). As shown in Figure 10c, the proportion of MVPA decreased by 38% and the other movement behaviors increased (sleep 8%, sedentary behavior 12%, LPA 18%) from the sample average between the two time points.

Table 18. Body composition and cardiometabolic health in early and late pregnancy (gestational weeks 14 and 37, respectively).

		Early pregnancy (n=273)	**Late pregnancy (n=242)**
Body composition	Weight (kg)	67.3 (11.3)	77.6 (11.5) *
	Height (m)	1.67 (0.06)	1.67 (0.06)
	BMI (kg/m2) [a]	24.1 (3.8)	27.8 (3.7) *
	Fat mass (%) [b]	31.7 (7.3)	31.8 (6.2)
	Fat mass (kg) [b]	22.0 (8.9)	25.2 (8.4) *
	Fat free mass (kg) [b]	45.4 (4.7)	52.5 (5.2) *
	FMI (kg/m^2) [b]	7.9 (3.1)	9.0 (2.9) *
	FFMI (kg/m^2) [b]	16.2 (1.3)	18.8 (1.5) *
Cardiometabolic health indicators	Glucose (mmol/l) [c, d]	4.8 (0.3)	4.7 (0.4) *
	Insulin (μU/l) [c, d]	6.4 (2.9)	10.8 (5.0) *
	HOMA-IR [d]	1.4 (0.7)	2.3 (1.2) *
	Systolic blood pressure (mmHg)	108 (9)	111 (10) *
	Diastolic blood pressure (mmHg)	70 (6)	73 (7) *
	Total cholesterol (mmol/l) [d]	4.7 (0.6)	6.7 (1.0) *
	Triglycerides (mmol/l) [d]	1.0 (0.4)	2.6 (0.9) *
	HDL cholesterol (mmol/l) [d]	2.00 (0.35)	1.95 (0.38) *

BMI, body mass index; FMI, fat mass index; FFMI, fat free mass index; HOMA-IR, homeostatic model assessment-insulin resistance; HDL, high density lipoprotein; SD, standard deviation. Values are reported as mean (SD) for continuous variables or n (%) for categorical variables.
*Statistically significant from corresponding values in gestational week 14 (P<0.001)
[a] n= 241 in gestational week 37
[b] n= 240 in gestational week 37
[c] n= 272 in gestational week 14
[d] n= 236 in gestational week 37

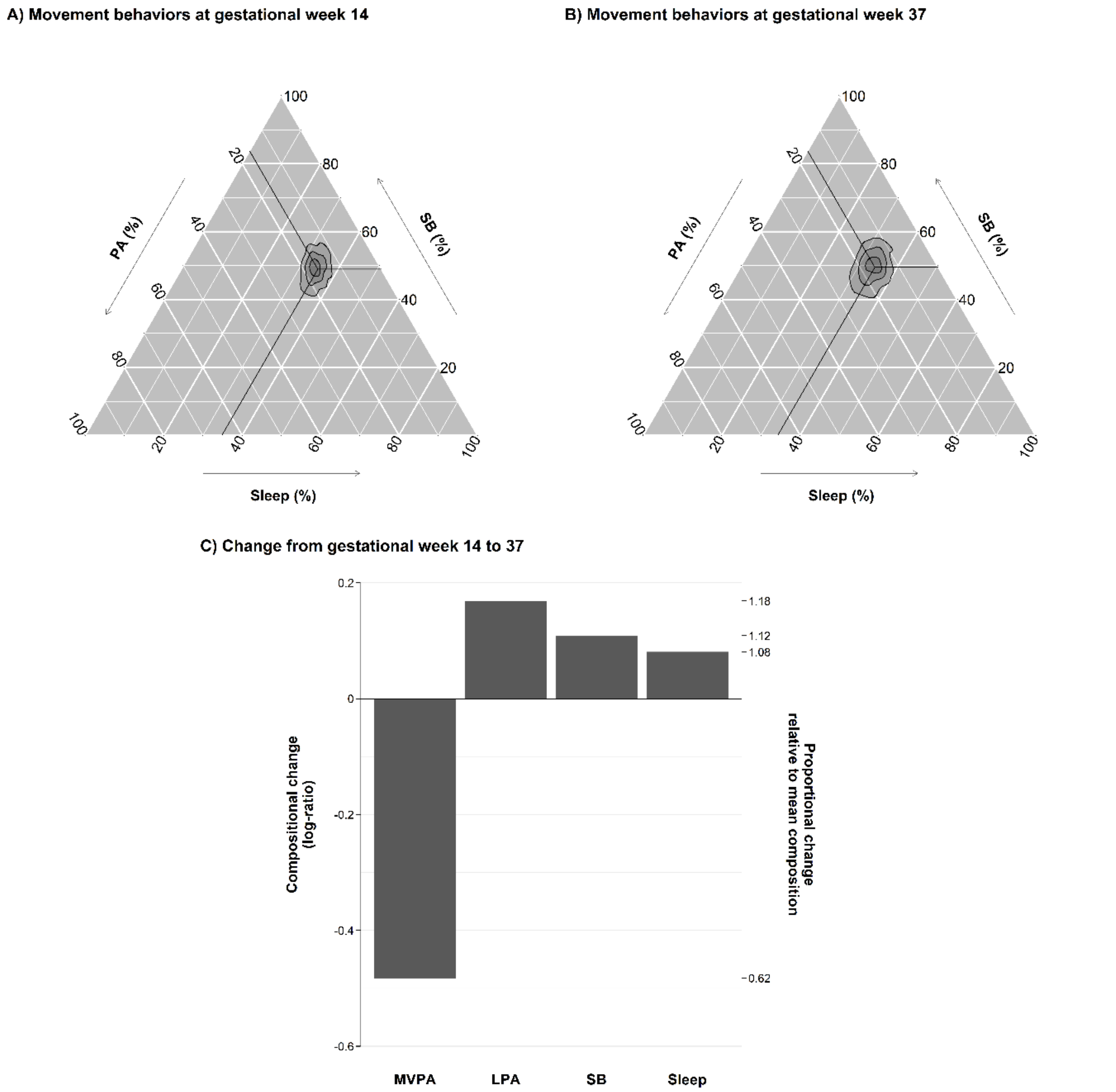


Figure 10. Figure from *Paper IV* [116] showing the distribution of movement behaviors at gestational weeks 14 and 37. (A) A ternary plot showing the women's movement behaviors, i.e., sleep, sedentary behavior (SB) and physical activity (PA) (which combines light [LPA] and moderate-to-vigorous PA [MVPA]). The crosshair marks the compositional mean at (A) gestational week 14 (i.e., MVPA: 32 min/day, LPA: 198 min/day, SB: 693 min/day, sleep: 493 min/day) and (B) gestational week 37 (i.e., MVPA: 18 min/day, LPA: 210 min/day, SB: 699 min/day, Sleep: 484 min/day). Concentric rings represent the 25, 50% and 75% confidence regions for the data. (B) A ternary plot showing the women's movement behaviors, i.e., sleep, sedentary behavior (SB) and physical activity (PA) at gestational week 37. Concentric rings represent the 25, 50% and 75% confidence regions. (C) Compositional change in MVPA, LPA, SB, and sleep with respect to the overall mean time composition. The left axis gives the log-ratio value, and the right axis displays the actual proportion relative to the mean composition (e.g., 1.25 means 1.25 times the compositional mean or a proportion higher by 25%).

Movement behaviors, body composition and cardiometabolic health in early pregnancy

The cross-sectional associations of movement behaviors with body composition and cardiometabolic health in gestational week 14 (**Table S1, Appendix 2**) showed that reallocating time to LPA from sedentary behavior and sleep was associated with lower body weight (adj. γ=-5.959, *P*=0.047) and HOMA-IR (all $\gamma \leq -0.495$, $P \leq 0.047$). Similarly, reallocating time to MVPA from the other behaviors was associated with lower MetS score (all $\gamma \leq -0.343$, all $P \leq 0.002$). The results remained after additional adjustments for diet quality (Table S1, Appendix 2). The dose-response curves relative to increasing one behavior while proportionally reducing the others (e.g., increasing MVPA while reducing LPA, sedentary behavior, and sleep) and pairwise reallocation plots (illustrating the effect size of replacing one behavior with another) are shown in **Figure 11** and **Figure S1-8** (Appendix 2). For example, reallocating 10 min/day to MVPA from the other behaviors was associated lower MetS score (-0.07 SD; 95% CI: -0.12 to -0.03), while the pairwise reallocation plot showed an association in the opposite direction from reallocating 10 min/day from MVPA to sedentary behavior (0.09 SD; 95% CI: 0.04 to 0.14) (Figure 11).

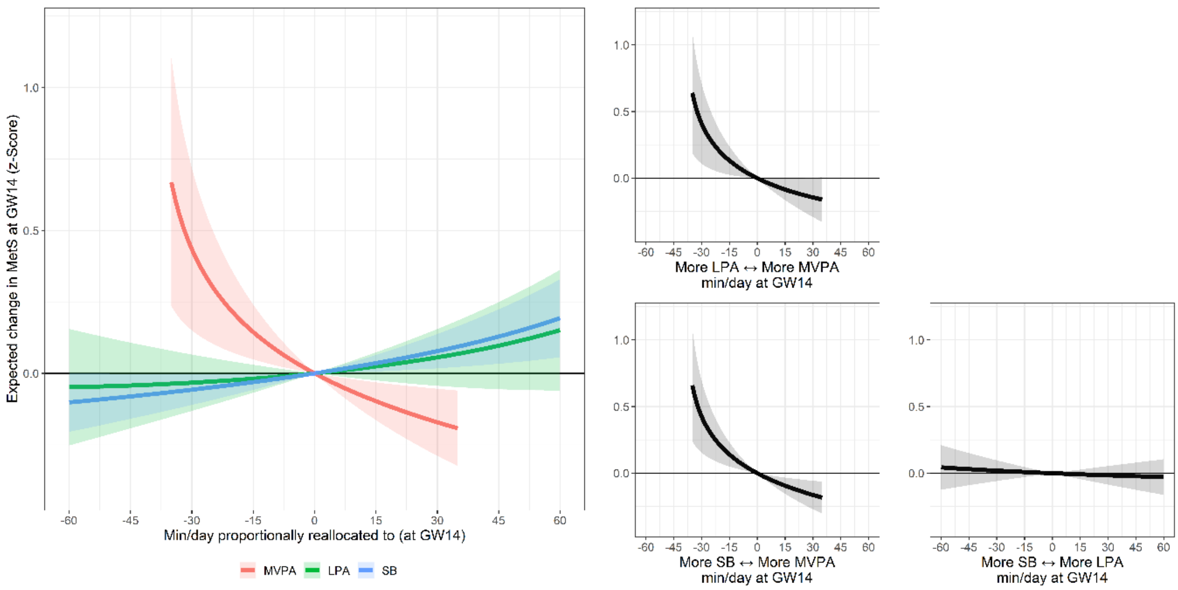


Figure 11. Cross-sectional associations of moderate-to-vigorous physical activity (MVPA), light physical activity (LPA), sedentary behavior (SB) and sleep relative to the other behaviors in gestational week (GW) 14 with metabolic syndrome (MetS) score in GW14 as presented in *Paper IV* [116]. The colored lines represent the effect of increasing one behavior while proportionally reducing the others (e.g., increasing MVPA while decreasing LPA, SB and sleep). The black line represents the effect of increasing one behavior while proportionally reducing another (e.g., increasing MVPA while decreasing SB). Models are adjusted for maternal age, parity (0 vs ≥ 1), and education level (university vs no university degree).

Movement behaviors in early pregnancy and outcomes in gestational week 37

Longitudinal associations of movement behaviors at baseline (gestational week 14) with body composition and cardiometabolic health in gestational week 37 are shown in **Table S2** (**Appendix 2**). Reallocating time to LPA from sedentary behavior and sleep in gestational week 14 was associated with lower FMI (adj.: γ=- 0.668, *P*=0.028), glucose levels (all $\gamma \leq$-0.219, all *P*≤0.043), HOMA-IR (all $\gamma \leq$-0.619, all *P*≤0.016) and MetS score (all $\gamma \leq$-0.410, all *P*≤0.040) in gestational week 37. These associations were independent of the change in behaviors from week 14 to week 37 and results remained the same after additional adjustments for diet quality (Table S2, Appendix 2). The dose-response curves and pairwise reallocation plots are shown in **Figure 12** and **Figure S9-16** (Appendix 2). As shown in Figure 12 below, replacing half an hour a day of sedentary behavior with LPA was associated with a decrease in MetS score (-0.05 SD; 95% CI: -0.11 to 0.00).

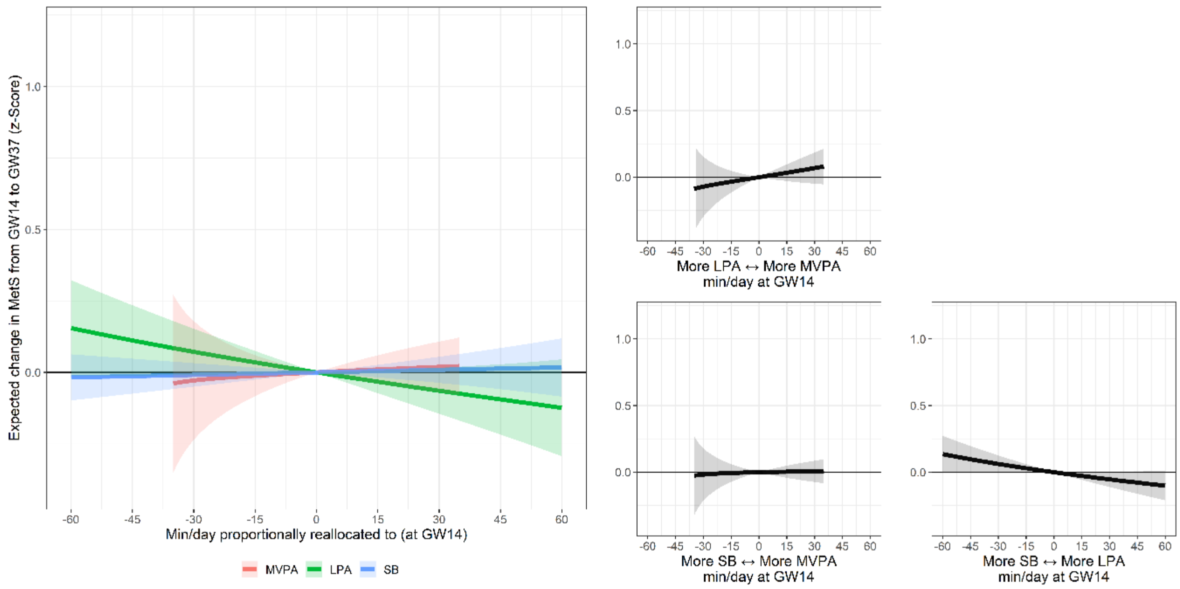


Figure 12. Longitudinal associations of moderate-to-vigorous physical activity (MVPA), light physical activity (LPA), sedentary behavior (SB) and sleep relative to the other behaviors in gestational week (GW) 14 with metabolic syndrome (MetS) score in GW37 as presented in *Paper IV* [116]. The colored lines represent the effect of increasing one behavior while proportionally reducing the others (e.g., increasing MVPA while decreasing LPA, SB and sleep). The black line represents the effect of increasing one behavior while proportionally reducing another (e.g., increasing MVPA while decreasing SB). Models are adjusted for physical activity (i.e., MVPA, LPA, SB, and sleep) and outcome at baseline and follow up and confounders (i.e., maternal age, parity [0 vs ≥ 1], education level [university vs no university degree] and group allocation [intervention vs control]).

Changes in movement behaviors between gestational weeks 14 and 37 and outcomes in gestational week 37

The change in movement behaviors from early to late pregnancy (**Table S3, Appendix 2**) showed that reallocating time to MVPA from LPA, sedentary behavior and sleep throughout pregnancy was associated with higher systolic (all $\gamma \leq 2.415$, all $P \leq 0.010$) and diastolic blood pressure (all $\gamma \leq 1.501$, all $P \leq 0.041$). These results remained essentially the same after additional adjustments for diet quality (Table S3, Appendix 2). However, the dose-response curves and pairwise reallocation plots (**Figure 13** and **Figure S17-24,** Appendix 2) showed that reallocating 10 min/day to MVPA from sedentary behavior was associated with only a very small increase in systolic- (0.40 mmHg; 95% CI: 0.10 to 0.71) and diastolic blood pressure (0.24 mmHg; 95% CI: 0.02 to 0.45) (Figure S23-24, Appendix 2); however, these showed no statistically significant associations for MetS score (Figure 13). Finally, replacing 30 min/day of sedentary behavior with LPA was associated with lower FMI (-0.08; 95% CI: -0.16 to -0.00) (Figure S19, Appendix 2).

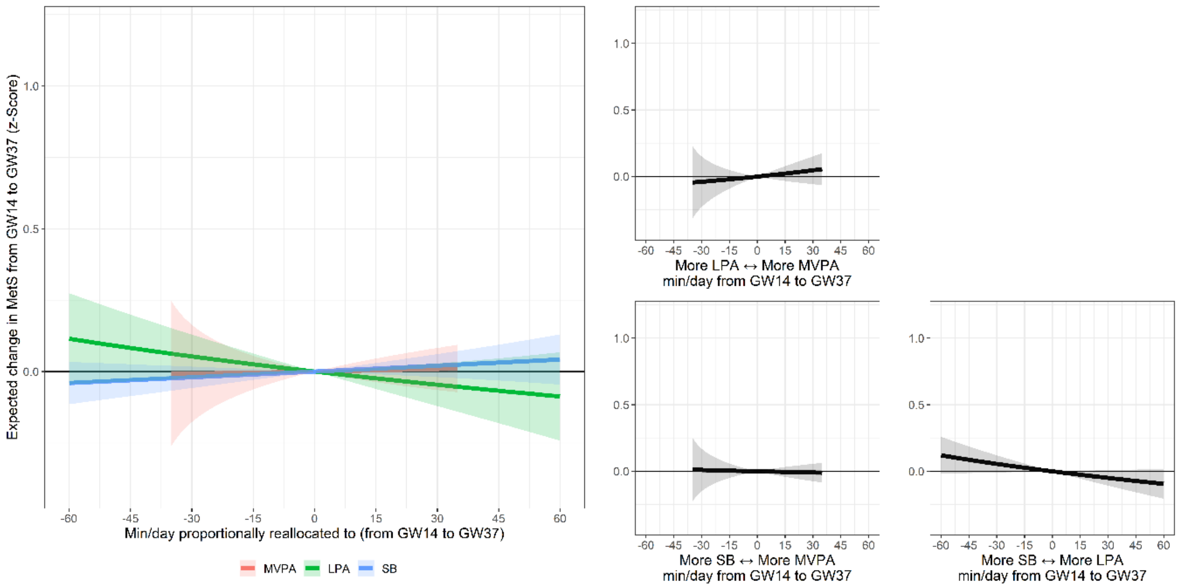


Figure 13. Longitudinal associations of change in moderate-to-vigorous physical activity (MVPA), light physical activity (LPA), sedentary behavior (SB) and sleep relative to the other behaviors between gestational weeks (GW) 14 and 37 with metabolic syndrome (MetS) score in GW37 as presented in *Paper IV* [116]. Each colored line represents the effect of increasing one behavior while proportionally reducing the others (e.g., increasing MVPA while decreasing LPA, SB and sleep). Each black line represents the effect of increasing one behavior while proportionally reducing another (e.g., increasing MVPA while decreasing SB). Models are adjusted for physical activity (i.e., MVPA, LPA, SB, and sleep) and outcome at baseline and follow up and confounders (i.e., maternal age, parity [0 vs ≥ 1], education level [university vs no university degree] and group allocation [intervention vs control].

5 DISCUSSION

This thesis is based on the HealthyMoms randomized controlled trial [108] which was the first study to examine the effectiveness of a 6-month comprehensive lifestyle and pregnancy intervention delivered exclusively through an app on GWG, diet, physical activity and glycemia in pregnant women covering all BMI categories (*Paper I*). The thesis also investigated whether there were any interventional effects on infant weight and body composition at 1-2 weeks of age (*Paper III*) as well as explored participants' engagement and satisfaction with this type of intervention (qualitative study, *Paper II*). Finally, associations of different movement behaviors with body weight and composition and cardiometabolic health markers in both early- and late pregnancy were studied with the potential to provide valuable knowledge on physical activity as target for future interventions in this field (*Paper IV*).

5.1 RESULTS DISCUSSION

5.1.1 Effects on the primary outcome: GWG

One main finding of this thesis is that no effect on GWG in the whole group in the HealthyMoms trial was observed; however, women in the intervention group with overweight or obesity prior to pregnancy gained less weight compared to their counterparts in the control group (-1.67 kg; 95% CI -3.26 to -0.09; *P*=0.031, n=271). As discussed in *Paper I* [113], and shown in a review by Rhodes et al. [40] previous studies investigating the effect of an app intended to promote a healthy GWG have been pilot studies and only included women with overweight and obesity. Nevertheless, a study in a similar population to our study (pre-pregnancy BMI ≥18.5-35 kg/m^2) evaluated the effectiveness of a website aimed to support a healthy lifestyle and weight gain in pregnancy also found no statistically significant effect on total GWG [44]. Our results showing that women with overweight or obesity prior to pregnancy who received the app gained statistically significantly less weight than the control group supports findings from previous pilot studies where digital interventional components have been evaluated [38,45]. To illustrate, results from a pilot study utilizing a multi-modality delivered intervention (i.e., text messages, a website, video messages and a chat room interaction via Facebook) in pregnant women with overweight and obesity found that women in the intervention group gained less weight compared to those in the control group [45]. Similarly, results from a 3-arm RCT in women with overweight and obesity found that the women who received the intervention (i.e., behavior modification counseling delivered remotely via an app or in-person in combination with a wireless Internet-connected bathroom scale and a pedometer) exceeded the GWG recommendations to a lower extent compared to the women who received usual care [38]. Moreover, the estimated intervention effect for women with overweight or obesity (-1.67 kg) is comparable to previous and more resource intense traditional interventions (i.e., face-to-face counselling) in pregnant women [17,19]. Altogether, the results from this thesis and existing pilot data suggests that mHealth interventions have potential to be useful tools to promote a healthier GWG in women with overweight and obesity.

5.1.2 Effects on secondary outcomes: diet and physical activity

In terms of the secondary outcomes, a statistically significant effect on diet with a higher SHEI score, indicating a healthier diet, in the intervention group compared to the control group in the HealthyMoms trial (0.27; 95% CI 0.05 to 0.50, P=0.017) was found. Similarly, a previous mHealth intervention (delivered by the research nutritionist/dietitian and obstetrician and access to an app) in pregnant women also found statistically significant effects on dietary outcomes (e.g., lower intake of glycemic index, free sugars, fat and sodium) [138]. The effect in our study was attributed to an overall shift towards a healthier diet with non-significant decreases in 7 out of 9 components (all $P \geq 0.17$). Noteworthy, the intervention group consumed 87 grams less red meat (P=0.03). This reduction might actually be a reflection of the content of the HealthyMoms app which was carefully designed to also include information on the benefits of a plant-based diet as well as vegetarian recipes. This was done to accommodate to recent trends in society with increased interest in such diets as well as requests from previously developed mHealth interventions by the research group. In contrast to diet, our results showed no effect on the secondary outcome MVPA even though the app had a large focus on physical activity (e.g., information on beneficial effects, exercise programs adapted to pregnancy). Previous mHealth interventions in pregnancy have demonstrated conflicting results as some have found beneficial effects on physical activity [45,138,139] while others have not [107]. However, these studies have evaluated self-reported outcomes [45,138] or manual imputation of steps (Fitbit) [107], or had short duration (i.e., 4 weeks) [139]. As described previously [55] studies have shown self-reported methods to overestimate MVPA in pregnant women, and the importance of using objective methods to assess physical activity in pregnancy has been highlighted. Indeed, the study by Hayman et al. [139] used objective methods to assess MVPA; however, the study was initiated in early pregnancy (eligibility criteria gestational age 10-20 weeks) and considering the short intervention period of 4 weeks, did not cover late gestation. Pregnancy is a period characterized by physiological changes as well as potential pregnancy complications (e.g., pelvic pain), and the ability to maintain or increase the level of MVPA in late gestation is most likely impaired. Indeed, observational data has shown that physical activity levels decline throughout pregnancy and few women reach the recommended levels of MVPA, especially in late pregnancy [88,92,93]. In that regard, pregnancy itself could be a potential explanation for the lack of intervention effect on MVPA in our study. Nevertheless, it is evident that more studies are needed to evaluate the potential of digital lifestyle interventions to promote physical activity throughout pregnancy using objective methods.

5.1.3 Engagement and satisfaction with the HealthyMoms app

The qualitative data (*Paper II* [114]) demonstrated that the participants were satisfied with the app and used it to a high extent. Moreover, engagement with HealthyMoms was influenced by both factors beyond the app and the functionalities in the app. Indeed, factors beyond the app seemed to influence usage to a high extent and life situation (e.g., number of children) and available time were described to limit app engagement which is similar to results from a previous study [45]. On a similar note, pregnancy itself (i.e., duration and pregnancy-related complications) was described to guide engagement with more frequent usage in early pregnancy followed by a decline which was explained by higher curiosity initially. This pattern has been seen among pregnant women previously [29], and indicates that it could be important to tailor the intervention to cover the most important information in the beginning. Moreover, in similarity to findings by Willcox et al. [45], pregnancy-related complications (e.g., back pain and morning sickness) were described as barriers to maintaining a healthy lifestyle. Thus, information and support on these issues are important elements in a health and pregnancy app. In addition, our participants also described that motivation influenced app usage and that usage could decrease due to establishment of new habits. This could be perceived as an indication that the app had fulfilled its purpose and the same level of engagement throughout an intervention might not be needed.

Further, factors within the app were described to have both positive and negative influence on engagement with the HealthyMoms app. Factors described to have a positive influence on engagement were regular updates, push notifications and feedback from the self-monitoring features. In similarity with a previous study which found reminders to be positive and also highlighted the importance of timing and frequency [140], the women described that push notifications could be perceived as annoying when received at a bad time. Moreover, participants described the wide range of features with focus on both pregnancy and health as valuable which is in line with previous studies [27,29,141,142]. The self-monitoring features were appreciated and described to increase awareness of GWG, dietary and exercise habits which in turn motivated higher usage and aided the establishment of healthier habits. Self-monitoring of weight in pregnancy has previously been described as helpful and motivating in terms of staying within the recommendations for GWG [143]; however, the participants in our study also described that it can cause feelings of stress and anxiety when exceeding the recommended weight gain. Nevertheless, participants also expressed that the recommendations for weight gain in pregnancy is not often discussed in maternity care. Similarly, both midwives and pregnant women have expressed challenges and stigma related to discussing GWG in maternity care [142,144,145] while also acknowledging the importance of GWG interventions [146]. The HealthyMoms app is also in line with Swedish maternity care which was described to enhance the relevance and usefulness of the app. Moreover, the participants perceived the app as trustworthy and a reliable source of information as it contained evidence-based information and was developed by experts. On a similar note, both healthcare professionals and pregnant women have expressed that they would prefer pregnancy apps from a trusted source which also is relevant to the healthcare provided in their area [27].

The participants also highlighted potential future improvements of the app which included a sharing and network feature, more personalized aspects of the app (e.g., making goals and feedback more individualized), a focus on mental health, earlier access to the app as well as a continuation to also cover the postpartum period. More focus on mental health has also been called for in commercial pregnancy apps [147]. Moreover, participants also wished for a revised diet registration and the possibility to automatically transfer physical activity from e.g., a pedometer or other apps.

5.1.4 Potential beneficial or harmful effects on infant body composition and growth

No effect on infant weight, length, body fat percentage or any other of the body composition variables as well as no mediation effect through GWG on infant body composition were found. As discussed in *Paper III* [115], only two previous full-scale studies [83,84] have investigated the effects of a lifestyle intervention in pregnancy on infant body composition using air-displacement plethysmography. In brief, although the existing studies have shown similar effects on GWG in women with overweight and obesity (HealthyMoms -1.67 kg, MOMFIT – 1.7 kg, LIFT -1.79 kg) the results regarding infant outcomes have been conflicting [83,84,115]. In short, only the LIFT study found an effect on infant body composition [84]; however, this effect did not persist at follow up at 14 weeks and 1 year of age [148]. The reasons for these conflicting results could be due to a number of reasons such as intervention characteristics, study sample (e.g., sex has been shown to influence body composition [149]) and methods used to assess infant body composition. In dissimilarity to HealthyMoms which involved no interactive human support and included women from all BMI categories, the intervention being evaluated in the two previous studies [83,84] consisted mainly of group counselling and targeted women with overweight and obesity. In that regard, it is relevant to emphasize that no statistically significant effect on infant body composition was found when only including women with overweight or obesity either (Table 16, *Paper III*) [115]. Moreover, all three studies shared some similarities such as intervention initiation and length (around gestational week 15-36), as well as study size and participant characteristics (i.e., almost equal proportion of boys and girls) [83,84,115]. Finally, air-displacement plethysmography was used in all three studies to assess infant body composition; however, an important distinction is the time of the measurement (HealthyMoms 1-2 weeks, MOMFIT and LIFT first days of life [83,84]) which is of relevance since infant body composition has been found to fluctuate during the first 4 days of life [150]. Due to the absence of an intervention effect in the LIFT study at follow up [148] this could be a possible explanation to the conflicting results.

Altogether, the existing evidence presented in this thesis (*Paper III*, [115]) and previous studies using air-displacement plethysmography [83,84] does not provide any support that lifestyle interventions initiated in pregnancy with positive effects on diet and reduced GWG have any impact on infant outcomes (e.g., fetal overgrowth or body fatness). This is also in line with results from a meta-analysis that evaluated the effect of lifestyle interventions in pregnant women with overweight or obesity on infant adiposity [151], and individual intervention studies [152,153] with infant body fatness as outcome, as well as reviews covering trials with birthweight as an outcome [154–156]. Moreover, although all the studies discussed above [83,84,113] exhibited an intervention effect on GWG, this effect (around -1.7 kg) might not be of enough magnitude to have an effect on the infant. It is possible that more pronounced effects on diet and consequently GWG could impact infant body composition; however, whether such effects are beneficial or not remains unclear. Nevertheless, it could be argued that beneficial or harmful effects likely depends on the effect size (e.g., magnitude of the decreased GWG). To illustrate, research on the impact of maternal nutrition during more extreme circumstances has shown that exposure to famine in the fetal period is associated with anthropometric profile (e.g., higher BMI and waist circumference, and decreased height) [157] and an increased risk of obesity in adulthood [158]. In contrast, the negative consequences of excessive GWG for the child [8,10] and the need for lifestyle interventions to prevent excessive weight gain in pregnancy are well-established [159]. Considering the effect sizes seen in previous intervention studies targeting pregnant women [15,17] and the results from the HealthyMoms trial (*Paper I* and *Paper III* [113]) it is unlikely that these types of low dose interventions would cause any drastic weight changes. Furthermore, as described above, all three studies were initiated around gestational week 15 [83,84,115], and thus did not cover the first trimester which has been suggested as a critical time for placental function to affect the growth and development of the fetus [160]. Indeed, it is possible that earlier intervention initiation is needed, and perhaps as early as prior to conception [161]. As described in a review by Stephenson et al [162], few interventions have been made for maternal diet and lifestyle before conception and interventions during this time is called for to improve maternal and child health. Clearly, further research is required to elucidate the effects of lifestyle interventions prior or during pregnancy on infant adiposity and obesity risk later in life. Finally, it is important to ascertain the safety of lifestyle interventions in pregnancy and to ensure that the intervention has no undesirable effects on the infant. In that aspect, no such effects (e.g., growth restriction) were observed (*Paper III*, [115]) which is in line with meta-analyses of previous face-to-face lifestyle interventions achieving reduced GWG while simultaneously observing no adverse effects on e.g., birthweight [14,154,155]. Altogether, our findings (*Paper I* and *Paper III* [113,116]) suggest that the HealthyMoms app may be implemented in maternity care to promote a healthier lifestyle and GWG in pregnancy without compromising infant growth.

5.1.5 Potential explanations for the modest intervention effects and future implications

A potential explanation to the modest intervention effects could be the baseline characteristics of the participants in the HealthyMoms trial. Although there was variation in the sample the women exhibited a rather healthy lifestyle at baseline in terms of SHEI score (mean 6.66 [SD 0.98], maximum score 9) and high levels of MVPA (mean 39 [SD 24] min/day) (*Paper I*). It is possible that more pronounced effects on physical activity and consequently GWG as well as infant outcomes could possibly have been observed in more sedentary women and/or women with more room for improvements in their diet. On a similar note, our study sample included women from all BMI-categories, which may have diluted the effect. Nevertheless, considering the high prevalence of excessive GWG also among women with normal weight [6] it is important to provide support to those women as well. Furthermore, although midwives consider GWG interventions to be important approximately one in five midwives avoid discussing GWG in fear of upsetting the women [146]. In that aspect, the continuous support from the HealthyMoms app with its extensive content regarding GWG (i.e., information and self-monitoring) can fill an important gap. Another potential explanation for the moderate effect could be the nature of the HealthyMoms app. Although strengths of the intervention include no efforts from healthcare and constant support throughout pregnancy it is possible that that the intensity of the intervention was not enough to achieve larger effects for the whole group. Indeed, the effects on GWG has been found to be greater from high-intensity face-to-face interventions (≥12 contacts) compared to interventions of moderate- or low intensity (3-11 and <2 contacts, respectively) [163]. Thus, a potential improvement of the intervention could be to increase its intensity through the addition of interactive support from healthcare professionals (e.g., a dietician or midwife) through the HealthyMoms app.

Another potential explanation of the moderate effect could be the magnitude of participants' engagement. As described above, user engagement has been depicted as a precondition for intervention effectiveness [85]. Overall, this thesis has shown high usage of the HealthyMoms app from both objective and self-reported data. No evaluation of the impact of usage with intervention effectiveness on maternal outcomes was included in this thesis. However, results from a secondary analysis of participant data in the HealthyMoms trial indicated that greater number of registrations (i.e., total number of registrations for weight, diet, and physical activity) was associated with greater intervention effectiveness (in terms of lower GWG (β=-0.20, *P*= 0.026) and improved diet quality (β=0.20, *P*=0.006) (submitted manuscript). These findings are interesting and should be taken into consideration when refining the HealthyMoms app prior to implementation. In contrast, no evidence of associations between app adherence and infant outcomes was found (*Paper III,* [116]). Thus, it is unlikely that low adherence was a major reason for the lack of effect in *Paper III*.

Interestingly, although the intervention had a positive effect on diet (*Paper I,* [113]), objective data on app usage showed that the average use of the diet registration was lower (0.2 [SD 0.3] times/week) than the encouraged frequency (i.e., once per week). Similarly, the qualitative evaluation (*Paper II,* [114]) revealed several reasons for low usage of the diet registration (e.g., risk of becoming too fixated with diet, that it was confusing and time-consuming) and expressed that it could be improved. In contrast, the physical activity registration was used to a higher extent (1.6 [SD 2.1] times/week) which is not surprising considering that participants could register after having completed a physical activity. However, no intervention effect on MVPA was found. In addition, this data is more difficult to interpret since participants could either register several activities per day or a summary of the accumulated activity minutes at the end of the week. Moreover, the majority of women reported that they found the app to be a good support for both healthy dietary and physical activity habits as well as GWG (*Paper I,* [113]). Evidently, there are individual differences in terms of preferences and needs when it comes to behavior change and it is possible that for instance information is more efficient in achieving behavior change for certain behaviors and self-monitoring more efficient for others. The qualitative evaluation (*Paper II* [114]) also demonstrated that "one size probably does not fit all" as participants expressed varied usage, needs and satisfaction with the app while also wishing for more personalized features. Moreover, goal-setting is also considered an important behavior change technique [121] which was incorporated in the app. Unfortunately, neither self-reported nor objective data on goal setting was collected and the influence on the intervention's effectiveness can only be speculated. Future studies should investigate associations between usage of specific app features (e.g., goal setting) and intervention effect.

5.1.6 Potential improvements of the HealthyMoms app

This thesis also illustrates potential improvements of the HealthyMoms app which could increase both the effectiveness and usability of the app before implementation. The results from *Paper II* [114] discussed above covered various aspects which could be improved ranging from existing content to adding additional information and features. Firstly, the app could be improved by extending the content to cover the preconception and postpartum period, adding a sharing and network function, more focus on mental health as well as more support on how to uphold the motivation to maintain a healthy lifestyle when experiencing pregnancy complications. Secondly, an improved diet registration and automatic transfer or linkage with other apps to track physical activity could increase the user-friendliness of the HealthyMoms app. Specific suggestions as to how the diet registration could be improved was not provided by the participants; however, they emphasized that it could not be too detailed or time-consuming. With that in mind, it might be preferable to choose one focus/goal (similar to the goal setting for physical activity) e.g., only eat sweets once per week and then fill in whether the goal has been fulfilled or not on a daily basis. Thirdly, a consistent theme in the interviews was greater personalization of the app to better suit women's interests and life situation (*Paper II* [114]). Such improvements could include settings for push notifications (e.g., timing and frequency), long and short text options, information adapted for nulliparous and multiparous women (e.g., more or less focus on the pregnancy, information on how to prepare the older child for a new sibling), as well as individualized more specific goals and feedback. In this respect, a screening questionnaire with questions on e.g., parity, experienced pregnancy complications, motivation and/or need of improving diet or physical activity habits, personal goals regarding lifestyle and GWG, and interests could be used when first accessing the app in order to provide more personalized app content. Fourthly, the addition of interactive support from healthcare professionals (e.g., a dietician or midwife) through the HealthyMoms app could be an improvement. Lastly, an important aspect of the app was its perceived trustworthiness. Thus, if the app would be distributed on a larger scale it could be important to clarify that the app is evidence-based and also highlight the experts behind the app. It is also important to highlight aspects related to implementation of HealthyMoms into standard maternity care. This would also require a HealthyMoms interface for the healthcare professionals in order to distribute the app to their patients. Prior to the design and implementation of such an interface, it is important to investigate the requirements of the end-users (i.e., the midwives) as well as barriers and facilitators to implementation.

5.1.7 Movement behaviors in pregnancy and health indicators

The findings showed that reallocating time to LPA or MVPA from the other behaviors was associated with lower weight and more favorable cardiometabolic health in early pregnancy. Additionally, LPA in early pregnancy seems to be beneficial for body composition and cardiometabolic health in late pregnancy while changes in movement behaviors during pregnancy seem to be of less importance in this aspect. As described in *Paper IV* [115] this is an unexplored field and, to the best of our knowledge, this is the first study to investigate associations between movement behaviors taking the 24-hour continuum into account with body composition and cardiometabolic health in pregnancy. The few existing studies that have investigated associations between individual movement behaviors and body composition and cardiometabolic health using objective methods have focused on outcomes in late pregnancy (e.g., [164–169]), while outcomes in early pregnancy are also presented here. Although pregnancy is characterized by physiological changes our results might reflect the non-pregnant state and lifestyle prior to pregnancy while late pregnancy is characterized by more pronounced physiological changes [170].

Starting with early pregnancy, our results showed positive associations for the reallocation of time to both MVPA and LPA relative to the other behaviors. In more detail, reallocating time to MVPA and LPA was associated with improved MetS score and lower body weight and HOMA-IR, respectively. Moreover, reallocating as little as 10 min/day to MVPA from the other behaviors was associated with a 0.07 SD decrease in MetS score. These findings indicating beneficial associations between physical activity with body composition and cardiometabolic health are in line with results from previous studies using objectively measured physical activity in pregnant women [169] and adults using compositional analysis (e.g., [62,171–174]). To illustrate, Loprinzi et al. [169] found that women who engaged in higher levels of LPA and MVPA had lower diastolic blood pressure and higher HDL cholesterol, respectively. This indicates that MVPA as well as LPA are of importance for metabolic health also in early pregnancy. In dissimilarity to the observed associations between accumulating more LPA while reducing time spent in the other behaviors with lower body weight in early pregnancy no such association was seen for weight (only FMI) in late pregnancy (*Paper IV*, [116]). Conflicting results have also been shown in previous studies in pregnant women using objective methods to assess physical activity [165,167]. Levels of LPA (i.e., accumulating more LPA relative to the other behaviors) in early pregnancy was also associated with more favorable cardiometabolic health in late pregnancy, independent of the change in physical activity (*Paper IV*, [116]). Similarly, previous studies in pregnant women have shown beneficial associations between higher levels of MVPA in early pregnancy with insulin response [165] and -release [166]. Further, no associations between change in movement behaviors between early and late pregnancy and cardiometabolic health in gestational week 37 were observed in HealthyMoms, which is in line with previous results [166]. In contrast, women with larger decrease in MVPA throughout pregnancy have been found to have higher fasting insulin levels and decreased insulin sensitivity in late pregnancy compared to women with smaller decreases or increases in MVPA [165]. The inconsistencies in results could be explained by factors related to e.g., study design including the time for assessment of physical activity and outcomes. However, all three studies assessed outcomes in the third trimester and observed a similar decrease in MVPA [115,165,166]. Moreover, women from all BMI categories were included in our study while the other studies [165,166] included women with overweight and obesity and those at an increased risk of gestational diabetes. Another distinct difference to our study, is that hip-worn accelerometers were used to assess physical activity [165,166] compared to wrist-worn in HealthyMoms. Nevertheless, hip- and wrist-worn accelerometers have been shown to have moderate to high correlations even though the latter has been described as more appropriate in pregnancy [60].

In summary, our results indicate that levels of physical activity in early pregnancy is of importance for health outcomes in early and late pregnancy, while the change in movement behaviors (e.g., decrease of MVPA) is seemingly less important. Moreover, MVPA has been the focus of physical activity guidelines [64] and most previous studies (e.g., [165–167]). Surprisingly, our results indicate that LPA is important for cardiometabolic health in late pregnancy while the role of MVPA appeared to be less pronounced. These results could be considered encouraging since it is likely easier for women to increase their levels of LPA and decrease the time spent on sedentary behaviors compared to increasing the amount of time spent in MVPA. Nevertheless, more research in this area is needed to make solid conclusions.

5.2 METHODOLOGICAL CONSIDERATIONS

The strengths and limitations of the individual studies (*Paper I-IV*) have been discussed in detail previously [113–116]; however, some of these are important to highlight. Firstly, a major strength of the HealthyMoms trial is the randomized controlled design, which is considered the gold standard in intervention research provided that the study is properly designed, conducted and reported [111]. As described previously [175], the selection of the study population, intervention arms and outcomes of interest as well as blinding are important aspects. In those regards, the HealthyMoms trial was thoroughly planned with a carefully designed intervention which was developed by a multi-disciplinary team and based in social cognitive theory. Moreover, the control group received standard care enabling comparison with current routine procedures in maternity healthcare. The statistical analyses were planned a priori in close collaboration with a statistician and included how to handle missing data. Indeed, it is common to have missing data in intervention studies and to rule out potential bias it is important to elucidate whether data is missing at random or not [176]. Fortunately, there was a high compliance rate (89% [271/305] in gestational week 37 and 84% [257/305] at the follow up 1-2 weeks postpartum). The major reasons for dropping out of the study was related to pregnancy complications and personal reasons, which are unlikely to be linked to the intervention and therefore unlikely to have any influence on the results. Also, the imputed analyses and complete case analyses produced similar results (*Paper I, III*), providing further support for robustness of the main findings of the trial. Moreover, the results for the primary outcome were supported by the results from the complementary analysis using Bayesian statistics (*Paper I*). This approach provides a more robust view of the collected data since e.g., null hypothesis testing can be sensitive to individual data points [136].

Another important aspect in RCT studies is the randomization process which, if successful, ascertain that observed intervention effects is due to the intervention and not participant characteristics since these are randomly distributed in the two groups. In that aspect, the randomization process in the HealthyMoms trial was successful considering that there were no differences in baseline characteristics between the participants in the intervention and control group. A possible limitation in the trial is related to blinding as the nature of the intervention made it impossible for participants and assessors to be blinded to their allocation. However, although participants could have revealed their group allocation at the follow ups, it is unlikely to have influenced the results considering the objective and standardized methods used. The use of reliable and objective methods (e.g., air-displacement plethysmography, accelerometry) to assess the outcomes is also a strength of the trial. Nevertheless, it should be noted that although accelerometers provide more reliable data on movement behaviors compared to other methods (e.g., questionnaires) [56,57] it does not have the ability to capture all types of physical activity [177] e.g., bicycling, and thus MVPA may have been underestimated in some women. However, with the randomized controlled trial design this error should be similar in both the intervention and control groups. On a similar note, assessment of diet is no easy feat as it relies on self-report and thus methods e.g., 24-hour dietary recalls may be associated with recall bias. The web-based 24-hour dietary recall method used to assess dietary habits in the HealthyMoms trial has been validated in adolescents showing that average dietary intakes of key components (e.g., fruits, vegetables, and whole grain) were comparable to corresponding values for recall interviews [54], but not yet in pregnant women. In this respect, it is relevant to note that a nested validation study within the HealthyMoms trial with doubly labelled water (n=24) as well as three 24-hour telephone dietary recalls (n=52) has been conducted. However, due to the COVID-19 pandemic the lab in Cambridge has not been able to analyze our urine samples for the doubly labelled water method yet. Nevertheless, the 24-hour recall method has been shown to be more reliable compared to other dietary assessment methods [47], and preliminary data from our validation study show moderate to strong correlations between the components of the SHEI score (r= 0.52-0.91; $P<0.001$, n=52, unpublished data) for the web-based and telephone 24-hour dietary recalls.

Paper II was a qualitative study where the following methodological considerations are motivated [178]. Firstly, credibility refers to the truth of the data and the interpretations, and can be increased by triangulation [178]. In that aspect, the thematic analysis (*Paper II*) was performed by two people (i.e., investigator triangulation) which enabled constant validation and provided two perspectives on the data which lowers the risk of biased interpretation and strengthens the credibility of the results. Moreover, the research team involved in the analysis had different experiences and professions. As for dependability, which refers to the stability of the data over time [178], this was strengthened by the use of an interview guide. Lastly, transferability refers to the extent to which the findings can be transferred to other settings or groups, and this is judged by the reader. A detailed description of the participants and the research process (e.g., context, recruitment strategy, sample size and characteristics, interview procedure and an interview guide) was provided to strengthen the transferability of the results. Finally, in terms of sample size in qualitative research (*Paper II*) no standards similar to quantitative research (i.e., power calculations) exists [179]. However, it can be discussed in terms of saturation which guide determination of adequate sample size as the sample should be sufficiently large and varied to elucidate the aims of the study [180]. In that aspect the sample in *Paper II* provided a broad and variety of experiences which were considered sufficient to fulfill the aim of the study.

In *Paper IV,* data from the HealthyMoms trial was used to investigate longitudinal associations. Using data from an RCT study could be a limitation when studying longitudinal associations considering the possibility that the intervention has influenced the results. However, in this case, the intervention had no effect on MVPA, and sensitivity analysis only including women in the control group showed similar results as for the whole sample.

Nevertheless, it is important to stress that the findings in *Paper IV* is observational and causality cannot be proven. Finally, a strength specific for the observational study (*Paper IV*) was the use of compositional data analysis which account for the multicollinearity of physical activity data [62,63]. This is important as movement behaviors are components of the 24-hour continuum where changes in one behavior will simultaneously result in changes in others.

5.3 STUDY POPULATION

Women participating in the HealthyMoms trial were recruited from maternity healthcare in October 2017 to November 2020. During that period, all women who fulfilled the inclusion criteria should have received an invitation to participate. In terms of generalizability, the final sample (n=305) had a higher education level compared to the general population (university degree 78% vs 47%, respectively) [181] which is a common issue in research. Moreover, as the app was only available in Swedish, the majority (89%) were Swedish born (versus 81% among pregnant women in the general population) [7]. Nevertheless, the sample covered a wide range of GWG (min-max: 0.8-21 kg, n=271) with a comparable proportion of women exceeding the GWG guidelines (50% vs 48% in the general population) [7]. Moreover, the women were similar in terms of mean age (age 31.3 vs 30.9 years) and relatively comparable for parity (57% vs 43% nulliparous) to Swedish women in general [3,182]. However, they exhibited a rather healthy lifestyle (e.g., high SHEI score and high levels of MVPA at baseline). Thus, it may be speculated that the intervention effect may be larger in a more sedentary population with less healthy eating behaviors at baseline. Also, the HealthyMoms app has been designed to be a health promotion support for all women irrespectively of pre-pregnancy BMI and the trial was also designed to evaluate the effect in women covering different BMI-categories. Consequently, with this design, the intervention effect may have been diluted. Indeed, an interaction with pre-pregnancy BMI was observed, indicating a larger effect among the ones that might need it the most. With regards to *Paper II*, the 19 participants were representative of the whole group (n=134) for essentially all baseline characteristics and self-reported data on usage and satisfaction with the app. However, one distinction was that the women in the interview study exhibited higher mean levels of MVPA (51 [SD 32] min/day vs 39 [24] min/day in the whole sample). Considering the small sample size, it is also relevant to consider the median MVPA since that, in contrast to the mean, is not influenced by extreme values. In that aspect, the median MVPA in the interview sample (42 min/day) was very similar to the accumulated levels of MVPA in the whole sample (35 min/day). Altogether, there is no reason to believe that the women in *Paper II* are different in any major aspects from the whole sample in the HealthyMoms trial. Finally, baseline characteristics for the women in *Paper IV* were similar to the whole study sample indicating that they were representative for the women in the HealthyMoms trial.

5.4 ETHICAL CONSIDERATIONS

All studies in this thesis [113–116] has been conducted in accordance with the guidelines of the Declaration of Helsinki [183] and have received ethical approval from the Regional Ethical Review Board in Linköping, Sweden. All participants in the HealthyMoms trial provided written informed consent and were informed that they could withdraw from the study at any given time without providing an explanation. Both parents provided consent for the measurement of their newborn child. Participation in the trial was not associated with any known harm to either mother or child. Although, the participants in the HealthyMoms trial did not raise any concerns regarding the handling of the collected data, the collected participant data can be classified as sensitive. In accordance with the European General Data Protection Regulation (GDPR) (2016/679) all data in the HealthyMoms trial have been anonymized and stored unavailable for unauthorized. Data from the HealthyMoms app is stored within the European Union (Amazon Web Services) under safe conditions in accordance with GDPR. It has been suggested that interventions focusing on weight, diet, and physical activity could potentially trigger eating disorders. As stated earlier both excessive and inadequate GWG has negative health outcomes and therefore the HealthyMoms app focus on supporting healthy lifestyle behaviors during pregnancy, and not the avoidance of excessive GWG (i.e., weight and diet restriction). Also, the advice in the app is in line with the information and guidance provided by maternity care. In addition, an exclusion criterion in the study was a previously diagnosed eating disorder. Therefore, the risk that the HealthyMoms app could trigger eating disorders can be considered minimal. A limitation of the HealthyMoms app is that it is only accessible to Swedish-speaking pregnant women, and thus the app is unavailable to a considerable proportion of pregnant women attending maternity care. To make the app accessible to women with other native languages, the next step is to adapt and tailor the app (e.g., revise and modify features in the app and include multiple language options). Although, participation in the HealthyMoms trial (i.e., in the control group) did not provide any advantages, the information from the studies has potential to contribute to improving maternity healthcare which could be beneficial to the participating women in future pregnancies.

6 CONCLUSIONS

- A 6-month digital lifestyle intervention in pregnancy (the HealthyMoms app) had no overall effect on the primary outcome GWG; however a statistically significantly lower GWG was observed among the women in the intervention group with overweight or obesity prior to pregnancy compared to their counterparts in the control group (mean difference approximately -1.7 kg).

- A statistically significantly higher Swedish Healthy Eating Index score was observed in the intervention group compared to the control; however, no other differences were observed between the groups for any of the other secondary outcomes (i.e., body fatness, MVPA, and glycemia).

- A qualitative evaluation of the 6-month usage of the HealthyMoms app revealed that the app was considered a valuable and trustworthy tool to mitigate excessive GWG, and that it had useful features and relevant information to initiate and maintain healthy habits during pregnancy.

- No differences in infant size and body composition were observed between the intervention and control group at the follow up 1-2 weeks postpartum in the HealthyMoms trial. Moreover, no mediation effect of GWG on infant outcomes was observed.

- Increasing LPA or MVPA while reducing SB and sleep was associated with more favorable weight and cardiometabolic health in early pregnancy. LPA seems to be more important for cardiometabilic health in late pregnancy, and the change in movement behaviors is seemingly less important.

7 POINTS OF PERSPECTIVE

7.1 NEED AND ROLE OF MHEALTH TOOLS IN HEALTHCARE

To date the majority of women in high income countries including Sweden gain excessive weight during pregnancy [4,7], and both effective and sustainable interventions are needed. Traditional lifestyle interventions in pregnancy have been found to reduce GWG as well as lower the risk of adverse maternal and infant outcomes which support the implementation of such interventions in standard care [19]. Moreover, support from healthcare professionals have been described as key to influence weight gain in pregnancy and should be offered within standard care [184]. However, insufficient knowledge of GWG guidelines among obstetricians and midwives have been reported [185]. Furthermore, midwives have expressed difficulties and hesitation about discussing weight with their patients [146] and absence of routine weighing in standard practice have also been described [186,187]. Pregnant women have also described challenges and stigma related to discussing GWG with their midwife [142,144,145]. In addition, our findings also showed that recommendations for GWG is not always discussed in maternity care (*Paper II* [114]). Healthcare professionals have also expressed that time constraints and communication difficulties (e.g., language barriers) make it challenging to prioritize spending time on providing advice and information on healthy lifestyle habits [188]. In addition, the lack of resources to promote health behaviors in pregnant migrant women has been highlighted [189]. In these aspects, digital technology (e.g., mHealth) offers opportunities to provide interventions which can also support healthcare delivery without substantially adding to the workload of healthcare professionals.

Furthermore, the potential of digitization in healthcare has been acknowledged by the Swedish National Board of Health and Welfare which states that with the help of electronically provided healthcare, the individual will be in focus, and healthcare will be equal, efficient, available and secure [190]. The use of digitalized healthcare (e.g., mHealth) has also been expressed as positive by both midwives and pregnant women [36,189]. In addition, studies have shown that women use digital resources (e.g., apps) to a high extent to gather information during pregnancy [191]. Nevertheless, commercial apps focusing on pregnancy [147] and promoting physical activity in pregnancy [192] have been found to lack evidence-based information and the design of the features in such apps needs improvement. Moreover, consistent support and reminders are important to maintain and establish new habits; however, standard maternity care consists of a limited number of appointments spread out over the pregnancy period with no support in-between appointments [193]. In these aspects and as demonstrated in this thesis, the HealthyMoms app had beneficial effects on GWG and dietary habits in pregnancy (*Paper I* [113]), and was appreciated and used to a high extent by the participating women (*Paper II* [114]). Thus, it has potential to be implemented in maternity care to reach many women and could aid midwives in their mission to promote a healthy lifestyle during pregnancy.

7.2 IMPLEMENTATION OF HEALTHYMOMS IN MATERNITY CARE AND TOPICS FOR FUTURE RESEARCH

As stated previously, the overall results provide support that the HealthyMoms app could be implemented in maternity care and benefit pregnant women. Nevertheless, the HealthyMoms trial was conducted under controlled circumstances and thus does not reflect the real world. An inclusion criteria in the HealthyMoms trial was sufficient literacy in Swedish in order to understand the content of the app, thus it was not available to all women. Considering that approximately 20% of women attending maternity care in Sweden are foreign born and excessive GWG is common in this population [7], it is important to provide support to these women as well. Moreover, linguistic barriers have been described to hinder the provision of advice and information on healthy lifestyle habits in healthcare [188]. Also, healthcare professionals in maternity care have described that a translated app could be a helpful tool in maternity care to support healthy lifestyle behaviors in migrant women during pregnancy [189]. Altogether, it is essential to make the HealthyMoms app accessible to migrant women as well and the next step should be to translate and culturally adapt the app. Indeed, our research group has initiated this work in Somali and Arabic speaking women [189].

Moreover, as discussed previously, the majority of women in the study had a university degree and overall the group exhibited a rather healthy lifestyle. Future research should investigate the effectiveness of the HealthyMoms app in a more heterogenous sample which reflect the general population to a larger extent and under real world circumstances. To make the HealthyMoms app available to more women, the next step would be to assess the large-scale implementation as well as real-world effectiveness of HealthyMoms in maternity care in Sweden. Prior to implementation the content of the app should be further improved and modified as described previously and could potentially also cover preconception, early pregnancy, and the postpartum period. Additionally, the results from *Paper IV* [116] show that the content of the app regarding physical activity could also be modified to put more emphasis on maintaining or increasing LPA throughout pregnancy.

Furthermore, to increase the chances of an effective implementation of HealthyMoms it is important to explore key factors (e.g., barriers and facilitators) for successful implementation. This could be done by conducting interviews with adopters (i.e., maternity healthcare coordinators and midwives) as well as end-users (i.e., pregnant women). Implementation in maternity care would also require development of a web-based interface in which midwives can register their patients as app users. This interface could also provide information on GWG and lifestyle in pregnancy to help increase the knowledge on these issues among midwives. To develop a user-friendly web-based interface which meets the requirements of end-users' needs as well as be compatible with healthcare IT systems a human-centered design approach (ISO 9241-210:2019) [194] could be employed. This includes understanding and specifying the context in which the intended solution (i.e., the web-based interface) will be used and involves the use of several different methods (e.g., stakeholder analysis, interviews). Indeed, early engagement and involvement of stakeholders has been shown to enhance the translation of research into practice [195], and can potentially increase the likelihood of successful scale-up [196]. Moreover, research on successful implementation and scale-up as well as cost-effectiveness of effective interventions into practice are also topics for future research. Indeed, research on the cost-effectiveness of mHealth interventions in pregnancy is lacking [197]; however, this delivery mode has the advantage of maximizing reach both geographically and across socioeconomic groups and it has also been described to have strong potential for scalability and cost-effectiveness [198]. Another advantage of mHealth is that it enables more comprehensive investigation into participant behavior and engagement with the intervention, for instance by using in-built tools to track usage. This facilitates in depth evaluation of the relationship between participants' engagement in different intervention components, and intervention effectiveness, which is information that can provide important knowledge on intervention strengths and weaknesses. These types of insights can be important for adaptation of interventions into routine practice and can serve as an important basis for future intervention development and modification. This has been demonstrated in studies targeting adults [199]; however, little is known about the role of engagement in mHealth interventions targeting pregnant women. Finally, a recent systematic review and meta-analysis highlighted the need of studies on the long term effects of lifestyle interventions in pregnancy on infant weight and growth [156]. In that aspect, the infants born to the participating women in the HealthyMoms trial could potentially be followed up to assess body composition and growth in childhood.

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