








ORIGINAL RESEARCH

Infant growth during the first year of life following a pregnancy lifestyle intervention in routine care—Findings from the cluster-randomised GeliS trial

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Summary

Background: Lifestyle interventions in pregnancy may influence postpartum development and obesity risk in offspring. The impact of lifestyle interventions as health system-based approaches is unclear.

Objective: To evaluate the effect of an antenatal lifestyle intervention conducted as public health approach on infant development and feeding practices.

Methods: We followed offspring born to women participating in the cluster-randomised GeliS trial who received usual care (CG) or repeated lifestyle counselling (IG). We collected data on offspring development and complementary feeding until the 12th month postpartum.

Results: Of the 1998 mother-child pairs, 1783 completed the follow-up. Mean infant weight at 12 months was comparable between groups (IG: 9497.9 ± 1137.0 g; CG: 9433.4 ± 1055.2 g; $P = .177$). There was no significant evidence of differences in sex- and age-adjusted z-scores or in the odds of offspring being overweight. More infants in the IG received whole-grain products compared to the CG (95.6% vs. 90.8%; $P = .003$). Despite small differences in the timing of introducing solid foods, there were no further significant differences in the pattern of complementary feeding.

Conclusions: The antenatal lifestyle intervention embedded in routine care did not substantially influence infant anthropometrics and is thus unlikely to impact future development.

KEYWORDS

childhood obesity, complementary feeding, gestational weight gain (GWG), lifestyle intervention, obesity prevention, routine care

Abbreviations: BMI, body-mass-index; CG, control group; CI, confidence interval; GEE, generalised estimating equations; GeliS, "Gesund leben in der Schwangerschaft"/"healthy living in pregnancy"; GWG, gestational weight gain; IG, intervention group; IOM, Institute of Medicine; OR, odds ratio; SD, standard deviation.

1 | INTRODUCTION

In Germany, 15.4% of children and adolescents aged 3-17 are classified as having overweight and 5.9% as having obesity.¹ Within the last

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decades.^{2,3} the worldwide prevalence of childhood obesity increased continuously, which is particularly alarming as childhood obesity was identified as a predictor for obesity during adolescence or later in life.⁴ For these reasons, the World Health Organization declared childhood obesity as one of the major public health challenges of the 21st century.⁵

The aetiology of childhood obesity is multifactorial. Research suggests that several antenatal exposures augment individual obesity risk.^{6,7} For example, a positive association between maternal pre-pregnancy BMI and the infant's obesity risk has consistently been observed.^{6,8} Among all antenatal factors, maternal obesity is the strongest predictor for infant adiposity, increasing the risk by up to sixfold.^{6,8} Moreover, total gestational weight gain (GWG) or GWG above a certain threshold (excessive GWG)⁹ have been shown to influence weight development of offspring and their obesity risk.^{6,8,10,11} Further, early postnatal factors such as breastfeeding pattern and formula feeding, introduction of solid foods, activity or inactivity level, and also sleeping behaviour and exposure to antibiotics are currently discussed to modify the infant's obesity risk in the short- and long-term.^{7,12,13}

Due to the potential to reverse health consequences of childhood obesity if weight normalisation is achieved by puberty,¹⁴ identifying effective early-life strategies that tackle modifiable risk factors are urgently needed. Within the last decade, several randomised controlled trials have been initiated primarily with the aim to improve maternal health outcomes during pregnancy and postpartum. Meta-analyses confirmed the potential of these lifestyle interventions to modestly ameliorate GWG and some other health outcomes such as the odds of caesarean section or the extent of maternal postpartum weight retention 1 year after birth.^{15,16} Although some studies also focused on long-term infant development as a secondary goal, a recent systematic review was unable to draw any conclusion on their influence on obesity outcomes in early childhood.¹⁷ Reviewed studies had either small to moderate sample sizes or were conducted in community settings and academic facilities. To date, nothing is known about the effect of a large-scaled antenatal lifestyle intervention performed under real-life conditions on early life development of the offspring. Herein, we assessed the influence of the "Gesund leben in der Schwangerschaft" ("healthy living in pregnancy," GeliS) lifestyle intervention, that was conducted within the German routine care system, on infant growth during the first year of life.

The cluster-randomised GeliS trial primarily aimed to reduce the proportion of women with excessive GWG by offering comprehensive counselling alongside routine visits. While the intervention was not successful in limiting excessive GWG, it yielded some improvements in maternal antenatal dietary and physical activity behaviour,^{18,19} as well as modest between-group differences in maternal breastfeeding behaviour.²⁰ Herein, our principle aim was to investigate the influence of the GeliS intervention on offspring weight development during the first year of life as well as on further developmental variables including obesity outcomes. We also examined the intervention effect on infant feeding practices. Additional cohort analyses sought to assess factors potentially influencing infant weight, BMI and obesity risk at 12 months of age.

2 | METHODS

2.1 | The GeliS study: Design and setting

The GeliS study is a prospective, cluster-randomised, controlled, open intervention trial, conducted in Bavaria (Germany). The primary outcome was to reduce the proportion of women with excessive GWG as defined by the Institute of Medicine (IOM).^{9,21} Primary and some secondary outcomes have been published recently.^{18-20,22-24}

Details on the study design and setting, and cluster-randomisation, have been described in the study protocol.²¹ In brief, the randomisation resulted in one control (CG) area and one intervention (IG) area for each study region. Recruitment and study procedures occurred in gynaecological and midwifery practices and thus under real-life conditions within the German antenatal routine care system.

Study procedures adhered to local regulatory requirements and laws and were performed in accordance with the declaration of Helsinki. The study protocol was approved by the Ethics Commission of the Technical University of Munich (project number 5653/13) and was registered at the ClinicalTrials.gov Protocol Registration System (NCT01958307).

2.2 | Participants and lifestyle intervention

Between 2013 and 2015, 71 participating gynaecological and midwifery practices (IG: $n = 39$; CG: $n = 32$) recruited participants with (a) a pre-pregnancy BMI between 18.5 and 40.0 kg/m², (b) a singleton pregnancy, (c) age between 18 and 43 years, (d) sufficient German language skills and (e) stage of pregnancy before the end of the 12th week of gestation. Prior to study participation, all women gave their written informed consent for inclusion. The following criteria were considered, a priori, as reasons for exclusion:^{21,22} miscarriage or late loss of pregnancy, terminations, pregnancy complications that interfered with the intervention, and maternal death during the course of the trial. If women were no longer reachable during the follow-up phase, did not provide contact details, or withdrew participation, they were defined as drop-outs in the follow-up.

While participants in the CG attended standard antenatal care and were provided with a flyer, which outlined general information on a healthy antenatal lifestyle and the importance of breastfeeding, the IG received a comprehensive lifestyle intervention programme.

Details on the lifestyle intervention programme have been described elsewhere.²¹ In brief, the IG received three antenatal (12th–16th, 16th–20th and 30th–34th week of gestation) and one postpartum (6th–8th week postpartum) face-to-face counselling sessions alongside routine care visits. These sessions lasted between 30 and 45 minutes and were given by previously trained midwives, medical personnel or gynaecologists in their practices. Participants were counselled on adequate GWG according to the IOM recommendations,⁹ and the importance of a healthy antenatal lifestyle in relation to optimal offspring development during childhood. In accordance with national and

international recommendations,²⁵⁻²⁷ women received lifestyle advice for the antenatal as well as the postpartum period including information on a healthy dietary and physical activity behaviour.²¹ Breastfeeding advice according to German recommendations were outlined, with additional emphasis and information on the importance of breastfeeding for both mothers and their offspring.^{21,25} Additionally, women were provided with information on the introduction of complementary food, infant hunger and satiety signals and infant feeding practices according to the recommendations.^{21,25}

A follow-up observation programme, which was identical in both groups, started subsequent to the intervention phase. Infant anthropometrics in the postpartum period, measured in paediatric practices and documented in routinely used health records, were enquired within a phone interview in the 12th month after birth. Moreover, data on infant feeding practices were collected via a set of questionnaires completed by women 12 months after birth. More information on the follow-up programme is provided elsewhere.²¹

2.3 | Data collection and outcomes

Anthropometric and sociodemographic characteristics of participating women were collected by means of a screening questionnaire at the time of recruitment. The women's weight was measured in participating gynaecological or midwifery practices during the course of pregnancy and 6-8 weeks postpartum and was retrieved from maternity records. Maternal pre-pregnancy BMI was calculated based on self-reported pre-pregnancy weight. GWG was defined as the difference between the last measured weight before delivery and the first measured weight at the time of recruitment. Preterm delivery was defined as giving birth before the 37th week of gestation.²²

Measurements of infant anthropometrics at birth (time point U1) were performed in hospitals and documented in maternity and birth records. Offspring with birth weight above the 90th percentile for gestational age were defined as being "large for gestational age" and below the 10th percentile for gestational age as being "small for gestational age." Infant development during the first 12 months was assessed at paediatric practices within the routine health check-up programme for infants. Weight, length and head circumference of the infants were measured at five time points in these health examinations (U2: 3rd-10th day postpartum; U3: 4th-6th week postpartum; U4: 3rd-4th month postpartum; U5: 6th-7th month postpartum; U6: 10th-12th month postpartum) and documented in the routinely used infant health records. Weight, length and BMI were converted into sex-specific percentiles and z-scores for age using a German reference group.²⁸ According to the German recommendations for children aged between 0 and 18 years, infants with a BMI-for-age-percentile below 10.0 were classified as being underweight, while a percentile above 90.0 and 97.0 was defined as being overweight and obese, respectively.²⁸

Data on infant feeding practices were collected within the set of questionnaires via questions adapted from the "German Health Interview and Examination Survey for Children and Adolescents" (KiGGS).²⁹ "Any breastfeeding" was defined as breastfeeding at any

time and "exclusively breastfeeding" as breastfeeding without the addition of any formula or complementary food. Moreover, self-reported paternal weight and height were enquired within the set of postpartum questionnaires.

2.4 | Statistical analysis

Power calculation was conducted based on the primary study outcome (excessive GWG defined by the IOM⁹) and was described elsewhere.²¹ Power calculations were not performed for secondary outcomes. All analyses presented herein were performed using SPSS software (IBM SPSS Statistics for Windows, version 24.0, IBM Corp, Armonk, New York).

Baseline characteristics are depicted for all mother-infant pairs that completed the active phase and thus entered the follow-up period. Analyses on infant anthropometrics included all mother-infant pairs that provided data for the corresponding time point (U1-U6) except those who were lost to follow up. For outcomes measured more than once, likelihood-based mixed models for repeated measures according to Bell et al.³⁰ were fit using data from each visit (U1-U6). Through the inclusion of visit number (as a factor) and group assignment, and their interaction, these models provide point estimates and 95% confidence intervals (CIs) for the mean differences between groups at each visit. In adjusted analyses, maternal age, pre-pregnancy BMI category, parity, infant sex, infant age in days at the corresponding visit and study region were considered as further independent variables. For outcomes only assessed at U6, and infant feeding practices, between-group differences were investigated using linear, binary logistic or proportional odds ordinal logistic regression models fit with generalised estimating equations (GEEs) according to Donner et al.³¹ These results are presented as estimated mean differences or odds ratios (OR) along with the 95% CI. In adjusted models, the same covariates as for likelihood-based mixed models for repeated measures were considered with one exception for feeding pattern; instead of infant age, the time interval between questionnaire completion date and birth date was used.

To identify predictors of infant weight and the risk for overweight or obesity at the 12th month postpartum, mother-infant pairs in the IG and CG were pooled to form one cohort. For all cohort analyses, unadjusted linear and binary logistic regression models were applied, as well as models adjusted for the aforementioned covariates and group assignment. As defined a priori,²² analyses related to GWG excluded subjects with preterm delivery.

For all analyses, *P* values below .05 were considered as statistically significant. No adjustment was made for multiple comparisons.

3 | RESULTS

3.1 | Participant flow and baseline characteristics

In total, 2261 participants were allocated to the IG (*n* = 1139) and CG (*n* = 1122) (Figure 1). Among them, 1998 mother-infant pairs entered

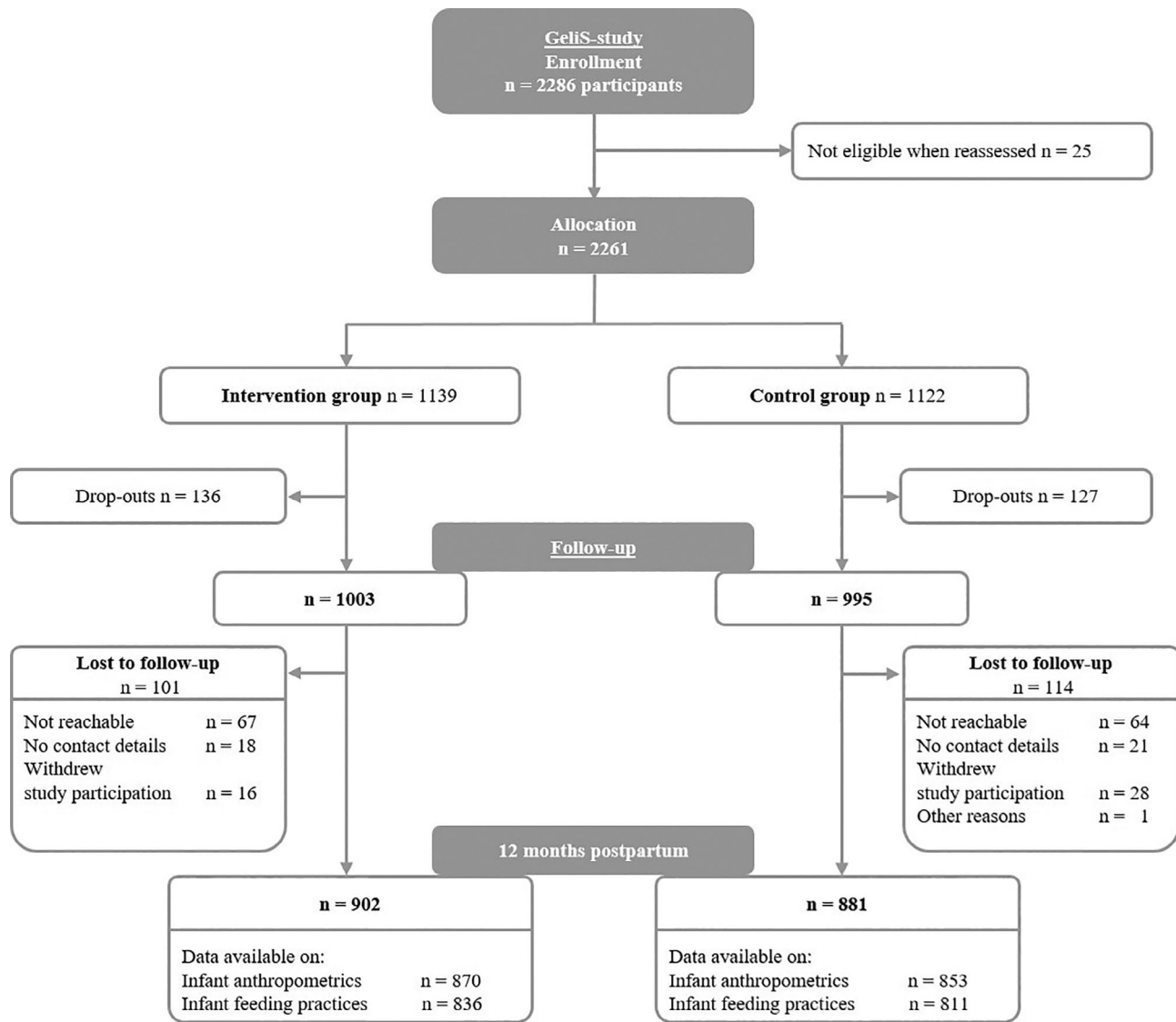


FIGURE 1 Participant flow

the follow-up phase (IG: $n = 1003$; CG: $n = 995$). Overall, 215 pairs were lost to follow up (Figure 1). The drop-out rate since group allocation until the 12th month postpartum was 21.1%, constituting 10.8% drop-outs in the follow-up phase. From the remaining 1783 pairs, 1723 provided data on infant anthropometrics and 1647 on infant feeding practices.

Table 1 shows characteristics of mother-infant pairs entering the follow-up including weight characteristics of the father. Mean self-reported weight of mothers and fathers were comparable between groups. In total, 64.9%, 23.1% and 12.0% of women had pre-pregnancy normal weight, overweight and obesity, respectively. As previously noted,²² there was a higher proportion of primiparous women (IG: 61.8% vs. CG: 53.2%), and a lower proportion of female infants in the IG (IG: 50.3% vs. CG: 53.8%). All other maternal characteristics and infant birth outcomes were comparable between groups (Table 1).

The proportions of mother-infant pairs that were lost to follow-up were comparable between groups (IG: 10.1%; CG: 11.5%). As shown in Table S1, characteristics of women that were lost to follow-up differed slightly from those remaining in the study in terms of educational level, history of GDM, parity, country of birth and smoking status. Infant birth outcomes were comparable between those that were lost to follow-up and those remaining in the study.

3.2 | Infant anthropometrics

Mean infant weight and further anthropometric outcomes are shown in Table 2. Figure S1 illustrates infant weight development during the first year of life for IG and CG, depicted as interquartile ranges. The relationship between infant weight in the CG and IG groups changed over the course of 12 months. From birth until the 3rd-4th month

TABLE 1 Characteristics of mother-infant pairs entering the follow-up

| | Intervention (n = 1003) | Control (n = 995) | Total (n = 1998) |
|---|-------------------------|------------------------|--------------------------|
| Maternal characteristics | | | |
| Pre-pregnancy age, years ^a | 30.2 ± 4.3 | 30.5 ± 4.6 | 30.3 ± 4.4 |
| Pre-pregnancy weight, kg | 68.3 ± 13.0 | 68.0 ± 13.7 | 68.2 ± 13.3 |
| Pre-pregnancy BMI, kg/m ² | 24.4 ± 4.3 | 24.3 ± 4.6 | 24.4 ± 4.5 |
| Pre-pregnancy BMI category, n (%) | | | |
| BMI 18.5-24.9 kg/m ² | 645/1003 (64.3%) | 652/995 (65.5%) | 1297/1998 (64.9%) |
| BMI 25.0-29.9 kg/m ² | 243/1003 (24.2%) | 218/995 (21.9%) | 461/1998 (23.1%) |
| BMI 30.0-40.0 kg/m ² | 115/1003 (11.5%) | 125/995 (12.6%) | 240/1998 (12.0%) |
| GWG, kg | 13.9 ± 5.3 | 13.9 ± 5.3 | 13.9 ± 5.3 |
| GDM, n (%) | 98/984 (10.0%) | 104/939 (11.1%) | 202/1923 (10.5%) |
| Educational level, n (%) | | | |
| General school ^b | 151/1002 (15.1%) | 164/992 (16.5%) | 315/1994 (15.8%) |
| Vocational secondary school | 435/1002 (43.4%) | 413/992 (41.6%) | 848/1994 (42.5%) |
| Academic high school | 416/1002 (41.5%) | 415/992 (41.8%) | 831/1994 (41.7%) |
| Country of birth, n (%) | | | |
| Germany | 889/1003 (88.6%) | 886/992 (89.3%) | 1775/1995 (89.0%) |
| Others | 114/1003 (11.4%) | 106/992 (10.7%) | 220/1995 (11.0%) |
| Primiparous, n (%) | 620/1003 (61.8%) | 529/995 (53.2%) | 1149/1998 (57.5%) |
| Smoking in late pregnancy, n (%) | 41/952 (4.3%) | 50/938 (5.3%) | 91/1890 (4.8%) |
| Paternal characteristics^c | | | |
| | n = 805 | n = 782 | n = 1587 |
| Weight, kg | 86.8 ± 14.1 | 86.5 ± 14.1 | 86.7 ± 14.1 |
| Height, cm | 180.6 ± 6.5 | 180.8 ± 7.0 | 180.7 ± 6.8 |
| BMI, kg/m² | 26.6 ± 3.9 | 26.5 ± 4.0 | 26.5 ± 4.0 |
| Infant characteristics at birth | | | |
| Gender, n (%) | | | |
| Female | 504/1001 (50.3%) | 535/995 (53.8%) | 1039/1996 (52.1%) |
| Male | 497/1001 (49.7%) | 460/995 (46.2%) | 957/1996 (47.9%) |
| Preterm birth, n (%) | 68/999 (6.8%) | 59/995 (5.9%) | 127/1994 (6.4%) |
| LGA, n (%) | 73/999 (7.3%) | 75/995 (7.5%) | 148/1994 (7.4%) |
| SGA, n (%) | 86/999 (8.6%) | 81/995 (8.1%) | 167/1994 (8.4%) |
| Birth weight > 4000 g, n (%) | 86/1001 (8.6%) | 83/995 (8.3%) | 169/1996 (8.5%) |

Abbreviations: BMI, body mass index; GDM, gestational diabetes mellitus; GWG, gestational weight gain; LGA, large for gestational age (> 90th percentile); SGA, small for gestational age (< 10th percentile).

^aMean ± SD (all such values).

^bSchool is completed through year 9.

^cCollected 12 months after birth.

postpartum, mean infant weight was lower in the IG compared to the CG. At the 6th-7th month postpartum, mean weight was similar in both groups, and at 12 months IG infants were estimated to be heavier (Table 2, Figure S1). Statistical significance of between-group differences was only observable at U2 (3rd-10th day postpartum) and U3 (4th-6th week postpartum) (Table 2).

The mean length of IG infants was significantly lower than in the CG until the 10th day after birth (Table 2). Likewise, IG infants had a smaller head circumference compared to the CG from the 4th week until the 12th month postpartum with significant findings at the U3

(4th-6th week postpartum), U4 (3rd-4th month postpartum) and U6 (10th-12th month postpartum). At 12 months of age, neither infant BMI nor any other age- and sex-specific outcomes differed significantly between the two groups. The proportions of infants in the different weight categories at 12 months postpartum were comparable between groups (Table 2). The incidence of overweight (> 90th BMI percentile) did not differ significantly between groups (IG: 12.2%; CG: 11.8%; adjusted OR: 1.02, 95% CI 0.73 to 1.43; P = .893). The mean weight and BMI in infants of mothers with overweight was significantly higher in the IG compared to the CG (Table S2). Moreover,

TABLE 2 Infant anthropometrics during the first year of life

| | Age | Intervention group | | Control group | | Adjusted effect size ^a (95% CI) | Adjusted P value ^a |
|---|--|--------------------|-----------------|-----------------|--|--|-------------------------------------|
| | | n | Mean ± SD | n | Mean ± SD | | |
| Weight, g | At birth | 901 | 3325.0 ± 524.5 | 881 | 3373.8 ± 488.1 | −36.15 (−83.46, 11.17) ^b | .134 |
| | 3 rd –10 th day | 865 | 3147.0 ± 491.5 | 851 | 3212.3 ± 474.1 | −45.66 (−90.74, −0.59) | .047 |
| | 4 th –6 th week | 869 | 4278.8 ± 671.2 | 852 | 4404.8 ± 654.0 | −73.44 (−131.60, −15.28) | .013 |
| | 3 rd –4 th month | 869 | 6282.6 ± 879.6 | 848 | 6342.3 ± 834.6 | 1.90 (−71.69, 75.51) | .959 |
| | 6 th –7 th month | 868 | 7907.5 ± 1003.7 | 850 | 7908.4 ± 953.2 | 48.29 (−41.04, 137.63) | .289 |
| | 10 th –12 th month | 866 | 9497.9 ± 1137.0 | 850 | 9433.4 ± 1055.2 | 71.11 (−32.13, 174.36) | .177 |
| Length, cm | At birth | 897 | 51.1 ± 2.7 | 871 | 51.6 ± 2.5 | −0.36 (−0.62, −0.11) | .006 |
| | 3 rd –10 th day | 838 | 51.0 ± 2.6 | 813 | 51.5 ± 2.8 | −0.40 (−0.66, −0.15) | .002 |
| | 4 th –6 th week | 869 | 54.4 ± 2.7 | 851 | 54.8 ± 2.6 | −0.17 (−0.40, 0.07) | .171 |
| | 3 rd –4 th month | 869 | 62.0 ± 2.8 | 847 | 62.3 ± 2.7 | −0.08 (−0.31, 0.16) | .524 |
| | 6 th –7 th month | 867 | 68.3 ± 2.8 | 850 | 68.4 ± 2.7 | 0.10 (−0.14, 0.33) | .425 |
| | 10 th –12 th month | 865 | 75.4 ± 2.9 | 850 | 75.3 ± 2.8 | 0.14 (−0.12, 0.40) | .283 |
| Head circumference, cm | At birth | 895 | 34.6 ± 1.6 | 856 | 34.8 ± 1.5 | −0.12 (−0.27, 0.03) | .131 |
| | 3 rd –10 th day | 858 | 34.6 ± 1.6 | 814 | 34.7 ± 1.5 | −0.10 (−0.25, 0.05) | .177 |
| | 4 th –6 th week | 867 | 37.0 ± 1.5 | 851 | 37.3 ± 1.5 | −0.26 (−0.40, −0.12) | <.001 |
| | 3 rd –4 th month | 866 | 40.5 ± 1.4 | 845 | 40.7 ± 1.4 | −0.14 (−0.26, −0.02) | .022 |
| | 6 th –7 th month | 868 | 43.3 ± 1.4 | 847 | 43.5 ± 1.4 | −0.11 (−0.23, 0.01) | .069 |
| | 10 th –12 th month | 862 | 45.9 ± 1.5 | 848 | 46.0 ± 1.4 | −0.13 (−0.26, −0.00) | .048 |
| | | | | | Adjusted effect size^c (95% CI) | Adjusted P value^c | |
| BMI, kg/m ² | 10 th –12 th month | 865 | 16.7 ± 1.5 | 850 | 16.6 ± 1.5 | 0.08 (−0.09, 0.25) | .373 |
| Weight z-score ^d | 10 th –12 th month | 865 | −0.05 ± 1.03 | 848 | −0.07 ± 0.97 | 0.01 (−0.08, 0.10) | .883 |
| Weight percentile ^d | 10 th –12 th month | 865 | 48.2 ± 29.5 | 848 | 47.7 ± 28.6 | 0.20 (−2.37, 2.77) | .878 |
| Length z-score | 10 th –12 th month | 864 | 0.08 ± 1.05 | 848 | 0.09 ± 1.00 | −0.01 (−0.08, 0.07) | .834 |
| Length percentile | 10 th –12 th month | 864 | 51.6 ± 29.2 | 848 | 52.3 ± 28.6 | −0.88 (−2.87, 1.11) | .386 |
| BMI z-score | 10 th –12 th month | 864 | −0.03 ± 1.18 | 848 | −0.06 ± 1.13 | 0.04 (−0.13, 0.20) | .686 |
| BMI percentile | 10 th –12 th month | 864 | 50.0 ± 31.4 | 848 | 48.9 ± 30.5 | 1.03 (−3.03, 5.08) | .620 |
| Weight category | 10 th –12 th month | n (%) | | n (%) | | Adjusted effect size^e (95% CI) | Adjusted P value^e |
| Underweight (< 10 th BMI percentile) | | 129/864 (14.9%) | | 124/848 (14.6%) | | 1.02 (0.79, 1.34) | .858 |
| Normalweight (10 th –90 th BMI percentile) | | 630/864 (72.9%) | | 624/848 (73.6%) | | | |
| Overweight (> 90 th –97 th BMI percentile) | | 64/864 (7.4%) | | 70/848 (8.3%) | | | |
| Obesity (> 97 th BMI percentile) | | 41/864 (4.7%) | | 30/848 (3.5%) | | | |

Abbreviations: BMI, body mass index; CI, confidence interval; GEE, generalised estimating equations; SD, standard deviation.

^aFrom mixed models for repeated measures with the use of data from each visit since birth and controlled for study region, maternal pre-pregnancy age, maternal pre-pregnancy BMI, parity, sex, infant age (days).

^bEstimated mean difference; in parentheses 95% CI (all such values).

^cFrom linear regression models fit using GEEs controlled for maternal pre-pregnancy age, maternal pre-pregnancy BMI, parity, sex, infant age (days) except age- and sex-specific percentiles and z-scores (not controlled for infant age and sex).

^dAll z-scores and percentiles were calculated according to Kromeyer-Hauschild et al.²⁸

^eFrom proportional odds ordinal logistic regression models fit using GEEs controlled for maternal pre-pregnancy age, maternal pre-pregnancy BMI, parity.

mean weight in infants of mothers with obesity was lower in the IG, however lacking statistical significance (Table S2, $P = .081$). There was significant evidence of an interaction effect between group allocation and maternal pre-pregnancy BMI (Table S2).

3.3 | Infant feeding practices

As previously reported,²⁰ women in the IG were more likely to breastfeed their infants exclusively. Further characteristics of infant

TABLE 3 Infant feeding practices

| | Intervention group | | Control group | | Adjusted OR ^a (95% CI) | Adjusted P value ^a |
|--------------------------------------|--------------------|------|---------------|------|-----------------------------------|-------------------------------|
| | n | % | n | % | | |
| Any breastfeeding ^b | 701/828 | 84.7 | 685/804 | 85.2 | 0.98 (0.55, 1.76) ^c | .954 |
| Exclusive breastfeeding ^b | 588/673 | 87.4 | 558/661 | 84.4 | 1.49 (1.22, 1.81) | <.001 |
| Any formula feeding | 550/819 | 67.2 | 528/795 | 66.4 | 0.94 (0.64, 1.38) | .764 |
| Hypoallergenic formula | 129/793 | 16.3 | 145/788 | 18.4 | 0.79 (0.54, 1.15) | .224 |
| Probiotic formula | 74/786 | 9.4 | 67/778 | 8.6 | 1.08 (0.77, 1.53) | .637 |
| Milk | 518/807 | 64.2 | 495/791 | 62.6 | 1.02 (0.79, 1.32) | .860 |
| Meat | 799/821 | 97.3 | 783/802 | 97.6 | 1.02 (0.61, 1.71) | .932 |
| Puree prepared with milk | 728/820 | 88.8 | 713/803 | 88.8 | 1.05 (0.87, 1.28) | .603 |
| Puree prepared without milk | 666/810 | 82.2 | 624/787 | 79.3 | 1.17 (0.85, 1.61) | .325 |
| Vegetables (puree) | 823/825 | 99.8 | 803/808 | 99.4 | 3.13 (0.73, 13.40) | .124 |
| Fruit juice | 352/819 | 43.0 | 363/799 | 45.4 | 0.91 (0.80, 1.04) | .194 |
| Fruits | 818/822 | 99.5 | 797/803 | 99.3 | 1.47 (0.31, 6.96) | .626 |
| Whole-grain products | 781/817 | 95.6 | 722/795 | 90.8 | 2.07 (1.28, 3.37) | .003 |
| Tea (sweetened) | 37/813 | 4.6 | 44/792 | 5.6 | 0.88 (0.74, 1.04) | .139 |
| Tea (unsweetened) | 584/817 | 71.5 | 568/801 | 70.9 | 1.05 (0.86, 1.18) | .949 |
| Family meal | 802/824 | 97.3 | 787/805 | 97.8 | 0.77 (0.57, 1.05) | .100 |

Abbreviations: CI, confidence interval; GEE, generalised estimating equations; OR, odds ratio.

^aFrom binary logistic regression models fit using GEEs controlled for maternal pre-pregnancy age, maternal pre-pregnancy BMI, parity, sex, time interval between questionnaire completion date and birth date.

^bData published previously by Hoffmann et al.²⁰

^cOdds ratio; in parentheses 95% CI (all such values).

feeding practices are shown in Table 3. There was no significant evidence of any differences in formula-related outcomes. A higher proportion of infants in the IG received whole-grain products (95.6% vs. 90.8%; $P = .003$). The proportion of infants receiving other specific solid foods did not differ between groups (Table 3). The timing of introducing some solid foods such as vegetables, fruits, fruit juice and puree prepared with milk to infants differed significantly by 3-12 days per food component between groups with women in the IG introducing these foods later to their infants (data not shown).

3.4 | Determinants of infant weight and risk for overweight at the 10th-12th month of life

In the GeliS cohort, infant weight and BMI in the 10th-12th month postpartum were positively associated with maternal pre-pregnancy BMI and GWG (Table S3, Table S4). There was a negative association between infant weight but not infant BMI and maternal pre-pregnancy age (Table S3, Table S4). An increase in paternal BMI was linked to an increase in infant BMI but not infant weight in the 10th-12th month postpartum (Table S3, Table S4). Infant weight and BMI at 1 year of life were positively related to large for gestational age and high birth weight and inversely associated with small for gestational age (Table S3, Table S4). There was a negative association between preterm birth, any breastfeeding or exclusive breastfeeding and infant weight but not infant BMI (Table S4). Moreover, higher GWG or

paternal BMI as well as a high birth weight or large for gestational age significantly increased the odds of being overweight or obese at the time point 10-12 months postpartum (Table 4).

4 | DISCUSSION

To the best of our knowledge, the GeliS study is the first large-scaled trial that assessed the effect of an antenatal lifestyle intervention for pregnant women conducted under real-life conditions on infant development during the first year of life. We could not identify a substantial effect on infant outcomes at 10-12 months of age. Some significant between-group differences during the first year of life were observed, such as a slightly lower mean infant weight (3rd-10th day and 4th-6th week assessment) and length (birth and 3rd-10th day assessment) in the IG. Importantly, the estimated mean differences were small and might be explained by a number of outliers in the IG. Moreover, there were no remarkable differences in BMI, age and sex-adjusted BMI z-scores at these time points (data not shown). Given that the minor difference in weight and length disappeared by the 12th month postpartum, we question the clinical relevance of observed significant differences. These concerns also extend to the findings on head circumference measurements during the first year. Difficulties in measuring infant head circumference in a standardised way were frequently reported and may explain observed differences. Apart from aforementioned findings, we found no significant

TABLE 4 Factors influencing the odds of being overweight or obese in the 10th–12th month after birth defined as BMI-for-age-percentile > 90.0

| Overweight/obesity in the 10 th –12 th month after birth | Unadjusted effect size ^a (95% CI) | P value ^a | Adjusted effect size ^b (95% CI) | Adjusted P value ^b |
|--|---|----------------------|--|-------------------------------|
| Maternal pre-pregnancy BMI ^c | 1.01 (0.98, 1.05) ^d | .454 | 1.01 (0.98, 1.05) | .421 |
| Maternal pre-pregnancy age ^e | 0.96 (0.93, 1.00) | .024 | 0.97 (0.93, 1.00) | .073 |
| GWG | 1.05 (1.02, 1.08) | .001 | 1.05 (1.02, 1.08) | .003 |
| GDM | 1.31 (0.83, 2.08) | .249 | 1.41 (0.88, 2.28) | .154 |
| Maternal educational level | | .400 | | .494 |
| General school ^f | Reference | | Reference | |
| Vocational secondary school | 0.85 (0.56, 1.29) | .444 | 0.84 (0.55, 1.28) | .412 |
| Academic high school | 0.75 (0.49, 1.15) | .183 | 0.77 (0.50, 1.19) | .235 |
| Paternal BMI | 1.05 (1.02, 1.09) | .004 | 1.06 (1.02, 1.10) | .002 |
| SGA at birth | 0.30 (0.13, 0.70) | .005 | 0.29 (0.13, 0.67) | .004 |
| LGA at birth | 1.65 (1.03, 2.66) | .039 | 1.71 (1.05, 2.77) | .030 |
| Birth weight > 4000 g | 1.77 (1.13, 2.76) | .012 | 1.83 (1.16, 2.87) | .009 |
| Preterm delivery (< 37 th week of gestation) | 1.50 (0.88, 2.53) | .136 | 1.48 (0.87, 2.52) | .145 |
| Any breastfeeding | 0.69 (0.63, 1.47) | .860 | 0.96 (0.63, 1.48) | .863 |
| Exclusive breastfeeding | 0.93 (0.57, 1.51) | .765 | 0.89 (0.55, 1.46) | .652 |

Abbreviations: BMI, body mass index; CI, confidence interval; GDM, gestational diabetes mellitus; GWG, gestational weight gain; LGA, large for gestational age (> 90th percentile); SGA, small for gestational age (< 10th percentile).

^aFrom binary logistic regression models.

^bFrom binary logistic regression models controlled for maternal pre-pregnancy BMI, maternal pre-pregnancy age, parity, group assignment.

^cAll above listed covariates except maternal pre-pregnancy BMI.

^dOdds ratio; in parentheses 95% CI (all such values).

^eAll above listed covariates except maternal pre-pregnancy age.

^fSchool is completed through year 9.

between-group differences in other sex- and age-adjusted outcomes at the 12th month postpartum including infant weight categories or the odds of being overweight. These findings suggest that the GeliS intervention did not have a sustained effect on infant anthropometrics up to the 12th month of life. Thus, we were unable to confirm that our lifestyle intervention impacted infant obesity risk.

Our results are consistent with findings from our pilot trial where we did not find any significant difference in infant weight between groups in the 10th to 12th month postpartum.³² Due to large variations in the type of reported offspring outcomes and different follow-up periods,³³ a comparison of our results with observations from other studies is difficult. Dalrymple et al.¹⁷ systematically reviewed current literature in this field, but the considerable heterogeneity of the type of reported study outcomes made data pooling for a meta-analysis impossible. Apart from our pilot trial,³² none of the studies which included women from all BMI categories reported data on infant weight^{34–37} and thus followed a pragmatic way of data reporting, and none of these studies observed an intervention effect on any measure of childhood adiposity.^{32,34–37} These results are consistent with our observations on 12 month z-scores. Moreover, key findings from studies that included only women with overweight or obesity were inconsistent: Some reported improvements in measures of infant adiposity at 6, 12 and 24 months follow-up,^{38–40} while others could not show any intervention effect on follow-up observations

ranging from 18 months to 5 years.^{41–43} Dalrymple et al.¹⁷ suggested a decreasing intervention effect, over time, in women of higher BMI categories. In our subgroup analyses, we found no intervention effect in the normal weight category, but a significantly higher mean weight and BMI in infants of mothers with overweight in the IG. In contrast, there was a trend towards a lower weight in infants of women with obesity in the IG compared to the CG. Thus, these analyses could not help explain the mixed findings in higher BMI ranges. In conclusion, we were unable to find a consensus on the impact of lifestyle interventions on infant obesity risk and could not identify any intervention effect scaled in the routine care setting. Given these findings, we suggest that future research should harmonise outcome variables and should assess the effectiveness stratified by the duration of the observation period. Two ongoing meta-analyses, assessing the impact of interventions in pregnancy on child weight and health outcomes, may help to disentangle the current state of results.^{44,45} Novel approaches in childhood obesity prevention should consider explored maternal and paternal determinants of offspring weight, BMI and risk for overweight/obesity as well as exposures which occur in the perinatal period.

As reported elsewhere,²⁰ we found small differences in the proportion of women exclusively breastfeeding, with a slightly longer duration of exclusive breastfeeding in the IG. This might partly explain group differences in infant growth in the first weeks, as weight gain

per month was shown to be higher in formula-fed infants.⁴⁶ We also observed that more infants in the IG were fed whole-grain products. This is consistent with the eating pattern of women in the IG, who also consumed more whole-grain products after the intervention compared to the CG.¹⁹ However, we found no evidence of between-group differences in the exposure to any other type of solid food. The absence of an intervention effect corresponds to observations in some other lifestyle intervention studies,^{34,35,47} but an extensive comparison with current literature is limited by the lack of reporting data on complementary feeding. The GeliS intervention resulted in a slightly later introduction of some food components in the IG. This corresponds to our findings on breastfeeding behaviour²⁰ and might be explained by the longer duration of exclusive breastfeeding in the IG.²⁰ While some researchers suggested an association between breastfeeding duration or a very early introduction of complementary food and increased infant weight gain,⁴⁸ others could not demonstrate consistent evidence of such an association and later risk for overweight/obesity.⁴⁹ Concerning our findings, we suppose that the observed differences in the timing, that occurred when introducing some solid foods, are too small to influence the infant's overall susceptibility for overweight and obesity in the future. However, further analyses on the cohort level might be valuable to assess whether differences in infant feeding patterns relate to the incidence of childhood diseases such as allergy, asthma and immune disorders.

Although the GeliS intervention was not able to prevent excessive GWG,²² it yielded some improvements in maternal dietary and physical activity behaviour,^{18,19} and was shown to be successfully implemented into the real-life routine care setting. However, observed modifications of the maternal antenatal lifestyle were not sufficient to exert beneficial effects on the infant development in the first year postpartum, as herein reported findings were small and thus unlikely to impact on future health. This underlines the need to modify the GeliS concept, still focusing on its scalability, to ultimately reach the intended impact on the infant development. Suggestions for improvements of future trials include incorporating technologies such as smartphone applications, involving nutritionists as counsellors, integrating behavioural change strategies consistently, and offering more individualised counselling.

The presented analyses have some limitations. Infant weight, length and head circumference were measured within the routine care setting and thus by varying personnel, which might not have been completely standardised; and assessment of inter-rater reliability was not feasible. Moreover, direct methods to assess infant body composition, which would have allowed us to estimate offspring obesity risk more accurately, were not feasible due to the public health design. The sex- and age-adjusted outcomes are not completely transferable to other populations as we used a German reference group.²⁸ Furthermore, we classified overweight and obesity in children under 5 years of age according to German recommendations standards,²⁸ which differs from World Health Organization standards.⁵⁰ In addition, the power calculation was based on the primary study outcome (excessive GWG)²¹ and secondary outcomes such as infant growth or feeding patterns were not taken into account. Moreover, we observed

differences in characteristics between mothers lost-to-follow-up and those who remained in the study, and cannot exclude a risk of bias, although some characteristics were adjusted as confounders in statistical models. We are aware that other factors such as sociodemographic characteristics, ethnicity, maternal smoking, paternal BMI or infant nutrition might have impacted offspring development but were not considered as confounders. Finally, data on infant feeding pattern were retrospectively collected which may limit their validity and are not adjusted for maternal education although this was shown to influence breastfeeding outcomes.²⁰

Notwithstanding, there are several strengths that merit particular attention. Other lifestyle intervention studies were mainly conducted under controlled conditions and lack either the proof of concept in the real-life setting or included only small to moderate sample sizes. To the best of our knowledge, we were the first to analyse the effect of a large-scaled routine care intervention for mothers across all BMI categories on their infant's outcomes 1 year after birth. Due to our effort to thoroughly inform participants about the importance of the long-term follow-up, we managed to maintain nearly 80% of the initially allocated participants. This resulted in a fairly low drop-out rate 1 year after birth and a remarkably large sample of children. Anthropometric outcomes were measured and documented in health records and thus present unique real-world data, which are seldom available in this field of research. Data on complementary feeding are rarely reported by other intervention studies. Our analyses provide valuable information not only on offspring development but also on infant feeding patterns during the first year of life. Although this intervention neither effectively influenced infant health outcomes nor feeding patterns, the GeliS cohort will continue to be followed throughout early childhood in order to investigate the potential long-term impact on obesity risk of both mother and child.

Evidence outlined above demonstrated a large heterogeneity of reported offspring variables which makes an overall estimation of the effectiveness of antenatal lifestyle interventions in improving infants health outcomes challenging.¹⁷ Currently ongoing meta-analyses might close this gap.^{44,45}

In conclusion, this analysis provides unique data on the effect of a real-life lifestyle intervention for pregnant women across all BMI categories on their infant's development and nutrition during the first year of life. The GeliS intervention was not able to substantively modify infant growth or feeding patterns. However, it is worthwhile to follow mother-child pairs in order to investigate the potential effects later on and to assess adiposity outcomes in early childhood as well as the incidence of obesity. As we were not able to demonstrate the effectiveness of our intervention at scale, we encourage further research to address the question of how maternal antenatal lifestyle can be targeted at the public health level to significantly improve health and long-term obesity outcomes of the mother and her offspring.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Hans Hauner, Julia Hoffmann, Julia Günther, Lynne Stecher, Monika Spies, Kristina Geyer, Roxana Raab, Dorothy Meyer and Kathrin Rauh are members of the GeliS study group. Hans Hauner and Kathrin Rauh designed the research project, developed the study protocol and established the lifestyle intervention programme. Julia Hoffmann was responsible for data collection. Kristina Geyer assisted Julia Hoffmann in the data entry. Julia Hoffmann developed the research question and was together with Lynne Stecher in charge of statistical analyses. Julia Hoffmann performed the literature search, generated tables and figures and wrote the manuscript. Julia Günther, Lynne Stecher, Kathrin Rauh, Roxana Raab, Dorothy Meyer, Kristina Geyer and Monika Spies provided scientific support. Julia Günther, Lynne Stecher, Kristina Geyer, Roxana Raab, Dorothy Meyer, Monika Spies and Hans Hauner assisted in writing the manuscript. Julia Hoffmann and Hans Hauner had primary responsibility for the final content. All authors read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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