Received: 11 October 2021 | Accepted: 11 January 2022
DOI: 10.1111/ijpo.12894

ORIGINAL RESEARCH

Pediatric OBESITY WILEY

The effects of a lifestyle intervention (the HealthyMoms app) during pregnancy on infant body composition: Secondary outcome analysis from a randomized controlled trial

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Funding information
ALF Grants, Region Östergötland, Grant/Award Numbers: LIO-893101, LIO-941191; Bo and Vera Ax:son Johnsons' Foundation; Karolinska Institutet; Lions Forskningsfond; The Strategic Research Area Health Care Science, Karolinska Institutet/Umeå University; The Swedish Research Council, Grant/Award Number: 2016-01147; The Swedish Research Council for Health, Working Life and Welfare (Forte), Grant/Award Numbers: 2017-00088, 2018-01410; The Swedish Society of Medicine

Summary

Background: Pregnancy has been identified as a window for childhood obesity prevention. Although lifestyle interventions in pregnancy can prevent excessive gestational weight gain (GWG), little is known whether such interventions also affect infant growth and body composition.

Objectives: To investigate (i) the effects of a 6-month lifestyle intervention (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.

Methods: This is a secondary outcome analysis of the HealthyMoms randomized controlled trial. Air-displacement plethysmography was used to measure body composition in 305 healthy full-term infants.

Results: We observed no statistically significant effect on infant weight ($\beta = -0.004$, $p = 0.94$), length ($\beta = -0.19$, $p = 0.46$), body fat percentage ($\beta = 0.17$, $p = 0.72$), or any of the other body composition variables in the multiple regression models (all $p \geq 0.27$). Moreover, we observed no mediation effect through GWG on infant body composition.

Conclusions: Our findings support that HealthyMoms may be implemented in healthcare to promote a healthy lifestyle in pregnant women without compromising offspring growth. Further research is required to elucidate whether lifestyle interventions in pregnancy also may result in beneficial effects on infant body composition and impact future obesity risk.

KEYWORDS
air-displacement plethysmography, body composition, digital lifestyle intervention, gestational weight gain, mHealth, neonatal

Abbreviations: BMI, body mass index; FFMI, fat-free mass index; FMI, fat mass index; GWG, gestational weight gain; NAM, National Academy of Medicine.

1 | INTRODUCTION

Childhood obesity is a significant public health priority with 39 million children under the age of 5 years having overweight or obesity globally.[1] Sweden is no exception with 11% of Swedish 4-year-olds having overweight or obesity,[2] and this figure almost doubles at 10–11 years of age.[2,3] Obesity tends to persist into adulthood[4] and is associated with increased risks for cardiovascular disease, diabetes type II, certain cancers, non-alcoholic fatty liver disease as well as impaired psychosocial well-being and stigmatization.[5–10] The development of obesity is multifactorial where genetic as well as environmental risk factors play a role. In addition, the developmental origins of health and disease posit that during periods of rapid development, such as prenatal life and early infancy, the organism is susceptible to in utero factors that have a persisting influence on obesity risk.[11,12] Early-life factors such as high birthweight and rapid infant growth, have been identified as risk factors for high childhood and adult body mass index (BMI).[13,14] In addition, maternal diet and lifestyle in pregnancy,[12,15,16] as well as gestational weight gain (GWG), have been shown to influence both short- and long-term health and disease risk in the infant.[17,18] In that aspect, pregnancy has been proposed as a key period for prevention of childhood obesity through improving maternal lifestyle factors (e.g., diet and physical activity) to reduce excessive GWG.[11,12,19] Consequently, and also due to the increased prevalence of maternal obesity globally,[20] an interest in lifestyle interventions (i.e., focusing on diet and physical activity) targeting pregnant women to promote healthy GWG with outcomes also in their offspring such as infant adiposity has emerged.[21,22] Compared to measurements of weight alone, assessment of body composition provides more detailed information on foetal growth, and it has been hypothesized that fat- and fat-free mass mediate the link between foetal nutrition experience and later disease.[23] In that aspect, air-displacement plethysmography (Pea Pod) has been described as an accurate method with high reliability to assess infant body fatness.[24,25] To date, only a few full-scale studies have investigated the effects of lifestyle interventions on detailed infant body composition (i.e., fat- and fat-free mass).[26–28] Although these interventions produced statistically significant reductions in maternal GWG (approximately −1.8 kg), their results on infant outcomes are somewhat inconsistent. Indeed, Gallagher et al. reported an intervention effect on infant fat-free mass at 1–4 days of age[26] while Van Horn et al. observed no effects on infant body composition.[28] Furthermore, previous studies only included women with periconceptional overweight and obesity.

We have previously developed the HealthyMoms app, which provides a 6-month exclusively digital lifestyle intervention and behaviour change programme to promote a healthy diet, physical activity and weight gain during pregnancy.[29] The effectiveness of the app was recently evaluated in a randomized controlled trial (the HealthyMoms trial) in women with various periconceptional BMIs with the primary time point and outcomes being maternal diet, physical activity and GWG in gestational week 37.[30] Briefly, our results showed that the intervention group had an improved healthy dietary index score regardless of BMI compared to standard care, as well as lower GWG in women with overweight and obesity before pregnancy.[30] Based on the rationale provided above, we also included a priori infant body size and composition (i.e., fat- and fat-free mass) at 1–2 weeks postpartum as secondary outcomes in the HealthyMoms trial.[29,31] These outcomes were also included to ascertain that the intervention has no undesirable effects on infant growth before a potential implementation at full-scale. Preferably such evaluations should be made for each individual trial as well as include detailed measures of infant body composition (i.e., fat- and fat-free mass) in addition to birthweight.

In this paper, we report the infant outcomes of the HealthyMoms trial.[29–31] Specifically, we aimed (i) to investigate the effects of a 6-month intervention (the HealthyMoms app) on body composition in healthy full-term infants 1–2 weeks postpartum, and (ii) to investigate whether a potential intervention effect on infant body composition is mediated through maternal GWG.

2 | METHODS

2.1 | Study design and participants

This study is a secondary outcome analysis of the HealthyMoms randomized controlled trial using data on healthy full-term infants born to women participating in the trial (clinicaltrials.gov; NCT03298555).[29] The design and rationale of the study have been described in detail previously.[29] In short, the study investigated the effect of a 6-month intervention (the HealthyMoms app) aimed at promoting a healthy lifestyle and GWG in pregnant women ($n = 305$). The trial was conducted between October 2017 and November 2020, and participants were recruited in early pregnancy at maternity clinics in Östergötland, Sweden. Women aged ≥18 years, pregnant with a singleton foetus, with no previously diagnosed eating disorder or medical conditions that may affect body weight and with the ability to read Swedish sufficiently well to understand the content of the app were eligible for participation. Outcome measures were assessed at baseline (gestational week 14) and follow-ups (gestational week 37 and 1–2 weeks postpartum) at Linköping University Hospital. The last measurement included assessment of infant body size and composition (described in more detail below) and is the focus of this manuscript. The women also filled in a questionnaire regarding age, education level, birth country, parity and pre-pregnancy weight, and objective data on app adherence (i.e., usage of the registration features for diet, weight and physical activity in the HealthyMoms app) was automatically retrieved from the app after intervention completion. The HealthyMoms trial was approved by the Regional Ethical Review Board in Linköping, Sweden (ref no: 2017/112-31 and 2018/262-32). All women provided written informed consent before entering the trial and both parents provided written informed consent for the participation of their newborn child. The study is reported according to the Consolidated Standards of Reporting Trials statement.[32]

2.2 | Study treatments

After the completion of baseline measures in gestational week 14, women were randomized in a 1:1 ratio to either the control- or intervention group using restricted randomization generated using STATA (version 13; StataCorp) (Marcus Bendtsen). Opaque envelopes were used to ensure allocation concealment (Pontus Henriksson). These were opened by assessors after completion of all the baseline measures whereupon participants were informed of their allocation. The control group received standard maternity care (consisting of regular midwife visits, and an optional lecture in early pregnancy on healthy lifestyle and pregnancy-related healthcare) while the intervention group also received the HealthyMoms app for 6-months. Following allocation to the intervention group, participants received information on the content of the app (described below) as well as instructions on how to download and access the app through Google Play (Android) or AppStore (iOS), and they were instructed to use it as much as they preferred. The design and content of the app have been described in detail previously.[29] In short, the app is grounded in social cognitive theory[33] and uses behaviour change techniques.[34] The app is built around 12 themes (with a new theme being introduced every other week), and includes several functions (i.e., self-monitoring of diet, physical activity and weight gain with accompanying feedback, an exercise function, a recipe function, a pregnancy calendar, a library with frequently asked questions, practical tips, information and push notifications).

2.3 | Outcomes

The outcomes in this study were infant body composition in healthy full-term infants approximately 1–2 weeks postpartum, and the mediated effect of the intervention through maternal GWG on infant outcomes (i.e., body weight, length, BMI, body fat percentage, fat mass index [FMI] and fat-free mass index [FFMI]).

2.4 | Infant study measures

Infant outcomes were assessed approximately 1–2 weeks postpartum (range 0.9–3.0 weeks, mean weeks 1.8 [SD 0.4]). Standardized measurements of length (measured while resting on a measuring board, with a movable foot plate that was placed by the child's heels) to the nearest 0.5 cm were performed. Air-displacement plethysmography was used to assess infant body composition (Pea Pod, COSMED), as described previously.[35,36] In short, the method measures body weight and body volume (when the infant is only wearing a tight cap) to calculate body density. Body fatness is then calculated using the measured body density and appropriate densities for fat mass and fat-free mass in infancy.[37] BMI was calculated as weight (kg) divided by squared length (m^2). FMI and FFMI were calculated as fat mass (kg) or fat-free mass divided by length squared (m^2), respectively. Finally, information on birthweight and length, birth mode (i.e., vaginal, caesarean, instrumental), infant sex, gestational weeks at delivery and feeding (i.e., breastfeeding, formula, combination of breastfeeding and formula) were collected at the measurement via a questionnaire.

2.5 | Maternal anthropometrics and GWG measures

Standardized measurements of the mothers' height (using a stadiometer) and weight wearing only underwear (Bod Pod, COSMED, at baseline and follow-ups) were performed. GWG was calculated as the difference in weight gain between gestational week 14 and 37. In addition, to analyse the proportion of women meeting the GWG recommendation,[38] GWG was expressed per week (kg/week) and compared to the trimester and pre-pregnancy BMI-specific recommendations.[38]

2.6 | Statistical analysis

Infant body composition was defined a priori as a secondary outcome (clinicaltrials.gov; NCT03298555), and the analyses reported here follow the same analysis plan as previously reported for the maternal outcomes in gestational week 37.[29,30] Thus, we used multiple linear regression (unadjusted and adjusted model) to examine the effect of intervention allocation (i.e., intervention vs. control) on infant outcomes (i.e., body weight, length, BMI, body fat percentage, FMI and FFMI). In the adjusted model, we adjusted for maternal pre-pregnancy BMI (underweight and normal weight vs. overweight and obesity), parity (0 vs. ≥1) and maternal height (m). As described previously,[30] multiple imputation with chained equations[39] with a total of 500 datasets imputed for each analysis (predictive mean matching with 50 iterations) were used to address missing data. Analyses were pooled using Rubin's rules.[40] We also conducted complete case analyses for all outcomes. Furthermore, as the intervention had different effect on GWG depending on pre-pregnancy BMI,[30] we investigated if there was a difference in intervention effect depending on pre-pregnancy BMI (underweight and normal weight vs. overweight and obese) by adding an interaction term (group × BMI category). Furthermore, we conducted a sensitivity analysis to examine the influence of app adherence (defined as high [i.e., above the median] and low [i.e., below the median] usage of the total number of registrations [i.e., diet, weight and physical activity]) on infant outcomes. This was done by rerunning the adjusted regression models described above (i.e., complete case and imputed analysis) examining the associations of high ($n = 61$) and low ($n = 61$) usage (defined above) with infant outcomes using the control group ($n = 125$) as reference. The usage of the registration features (i.e., diet, weight and physical activity) in the app has been published in the main outcome paper[30] with the median of total registrations being 37.5 (quartile 1: 11; quartile 3: 105; range 0–270; $n = 122$) throughout the intervention period. These statistical analyses were conducted in R version 4.0.3 (R Foundation for Statistical Computing) and two-sided p values <0.05 were considered statistically significant. As reported elsewhere,[29] the HealthyMoms trial was powered for the primary outcome (i.e., GWG). For intervention effects on infant outcomes, our sample size would provide at least 80% power (two-tailed, $\alpha = 0.05$) to detect an effect size of Cohen's d of 0.36 (medium to strong effect size). This corresponds to a difference of 1.4% in body fat.[36]

Finally, to explore potential mediation effects of maternal GWG on infant body composition, we performed simple mediation analyses using the PROCESS macro version 3.5, with 5000 bias-corrected bootstrap samples and 95% confidence intervals, in SPSS (IMB SPSS statistics, version 26, IBM Corp., Armonk, NY). As illustrated in Figure 1, mediation was assessed by the indirect effect of group allocation (independent variable) on infant body composition (dependent variable) through maternal GWG.

3 | RESULTS

3.1 | Participants

The flowchart of the HealthyMoms trial from baseline to the measurement 1–2 weeks postpartum is shown in Figure 2. In total, 305 women completed baseline measures in gestational week 14 (intervention = 152; control = 153), and 271 women also completed the follow-up measurement in gestational week 37 (intervention = 134; control = 137). Of these 271 women, 14 participants dropped out prior to the postpartum measurement due to personal reasons ($n = 4$), premature birth ($n = 1$), complications after delivery ($n = 7$) or unknown reasons/no contact ($n = 2$), resulting in that 257 mother–infant pairs returned for the measurement 1–2 weeks postpartum. For the complete case analysis, 10 mother–infant pairs were excluded due to the following reasons: infant hip dislocation ($n = 2$) or other conditions ($n = 2$), or that the measurements were not performed according to the PeaPod protocol ($n = 6$) ($n = 247$).

The women were on average 31.4 (SD 4.1) years of age, 78.5% (194/247) had a university degree, 56.3% (139/247) were primiparous and gained on average 10.7 (SD 3.2) kg between baseline and follow-up in gestational week 37. Regarding infant characteristics at birth, average gestational age at birth was 40.2 (SD 1.2) weeks, 54.3% (134/247) were boys, and the average weight and length at birth were 3.53 (SD 0.46) kg and 50.4 (SD 2.0) cm, respectively. As shown in Table 1, maternal and infant characteristics were similar in the intervention and the control group.

3.2 | Intervention effects on infant body composition

The intervention's effects on infant body composition for the unadjusted and adjusted imputed analyses ($n = 305$) and complete case analyses ($n = 247$) are presented in Table 2. No statistically significant differences were observed in any of the infant body composition variables between the intervention and control group in the unadjusted and adjusted model for the imputed analyses ($p \geq 0.27$). Similar results were attained for the complete case analyses ($p \geq 0.13$).

Results from the regression analyses investigating differences in intervention effect on infant body composition depending on pre-pregnancy BMI (underweight and normal weight [$n = 181$] vs. overweight and obesity [$n = 66$]) are presented in Table S1. Overall, infant body composition was comparable between the intervention and control group for women with underweight–normal weight as well as for women with overweight–obesity in the imputed analysis. Similar results were found in the complete case analysis. Thus, we found no evidence that the intervention effect differed by pre-pregnancy BMI. Similarly, no associations between app adherence and infant outcomes were found (Table S2).

Table 3 presents the total, direct and indirect effects of the simple mediation analyses investigating GWG as a mediator in the association of group allocation (intervention vs. control) and infant body composition ($n = 247$). As shown in Table 3, none of the effects were statistically significant.

4 | DISCUSSION

4.1 | Main findings

This study reports results from a secondary outcome analysis of the HealthyMoms trial[29,30] and is the first to examine the effects of a 6-month lifestyle intervention delivered through an app during pregnancy on infant body composition. Although our study was powered to detect medium to strong effects, we did not observe any statistically significant intervention effects on infant body size and composition, nor did we observe a mediation effect through GWG.

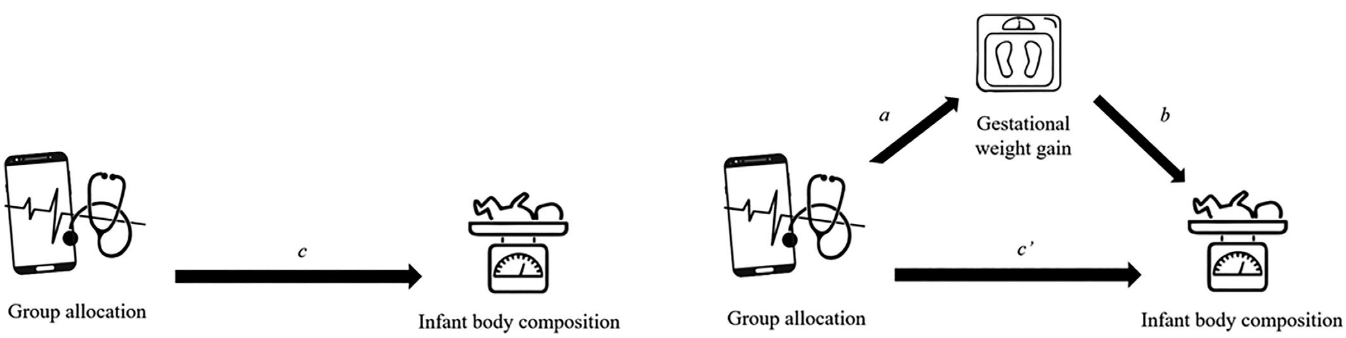

FIGURE 1 Diagram illustrating the mediation analyses. Pathway c shows the association between independent (group allocation) and dependent variable (infant body composition). The indirect effect pathway follows $a \times b$, and c' is the direct effect pathway

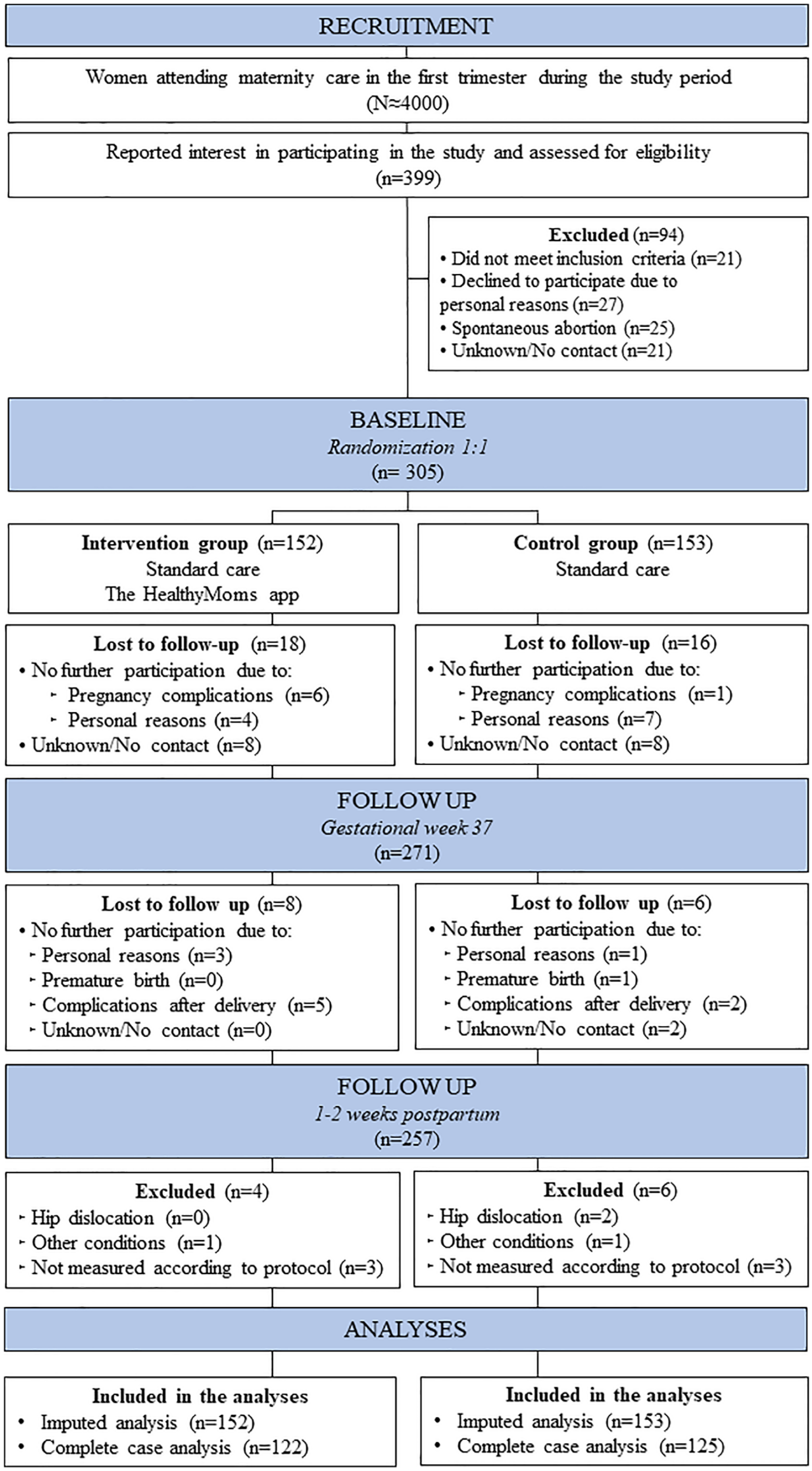

FIGURE 2 The flow of the HealthyMoms trial from baseline in early pregnancy until follow-up 1–2 weeks postpartum

4.2 | Comparison with previous studies

To the best of our knowledge, only two previous full-scale studies[26,28] have investigated the effects of a lifestyle intervention aimed at promoting a healthy GWG on infant body composition (i.e., fat- and fat-free mass) using accurate and reliable methodology (i.e., air-displacement plethysmography). Both the MOMFIT[28] and the LIFT study[26] evaluated traditional lifestyle interventions with individual and group counselling as core features in women with overweight and obesity. Thus, these interventions are substantially different from ours

TABLE 1 Maternal and infant characteristics (*n* = 247)

	All (*n* = 247)	Intervention (*n* = 122)	Control (*n* = 125)
Maternal characteristics			
Age (years)	31.4 (4.1)	31.5 (4.3)	31.2 (3.8)
Swedish born, (*n*, %)	219 (88.7)	111 (91.0)	108 (86.4)
Education level, (*n*, %)			
Primary school (9 years)	2 (0.8)	0 (0)	2 (1.6)
High school (12 years)	51 (20.6)	29 (23.8)	22 (17.6)
University degree	194 (78.5)	93 (76.2)	101 (80.8)
Pregnancy information			
Gestational age at baseline (weeks)	13.9 (0.7)	13.8 (0.6)	14.0 (0.8)
Height (m)	1.67 (0.06)	1.67 (0.06)	1.68 (0.06)
Baseline weight (kg)	67.5 (11.1)	68.1 (12.5)	66.9 (9.6)
Pre-pregnancy BMI (kg/m^2)	23.5 (3.7)	24.0 (4.1)	23.1 (3.1)
Pre-pregnancy BMI-categories, (*n*, %)			
Underweight (<18.5 kg/m^2)	5 (2.0)	1 (0.8)	4 (3.2)
Normal weight (18.5–24.9 kg/m^2)	176 (71.3)	84 (68.9)	92 (73.6)
Overweight (25.0–29.9 kg/m^2)	53 (21.5)	28 (23.0)	25 (20.0)
Obesity (>30 kg/m^2)	13 (5.3)	9 (7.4)	4 (3.2)
Parity, (*n*, %)			
0	139 (56.3)	69 (56.6)	70 (56.0)
≥1	108 (43.7)	53 (43.4)	55 (44.0)
GWG (from baseline to follow-up) (kg)[a]	10.7 (3.2)	10.6 (3.2)	10.8 (3.2)
Total GWG (kg)[b]	14.5 (4.8)	14.5 (5.1)	14.5 (4.4)
GWG according to the NAM guidelines, (*n*, %)			
Inadequate	31 (12.6)	13 (10.7)	18 (14.4)
Adequate	95 (38.5)	50 (41.0)	45 (36.0)
Excessive	121 (49.0)	59 (48.4)	62 (49.6)
Infant characteristics			
Birth mode[c], (*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)
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)
Age at measurement (weeks)	1.8 (0.4)	1.7 (0.4)	1.8 (0.4)
Feeding[d,e], (*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)

Note: Data are given as mean (SD) unless otherwise stated (i.e., *n*, %).
Abbreviations: BMI, body mass index; GWG, gestational weight gain; NAM, National Academy of Medicine.
[a]Gestational weight gain between baseline in gestational week 14 and follow-up in gestational week 37.
[b]Total GWG calculated as the difference in weight between pre-pregnancy weight (self-reported data collected in gestational week 14) and last weight prior to delivery (self-reported data collected 1–2 weeks postpartum).
[c]*n* = 245 (intervention group, *n* = 120; control group, *n* = 125).
[d]*n* = 246 (intervention group, *n* = 122; control group, *n* = 124).
[e]Feeding reported at the time of the measurement 1–2 weeks postpartum.

TABLE 2 Intervention effects on infant body composition

Outcome	Descriptive data		Intervention effect using regression analysis							
	Mean (SD)		Imputed analysis ($n = 305$)				Complete case analysis ($n = 247$)			
			Unadjusted		Adjusted[a]		Unadjusted		Adjusted[a]	
	Intervention	Control	Unstandardized coefficients beta (95% CI)	*p*	Unstandardized coefficients beta (95% CI)	*p*	Unstandardized coefficients beta (95% CI)	*p*	Unstandardized coefficients beta (95% CI)	*p*
Infant anthropometrics										
Weight (kg)	3.66 (0.46)	3.71 (0.46)	−0.03 (−0.14 to 0.08)	0.60	−0.004 (−0.11 to 0.11)	0.94	−0.04 (−0.16 to 0.07)	0.45	−0.01 (−0.12 to 0.10)	0.88
Length (cm)	52.1 (2.1)	52.5 (1.8)	−0.28 (−0.78 to 0.22)	0.27	−0.19 (−0.69 to 0.31)	0.46	−0.39 (−0.89 to 0.11)	0.13	−0.27 (−0.75 to 0.22)	0.28
BMI (kg/m^2)	13.4 (1.0)	13.4 (1.1)	0.03 (−0.26 to 0.32)	0.84	0.08 (−0.21 to 0.36)	0.60	0.03 (−0.24 to 0.30)	0.81	0.10 (−0.16 to 0.36)	0.45
Body fat (%)	13.3 (4.3)	13.2 (3.8)	0.10 (−0.86 to 1.06)	0.83	0.17 (−0.79 to 1.13)	0.72	0.12 (−0.89 to 1.13)	0.82	0.25 (−0.76 to 1.25)	0.63
FMI (kg/m^2)	1.8 (0.7)	1.8 (0.6)	0.01 (−0.14 to 0.16)	0.89	0.03 (−0.12 to 0.18)	0.73	0.01 (−0.15 to 0.17)	0.88	0.04 (−0.12 to 0.20)	0.63
FFMI (kg/m^2)	11.6 (0.8)	11.5 (1.2)	0.10 (−0.16 to 0.37)	0.44	0.12 (−0.15 to 0.38)	0.40	0.11 (−0.15 to 0.36)	0.42	0.13 (−0.13 to 0.38)	0.32

Abbreviations: BMI, body mass index; CI, confidence interval; FFMI, fat-free mass index; FMI, fat 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.

where we delivered the intervention through a smartphone app and included women from all BMI-categories. Nevertheless, all three studies found comparable effects on GWG in women with overweight and obesity (HealthyMoms −1.67 kg, MOMFIT −1.7 kg, LIFT −1.79 kg).[26,28,30] However, only the LIFT study found an effect on infant body composition. Interestingly, they found that infants born to women in the intervention group had greater weight (131 g, $p = 0.03$) and fat-free mass (98 g, $p = 0.03$) in the adjusted model.[26] In comparison, the results from this study showed no statistically significant effect on infant body composition when analysing women from all BMI-categories (Table 2) or only women with overweight or obesity before pregnancy (Table S1). We can only speculate on the reasons for these somewhat conflicting results, however, there are several possible explanations. First, differences in intervention characteristics (e.g., length and gestational week at study initiation), study populations, as well as exposure- and outcome measures could explain the different findings. However, all three interventions were similar in length and initiation (approximately gestational week 15–36), and study size ($n = 210$–305). In addition, sex has been reported to influence body composition[41]; however, the proportion of girls and boys was almost equal in all three trials.[26,28] Finally, all three studies used air-displacement plethysmography for measurement of infant body composition; however, the time of the measurement was different. In both LIFT[26] and MOMFIT,[28] infant adiposity was measured during the first days of life prior to hospital discharge, compared to approximately 1–2 weeks postpartum in our study. This difference in time of measurement could be a potential explanation for the observed differences between trials, since infant body composition has been found to fluctuate during the first 96 h of life.[42] In this respect, it is also relevant to note that the observed differences in body composition between intervention and control in the LIFT study did not persist at follow-up when the infants were 14 weeks and 1 year of age.[27] Finally, another potential explanation could be differences in covariates used in the analyses. To conclude, current evidence from lifestyle interventions initiated in pregnancy, including this analysis from the HealthyMoms trial, indicates that even though improvements of maternal lifestyle factors such as healthier eating and reduced GWG are observed, no effects on foetal overgrowth and adiposity have been shown. This was also the conclusion of a recent meta-analysis using data on existing randomized controlled trials with infant body fatness as outcome[22] as well as several individual studies,[43,44] and reviews that compiled evidence from trials with infant outcomes related to birthweight.[45,46] This may appear discouraging; however, evidence is still scarce making it relevant to call for further studies. In addition, it is also relevant to reflect on potential explanations for the lack of an effect. One apparent explanation could be the timing of the intervention. The first trimester has been suggested as a critical window for placental function to affect foetal growth and development,[47] and to have impact on the offspring, intervention initiation may be required already prior to conception.[48] Clearly, further research is needed to establish whether lifestyle interventions before or during pregnancy can have beneficial effects on neonatal adiposity as well as decrease future obesity risk in the offspring.

TABLE 3 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

Note: Data presented as absolute beta values (SE) 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.
Abbreviations: BC, bias-corrected (the calculated confidence interval for the indirect effect); BMI, body mass index; CI, confidence interval; FFMI, fat-free mass index; FMI, fat mass index.

Our results can also be discussed in the light of safety aspects of delivering a lifestyle intervention to pregnant women as it is important to ascertain that no undesirable effects on the infant (e.g., growth restriction) are inflicted. As for body composition, we did not observe any differences in birthweight and length between the intervention and control group. This is very reasonable since our intervention only included advice on healthy eating and physical activity based on current guidelines for pregnant women.[49–51] Our results are also in accordance with meta-analyses of previous face-to-face lifestyle interventions (i.e., focusing on diet and physical activity) that have observed reduced GWG but no adverse effects on birthweight or the number of small for gestational age infants.[45,46,52] Altogether, our findings together with our previously published results for the maternal outcomes[30] suggest that the HealthyMoms app may be safely implemented into maternity healthcare to promote a healthier diet and GWG in pregnant women without compromising infant growth.

Finally, it is important to reflect on whether one contributing factor to the lack of an intervention effect on infant body composition observed in this study could be due to the nature of the intervention or low intervention adherence. Indeed, the HealthyMoms intervention only includes a smartphone app with no additional support or coaching through their healthcare providers. It may be argued that more intensive interventions are required to also achieve potential health benefits in their offspring. However, in this context, it is relevant to note that our intervention had similar effects on GWG in women with overweight and obesity[30] as face-to-face counselling.[53] In addition, the nature of the intervention can also be seen as a strength, as it requires minimal or no effort from healthcare and provides information and support throughout pregnancy from the comfort of the participants' home. In addition, observational data have indicated that increasing physical activity in pregnancy may have beneficial impacts on infant adiposity.[54,55] Our women were relatively active at baseline (mean: 39 [SD: 24] min/day spent in moderate-to-vigorous physical activity),[30] and it may be speculated that larger effects on physical activity could lead to lower GWG as well as beneficial effects on infant body composition in more sedentary women. In terms of adherence, our women reported high usage in general in our quantitative[30] as well as qualitative process evaluation,[56] and we did not observe any evidence that app adherence (defined as usage above and below the median total usage of registration features) was associated with infant outcomes in our sensitivity analyses. Thus, in summary, we do not consider low adherence to be a major reason for the lack of an effect on infant body composition. Still, topics for future research include to investigate whether modifications to the HealthyMoms intervention (e.g., via inclusion of individual coaching by the midwife in a healthcare provider interface) may further increase the effect on maternal outcomes and whether that would pose significant potential beneficial effects on infant body composition.

4.3 | Strengths and limitations

Major strengths of this study are the randomized controlled design, the high compliance (81% attrition rate at follow-up) and the use of accurate and reliable methodology (i.e., air-displacement plethysmography) to assess infant body composition. Limitations to acknowledge are the somewhat higher education level in the study sample compared to the general population (78.5% vs. 47% with a university degree[57]), as well as the fact that 89% of the women in our study were Swedish born (vs. 61% of pregnant women in Sweden in general[58]), which might somewhat decrease generalizability. Nevertheless, the proportion of women meeting the GWG recommendations was similar to the general population (39% vs. 35%),[58] and infant body composition was comparable to previous data on healthy Swedish infants.[59] Another possible limitation is that participants were not blinded to the group allocation due to the nature of the intervention and may have revealed their group allocation to the assessor at the measurement 1–2 weeks postpartum. However, considering the objective and standardized methods used to assess the outcomes (i.e., air-displacement plethysmography) it is unlikely to have influenced the results. In addition, although this study had a fairly large sample size and was powered to detect medium to strong effect sizes it might have been underpowered to detect weak effect sizes. Finally, as our study only included one measurement during the first weeks of life, we cannot draw any conclusions on long-term effects.

4.4 | Clinical and public health relevance

Excessive GWG is of great concern both globally and in Sweden and considering the rising trend and negative health implications, effective and scalable interventions are warranted. To date, lifestyle interventions have been shown to successfully limit excessive GWG,[60] with only a few studies evaluating digital interventions, which can be considered both cost-effective and lessen the burden on healthcare. Regardless of intervention delivery mode (face-to-face or digital) it is essential to ascertain that the intervention has no adverse health effects on the infant prior to implementing them in healthcare. In that aspect, our study is one of the first to investigate the effects on infant body composition following a lifestyle intervention in pregnant women with a positively observed effect on GWG (in women with overweight or obesity prior to pregnancy).[30] Importantly, we observed no effects on infant outcomes, while simultaneously observing a positive effect on dietary habits in pregnancy across all BMI-categories and GWG in women with overweight and obesity.[30] Altogether,[30] these findings indicate that the HealthyMoms app may have the potential to be implemented at larger scale within Swedish maternity care without compromising infant growth.

5 | CONCLUSIONS

This study provides novel data on the effects of a lifestyle intervention (the HealthyMoms app) delivered in pregnancy on infant body composition. Our results showed similar body size and composition variables in the intervention and control group. These findings support that the HealthyMoms app may be implemented in healthcare to promote a healthy lifestyle in pregnant women without compromising offspring growth. Further research is required to elucidate the potential of lifestyle interventions in pregnancy regarding beneficial effects on infant body composition with implications for later obesity risk.

ACKNOWLEDGEMENTS

Marie Löf is the principal investigator of the HealthyMoms trial and designed the study together with Pontus Henriksson and Marie Blomberg. Johanna Sandborg and Emmie Söderström were responsible for data recruitment and collection. Johanna Sandborg performed the data analysis with support from Marcus Bendtsen, Pontus Henriksson and Jairo H. Migueles. Johanna Sandborg, Marcus Bendtsen, Jairo H. Migueles, Pontus Henriksson and Marie Löf interpreted the data. Johanna Sandborg performed the literature search, generated the figures and tables and drafted the manuscript, which was critically reviewed by Pontus Henriksson, Emmie Söderström, Jairo H. Migueles, Marie Blomberg and Marie Löf. All authors reviewed and approved the final draft of the manuscript submitted for publication. The authors would like to extend their outmost gratitude to the participating women in the HealthyMoms trial as well to Eva Flinke and Ellinor Nilsson for invaluable help with the data collection, Elias Björheden for help with data quality checking and the midwifes in Region Östergötland for their help with recruitment. Funding for the HealthyMoms trial has been provided by the following: the Swedish Research Council (2016-01147 to Marie Löf); the Swedish Research Council for Health, Working Life and Welfare (Forte, 2017-00088 to Pontus Henriksson; 2018-01410 to Marie Löf); Bo and Vera Ax:son Johnsons' Foundation (to Marie Löf); the Strategic Research Area Health Care Science, Karolinska Institutet/Umeå University (to Pontus Henriksson); the Swedish Society of Medicine (to Pontus Henriksson); Karolinska Institutet (to Pontus Henriksson and Marie Löf); Lions Forskningsfond (to Pontus Henriksson) and ALF Grants, Region Östergötland (LIO-893101, LIO-941191 Marie Löf). Open access funding enabled and organized by Projekt DEAL.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Marcus Bendtsen owns a private company (Alexit AB) that develops and disseminates eHealth apps to both private and public health organizations. The company Alexit AB was not involved in this study.

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How to cite this article: Sandborg J, Henriksson P, Söderström E, et al. 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. doi:10.1111/ijpo.12894