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‘Healthy living in pregnancy (GeliS)’

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Effects of a lifestyle intervention in the antenatal routine care setting on physical activity and breastfeeding behaviour and maternal weight development

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‘The womb may be more important than the home’ (*David Barker*)

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Abstract

It has increasingly been recognised that maternal lifestyle factors during pregnancy and in the postpartum (pp) period can impact the future health of mothers and their infants.

The cluster-randomised 'Gesund leben in der Schwangerschaft' / 'healthy living in pregnancy' (GeliS) trial investigated the effect of a lifestyle intervention on the incidence of excessive gestational weight gain (GWG), associated complications, and behavioural outcomes. Trained health care professionals provided women in the intervention group (IV) with three antenatal and one pp counselling sessions on a healthy antenatal lifestyle and adequate GWG. These sessions were conducted alongside antenatal routine care and took place between the 12^{th}–16^{th}, 16^{th}–20^{th} and 30^{th}–34^{th} weeks of gestation, and 6^{th}–8^{th} weeks pp. Women in the control group (C) received standard care. Data were collected by maternity and birth records, and questionnaires. Within a 1-year-follow-up, data on maternal and infant health parameters were collected in both groups via a questionnaire and a phone interview.

This work investigated the effect of the GeliS intervention on pre- and postnatal weight development of women until the 12^{th} month after birth, on their prenatal physical activity (PA) behaviour, and on their breastfeeding behaviour. In the pooled cohort, associations between maternal prenatal PA and obstetric and neonatal complications were studied.

Overall, 2286 participants were recruited (IV: n = 1152, C: n = 1134). There was no evidence of an intervention effect on the incidence of excessive GWG (IV: 45.1%; C: 45.7%, $p = 0.789$). The GeliS intervention yielded some improvements in maternal PA behaviour, in particular in PA of higher intensity. Cohort analyses found significant associations between neonatal weight-related outcomes and the intensity level of prenatal PA during the course of pregnancy. There was no convincing evidence that the GeliS intervention influenced maternal pp weight retention at the 12^{th} month after birth (IV: –0.2 ± 4.8 kg; C: 0.6 ± 5.2 kg, $p = 0.123$). Albeit women in the IV showed a greater weight loss after delivery ($p = 0.008$), its clinical meaning remains unclear. In addition, the rate of exclusive breastfeeding was higher in the IV ($p < 0.001$), however, results did not suggest major clinical significance.

In conclusion, the GeliS intervention demonstrated minor improvements in the prenatal PA and breastfeeding behaviour, and the mother's pp weight loss. However, the clinical significance of these findings needs to be further investigated. A considerable proportion of women in both groups retained more than 5 kg weight one year after birth. Hence, there remains an urgent need for effective interventions performed within the real-life setting. Findings presented herein support the importance to further investigate the effect of the GeliS intervention on long-term maternal and infant health until the 5^{th} year after birth.

Zusammenfassung

Eine übermäßige Gewichtszunahme während der Schwangerschaft ist mit kurz- und langfristigen gesundheitlichen Einschränkungen von Mutter und Kind assoziiert. Der pränatale Lebensstil trägt maßgeblich zur Gewichtsentwicklung während der Schwangerschaft bei. Effektive Maßnahmen, die innerhalb der Routinevorsorge einer exzessiven Gewichtszunahme und damit einhergehenden Komplikationen vorbeugen, sind zwingend erforderlich.

Die cluster-randomisierte „Gesund leben in der Schwangerschaft“ (GeliS)-Studie zielte darauf ab, durch eine Lebensstilintervention eine übermäßige Gewichtszunahme und damit einhergehende Komplikationen zu reduzieren, sowie das Gesundheitsbewusstsein zu verbessern. Frauen in der Kontrollgruppe (C) durchliefen die gewöhnliche Schwangerenvorsorge. Frauen in der Interventionsgruppe (IV) erhielten ein Lebensstil-programm, das von speziell geschulten Hebammen, medizinischen Fachangestellten oder Gynäkologen durchgeführt wurde. Dieses fand parallel zu den routinemäßigen Vorsorgeuntersuchungen statt. In drei Gesprächen während der Schwangerschaft (12.–16., 16.–20. und 30.–34. Schwangerschaftswoche) und einem nach der Geburt (6.–8. Woche postpartum (pp)) wurden Teilnehmerinnen der IV zu einem gesunden prä- und postnatalen Lebensstil und einer angemessenen Gewichtszunahme in der Schwangerschaft beraten. Daten wurden anhand von Mutterpässen, Geburtsprotokollen und Fragebögen erhoben. Mit Hilfe eines Fragebogens und eines Telefonats wurden beide Gruppen ein Jahr nach der Geburt zu mütterlichen und kindlichen Gesundheitsparamatern befragt.

Die vorliegende Arbeit untersucht den Effekt der Intervention auf die prä- und postnatale Gewichtsentwicklung der Mütter, sowie deren Bewegungs- und Stillverhalten. Innerhalb der gesamten Kohorte wird der Einfluss von pränataler körperlicher Bewegung auf Geburtskomplikationen und neonatale Parameter analysiert.

Insgesamt wurden 2286 werdende Mütter rekrutiert (IV: $n = 1152$, C: $n = 1134$). Die Intervention zeigte keinen Einfluss auf den Anteil an Frauen mit exzessiver Gewichtszunahme (IV: 45.1%; C: 45.7%, $p = 0.789$), aber Verbesserungen im pränatalen Bewegungsverhalten. Diese waren vor allem in Bezug auf die Intensität der körperlichen Aktivität zu beobachten. Das Intensitätsniveau der körperlichen Bewegung beeinflusste gewichtsbezogene Parameter der Kinder bei Geburt. Obwohl Frauen aus der Interventionsgruppe eine signifikant höhere Gewichtsabnahme ab der Geburt bis zum 12. Monat pp aufwiesen ($p = 0.008$), waren keine signifikanten Gruppenunterschiede in dem mittleren Gewichtsbehalt der Mütter zu beobachten (IV: $–0.2 \pm 4.8$ kg; C: 0.6 ± 5.2 kg, $p = 0.123$). Eine deutliche Anzahl an Teilnehmerinnen aus beiden Gruppen zeigte einen pp

Gewichtsbehalt über 5 kg und hat demnach ein erhöhtes Risiko für Übergewicht/Adipositas und assoziierte Folgeerkrankungen. Eine signifikant höhere Anzahl an Frauen in der IV stillten ihre Kinder ausschließlich ($p < 0.001$), allerdings war der Gruppenunterschied gering.
Die Ergebnisse der GeliS-Studie bestätigen den dringenden Handlungsbedarf in der zugrundeliegenden Zielgruppe, um einer übermäßigen Gewichtszunahme in der Schwangerschaft und assoziierten Einschränkungen für Mutter und Kind nachhaltig und effektiv vorzubeugen. Die teilnehmenden Mutter-Kind-Paare werden über einen Zeitraum von 5 Jahren nachbeobachtet. Dadurch können der Langzeiteffekt der Intervention sowie potenzielle Einflussfaktoren auf die mütterliche und kindliche Gesundheit über die ersten 5 Lebensjahre nach der Geburt beleuchtet werden.

Abbreviations

ACOG	American College of Obstetrics and Gynecology
App	Smartphone application
BMI	Body mass index
C	Control group
CI	Confidence interval
FeLIPO	Feasibility of a lifestyle-intervention in pregnancy to optimize maternal weight development
GDM	Gestational diabetes mellitus
GEE	Generalised estimating equations
GeliS	‘Gesund leben in der Schwangerschaft’ / ‘healthy living in pregnancy’
GWG	Gestational weight gain
HbA1c	Glycosylated haemoglobin A_{1c}
IOM	Institute of Medicine
IV	Intervention group
i-WIP	The International Weight Management in Pregnancy Collaborative Group 2017
KErn	‘Kompetenzzentrum für Ernährung’ / ‘Competence Centre for Nutrition’
KiGGS	‘German Health Interview and Examination Survey for Children and Adolescents’ / ‘Studie zur Gesundheit von Kindern und Jugendlichen in Deutschland’
LC	Lifestyle counselling
LGA	Large-for-gestational age
MET	Metabolic equivalent of task
OGTT	Oral glucose tolerance test
OR	Odds ratio
PA	Physical activity

pp	Postpartum
PPAQ	Pregnancy Physical Activity Questionnaire
Q	Questionnaire
Q1	Set of questionnaires 1
Q2	Set of questionnaires 2
QS	Screening questionnaire
RCT	Randomised-controlled trial
SGA	Small-for-gestational age
T0	Assessment before or in the 12th week of gestation; time point 0
T1	Assessment after the 29th week of gestation; time point 1
$T1_{pp}$	Time point of the first data collection postpartum (between the 6th and the 8th week postpartum)
$T2_{pp}$	Time point of the second data collection postpartum (at the 12th month postpartum)
TALIA	Total physical activity of light-intensity and above
TUM	Technical University of Munich
UPBEAT	'UK Pregnancies better Eating and Activity Trial'
V0	Screening visit, visit zero
WBCB	Well baby check-up booklet
WHO	World Health Organization

1 Introduction

1.1 Overweight and obesity – a worldwide health problem

Obesity is one of the major public health concerns worldwide and contributes considerably to the global burden of disease (Ezzati et al. 2002; GBD 2015 Eastern Mediterranean Region Obesity Collaborators 2018). According to the World Health Organization (WHO), the worldwide obesity prevalence has nearly tripled between 1975 and 2016. In 2016, 1.9 billion adults were estimated to have a body mass index (BMI) ≥ 25.0 kg/m^2 and were classified as being overweight and 650 million as being obese with a BMI ≥ 30.0 kg/m^2 (World Health Organization 2019). Obesity is described as epidemic and its prevalence substantially increased in almost all countries (NCD Risk Factor Collaboration 2016; World Health Organization 2019).

For the health care systems and their providers, the prevention of overweight and obesity represents a major challenge in particular when considering concomitant comorbidities (Swinburn et al. 2011; Ng et al. 2014). A further concern is the considerable proportion of children and adolescents with overweight and obesity. The 'German Health Interview and Examination Survey for Children and Adolescents' (KiGGS) estimated that around 15% of German children and adolescents have overweight and around 6% obesity (Robert Koch-Institut 2018). Evidence suggests that obesity persists from childhood into adolescence and adulthood (Freedman et al. 2005; Singh et al. 2008; Simmonds et al. 2015). This highlights the urgent need for effective strategies to prevent and cope with both childhood as well as adulthood obesity.

As maternal overweight and obesity were found to strongly contribute to maternal and foetal long-term complications (see 1.2.2), early prevention in young to middle-aged women received growing attention over the last decades (see 1.4.3).

1.2 Maternal pre-pregnancy obesity and excessive gestational weight gain

It has increasingly been recognised that maternal overweight and obesity substantially contribute to the risk for foetal, pregnancy, obstetric and neonatal complications (see 1.2.2). Yet, evidence suggests that not only maternal overweight and obesity before conception but also gestational weight gain (GWG) above a certain threshold, defined as excessive GWG (see 1.2.4), increases the risk for complications. This chapter outlines the scope of maternal pre-pregnancy obesity and excessive GWG.

1.2.1 Epidemiology

In Germany, more than 53.0% of adult women were reported to have overweight. The prevalence of obesity was estimated to be more than 23.0% (Mensink et al. 2013). The proportions were lower in women of reproductive age, but still amounted to 30.0% (overweight) and 9.6% (obesity) in women aged 18 to 29 years and 38.0% (overweight) and 17.9% (obesity) in women aged 30 to 39 years (Mensink et al. 2013). Moreover, total GWG has continuously increased in Germany by more than 2 kg over the last two decades: In 1986 women gained on average 13 kg during pregnancy, while the mean GWG reported in 2006 was 15 kg (Bergmann et al. 2007). Correspondingly, an observational analysis, including clinical routine data of 11771 German women, found that excessive GWG continuously increased from 1996 to 2012. In 2012, excessive GWG was reported for more than 40% of women with singleton pregnancies (Ferrari et al. 2014). Similar findings were reported for Bavaria (Beyerlein et al. 2009). These observations pose a major public health concern with respect to adverse effects of maternal pre-pregnancy overweight/obesity and excessive GWG.

1.2.2 Health consequences for mothers and infants

Pregnancy-induced physiological changes depict a major challenge for the entire metabolism. Obviously, the metabolism of women with overweight/obesity is less likely to compensate and tolerate these adaptations leading to adverse consequences for mothers and the offspring (Neri and Edlow 2015; Roberts et al. 2015). Weight gain above the amount needed for the development of the placenta, physiological adaptations and the foetal development and growth seems to negatively influence the maternal metabolism. This could ultimately result in health impairments (IOM 2009):

Clinical investigations showed that both maternal overweight/obesity and excessive GWG are associated with several pregnancy and obstetric complications, such as gestational diabetes mellitus (GDM), hypertensive disorders or caesarean section, and contribute to the long-term maternal and infant health development in the postpartum (pp) period (Catalano and Ehrenberg 2006; Mamun et al. 2010; Margerison Zilko et al. 2010; Dodd et al. 2011a; Mamun et al. 2014). The combination of both was found to increase the risk for some adverse outcomes, *e.g.* maternal postpartum weight retention (PPWR) (Nohr et al. 2008).

The association between maternal overweight/obesity and excessive GWG and adverse health outcomes has been reported by several observational studies, clinical trials, (systematic) reviews and meta-analyses (Sebire et al. 2001; Ehrenberg et al. 2004; Catalano

and Ehrenberg 2006; Cedergren 2006; Hedderson et al. 2006; Guelinckx et al. 2008; Heslehurst et al. 2008; Nohr et al. 2008; Viswanathan et al. 2008; IOM 2009; Margerison Zilko et al. 2010; Dodd et al. 2011a; Kries et al. 2011; Nehring et al. 2011; Jang et al. 2011; Begum et al. 2012; Nehring et al. 2013; Mamun et al. 2014; Marchi et al. 2015; Poston et al. 2016; Goldstein et al. 2017). **Figure 1** summarises the short- and long-term health consequences that may be triggered by pre-pregnancy overweight/obesity or excessive GWG.

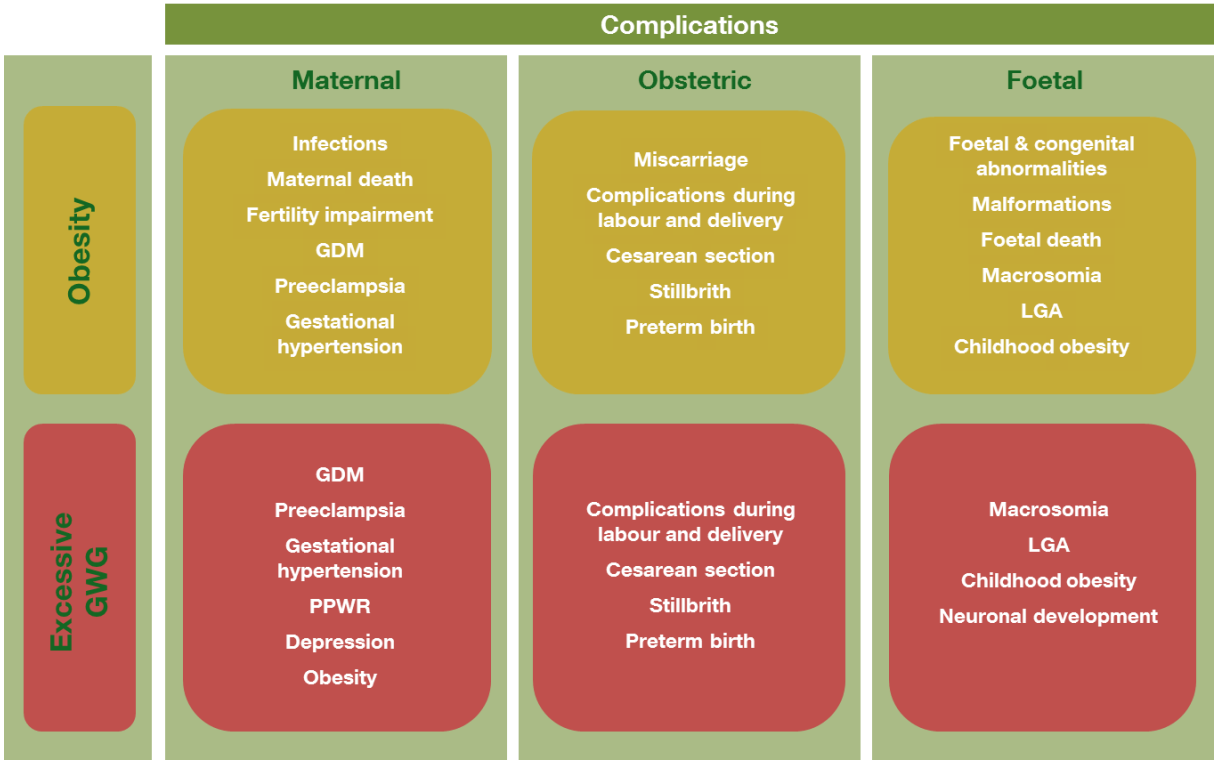

Figure 1: Health consequences of maternal overweight/obesity and excessive GWG
Abbreviations: GDM: gestational diabetes mellitus; GWG: gestational weight gain; LGA: large-for-gestational age; PPWR: postpartum weight retention.
Data source: own contribution.

The influence of maternal pre-pregnancy overweight/obesity on infant health outcomes might be explained by the concept of foetal programming. This concept hypothesises that the intrauterine environment might trigger metabolic adaptations of the offspring. These are discussed to be associated with lifelong adverse health outcomes (Paes et al. 2016).

1.2.3 Foetal programming and the vicious cycle of obesity

The concept of foetal programming describes a complex interaction between maternal physiological and environmental factors that might be responsible for transmitting metabolic traits into the next generation through an intrauterine programming of the foetal metabolism

(Barker 1990; Battista et al. 2011). This concept was firstly introduced by David Barker (1990) who described 'critical periods of development' *in utero* through which a foetal organism has to pass. During these periods, certain maternal stimuli, such as hormones or oxidative stress, might trigger foetal adaptations to the intrauterine environment which could increase its susceptibility for metabolic diseases later in life (Barker 1990, 1998; Battista et al. 2011). On the molecular level, the underlying processes are still not completely understood. There is evidence that the intrauterine programming is triggered by epigenetic alterations (Waterland and Jirtle 2003; Yajnik 2010). However, current findings are mainly based on animal experiments (Neri and Edlow 2015).

In this context, cohort studies described the influence of maternal under- and overnutrition on infant birth weight and childhood obesity (Barker 1998; Ravelli et al. 1999; Roseboom et al. 2001; McMillen et al. 2004; Heerwagen et al. 2010). Growing evidence suggests an intergenerational cycle of obesity mediated through maternal overweight/obesity and excessive GWG. Both are discussed to be risk factors for elevated birth weight which ultimately increase the risk for child- and adulthood obesity (Oken et al. 2008; Battista et al. 2011; Dabelea and Crume 2011; Simmonds et al. 2015): Women with obesity give birth to heavier daughters who are more likely to become obese during their reproductive age and thus impose an increased risk for metabolic adaptations and elevated birth weight on their offspring. This is described by researchers as a 'vicious cycle of obesity' (Dabelea and Crume 2011).

In consideration of the global obesity epidemic, efficacious and effective approaches are urgently needed to intervene against the vicious cycle of obesity and to prevent excessive GWG.

1.2.4 Recommendations for gestational weight gain

In order to give concrete recommendations, the U.S. Institute of Medicine (IOM) published guidelines for adequate GWG in 1990. These have been revised in 2009 based on new evidence in this field (IOM 2009).

The IOM guidelines define the recommended range of weight gain according to a woman's pre-pregnancy BMI (**Table 1**). Gaining weight below ranges is defined as inadequate, within as adequate and above as excessive GWG (IOM 2009).

Table 1: Recommendations for adequate weight gain during pregnancy according to the IOM

Weight category	Pre-pregnancy BMI [kg/m²]	Weight gain recommendations [kg]
Underweight	< 18.5	12.5–18.0
Normal weight	18.5–24.9	11.5–16.0
Overweight	25.0–29.9	7.0–11.5
Obesity	≥ 30.0	5.0–9.0

Abbreviations: BMI: body mass index; IOM: Institute of Medicine.
Recommendations provided by the IOM (IOM 2009).

Given that uniform recommendations for adequate GWG are lacking, the IOM guidelines provide a reasonable orientation for primary care. In relation to the high prevalence of excessive GWG and associated health risks, health care providers should be encouraged to counsel pregnant women about adequate GWG according to the IOM.

1.3 Beyond pregnancy: Postpartum weight retention

Analogous to weight changes in the antenatal period, maternal weight is constantly subject to changes during the pp period. At birth, the weight of the foetus, the placenta and the amniotic fluid is lost (IOM 2009). In the subsequent 6 weeks after birth, the extracellular and extravascular water gets lost, the plasma volume normalises and the uterus returns to its normal size. Weight remaining beyond pre-pregnancy weight is mainly attributed to body fat stores and described as PPWR (IOM 2009; McKinley et al. 2018).

PPWR is defined as the difference between maternal weight at a certain pp time point and pre-pregnancy or early pregnancy weight (IOM 2009). PPWR decreases gradually during the first year pp (Schmitt et al. 2007; Gunderson 2009), but not every women reaches the pre-pregnancy weight: A study, which investigated pp weight development in a Swedish cohort, found that women retaining more than 2.2 kg weight at the 12th month pp retained this additional weight 15 years after delivery (Linné et al. 2004). Moreover, approximately 25% of women were reported to retain more than 4.55 kg (Olson et al. 2003; Lipsky et al. 2012) or more than 5 kg (Bogaerts et al. 2017b) at the 12th month pp. PPWR above 4.55 kg or 5 kg is defined as ‘substantial’ or ‘relevant’ PPWR and commonly used as marker for clinically significant PPWR. Accordingly, relevant PPWR but also mild to moderate PPWR, have been shown to increase the risk for long-term health complications including continuous weight gain, and overweight and obesity in the future (Gunderson and Abrams 1999; Gore et al. 2003; Olson et al. 2003; Mamun et al. 2010).

Various factors have been discussed as potential predictors of maternal PPWR. Excessive GWG seems to be the most important determinant of short- and long-term PPWR (Margerison Zilko et al. 2010; Nehring et al. 2011; Mannan et al. 2013; Rong et al. 2015). Nehring et al. (2011) reported in a meta-analysis that women with GWG above the IOM recommendations had 3.06 kg more weight at 3 years pp and 4.72 kg more weight after more than 15 years pp compared to women with GWG within the IOM recommendations. Apart from GWG, breastfeeding was shown to play a fundamental role in the pp weight development and was found to reduce PPWR (Baker et al. 2008; Tahir et al. 2019). The duration of breastfeeding in turn is discussed to decrease the risk for maternal overweight later in life (Harder et al. 2005). Further factors such as parity, educational level, the maternal mental state and the socioeconomic background are considered as potential determinants of PPWR, but evidence is still inconclusive (Hollis et al. 2017).

PPWR is discussed to imply adverse consequences for a successive pregnancy as it is accompanied by an increase in inter-pregnancy BMI (**Figure 2**). It is estimated that one out of five women move into a higher BMI category at 18 months pp, irrespective of their pre-pregnancy BMI (Crosby et al. 2015). An increase in inter-pregnancy BMI may result in entering a subsequent pregnancy with overweight or obesity. This places women at a higher risk for pregnancy, obstetric, and neonatal complications (see 1.2.2; **Figure 2**). Inter-pregnancy weight gain affects a considerable proportion of women. It is suggested that PPWR together with inter-pregnancy weight gain strongly contribute to the development of obesity (McKinley et al. 2018; Sumithran et al. 2018).

This underlines the urgent demand for strategies to tackle obesity progression as early as possible. Approaches should encompass the prevention of excessive GWG as well as PPWR in order to lower the obesity risk for both mothers and their infants.

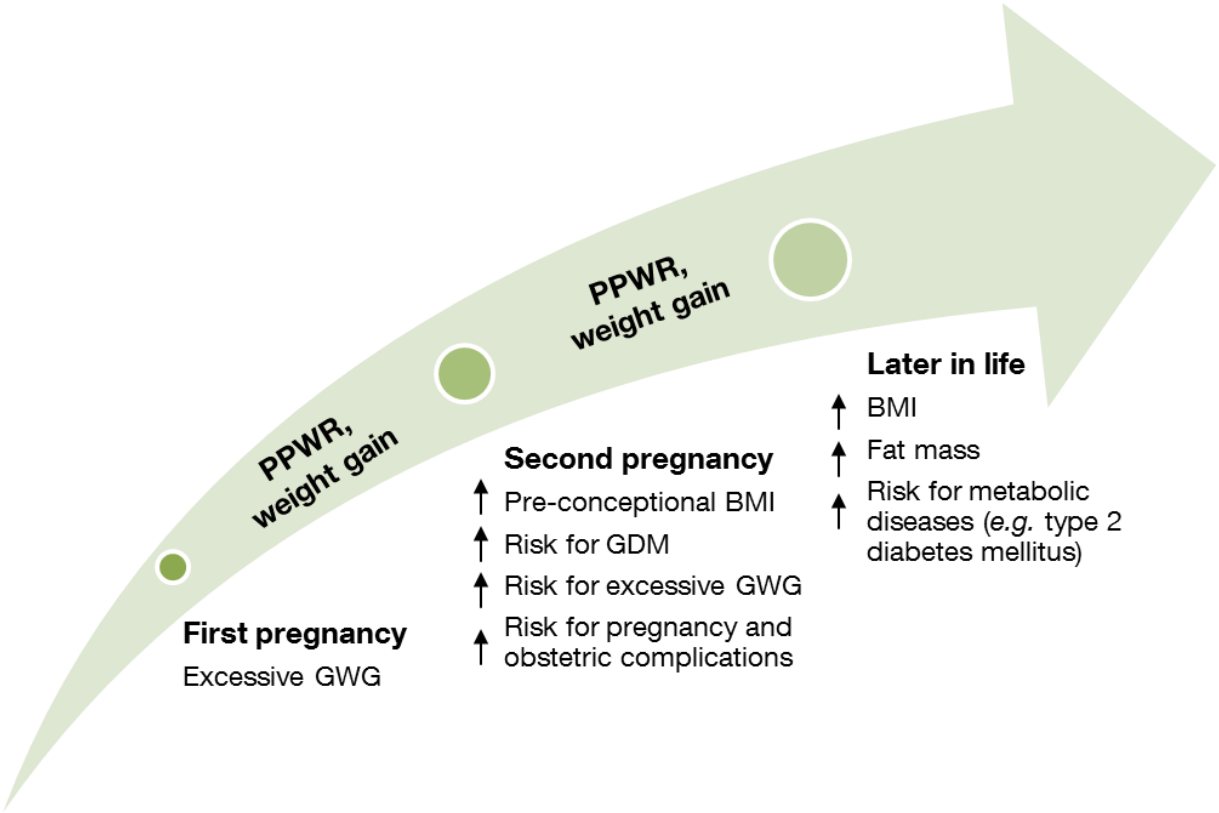

Figure 2: PPWR and inter-pregnancy weight gain
Abbreviations: BMI: body mass index; GDM: gestational diabetes mellitus; GWG: gestational weight gain; PPWR: postpartum weight retention.
Data source: own contribution.

1.4 Lifestyle during pregnancy and the postpartum period

Pregnancy has been recognised as a 'teachable moment', a period in which women are highly motivated to adopt a risk-reducing health behaviour (Phelan 2010; Ronnberg and Nilsson 2010). Moreover, the pp period has been described as a time when women may increasingly be aware of their own health and the health of their families (McKinley et al. 2018). For health care professionals, the antenatal and early pp period may represent a 'window of opportunity'. Thus, it may be the optimal time to shape new health behaviours in order to prevent excessive GWG, PPWR, and associated adverse consequences including the progression to long-term obesity.

The contribution of a healthy antenatal and pp lifestyle on long-term maternal and infant health has reached increasing awareness worldwide. A healthy ante- and postnatal lifestyle is mainly characterised by a balanced diet, regular physical activity (PA) and a general health-conscious behaviour. As prenatal PA is a major focus of this thesis, its beneficial effects on maternal and infant health are emphasised in the following.

1.4.1 Beneficial effects of prenatal physical activity

The former opinion about negative maternal and foetal consequences of prenatal PA has changed. For uncomplicated pregnancies, several beneficial effects have been recognised over the last decades. This led the 'American College of Obstetrics and Gynecology' (ACOG) to state that 'physical activity in pregnancy is safe and desirable, and pregnant women should be encouraged to continue or to initiate safe physical activities' (ACOG 2015, page e136):

Pregnancy induces anatomic and physiological changes that affect the cardiovascular, respiratory and muscular system and frequently lead to discomfort (ACOG 2015). Back pain, as an example, is a problem commonly experienced by pregnant women (Wang et al. 2004). Back strengthening exercises are highly recommended for pregnant women as they lower the risk for back pain (ACOG 2015). There are further outcomes that are discussed to be beneficially influenced by prenatal PA, such as the cardiorespiratory fitness, the antenatal well-being or the risk for pp depression, the cardiovascular function and the risk for hypertension and preeclampsia, the mode of delivery as well as infant birth weight (Da Costa et al. 2003; Dempsey et al. 2005; Nascimento et al. 2012; Domenjoz et al. 2014; Barakat et al. 2016; Bisson et al. 2016; Bisson et al. 2017; Nakamura et al. 2019).

Probably the best studied pregnancy complication that can beneficially be influenced by PA is GDM: An active lifestyle before pregnancy has been found to reduce insulin resistance and to improve the glucose tolerance in late pregnancy (Hopkins and Artal 2013). A recent meta-analysis described a significant reduction of the risk for GDM in women being physically active before pregnancy or during early pregnancy (Aune et al. 2016). In particular leisure-time PA was shown to lower the risk of GDM (Dempsey et al. 2004; Badon et al. 2016). Sedentary behaviour and inactivity are discussed to increase the risk for the development of GDM, but evidence is inconclusive (Oken et al. 2006; Fazzi et al. 2017). Furthermore, PA and in particular aerobic training was found to lower blood glucose levels in women who developed GDM (Brankston et al. 2004).

Apart from GDM, several observational studies sought to explain the relationship between PA and GWG. Albeit a study found no association between prenatal PA and GWG or excessive GWG in hispanic women (Chasan-Taber et al. 2014), others identified PA to be protective for excessive GWG (Streuling et al. 2011; Sanabria-Martínez et al. 2015; Ruchat et al. 2018). Women with a sedentary behaviour before pregnancy were found to have a higher GWG (Skreden et al. 2016). However, the effect of sedentary behaviour during pregnancy on GWG is not well discussed (Fazzi et al. 2017). A recent meta-analysis

assessed the effect of prenatal PA beyond pregnancy. Therein, Ruchat et al. (2018) reported that exercise-only interventions during pregnancy are effective at lowering PPWR although the quality of evidence was defined as ‘low’ to ‘moderate’.

As outlined herein, PA is one key component of the antenatal lifestyle that is responsible for the improvement or prevention of several pregnancy-induced complications. Thus, pregnant women should be encouraged to be physically active in both the prenatal as well as the pp period.

1.4.2 Dietary, physical activity and breastfeeding recommendations

In Germany, the network ‘Healthy Start – Young Family’, which is supported by the German government, developed nationwide recommendations for a healthy antenatal and pp lifestyle, adequate GWG as well as breastfeeding behaviour (Koletzko et al. 2012; Koletzko et al. 2016; Koletzko et al. 2018). In the following, these recommendations are summarised.

Dietary recommendations for the antenatal period, including energy and nutrient requirements for pregnant women, are outlined. Recommendations for the supplementation of critical nutrients, such as folic acid and iodine, are given. Healthy food choices, such as a preferred intake of whole grain or low-fat dairy products, are elucidated. Additionally, the pros and cons of an ovo-lacto vegetarian diet are discussed and the concerns over a vegan diet are extensively addressed. Recommendations to prevent food-borne diseases are given. Moreover, the importance of an adequate nutrition during pregnancy for the prevention of infant allergies is outlined. The recommendations cover the importance of alcohol and nicotine abstinence, and the limitation of caffeine intake including the consumption of caffeinated beverages. Particular nutritional requirements during lactation are extensively addressed (Koletzko et al. 2012; Koletzko et al. 2016; Koletzko et al. 2018).

The German recommendations for the pre- and postnatal ***physical activity behaviour*** mainly correspond to guidelines of the ACOG. Within these recommendations, beneficial effects of maternal antenatal PA behaviour on both maternal as well as infant health are described. According to the ACOG, there are some contraindications for prenatal PA (**Table 2**)**.** Women with obstetric or medical contraindications should consult a health care provider before engaging in PA.

Table 2: Absolute and relative contraindications to exercise during pregnancy
Adapted from ACOG (2015).

Absolute contraindications	Relative contraindications
Hemodynamically significant heart disease	Anemia
Restrictive lung disease	Maternal cardiac arrhythmia
Incompetent cervix	Chronic bronchitis
Multiple gestation at risk of premature labour	Poorly controlled type 1 diabetes mellitus
Persistent second- or third-trimester bleeding	Extreme morbid obesity
Placenta previa after 26 weeks of gestation	Extreme underweight (BMI < 12.0 kg/m^2)
Premature labour during the current pregnancy	History of extremely sedentary lifestyle
Ruptured membranes	Intrauterine growth restriction in current pregnancy
Preeclampsia or pregnancy-induced hypertension	Orthopedic limitations
Severe anemia	Poorly controlled seizure disorder
	Poorly controlled hyperthyroidism
	Heavy smoker

In case of uncomplicated pregnancies, women should be encouraged to be physically active and are recommended to engage at least 30 minutes in moderate-intensity PA on most days. Moderate intensity is reached when still being able to converse while exercising / being active (talk test). It is suggested to reach the recommended PA level by simple changes in the daily routine, such as walking instead of taking the bus, or taking the bike instead of the car. Women should avoid sedentary behaviour and should maintain the level of daily routine activity (Koletzko et al. 2012; ACOG 2015; Koletzko et al. 2018).

Previously inactive women should be encouraged to increase their PA level in pregnancy. It is recommended to perform low-impact endurance exercises, such as swimming, walking, cycling or aquatic exercise instead of weight-bearing sports. Inappropriate types of sports comprise activities with a high risk for injuries and falls, such as contact or fighting sports (Koletzko et al. 2012). **Table 3** summarises activities that are described as ‘safe’ and that should be maintained or initiated as well as activities that are defined as ‘unsafe’ and should be avoided (ACOG 2015).

Compared to prenatal PA recommendations, recommendations for the period of lactation are less concrete. Therein, an early start of PA dependent on the maternal health status is suggested (Koletzko et al. 2012; Koletzko et al. 2016; Koletzko et al. 2018).

Table 3: Examples of safe and unsafe prenatal physical activities
Adapted from ACOG (2015).

Safe activities during pregnancy	Unsafe activities during pregnancy
Walking	Contact sports (*e.g.* ice hockey, boxing, soccer, and basketball)
Swimming	Activities with a high risk of falling (*e.g.* downhill and water skiing, surfing, and horseback riding)
Stationary cycling	Scuba diving
Low-impact aerobics	Particular positions of yoga or pilates
Yoga, modified[a]	
Pilates, modified	
Running or jogging[b]	
Strength training[b]	

[a] Some yoga positions result in decreased venous return and hypotension and should be avoided.
[b] Running, jogging and strength training may be safe for pregnant women who regularly engaged in these activities before pregnancy. However, consultation of health care provider required.

The German ***breastfeeding recommendations*** outline the importance of breastfeeding for maternal and infant health. Exclusive breastfeeding is recommended at least until the end of the 4th month after delivery. Complementary feeding should be introduced not later than at the beginning of the 7th month after delivery. Furthermore, strategies to overcome barriers of breastfeeding together with advice on the introduction of complementary feeding are given (Koletzko et al. 2016).

1.4.3 Lifestyle interventions to prevent excessive gestational weight gain and postpartum weight retention

Considerable effort has been made to reveal strategies that are effective in preventing perinatal complications and long-term health impairments through antenatal and pp lifestyle changes. National and international guidelines on an adequate prenatal lifestyle provided the basis for several randomised-controlled trails (RCTs) that have been initiated within the last decades. In the following, specific characteristics of some RCTs are summarised which serve as examples for current investigations in this field of interest.

RCTs provided pregnant women with information and advice on a healthy lifestyle. However, the applied ***methods*** are diverse. Some interventions focused exclusively on dietary behaviour (Wolff et al. 2008; Walsh et al. 2012), while others aimed to improve PA pattern (Sedaghati et al. 2007; Barakat et al. 2009; Jackson et al. 2011), or offered a comprehensive lifestyle programme addressing both diet and PA behaviour (Jackson et al.

2011; Phelan et al. 2011; Rauh et al. 2013; Dodd et al. 2014b; Hui et al. 2014; Poston et al. 2015). The methods how lifestyle information was delivered, varied from brochures, individual plans, exercise sessions to group or face-to-face counselling, e-mail, telephone- or video-based counselling as well as to the provision of specifically established smartphone applications (apps) (Dodd et al. 2011b; Jackson et al. 2011; Phelan et al. 2011; Rauh et al. 2013; Sagedal et al. 2013; Briley et al. 2014; Poston et al. 2015; Dodd et al. 2018; Henriksson et al. 2019; Rissel et al. 2019). The intensity of the lifestyle interventions differed in terms of the duration and frequency of the sessions. Some started already in the early antenatal period, others in late pregnancy. The duration of counselling ranged from 15 minutes to 1.5 hours. Some approaches exclusively focused on the antenatal period, while others also provided support after birth (Althuizen et al. 2006; Phelan et al. 2011; Rauh et al. 2013; Briley et al. 2014). Health care providers with different professional background (nurses, gynaecologists, PA and dietary experts) were included as lifestyle coaches to support several target groups (Dodd et al. 2011b; Rauh et al. 2013; Briley et al. 2014). While some trials specifically recruited women with overweight or obesity (Dodd et al. 2011b; Quinlivan et al. 2011; Poston et al. 2015), others included women within all BMI categories (Rauh et al. 2013; Hui et al. 2014).

Although all trials sought to optimise the antenatal lifestyle of the mother-to-be, different ***study outcomes*** were chosen. Some studies primarily aimed at decreasing the GDM incidence or adverse neonatal outcomes (Briley et al. 2014; Rönö et al. 2014), whereas others aimed to prevent excessive GWG (Phelan et al. 2011; Rauh et al. 2013; Hui et al. 2014) together with the prevention of PPWR (Althuizen et al. 2013).

Among ***RCTs*** that reported GWG data, some found significant evidence for a lower proportion of women with *excessive GWG* (Phelan et al. 2011; Rauh et al. 2013). Other trials failed to provide sufficient evidence on an intervention effect on GWG (Althuizen et al. 2013; Dodd et al. 2014b). Research suggests that these contradictory findings may result from the different weight categories of target populations. Some reported significant differences in the subgroup of women with overweight and obesity but not with normal weight (Althuizen et al. 2013). Others observed favourable trends in women with normal weight but not with overweight/obesity (Rauh 2013). In contrast to this, some trials recruiting exclusively women with overweight and/or obesity showed beneficial interventions effects on GWG (Wolff et al. 2008; Quinlivan et al. 2011; McGiveron et al. 2014; Poston et al. 2015), but evidence remains contradictory (Dodd et al. 2014b; Hui et al. 2014).

Some trials followed the women in the pp period and reported data on *maternal PPWR* as a secondary outcome. However, findings on the effect of lifestyle interventions on PPWR are inconsistent: While some lifestyle interventions beneficially influenced PPWR (Huang et al. 2011; Phelan et al. 2014), others found no evidence for an improvement of maternal pp weight characteristics (Althuizen et al. 2013; Rauh et al. 2015). The comparison of study results is complicated by the huge heterogeneity in study designs and primary outcomes.

In order to elucidate the inconclusive opinion on the influence of lifestyle interventions on GWG and PPWR, several ***meta-analyses*** have been performed. Some support the hypothesis that dietary interventions alone are successful in limiting excessive GWG (Thangaratinam et al. 2012b). Others showed that interventions focusing exclusively on PA behaviour lower the risk for excessive GWG (Elliott-Sale et al. 2015). Muktabhant et al. (2015) concluded from their systematic review that combined lifestyle interventions including both dietary and PA advices were most successful in optimising GWG. Two other meta-analyses supported this observation by reporting beneficial effects on GWG by interventions focusing on diet and PA (Streuling et al. 2010; Agha et al. 2014). Agha et al. (2014), who included only women with obesity (n=1771), reported an average reduction in GWG of -1.66 kg (95% confidence interval (CI) –3.12 to –0.21 kg) due to the intervention. However, when considering exclusively studies determined as 'high quality studies', the significance of this observation disappeared. Conflicting findings of meta-analyses on the study level might result from the absence of published details about study designs. Moreover, it has been rarely analysed which subgroups of women benefited the most (Thangaratinam et al. 2012a; O'Brien et al. 2019).

To overcome this lack of evidence, the 'International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017' recently conducted a meta-analysis using raw data on the individual level. The purpose was to investigate the effect of interventions providing diet, or PA advices or both on several pregnancy and neonatal outcomes. In total, 12526 individual participant data of 36 RCTs were included in the analysis. Researchers performed subgroup analyses by dividing women into different BMI categories. Diet- and PA-based interventions were found to lower GWG by –0.70 kg (95% CI –0.92 to –0.48 kg) irrespective of the pre-pregnancy BMI. There was no evidence that women with normal weight would benefit more from the intervention than women with overweight or obesity (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). Moreover, recent findings suggest that the success of the intervention depends on the educational level of women (O'Brien et al. 2019).

In recent years, some systematic reviews and few meta-analyses have been published that investigated the impact of lifestyle interventions on maternal PPWR. While some failed to provide sufficient evidence of an intervention effect (Elliott-Sale et al. 2015; Muktabhant et al. 2015), others reported promising findings (Choi et al. 2013; van der Pligt et al. 2013; Agha et al. 2014; Shepherd et al. 2017). Ultimately, none of them examined the long-term influence of interventions or performed subgroup-analyses in women with overweight or obesity. Recently, colleagues from the Institute of Nutritional Medicine (Technical University of Munich (TUM)) conducted a systematic review and a subsequent meta-analysis in order to close this gap of knowledge. Overall, 14 RCTs with data from 7116 participants were included (Michel et al. 2018). The researchers found significant evidence that weight-related lifestyle interventions, which began in pregnancy, yielded an overall lower PPWR of –0.73 kg (95% CI −1.32 to −0.14 kg; p = 0.015) compared to standard care. The greatest weighted mean difference between women in the intervention and control groups was observed at 4 to 6 months pp with a difference of –1.32 kg (95% CI −2.11 to −0.53 kg; p = 0.001). The intervention effect decreased, but remained statistically significant when assessing PPWR at 12 months pp (–0.68 kg, 95% CI −1.28 to −0.09 kg; p = 0.023). In studies, where only women with overweight or obesity were included, the effect on maternal PPWR was missing (Michel et al. 2018). Although the authors were able to report beneficial effects of antenatal interventions on PPWR, they questioned the clinical relevance of the results and emphasised a general lack of reporting substantial PPWR.

Research outlined above suggests some beneficial effects of lifestyle interventions during pregnancy on both overall GWG and long-term PPWR. Notwithstanding, only a limited number of RCTs with small sample sizes have been conducted outside academic settings or under real-life conditions (Kinnunen et al. 2008; Harrison et al. 2013; Daley et al. 2016). Thus, there is a gap between the proof-of-concept reported by some RCTs as well as meta-analyses and the successful implementation of lifestyle interventions into routine antenatal care. Hence, it remains a challenge to establish primary care strategies for the prevention of excessive GWG, PPWR, and associated long-term health impairments of mothers and their infants. This is in particular important when considering their contribution to inter-pregnancy weight gain, the vicious cycle of obesity, and their overall impact on the obesity epidemic.

In Germany, researchers of the Institute of Nutritional Medicine at the TUM conducted a pilot trial named ‘Feasibility of a lifestyle-intervention in pregnancy to optimize maternal weight development’ (FeLIPO). This trial was embedded into the German antenatal care setting. The primary aim was to prevent excessive GWG as defined by the IOM. Secondary

aims included an improvement in dietary and PA behaviour, in several infant outcomes (*e.g.* small-for-gestational age (SGA) or large-for-gestational age (LGA)) as well as in maternal PPWR. In total, 250 participants were recruited. Participants in the control group (n = 83) obtained usual care. In contrast to this, participants in the intervention group (n = 167) received a low-impact lifestyle intervention consisting of two structured counselling sessions on a healthy diet and regular PA behaviour during pregnancy. These sessions were given by one dietary expert. Analyses showed that a lower proportion of women in the intervention group gained weight above the IOM recommendations compared to the control group (38% vs. 60%; adjusted p = 0.032; Rauh et al. 2013). Women in the intervention group tended to have a lower PPWR at the 4th (2.1 kg vs. 3.3 kg; adjusted p = 0.070) and 12th month pp (0.2 kg vs. 0.8 kg; adjusted p = 0.402). At both time points, there was significant evidence for a lower proportion of women with clinically relevant PPWR in the intervention compared to the control group (Rauh et al. 2013; Rauh et al. 2015). Apart from maternal weight characteristics, the FeLIPO trial reported no major improvements in obstetric and neonatal outcomes such as SGA, LGA or delivery mode. However, some beneficial effects on maternal energy intake and average PA level were found (Rauh et al. 2013; Rauh et al. 2015). In conclusion, the FeLIPO pilot trial demonstrated promising results on the prevention of excessive GWG and relevant PPWR and proved the efficacy and feasibility of a lifestyle intervention alongside antenatal routine care in Germany. Thus, it remains to assess the FeLIPO concept on a broader scale.

The ‘Gesund leben in der Schwangerschaft’ / ‘healthy living in pregnancy’ (GeliS) trial aimed to scale up the FeLIPO concept and forms the basis of this work.

2 Aim of the thesis

The GeliS study was designed aiming to reduce the proportion of women with excessive GWG and targeted to prevent short- and long-term pregnancy, obstetric and neonatal complications by offering a comprehensive lifestyle intervention alongside antenatal routine care. This work presents data on primary and secondary outcomes of the GeliS study, which are addressed in four different chapters (**Figure 3**).

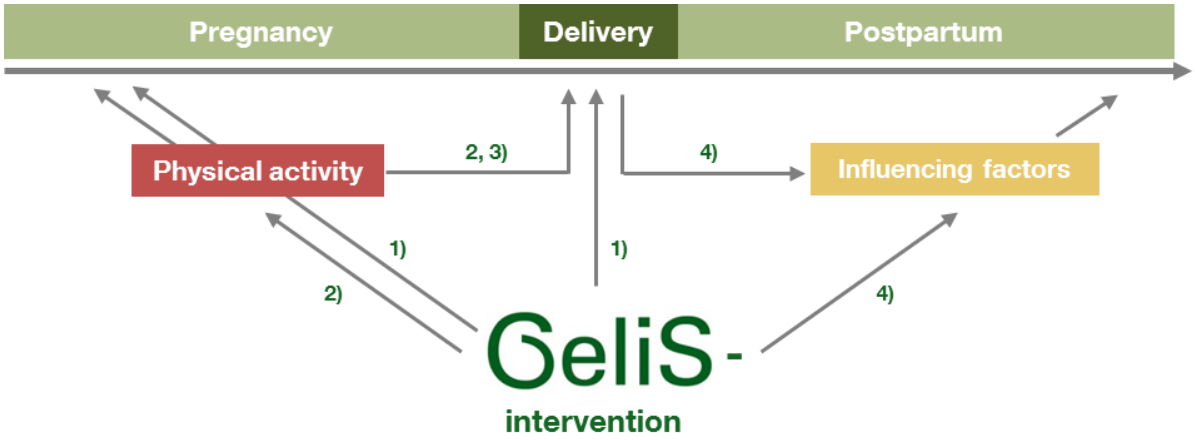

Figure 3: Schematic view of aims of this thesis

The major aims of this thesis addressed in the four chapters are:

1) To assess the effect of the GeliS lifestyle intervention on maternal GWG, and pregnancy, obstetric and neonatal outcomes (Chapter 4.1).
2) To assess the effect of the GeliS lifestyle intervention on prenatal PA and to investigate the influence of prenatal PA on GWG in the pooled cohort (Chapter 4.2).
3) To investigate associations between prenatal PA and neonatal and obstetric outcomes on the cohort level (Chapter 4.3).
4) To assess the effect of the GeliS intervention on short- and long-term PPWR and on maternal breastfeeding behaviour as well as to identify determinants of long-term PPWR and breastfeeding (Chapter 4.4).

This work describes the effect of the GeliS intervention beyond its implications on the primary outcome and seeks to derive suggestions for both a successful implementation within routine care and future research on long-term maternal and infant health.

3 Methods

3.1 Design and setting

Designed as a public health project, the GeliS study targeted to reduce adverse maternal and infant health outcomes in the pre- and perinatal as well as in the pp period by providing a comprehensive lifestyle intervention for pregnant women. The primary aim was to reduce the proportion of women with excessive GWG. Further goals were to improve maternal dietary, PA and breastfeeding behaviour and maternal PPWR (Rauh et al. 2014).

The GeliS study is a prospective, multicentre, cluster-randomised, controlled, open intervention trial, which was carried out in five administrative regions in Bavaria (Germany). The study was conducted within the routine prenatal health care system (Rauh et al. 2014). Cluster-randomisation was performed by randomly matching two districts (clusters) per region according to birth figures, sociodemographic and geographic criteria. This resulted in one control and one intervention district per region. Both urban and rural areas were included in these districts. Participants recruited in any of the control districts form together the control group (C) and participants recruited in intervention districts the intervention group (IV). The recruitment as well as all study procedures were executed in gynaecological and midwifery practices. Further details about the design, setting and randomisation have been described previously (Rauh et al. 2014).

The study was performed according to the ‘Declaration of Helsinki’ and to local regulatory requirements and laws. The study protocol was approved by the ethics committee of the TUM (project number 5653/13) and was retrospectively registered at the ClinicalTrials.gov Protocol Registration System (NCT01958307; U.S. National Library of Medicine - ClinicalTrials.gov).

3.2 Study population

In order to assess the primary outcome with a power of 90% using a significance level of 0.05 and taking into account a drop-out rate of 20% as well as possible intergroup imbalances, the aim was to recruit a total number of 2500 participants (1250 per group). The recruitment took place from 2013 to 2015. Due to a lower drop-out rate than expected, the recruitment phase was terminated after the inclusion of 2286 women (Kunath et al. 2019).

3.2.1 Recruitment and screening

The recruitment was performed in 71 gynaecological and midwifery practices. During a screening visit (V0), practice personnel informed women before the end of the 12th week of gestation about the purpose of the study as well as the study procedures and asked them to complete a screening questionnaire (QS). The purpose of the QS was to collect anthropometric, anamnestic and demographic information. Based on this information, inclusion and the exclusion criteria were verified (Rauh et al. 2014).

3.2.2 Inclusion and exclusion criteria

Inclusion and exclusion criteria are shown in **Table 4**. Eligible were women with a stage of pregnancy before the end of the 12th week, aged between 18 and 43 years, a pre-pregnancy BMI ≥18.5 kg/m^2 and ≤ 40.0 kg/m^2, a singleton pregnancy and sufficient German language skills. All participants gave their written informed consent before participating in the study (Rauh et al. 2014).

Table 4: Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
Gestational age ≤ 12th week of gestation	Multiple pregnancy
Age between 18 and 43 years	High risk pregnancy (*e.g.* placenta previa)
Pre-pregnancy BMI ≥18.5 kg/m^2 and ≤ 40.0 kg/m^2	Pre-pregnancy diabetes mellitus or early GDM
Singleton pregnancy	Uncontrolled chronic disease (*e.g.* thyroid dysfunction)
Sufficient German language skills	Psychiatric or psychosomatic disease

Abbreviations: BMI: body mass index; GDM: gestational diabetes mellitus.

3.2.3 Intervention and control groups

In addition to usual care, the C obtained basic information on a healthy antenatal lifestyle and the importance of breastfeeding within a flyer. In comparison to this, participants of the IV received a comprehensive lifestyle intervention programme (Rauh et al. 2014).

3.3 Curriculum of the GeliS trial and lifestyle intervention programme

Figure 4 shows the curriculum of the GeliS study including time points of counselling sessions, laboratory examinations and timing and mode of data collection in the pre- and postnatal period. Details on the curriculum of the GeliS trial and counselling contents have already been described elsewhere (Rauh et al. 2014; Günther et al. 2019a; Hoffmann et

al. 2019a; Hoffmann et al. 2019b; Hoffmann et al. 2019c; Kunath et al. 2019). In the following, the schedule of the GeliS study is briefly introduced.

Within a two-days seminar, medical personnel, midwives and gynaecologists received background information on an adequate GWG, a healthy pre- and postnatal lifestyle and the recommended breastfeeding behaviour. These training sessions qualified them as counsellors for the GeliS trial and enabled them to provide the lifestyle intervention programme for women in the IV (Rauh et al. 2014).

The lifestyle intervention programme consisted of three structured and standardised face-to-face counselling sessions during pregnancy and one visit pp which were given at predefined time points (12^{th}–16^{th}, 16^{th}–20^{th}, 30^{th}–34^{th} week of gestation, 6^{th}–8^{th} week pp; **Figure 4**). In the first and second counselling session, counselling content mainly focused on adequate GWG according to recommendations of the IOM (IOM 2009), and a healthy antenatal dietary and PA behaviour in accordance with recommendations for the prenatal period (Koletzko et al. 2012; ACOG 2015; Koletzko et al. 2016). Moreover, the risks of alcohol, smoking and foodborne infections as well as the need to supplement critical nutrients were addressed. In the third counselling session, the main emphasis was on the importance of breastfeeding for the maternal and infant well-being. Furthermore, advice how to maintain a healthy and active lifestyle in the pp period was given. The counselling session in the pp period included information on breastfeeding and the introduction of complementary food. For all counselling sessions, counsellors were instructed to respond to questions and behavioural patterns of participants individually (Rauh et al. 2014).

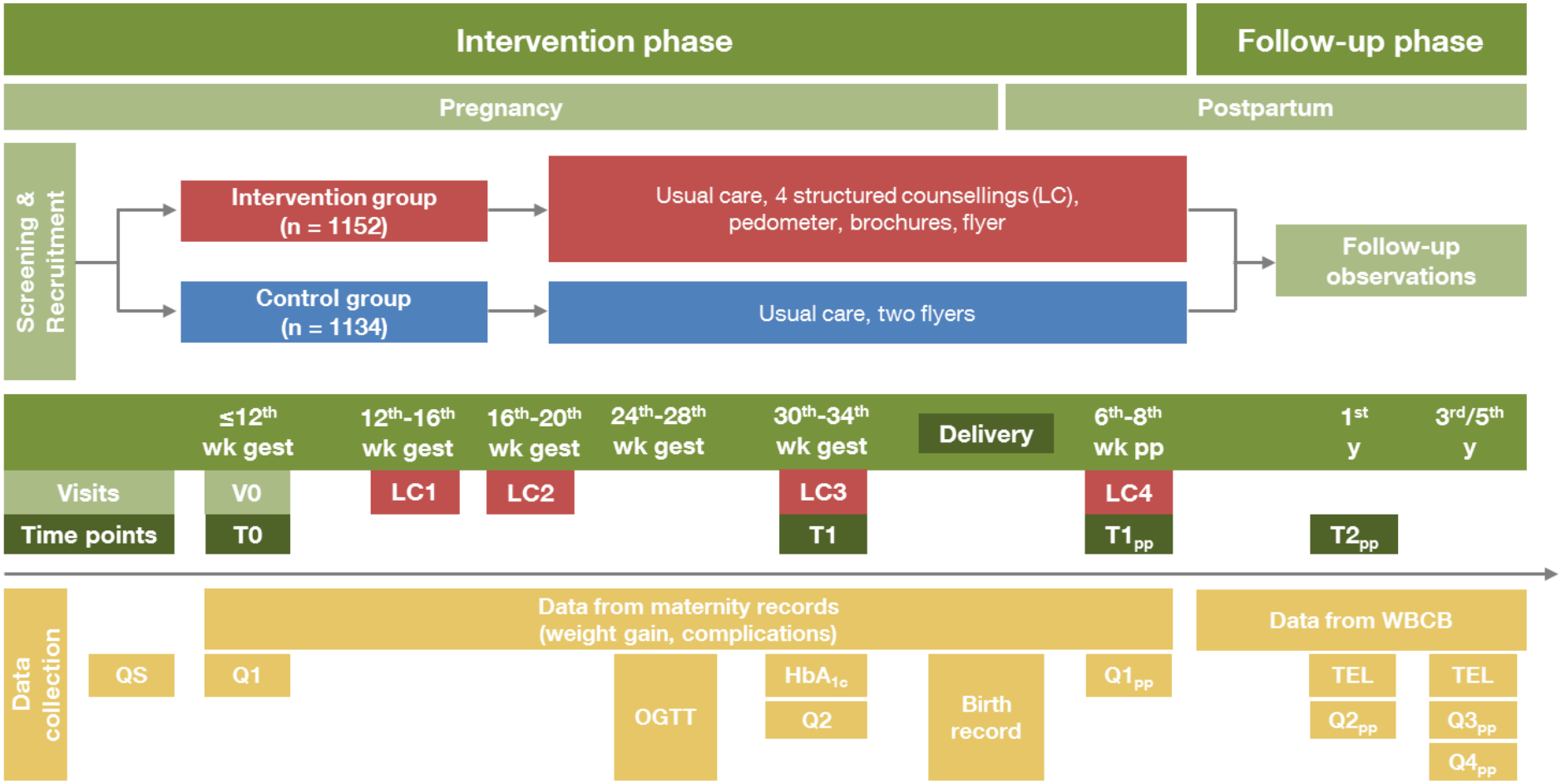

Figure 4: Scheme of the GeliS trial
HbA_{1c}: glycosylated haemoglobin A_{1c}; LC: lifestyle counselling session; OGTT: oral glucose tolerance test; pp: postpartum; Q: questionnaire; QS: screening questionnaire; T: time point; $T1_{pp}$: time point of the first data collection postpartum (between the 6th and 8th week pp); $T2_{pp}$: time point of the second data collection postpartum (at the 12th month postpartum); TEL: telephone call; V: visit; WBCB: well baby check-up booklet; wk gest: weeks of gestation; y: year. Data source: own contribution.

Apart from the counselling sessions, women in the IV were encouraged to monitor their weight gain weekly, using a weight gain chart. Moreover, they were provided with a pedometer as well as brochures and flyers containing advice on a healthy lifestyle and breastfeeding (Rauh et al. 2014).

Participants in both groups could optionally attend a two-hours 75 g oral glucose tolerance test (OGTT) and an additional blood withdrawal for the measurement of glycosylated haemoglobin A1c (HbA_{1c}) (**Figure 4**).

Subsequent to the intervention phase, participants in both the IV and the C underwent the same follow-up observation programme together with their infants. The follow-up programme comprises data collocation during telephone interviews and by means of questionnaires. The follow-up until the first year after delivery assessed mainly maternal outcomes, has already been completed, and is subject of this thesis (Rauh et al. 2014; Hoffmann et al. 2019c). The follow-up until the 5^{th} year after delivery is still ongoing and primarily focuses on infant development and health parameters.

3.4 Data collection and outcomes

In this chapter, data collection (see 3.4.1 – 3.4.3) and definitions of the main study outcomes (see 3.4.4) of this thesis are outlined. For outcomes that are included in sub-analyses, data collection and definition have been described in the corresponding publications (Hoffmann et al. 2019a; Hoffmann et al. 2019b; Hoffmann et al. 2019c; Kunath et al. 2019).

3.4.1 Anthropometric data, pregnancy complications, neonatal and obstetric parameters

Maternal anthropometric data and data on the weight development during pregnancy and the pp period were collected using the QS as well as maternity records. The first weight assessment after delivery took place at 6–8 weeks pp and is defined as time point 1 pp ($T1_{pp}$). The second data collection on maternal pp weight is defined as time point 2 pp ($T2_{pp}$) and was conducted at the 12^{th} month pp using a questionnaire ($QT2_{pp}$). If participants did not return $QT2_{pp}$, weight data were collected in a phone interview, which was scheduled with the main purpose of obtaining data on infant anthropometrics.

Pregnancy-related, obstetric, and neonatal outcomes were retrieved from maternity and birth records. Time points of data collection are shown in **Figure 4** and are defined elsewhere (Rauh et al. 2014; Hoffmann et al. 2019c).

3.4.2 Physical activity

Prenatal PA was assessed at baseline and in the third trimester using the validated Pregnancy Physical Activity Questionnaire (PPAQ; Chasan-Taber et al. 2004). The assessment in early pregnancy (before or in the 12th week of gestation) was defined as time point 0 (T0) and in late pregnancy (after the 29th week of gestation) as time point 1 (T1). The PPAQ was slightly adapted to German habits (see Appendix A1) and was included in a set of questionnaires which entailed questions to lifestyle factors (set of questionnaires 1 and 2 (Q1 and Q2); Rauh et al. 2014). In the PPAQ, participants were asked to estimate the mean time spent engaging in 32 activities in the past month. PA data were self-reported without supervision (Hoffmann et al. 2019b) and were analysed according to the instructions of Chasan-Taber and Schmidt (2016). PA was reported as a measure of average weekly energy expenditure in MET-h/week (metabolic equivalent of task, MET) and grouped into 'types' and 'intensity' of PA or reported as total PA (Hoffmann et al. 2019a; Hoffmann et al. 2019b). Over-reporting was defined as described by Hoffmann et al. (2019a; 2019b). The PPAQ allowed for the analysis of the adherence to national and international PA recommendations (Koletzko et al. 2012; ACOG 2015) as described elsewhere (Hoffmann et al. 2019a; Hoffmann et al. 2019b).

3.4.3 Breastfeeding behaviour

Data on maternal breastfeeding behaviour were collected within $QT2_{pp}$ via questions that were adapted from the 'German Health Interview and Examination Survey for Children and Adolescents' (KiGGS; Lippe et al. 2014). In $QT2_{pp}$, women were asked whether they breastfed at any time ('any breastfeeding'), performed 'exclusive breastfeeding', and to estimate the duration of any and exclusive breastfeeding (see Appendix A2).

3.4.4 Definition of outcome parameters

In **Table 5**, main study outcomes are listed together with their definitions. Further outcomes, which are included in subgroup analyses, have been described and defined elsewhere (Hoffmann et al. 2019a; Hoffmann et al. 2019b; Hoffmann et al. 2019c; Kunath et al. 2019).

Table 5: Definitions of the main study outcomes

Outcome	Definition
Maternal outcomes	
GWG	Difference between the last measured weight before delivery and the first measured weight at the time of recruitment
Excessive GWG	GWG above the thresholds recommended by the IOM[a]
GDM	Diagnosis if blood glucose values measured in a fasting 75 g OGTT equalled or exceeded thresholds provided by Kleinwechter et al. (2016)
Short-term PPWR	Difference between measured weight at $T1_{pp}$ and first measured weight at time of recruitment
Long-term PPWR	Difference between self-reported weight at $T2_{pp}$ and first measured weight at time of recruitment
Relevant PPWR	PPWR > 5 kg.
Neonatal and obstetric outcomes	
Preterm birth / delivery	Delivery before the 37th week of gestation
Low birth weight	Birth weight < 2500 g
High birth weight	Birth weight > 4000 g
Macrosomia	Birth weight > 4500 g
LGA	Offspring with weight > the 90th percentile for gestational age
SGA	Offspring with weight < the 10th percentile for gestational age
Physical activity outcomes	
Sedentary-intensity PA	MET < 1.5
Light-intensity PA	MET ≥ 1.5 and < 3.0
Moderate-intensity PA	MET ≥ 3.0 and ≤ 6.0
Vigorous-intensity PA	MET > 6.0
Meeting PA recommendations	Threshold of ≥ 7.5 MET-h/week in the category sport activities of moderate-intensity or above
Breastfeeding outcomes	
Any breastfeeding	Breastfeeding at any time
Exclusive breastfeeding	Breastfeeding without offering any formula or complementary food
Meeting the breastfeeding recommendations	Definition according to the German breastfeeding recommendations[b]: Exclusive breastfeeding until the end of the 4th month pp

[a] IOM 2009.

[b] Koletzko et al. 2016.

Abbreviations: GDM: gestations diabetes mellitus; GWG: gestational weight gain; IOM: Institute of Medicine; LGA: large-for-gestational age; MET: metabolic equivalent of task; OGTT: oral glucose tolerance test; PA: physical activity; pp: postpartum; PPWR: postpartum weight retention; SGA: small-for-gestational age; $T1_{pp}$: time point of the first data collection postpartum (between the 6th and 8th week pp); $T2_{pp}$: time point of the second data collection postpartum (at the 12th month postpartum).

3.5 Data analyses

3.5.1 Drop-out criteria / loss of participants

The following characteristics were considered as drop-out reasons during the course of the active intervention phase (from inclusion until the 6th–8th week pp):

- miscarriage or late loss of pregnancy,
- termination,
- pregnancy complications which interfered with the intervention,
- maternal death or,
- other reasons such as decline of further study visits or change of practice / residence.

Participants, who dropped out before delivery, were not included in the analyses, investigating outcomes for the antenatal period. For participants, who dropped out between delivery and the 6th–8th week pp, pregnancy, obstetric, and neonatal outcomes were analysed.

Participants were defined as being lost to follow-up and thus as drop-outs in the follow-up period, if they:

- were not reachable,
- withdrew study participation or,
- did not provide contact information.

3.5.2 Analyses sets and applied approaches

Two approaches (assessment of the intervention effect or cohort analyses) considering different sets of participants were applied. **Table 6** gives an overview of participant sets and applied approaches.

Table 6: Sets of participants and applied approaches

Chapter / Manuscript	Approach	Participant set
4.1 Kunath et al. (2019)	**Analysis of intervention effect** *(Aim: Effect of the intervention on GWG and pregnancy and obstetric complications)*	Included all women except - those who dropped out before delivery. *For GWG:* Included all women except - those who dropped out before delivery, - those with a preterm delivery (<37th week of gestation).
4.2 Hoffmann et al. (2019b)	**Analysis of intervention effect** *(Aim: Effect of the intervention on prenatal PA behaviour)*	Included all women except - those who dropped out before delivery, - over-reporters[a].
	Cohort approach *(Aim: Associations between prenatal PA intensity and GWG)*	Included all women except - those who dropped out before delivery, - those with a preterm delivery (<37th week of gestation), - over-reporters[a].
4.3 Hoffmann et al. (2019a)	**Cohort approach** *(Aim: Associations between prenatal PA and obstetric and neonatal outcomes)*	Included all women except - those who dropped out before delivery, - those with a preterm delivery (<37th week of gestation), - over-reporters[a], - those who missed infant examination at birth.
4.4 Hoffmann et al. (2019c)	**Analysis of intervention effect** *(Aim: Effect of intervention on PPWR and breastfeeding behaviour)*	*For short-term PPWR:* Included all women except - those who dropped out until the 6th–8th week pp. *For long-term PPWR:* Included all women except - those who were lost to follow-up, - those who were pregnant at the 12th month pp. *For breastfeeding analyses:* Included all women except - those who were lost to follow-up.
	Cohort approach *(Aim: Identification of determinants of PPWR and breastfeeding)*	Same criteria as applied for the analyses of long-term PPWR and GWG.

[a] as defined by Hoffmann et al. (2019a, b). Abbreviations: GWG: gestational weight gain; PA: physical activity; pp: postpartum; PPWR: postpartum weight retention.

3.5.3 Statistical analyses

Analyses were performed using SPSS software (IBM SPSS Statistics for Windows, version 24.0, IBM Corp, Armonk, NY, USA) or SAS software (version 9.4 for Windows (SAS Institute Inc., Cary, NC, USA)). Due to the cluster-randomised design, linear regression models and binary logistic regression models fit with generalised estimating equations (GEE) were applied to analyse differences between IV and C according to Donner et al. (2000). Group differences were presented as estimated mean differences or odds ratios (OR) with 95% CIs. For all cohort analyses, linear and binary logistic regression models were applied. For all analyses, p-values below 0.05 were considered as statistically significant. More information on applied statistics and included covariates is given in references of sections 4.1–4.4.

4 Results

In the following, results and manuscripts of the GeliS study that are subject of this work are briefly summarized.

4.1 Effects of the GeliS intervention on gestational weight gain, pregnancy complications, obstetric and neonatal outcomes

Title: 'Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care - the cluster-randomised GeliS trial'.

Authors: Julia Kunath*, Julia Günther*, Kathrin Rauh, **Julia Hoffmann**, Lynne Stecher, Eva Rosenfeld, Luzia Kick and Hans Hauner; *authors share the first authorship of this work.

Access: BMC Medicine 2019; 17, 5; Open Access article available from: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-018-1235-z.

Summary of findings:

By providing a comprehensive lifestyle intervention alongside routine antenatal care, the GeliS study primarily aimed to reduce the proportion of women showing excessive GWG. Moreover, the study sought to reduce the incidence of pregnancy, obstetric and neonatal complications.

Overall, 71 gynaecological practices participated in the GeliS study and 63 previously trained gynaecologists, medical personnel or midwives provided lifestyle counselling for women in the IV. In total, 2286 pregnant women were recruited (IV: n = 1152; C: n = 1134). Overall, 64.9% of participants were women with normal weight, 23.0% with overweight and 12.1% with obesity. There was no significant evidence of an effect of the intervention on excessive GWG with 45.1% of women in the IV, showing excessive GWG and 45.7% in the C (adjusted OR 0.95, 95% CI 0.66 to 1.38, p = 0.789). In both groups, the incidence of excessive GWG was higher in women with overweight or obesity compared to women with normal weight. In the IV, 10.8% of women were diagnosed with GDM and 11.1% in the C, respectively (adjusted OR 0.84, 95% CI 0.41 to 1.71, p = 0.622). Newborns in the IV showed a slightly lower birth weight and length compared to the C (3313 ± 536 g vs. 3363 ± 498 g; adjusted p = 0.020; 51.1 ± 2.7 cm vs. 51.6 ± 2.5 cm; adjusted p = 0.001). There was no significant evidence of between-group differences in other neonatal outcomes such as LGA, SGA, or macrosomia. Process evaluation revealed a high consistency with the study

protocol in terms of intervention delivery and adherence to the correct time interval and a moderate consistency with regard to the utilisation of study material.

In conclusion, the GeliS intervention, which was conducted alongside routine care, was not able to prevent excessive GWG or other pregnancy complications. Nevertheless, its impact on antenatal dietary and physical activity behaviour as well as its long-term influence on maternal weight development remains to be assessed.

Personal contribution: **Julia Hoffmann** was responsible for performing parts of the process evaluation and provided support concerning the definition of outcomes and analytical procedures. In addition, **Julia Hoffmann** revised the manuscript and commented on the publication as a co-author.

4.2 Effects of the GeliS intervention on prenatal physical activity

Title: 'Effects of a lifestyle intervention in routine care on prenatal physical activity – findings from the cluster-randomised GeliS trial'.

Authors: **Julia Hoffmann***, Julia Günther*, Kristina Geyer, Lynne Stecher, Kathrin Rauh, Julia Kunath, Dorothy Meyer, Christina Sitzberger, Monika Spies, Eva Rosenfeld, Luzia Kick, Renate Oberhoffer and Hans Hauner; *authors share the first authorship of this work.

Access: Article accepted for publication in BMC Pregnancy & Childbirth (approval letter see Appendix A3).

Summary of findings:

The aim of this secondary analysis was to assess the effect of the GeliS intervention that provided basic PA advice on a woman's prenatal PA behaviour. Moreover, the purpose was to assess the effect of different intensity levels of prenatal PA on GWG. Herein, a mixed approach was conducted analysing primarily differences between IV and C and with a second priority assessing the effect of PA on GWG in the pooled GeliS cohort.

In total, 93% (IV: n = 1061; C: n = 1040) of participants in both groups provided PA data. In late pregnancy, the level of *total PA* (adjusted effect size 6.00, 95% CI 4.93 to 7.07 MET–h/week, adjusted $p < 0.001$), '*total PA of light-intensity and above*' (TALIA, adjusted effect size 6.78, 95% CI 5.64 to 7.93 MET–h/week, adjusted $p < 0.001$), *moderate-intensity PA* (adjusted effect size 2.39, 95% CI 0.31 to 4.48 MET–h/week, adjusted $p = 0.024$) as well as *vigorous-intensity PA* (adjusted effect size 0.32, 95% CI 0.12 to 0.51 MET–h/week, adjusted $p = 0.024$) differed significantly between IV and C groups. Moreover, the level of activity in

the category sports was higher in the IV compared to the C (adjusted $p < 0.001$). In the C, the level of sport activity remained stable during the course of pregnancy (adjusted $p = 0.305$), while it significantly increased in the IV from T0 until T1 (adjusted $p < 0.001$). In the IV, 63.6% of women met the PA recommendations for pregnant women compared to 49.2% in the C (adjusted $p < 0.001$). In late but not in early pregnancy, the level of light-intensity PA (adjusted $p = 0.002$) and vigorous-intensity PA (adjusted $p = 0.014$) was significantly inversely associated with overall GWG in the GeliS cohort.
In conclusion, basic PA advice during pregnancy yielded improvements in prenatal PA behaviour in the IV. There was significant evidence for an inverse association between light- and vigorous-intensity PA in late pregnancy and GWG. This highlights the importance of PA in the prevention of excessive GWG.

Personal contribution: **Julia Hoffmann** processed the experimental data and conducted the statistical analysis. **Julia Hoffmann** designed the research question for the article together with co-authors, prepared tables and figures and wrote the manuscript.

4.3 Associations between prenatal physical activity and neonatal and obstetric outcomes

Title: 'Associations between prenatal physical activity and neonatal and obstetric outcomes—a secondary analysis of the cluster-randomised GeliS trial'.

Authors: **Julia Hoffmann**, Julia Günther, Kristina Geyer, Lynne Stecher, Julia Kunath, Dorothy Meyer, Monika Spies, Eva Rosenfeld, Luzia Kick, Kathrin Rauh and Hans Hauner.

Access: Article under revision in the Journal of Clinical Medicine.

Summary of findings:

Combining the IV and C to one cohort, the aim of this analysis was to examine associations between different PA intensities in early and late pregnancy and neonatal and obstetric outcomes. A further objective was to reveal differences in these outcomes between women meeting the PA recommendations for pregnant women and women not adhering to the recommendations. Women, who met the PA recommendations were defined as *active*, and those who did not meet recommendations as *inactive*. Infants of women meeting the PA recommendations in late pregnancy had a significantly higher birth weight than neonates of inactive women (active mean: 3364.5 ± 481.0 g; inactive mean: 3341.4 ± 492.5 g, adjusted $p = 0.030$). Sedentary-intensity activity at T1 was found to be significantly inversely

associated with birth weight (adjusted p = 0.026). In congruence with this, sedentary-intensity at T0 and T1 was shown to increase the odds of low birth weight (T0: adjusted p = 0.004, T1: adjusted p = 0.005). Women who were active at T1 were less likely to give birth prematurely compared to inactive women (adjusted p = 0.038). The odds of preterm delivery tended to be slightly increased by the level of sedentary-intensity activity at T0 and T1 (T0: adjusted p = 0.051; T1: adjusted p = 0.070). Neither at T0 nor at T1, there was significant evidence for further differences in infant anthropometrics, neonatal and obstetric outcomes between active and inactive women.

In conclusion, prenatal PA slightly influenced some neonatal and obstetric outcomes. Thereby, intensity and timing of PA seemed to be decisive. A follow-up might reveal whether effects are persistent and may elucidate the implications of maternal PA behaviour during the course of pregnancy on the infant's development.

Personal contribution: **Julia Hoffmann** processed the experimental data and conducted the statistical analysis. **Julia Hoffmann** designed the research question for the article, prepared tables and figures and wrote the manuscript.

4.4 Effects of the GeliS intervention on short- and long-term maternal weight retention and breastfeeding behaviour

Title: 'Effects of a lifestyle intervention in routine care on short- and long-term maternal weight retention and breastfeeding behavior – 12 months follow-up of the cluster-randomized GeliS trial'.

Authors: **Julia Hoffmann**, Julia Günther, Lynne Stecher, Monika Spies, Dorothy Meyer, Julia Kunath, Roxana Raab, Kathrin Rauh and Hans Hauner.

Access: Journal of Clinical Medicine 2019; 8, 876. Open Access article available from: https://www.mdpi.com/2077-0383/8/6/876.

Summary of findings:

The main objective was to assess the effect of the GeliS intervention on maternal short- and long-term PPWR and maternal pp weight development as well as on maternal breastfeeding behaviour. A further objective was to identify determinants of long-term PPWR and exclusive breastfeeding within the pooled GeliS cohort. Among the 2286 initially enrolled participants, 1998 entered the follow-up observation programme and provided data at $T1_{pp}$ (IV: n = 1003; C: n = 995). From $T1_{pp}$ until $T2_{pp}$, 10.8% of participants were lost to follow-up.

Mean PPWR at $T1_{pp}$ was comparable between groups (4.0 ± 4.8 kg vs. 4.3 ± 4.8 kg; adjusted p = 0.694) whereas PPWR at $T2_{pp}$ was by trend lower in the IV (-0.2 ± 4.8 kg vs. 0.6 ± 5.2 kg; adjusted effect size –0.69, 95% CI –1.57 to 0.19 kg, p = 0.123). However, there was no statistically significant evidence of a difference between groups. Women in the IV lost significantly more weight from delivery until $T2_{pp}$ compared to the C (14.3 ± 5.9 kg vs. 13.4 ± 6.0 kg; adjusted effect size 0.85, 95% CI 0.22 to 1.49 kg, p = 0.008). In both groups, around 40% of participants showed the same or a lower weight as before pregnancy (IV: 40.5%; C: 40.1%; adjusted p = 0.823) and more than 10% demonstrated PPWR > 5 kg (IV: 11.4%; C: 14.8%; adjusted p = 0.142). Compared to the C, women in the IV showed a higher rate of exclusive breastfeeding (IV: 87.4%; C: 84.4%; adjusted p < 0.001). However, the proportion of women that ever breastfed did not differ between groups (adjusted p = 0.954). Exclusive breastfeeding (adjusted p = 0.005), excessive GWG (adjusted p < 0.001), parity (adjusted p = 0.002), pre-pregnancy BMI category (adjusted p = 0.013), and educational level (adjusted p = 0.001) were identified as consistent determinants of long-term PPWR. Exclusive breastfeeding was influenced by pre-pregnancy BMI category (adjusted p = 0.001), and educational level (adjusted p = 0.024).

In conclusion, the GeliS lifestyle intervention yielded slight improvements in maternal pp weight development and maternal breastfeeding behaviour. Nevertheless, the clinical relevance of these findings needs to be further investigated. A follow-up until the 5th year pp will elucidate whether the intervention remains contributing to the maternal pp lifestyle and pp weight development beyond the first year after delivery. This is important regarding the long-term prevention of overweight and obesity in these women.

Personal contribution: **Julia Hoffmann** was in charge of data collection, processed the experimental data and conducted the statistical analysis. **Julia Hoffmann** designed the research question for the article, prepared tables and figures and wrote the manuscript.

5 Discussion

The GeliS trial was the first study that analysed the effect of a lifestyle intervention comprising diet and PA counselling within the German antenatal routine care setting on a large scale. The purpose of this work was to assess the effect of the GeliS intervention on the primary study outcome, the proportion of women with excessive GWG, on pregnancy and neonatal complications, the antenatal PA behaviour, maternal short- and long-term PPWR and breastfeeding behaviour. Furthermore, a cohort approach sought to investigate associations between prenatal PA and neonatal and obstetric outcomes. Strengths and limitations of applied methods and obtained findings have been outlined in detail elsewhere (Hoffmann et al. 2019a; Hoffmann et al. 2019b; Hoffmann et al. 2019c; Kunath et al. 2019), and are not subject of the subsequent discussion. In the following, main results from chapters 4.1–4.4 are discussed. Moreover, implications for future approaches are derived.

5.1 Discussion of main findings

As 45.1% of women in the IV and 45.7% in the C were found to exceed the IOM weight gain thresholds, the GeliS intervention was not able to significantly influence ***the primary study outcome and thus the proportion of women showing excessive GWG***. Moreover, there was no evidence for a reduction in obstetric and neonatal complications such as the incidence of GDM (Kunath et al. 2019). These findings were unexpected as the FeLIPO pilot trial showed substantial improvements in the proportion of women with excessive GWG (60% of women in C vs. 38% in the IV, p = 0.032; Rauh et al. 2013). As extensively outlined in chapter 1.4.3, the overall opinion on the effect of lifestyle interventions on GWG is conflicting. Recently, two other large scaled studies (UPBEAT and LIMIT) assessed – among others – the effect of intensive lifestyle interventions provided for women with overweight and/or obesity on GWG. While the UPBEAT trial reported a small reduction in GWG (-0.55 kg, p = 0.041) in women receiving lifestyle counselling (Poston et al. 2015), the LIMIT intervention was not able to reduce the proportion of women with excessive GWG (42% vs. 42%, p = 0.85; Dodd et al. 2014b), which is consistent with our GeliS findings. As outlined above (see 1.4.3) and comprehensively demonstrated by the i-WIP collaborative group in their meta-analysis, there is some evidence that antenatal lifestyle interventions are effective in modestly reducing overall GWG (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). In contrast to the GeliS study, trials in this field were mainly performed under controlled conditions and in community or academic settings. This limits

the comparability with our findings and might partly explain why we found no effect of the GeliS intervention on GWG.

Apart from GWG, the GeliS intervention yielded some improvements in ***antenatal PA behaviour***: At study entry, there were between-group differences in the baseline PA level. The C reported a higher level of several PA outcomes compared to the IV (Hoffmann et al. 2019b). To overcome these inconsistencies and to accurately assess the intervention effect on prenatal PA, the level of baseline PA was included as covariate in adjusted models. In late pregnancy, the mean PA level in some PA outcomes (*e.g.* total PA) was comparable between groups although we found significant evidence for between-group differences in adjusted models (Hoffmann et al. 2019b). This can be attributed to differences in the baseline PA level and T0 as covariate. In conclusion, women in the IV reached the same or – in some outcomes (*e.g.* in the category sport) a higher – level of PA compared to women in the C. Thus, the intervention improved the prenatal PA of women in the IV. There was significant evidence for between-group differences in the level of total PA, TALIA, moderate- and vigorous-intensity activities in late pregnancy. A higher rate of activities in the category sport was observed in late pregnancy in women receiving antenatal counselling compared to the control. Moreover women in the IV met PA recommendations for pregnant women more often than women in the C (Hoffmann et al. 2019b). In line with our observations, the LIMIT and the UPBEAT trials also reported improvements in the women's PA behaviour followed by their intervention. More specifically, the latter two mainly identified improvements in household activities and in the time spent walking (Dodd et al. 2014a; Poston et al. 2015). In contrary, we primarily attributed between-group differences to higher intensity levels. However, the here named studies differ highly in their intensity of PA counselling, mode of data collection, and also in their study population. This complicates a direct comparison of observations on PA behaviour. As outlined above (see 1.4.3) and elsewhere (Hoffmann et al. 2019b), there is evidence that lifestyle interventions, including PA advice only or in combination with dietary advice, are effective in preventing from excessive GWG. This effect was not observed in the GeliS trial.

Cohort analyses assessing the contribution of different PA intensities on GWG found that in particular light- and vigorous-intensity activities in late pregnancy were inversely associated with GWG. The influence of antenatal PA on GWG is commonly not described on the intensity level, which makes it difficult to compare our findings with current research.

As the prenatal diet is – together with the PA – an important determinant of GWG, the contribution of the prenatal diet has to be considered likewise. The GeliS intervention

comprised both dietary and PA advice and was effective in improving some dietary aspects in women receiving counselling as well (Günther et al. 2019a). Our findings suggest that a moderate change in PA and in some dietary aspects might not be sufficient to significantly lower GWG and to reduce the proportion of women with excessive GWG. Thus, controlled studies offering exercise groups, walking classes or continuous observation and discussion of the individual dietary behaviour might have more success in the prevention of excessive GWG (Barakat et al. 2011; Barakat et al. 2016; Robertson and Ladlow 2018).

It is noteworthy that ***prenatal PA*** behaviour is not only discussed to determine GWG, but also to ***impact on neonatal and obstetric outcomes***. Combing the intervention and control groups to one cohort, we investigated the impact of different PA intensities in early as well as in late pregnancy on these outcomes. We found significant evidence for associations between PA intensities and weight-derived infant outcomes as well as the risk for preterm and caesarean section deliveries. For instance, late sedentary-intensity PA was inversely associated with infant birth weight and increased the risk for low birth weight (Hoffmann et al. 2019a). Moreover, we performed a subgroup analysis, assessing differences in neonatal and obstetric outcomes between active and inactive women. Thereby, we found among others that preterm delivery was less likely in active women. Further, offspring of mothers who were active in late pregnancy, showed a small increase in birth weight by 49.7 g compared to infants of inactive women (Hoffmann et al. 2019a). In general, the contribution of prenatal PA on infant birth weight and obstetric outcomes is highly debated and controversial. Our findings on infant birth weight are consistent with current research assessing the contribution of sedentary behaviour on birth weight (Badon et al. 2018) or differences in infant birth weight in exercising vs. non-exercising women in late pregnancy (Koushkie Jahromi et al. 2011). However, these findings are in contrast to results of others who reported an inverse association between the level of sports in the first trimester and birth weight (Bisson et al. 2017). A considerable heterogeneity in the assessment of prenatal PA complicates the comparison of study outcomes. Current investigations often rely on prenatal PA as binary outcome, comparing active vs. inactive women irrespective of the corresponding intensity level. The contribution of multiple PA intensities or even the timing during the course of pregnancy is frequently not analysed or reported (Ferraro et al. 2012), which may explain some inconsistencies. Despite this, Bisson et al. (2016) systematically reviewed observational studies which analysed the effect of prenatal PA on infant birth weight and subsequently performed a meta-analysis. Therein, they suggested an inverted U-shaped relationship between PA intensities and infant birth weight. This hypothesis provides a possible explanation of our observations on the direction

of the associations of different PA intensities and infant birth weight. Drawing evidence from above, we conclude that prenatal PA influences infant birth weight and weight-derived outcomes, such as LGA, SGA, high and low birth weight. However, whether there was an inverse or positive association with infant outcomes depended on the intensity and timing of PA during the course of pregnancy (Hoffmann et al. 2019a).

It has to be acknowledged that prenatal PA is not the only determinant of infant birth weight. Apart from maternal pre-pregnancy weight and GWG, the maternal antenatal diet is discussed to influence infant birth weight (Grieger and Clifton 2014). We recently examined the contribution of maternal diet on birth weight in the entire GeliS cohort by associations between dietary components and birth weight and weight-derived neonatal outcomes (Günther et al. 2019b).

Besides the effect of prenatal PA on infant birth weight, we additionally investigated its influence on the risk for preterm and caesarean section deliveries. Our findings mainly correspond to current investigations in this field supporting the opinion that prenatal PA during late pregnancy does not increase the risk for preterm and caesarean deliveries (Domenjoz et al. 2014; Di Mascio et al. 2016; Magro-Malosso et al. 2017; Baena-García et al. 2018; Du et al. 2018; Davenport et al. 2019; Hoffmann et al. 2019a).

The GeliS intervention was not successful in reducing the proportion of women with excessive GWG (Kunath et al. 2019), but modestly improved prenatal dietary and PA behaviour of women (Günther et al. 2019a; Hoffmann et al. 2019b). Hence, the question remained as to whether the lifestyle intervention contributed to ***maternal weight development beyond birth***. This issue was investigated within the 12 month follow-up analyses. Results demonstrated minor improvements in pp maternal weight development. Albeit PPWR at the 12th month after delivery seemed to be lower in women receiving antenatal counselling (mean PPWR -0.2 kg), there was no significant evidence of differences between groups (C: mean PPWR 0.6 kg; adjusted $p = 0.123$). However, women obtaining the lifestyle intervention showed a significantly higher weight loss from delivery until the 12th month pp compared to women in the C (Hoffmann et al. 2019c).

As outlined in section 1.4.3 and elsewhere (Hoffmann et al. 2019c), evidence on the effect of lifestyle interventions on PPWR in the first months after birth is inconclusive. Notwithstanding, Michel et al. (2018) recently reported in their meta-analysis promising findings on the effect of lifestyle interventions not only on short-, but also on long-term PPWR. The between-group difference observed at 4–6 months pp remained significant 12 months after birth. In the GeliS trial, changes in maternal dietary and PA behaviour

ultimately did not influence either GWG or PPWR one year after birth and are thus unlikely to decrease the risk for future health complications on the long-run (Hoffmann et al. 2019c; Kunath et al. 2019). A majority of the trials, included in the meta-analysis, were not performed under real-life conditions (Michel et al. 2018). This raises the question whether the antenatal routine care setting is decisive for the failure of the GeliS intervention to effectively impact on maternal PPWR.

Besides reporting the intervention effect on maternal pp weight development, we sought to assess the clinical meaning of our findings by determining the proportion of women with sustained PPWR within the 12 months follow-up. The FeLIPO trial demonstrated promising findings, reporting a significant lower proportion of women with relevant PPWR at the 4th month pp and at the 12th month pp in women receiving antenatal counselling (Rauh et al. 2013; Rauh et al. 2015). In the GeliS trial, we found no differences either in PPWR or relevant PPWR between groups. However, we identified a considerable proportion of women with clinically relevant PPWR in both groups (Hoffmann et al. 2019c). Thus, we share the concern of Michel et al. (2018) who noted a general lack of reporting data on PPWR above 5 kg. We agree to question the clinical meaning of reports on PPWR that do not consider sustained PPWR. Concluding therefrom and given that we identified sustained PPWR at 6–8 weeks pp as strong contributor of PPWR at the 12th month pp, we highly encourage future initiatives to address and assess sustained PPWR. Moreover, tailored interventions considering identified determinants of PPWR, such as the educational level (Hoffmann et al. 2019c), might be more successful in improving maternal weight at the 12th month after birth.

The beneficial effects of breastfeeding (duration) on PPWR and the risk for maternal obesity have previously been recognised (Harder et al. 2005; Baker et al. 2008; Vinter et al. 2014). Due to these associations, the GeliS intervention sought to improve ***maternal breastfeeding behaviour***. Aside from a slight positive effect on the proportion of women who exclusively breastfed, no other breastfeeding outcomes (*e.g.* any breastfeeding or the adherence of the German breastfeeding recommendations) was influenced by our intervention (Hoffmann et al. 2019c). This might be explained by the fact that midwives offer face-to-face pp-check-ups at the women's home including comprehensive and detailed counselling and advice on breastfeeding in Germany. These check-ups are covered by health-insurances and were most likely also received by a majority of women in the C. More than 80% of participants in both groups initiated breastfeeding which is consistent with German observations reporting breastfeeding rates of 82% (Lippe et al. 2014). The fact that

both the IV and C showed similar high breastfeeding rates leads to the suggestion that our counselling concept does not improve maternal breastfeeding behaviour beyond routine midwife care. Only few comparable studies included breastfeeding advice in the counselling concept or reported relevant data. Thus, a comparison with other study findings is limited and hardly applicable as breastfeeding support differs between countries. Irrespective of this, we were able to identify predictors of the initiation of breastfeeding (*e.g.* educational level, pre-pregnancy BMI, pp depression) and to reveal determinants of exclusive breastfeeding (*e.g.* educational level, pre-pregnancy BMI; Hoffmann et al. 2019c). In conclusion, we suggest future approaches to consider these determinants and to offer tailored breastfeeding advice based on the women's needs.

5.2 Lessons learned from the GeliS findings

To the best of our knowledge, the GeliS trial was the first study that evaluated the effect of a comprehensive lifestyle intervention in the German routine care setting on a broader scale. Findings from a process evaluation suggest a moderately successful implementation of the GeliS concept into the German antenatal care system (Kunath et al. 2019). However, the herein shown results raise the question why modifications in maternal antenatal dietary and PA behaviour (Günther et al. 2019a; Hoffmann et al. 2019b) were not effective in improving health outcomes in the GeliS study and why findings of the FeLIPO trial could not be replicated.

For practical reasons and due to feedback of participants, the FeLIPO concept was modified for the use in the GeliS study. While participants of the FeLIPO trial received two antenatal counselling sessions (Rauh et al. 2013), the intervention in the GeliS trial consisted of three antenatal and one pp session (Rauh et al. 2014). The predefined time points of sessions during the course of pregnancy differed between studies and the counselling content was slightly adapted. For instance, breastfeeding behaviour was not addressed within the FeLIPO trial but in the GeliS study (Rauh et al. 2013; Rauh et al. 2014). In the GeliS study, a predefined schedule of the content including basic information on a healthy lifestyle was followed during counselling. For some women, advice might have been too superficial and not adequately tailored. More intense support, such as supervised exercise sessions and continuous dietary feedback, might be more effective in improving maternal and foetal health outcomes (Hoffmann et al. 2019b).

Most importantly, the counselling in the FeLIPO trial was given by one dietary expert who individually addressed particular problems. In contrast to this, previously briefly trained

gynaecologists, midwives and medical personnel conducted the lifestyle intervention in the GeliS trial (Rauh et al. 2013; Rauh et al. 2014). A continuous increase of knowledge, in particular concerning GWG, has been reported by counsellors at the end of the seminar (Aicher 2015). Nevertheless, a two-day seminars might not have been enough to provide gynaecologists, midwives and medical personnel with sufficient knowledge for lifestyle coaching (Kunath et al. 2019). This fact might have been the most likely explanation for the failure to reproduce findings from the FeLIPO trial on a larger scale.

The inclusion of behaviour change strategies within lifestyle interventions has been proposed as key component to limit GWG (Skouteris et al. 2010; Hill et al. 2013). Neither in the FeLIPO nor in the GeliS trial, these strategies have comprehensively been included in the counselling, but some measures intended to provide individual feedback (Rauh et al. 2013; Rauh et al. 2014). In the second counselling session of the FeLIPO trial, individual problems were discussed and concrete goals were defined (Rauh et al. 2013). The GeliS counsellors were provided with materials to identify and address individual problems (Rauh et al. 2014). Yet, process evaluation revealed that these materials were rarely used which frequently resulted in a lack of personal feedback (Hoffmann 2014; Kunath et al. 2019). It is a decisive limitation that GeliS counsellors were not trained and had no experience in behavioural change techniques. The attempts to incorporate these techniques without training were obviously not successful.

Despite positive effects on maternal dietary and PA behaviour (Günther et al. 2019a; Hoffmann et al. 2019b), the GeliS intervention was ultimately not able to limit GWG or to beneficially influence health parameters with a clinically relevance while being conducted in the antenatal routine care setting (Hoffmann et al. 2019c; Kunath et al. 2019). Hence, the scaling-up from FeLIPO to GeliS was not proven to be successful. However, this seems to be a rather general phenomenon. Scaling-up interventions after a promising pilot phase has been recognised as a common problem in the field of obesity prevention. McCrabb et al. (2019) recently reported markedly decreasing effect sizes of interventions when being performed at large scale. Unquestionably, assessing the success of an intervention and ultimately its effectiveness highly depends on its scalability. Through the public health design, we were able to reach a large number of individuals and could show that the GeliS concept was principally implementable into pre-existing structures of the German routine care setting. The remarkable low drop-out rate of participants during the course of pregnancy and the follow-up period underlined their motivation and engagement in the trial (Hoffmann et al. 2019c; Kunath et al. 2019). Notably, a majority of participants in both

groups considered routinely offered lifestyle advice during pregnancy as important (Bär 2018). Thus, there is a substantial gap between the women's needs as well as wishes and the nature of existing routine care structures. The considerable high rates of women with excessive GWG (Kunath et al. 2019), and sustained PPWR (Hoffmann et al. 2019c) underpin the demand for effective prevention strategies in primary care.

The GeliS study depicts a promising first step towards comprehensively addressing the antenatal lifestyle and associated maternal and infant complications within the German antenatal routine care setting. Reported findings provide unique information about barriers of an implementation under real-life conditions and are valuable to derive suggestions for future research.

5.3 Implications for future research

Findings from the GeliS study demonstrated an urgent demand for lifestyle interventions embedded into the German routine care system that successfully prevent excessive GWG and sustained PPWR. The following concerns might be important in order to overcome potential limitations and to tackle barriers of the GeliS intervention (see also **Figure 5**):

As individual characteristics of participants varied in terms of *e.g.* sociodemographic criteria, educational level, BMI classification and parity, a 'one-size-fits-all' approach might not be appropriate to prevent maternal and infant complications on the population level. A tailored intervention adapted to the specific characteristics, concerns and problems might be more successful in limiting GWG and associated health consequences. The consideration of herein reported determinants of long-term PPWR and breastfeeding might be useful (Hoffmann et al. 2019c). Counselling given by experts, such as dietary and PA professionals, who are trained in behavioural change techniques might trigger lifestyle changes with sufficient impact on health outcomes. Experts do not simultaneously have to cope with additional work load and are able to explicitly concentrate on counselling. There is reason to assume that a counselling given by experts will be more intense and could significantly impact on GWG and PPWR. However, cooperating with experts would include to modify established health care structures.

In recent years, the advantage of innovative technologies to facilitate and to improve primary care has increasingly been recognised. E-health approaches are considered as upcoming, cost-effective opportunities to complement primary care by providing evidence-based, time-independent, and quality-assured services on a broader scale (Lau et al. 2017; van den Heuvel et al. 2018). Within these approaches, electronically-based platforms are

used to deliver lifestyle interventions via websites, telephones, apps, e-mails, or videos (Jackson et al. 2011; Albright et al. 2014; Choi et al. 2016; Dodd et al. 2018; Henriksson et al. 2019; Rissel et al. 2019). Thereby, behavioural change strategies are sometimes implemented by individualised, automatically generated reminders, such as push notifications, in order to self-empower users and to reinforce their personal engagement (van den Heuvel et al. 2018; Brown et al. 2019). Notably, e-based platforms and in particular apps have been shown to be common resources for pregnant women seeking information on pregnancy-, diet-, and PA-related issues. Women used them to share information with peers and to request support from professionals (Thomas and Lupton 2015; Lau et al. 2017; Daly et al. 2018).

In the last few years, some pilot studies have been initiated to assess the potential of e-health approaches in limiting GWG and in improving the pre-conceptual, prenatal, and pp lifestyle as well as associated health complications (Choi et al. 2016; Bogaerts et al. 2017a; Dodd et al. 2018; Henriksson et al. 2019; Rissel et al. 2019). Some promising observations demonstrated that e-based lifestyle interventions may be effective in limiting GWG as well as in improving short-term weight loss after delivery, maternal PA, and dietary behaviour (Lau et al. 2017). However, research in this field is still limited: Due to a considerable heterogeneity of methods, interventions, controls, and outcome measures, the effect of interventions integrating innovative technologies on maternal and offspring health outcomes is inconclusive and needs further investigation (Lau et al. 2017; Daly et al. 2018; van den Heuvel et al. 2018). It might be worth to expect results of still ongoing pilot studies.

Notwithstanding, a combination of the GeliS concept with modern e-health technologies appear to be a promising next step in order to offer a more intense, individual, and flexible intervention alongside antenatal routine care. Already existing cooperations provide optimal conditions to overcome the GeliS limitations and to translate ‘lessons learned’ into action within a subsequent project (GeliS 2.0). Established networks between stakeholders, participating midwifes, and gynaecological practices could be complemented by professional counsellors, such as lifestyle (dietary and PA) experts. Establishing an electronic platform with access for all providers will improve their exchange of knowledge and ultimately primary care. In order to intensify counselling and to enable flexibility, dietary experts could conduct counselling either via telephone or within an app. The consideration of feedback given by GeliS participants as well as other shortcomings revealed during process evaluation will be valuable to improve the entire counselling concept.

In cooperation with the 'Stiftung Kindergesundheit', the Competence Centre for Nutrition (KErn) recently established an app-trilogy for pregnant women or women desiring to have children as informative tool (Kompetenzzentrum für Ernährung 2019). The three apps provide information on a healthy antenatal lifestyle (diet and PA), on breastfeeding, and on the introduction of complementary food. All recommendations are based on national guidelines (Koletzko et al. 2012; Koletzko et al. 2016). Within the first app 'Schwanger & Essen', GWG according to IOM recommendations can be monitored via an interactive weight gain chart. This app has already been validated and would be a valuable tool for GeliS 2.0 as it is focusing on the prenatal phase. After slight modifications, such as adaptations to updated recommendations (Koletzko et al. 2018) or implementation of further interactive tools (tracking of daily steps, exercise videos, seasonal recipes), the app could be used to provide pregnant women with evidenced-based information on an healthy antenatal lifestyle and ultimately as resource to increase their awareness for excessive GWG and associated complications for themselves and their infants.

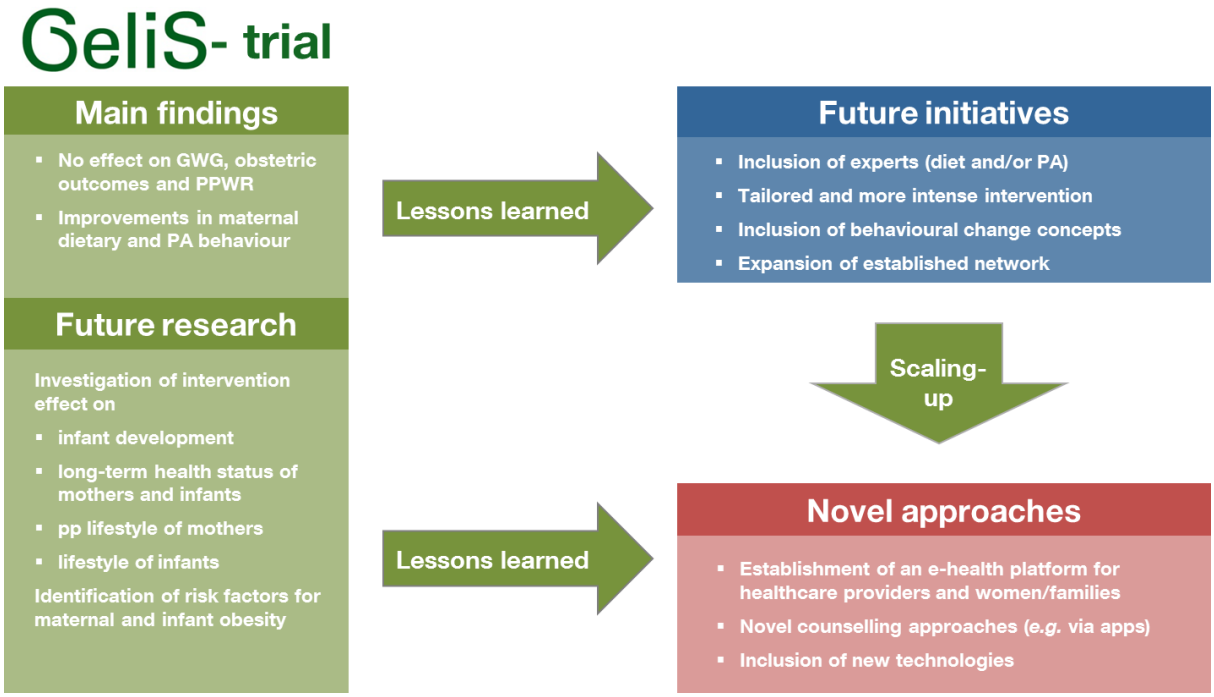

Figure 5: From findings of the GeliS trial to novel approaches at scale
Abbreviations: GWG: gestational weight gain; PA: physical activity; PPWR: postpartum weight retention. Data source: own contribution.

Irrespective of the 'lessons learned from GeliS' and implications for the future project, it has to be highlighted that until now some questions remain unanswered: Data on the pp lifestyle are not yet analysed. In general, data on maternal pp dietary and PA behaviour subsequent to an antenatal lifestyle intervention are limited. Data from the GeliS cohort can valuably

contribute to current research. Assessing the effect of the GeliS intervention on the maternal pp lifestyle would enable to identify further predictors of PPWR beyond the first year after delivery.

Evidence on the effect of antenatal lifestyle interventions on markers for childhood obesity is inconclusive (Dalrymple et al. 2018). The influence of the GeliS intervention on infant development during the first year of life is currently ongoing and might help to further elucidate this uncertainty.

The GeliS trial provides a unique set of data directly retrieved from the German routine care setting which is valuable to advance the understanding of a possible intergenerational cycle of obesity. Data from the infant cohort provides the basis to study BMI changes during childhood and the currently discussed determinants of the early adiposity rebound (Ip et al. 2017; Geserick et al. 2018; Kang 2018). The 5-year follow-up will enable to address the effect of the antenatal lifestyle on infant health on the long term and to better identify early risk factors for obesity later in life.

6 Conclusion and outlook

In relation to the global obesity epidemic, approaches focusing on a healthy pre- and postnatal lifestyle of mothers have gained major importance in order to prevent excessive GWG, adverse maternal and infant health complications and to tackle a possible intergenerational cycle of obesity. There is some evidence that lifestyle interventions are effective in limiting GWG. However, little is known about their success after being scaled up or being conducted under real-life conditions in the routine care setting. The GeliS trial aimed to reduce the proportion of women with excessive GWG by providing a comprehensive lifestyle intervention alongside antenatal routine care setting. The intervention did not result in considerable improvements in maternal GWG, pregnancy as well as obstetric outcomes and PPWR. Nevertheless, it seemed to be feasible within routine care and ameliorated maternal prenatal PA and dietary behaviour. Maternal prenatal PA *per se* was found to influence overall GWG, infant birth weight and associated health outcomes as well as obstetric parameters. In the GeliS cohort, a considerable proportion of women showed excessive GWG and sustained PPWR which increase the women's risk for overweight and obesity later in life.

The herein presented results underline the urgent need for lifestyle interventions that are performed under real-life conditions and effectively influence clinical parameters during pregnancy and the early pp phase. Despite the missing evidence on these outcomes, the GeliS trial depicts a unique flagship project which established a close cooperation between scientific and governmental institutions and helped to translate scientific knowledge into public health structures. The comprehensive process evaluation of the GeliS concept offers valuable information on the implementation into routine care and possible barriers. Herein presented findings will support to expand the GeliS concept into a more individualised and tailored format. The inclusion of e-health tools could be useful to enable professional support alongside routine care, flexibility, and self-empowerment of pregnant women. Such an e-health programme may reach clinically relevant results at scale. Irrespective of novel approaches, the 5-year follow-up of the GeliS mother-child pairs will elucidate the long-term intervention effect and might be valuable to address for future research questions on the cohort level.

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Appendix

A1 – Pregnancy physical activity questionnaire – modified German version

GeliS Gesund leben in der Schwangerschaft

Teilnehmer ID _ _ _ _ _ _ _ Praxis ID _ _ _ _ _

Fragebogen zur Bewegung

- Sie werden gefragt, **wie viel Zeit** Sie in den letzten vier Wochen mit verschiedenen körperlichen Aktivitäten verbracht haben.
- Bitte beantworten Sie **jede** Frage. Wenn Sie sich nicht sicher sind, dann schätzen Sie. Eine ungefähre Schätzung ist besser als gar keine Antwort.
- Denken Sie bitte nur an Ihre Bewegung **in den letzten vier Wochen!**
- Bei den Zeitangaben geht es um **durchschnittliche Werte.**
- Bitte bei jeder Frage nur **eine Antwort** ankreuzen.

Beispiel:
Wie viel Zeit haben Sie **während der letzten 4 Wochen** durchschnittlich mit folgender Tätigkeit verbracht:

→ Wenn Sie täglich 2 Stunden lang Ihre Mutter pflegen, dann sollte Ihre Antwort folgendermaßen aussehen:

7	Ältere Erwachsene pflegen
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☒	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

8 Fragebogen zur Bewegung 1

Gesund leben in der Schwangerschaft GeliS

Zu Hause...

Wie viel Zeit haben Sie während der letzten 4 Wochen durchschnittlich mit folgenden Tätigkeiten verbracht:

1	Mahlzeiten vor- oder zubereiten (Kochen, Tisch decken, Geschirr spülen)
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

2	Im Sitzen Kinder ankleiden, baden oder füttern
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

3	Im Stehen Kinder ankleiden, baden oder füttern
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

4	Im Sitzen oder Stehen mit Kindern spielen
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

5	Im Gehen oder Rennen mit Kindern spielen
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

6	Kinder tragen
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

7	Ältere Erwachsene pflegen
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

8	Am Schreibtisch oder Computer sitzen, ohne in der Arbeit zu sein
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

GeliS Gesund leben in der Schwangerschaft

9	Fernsehen oder DVD schauen
	☐ Keine
	☐ Weniger als ½ Stunde pro Tag
	☐ ½ bis annähernd 2 Stunden pro Tag
	☐ 2 bis annähernd 4 Stunden pro Tag
	☐ 4 bis annähernd 6 Stunden pro Tag
	☐ 6 oder mehr Stunden pro Tag

10	Sitzen und lesen, reden oder telefonieren, ohne in der Arbeit zu sein
	☐ Keine
	☐ Weniger als ½ Stunde pro Tag
	☐ ½ bis annähernd 2 Stunden pro Tag
	☐ 2 bis annähernd 4 Stunden pro Tag
	☐ 4 bis annähernd 6 Stunden pro Tag
	☐ 6 oder mehr Stunden pro Tag

11	Mit Tieren spielen
	☐ Keine
	☐ Weniger als ½ Stunde pro Tag
	☐ ½ bis annähernd 1 Stunde pro Tag
	☐ 1 bis annähernd 2 Stunden pro Tag
	☐ 2 bis annähernd 3 Stunden pro Tag
	☐ 3 oder mehr Stunden pro Tag

12	Leichte Aufräum- oder Putzarbeiten erledigen (Betten machen, Wäsche waschen)
	☐ Keine
	☐ Weniger als ½ Stunde pro Tag
	☐ ½ bis annähernd 1 Stunde pro Tag
	☐ 1 bis annähernd 2 Stunden pro Tag
	☐ 2 bis annähernd 3 Stunden pro Tag
	☐ 3 oder mehr Stunden pro Tag

13	Einkaufen (Essen, Kleidung oder Sonstiges)
	☐ Keine
	☐ Weniger als ½ Stunde pro Tag
	☐ ½ bis annähernd 1 Stunde pro Tag
	☐ 1 bis annähernd 2 Stunden pro Tag
	☐ 2 bis annähernd 3 Stunden pro Tag
	☐ 3 oder mehr Stunden pro Tag

14	Anstrengende Putzarbeiten erledigen (Staub saugen, Fenster putzen, fegen)
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

15	Rasen mähen (kein Rasenmähertraktor), rechen oder andere Gartenarbeiten erledigen
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

GeliS

An Orte gehen...

Wie viel Zeit haben Sie während der letzten 4 Wochen durchschnittlich mit folgenden Tätigkeiten verbracht:

16	Langsam an diverse Orte gehen (z.B. zum Bus, zur Arbeit, zu Besuchen) nicht zum Spaß oder Sport
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

17	Schnell an diverse Orte gehen (z.B. zum Bus, zur Arbeit, zu Besuchen) nicht zum Spaß oder Sport
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

18	Mit Auto oder Bus fahren
☐	Keine
☐	Weniger als ½ Stunde pro Tag
☐	½ bis annähernd 1 Stunde pro Tag
☐	1 bis annähernd 2 Stunden pro Tag
☐	2 bis annähernd 3 Stunden pro Tag
☐	3 oder mehr Stunden pro Tag

Spaß oder Sport...

Wie viel Zeit haben Sie während der letzten 4 Wochen durchschnittlich mit folgenden Tätigkeiten verbracht:

19	Langsam gehen zum Spaß oder Sport
☐	Keine
☐	Weniger als ½ Stunde pro **Woche**
☐	½ bis annähernd 1 Stunde pro **Woche**
☐	1 bis annähernd 2 Stunden pro **Woche**
☐	2 bis annähernd 3 Stunden pro **Woche**
☐	3 oder mehr Stunden pro **Woche**

20	Schnell gehen zum Spaß oder Sport
☐	Keine
☐	Weniger als ½ Stunde pro **Woche**
☐	½ bis annähernd 1 Stunde pro **Woche**
☐	1 bis annähernd 2 Stunden pro **Woche**
☐	2 bis annähernd 3 Stunden pro **Woche**
☐	3 oder mehr Stunden pro **Woche**

GeliS Gesund leben in der Schwangerschaft

21	Schnell Berge hoch gehen, zum Spaß oder Sport
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

22	Joggen
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

23	Geburtsvorbereitungskurse besuchen
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

24	Schwimmen
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

25	Tanzen
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

Andere Dinge zum Spaß oder Sport getan? Bitte sagen Sie uns welche:

26	
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

27	
	☐ Keine
	☐ Weniger als ½ Stunde pro **Woche**
	☐ ½ bis annähernd 1 Stunde pro **Woche**
	☐ 1 bis annähernd 2 Stunden pro **Woche**
	☐ 2 bis annähernd 3 Stunden pro **Woche**
	☐ 3 oder mehr Stunden pro **Woche**

Gesund leben in der Schwangerschaft GeliS

Bitte füllen Sie den nächsten Abschnitt nur aus, wenn Sie erwerbstätig sind, ehrenamtlich arbeiten oder Schülerin/Studentin sind. Wenn Sie Hausfrau, arbeitslos oder arbeitsunfähig sind, bitte weiter mit dem Fragebogen zur Ernährung (Seite 14).

In der Arbeit...

Wie viel Zeit haben Sie während der letzten 4 Wochen durchschnittlich mit folgenden Tätigkeiten verbracht:

28 In der Arbeit/Schule/Studium sitzen

- ☐ Keine
- ☐ Weniger als ½ Stunde pro Tag
- ☐ ½ bis annähernd 2 Stunden pro Tag
- ☐ 2 bis annähernd 4 Stunden pro Tag
- ☐ 4 bis annähernd 6 Stunden pro Tag
- ☐ 6 oder mehr Stunden pro Tag

29 In der Arbeit stehen oder langsam gehen und dabei nichts tragen

- ☐ Keine
- ☐ Weniger als ½ Stunde pro Tag
- ☐ ½ bis annähernd 2 Stunden pro Tag
- ☐ 2 bis annähernd 4 Stunden pro Tag
- ☐ 4 bis annähernd 6 Stunden pro Tag
- ☐ 6 oder mehr Stunden pro Tag

30 In der Arbeit stehen oder langsam gehen und dabei Dinge tragen (schwerer als 4 kg = 4 Flaschen Wasser oder 4 Kartons Milch)

- ☐ Keine
- ☐ Weniger als ½ Stunde pro Tag
- ☐ ½ bis annähernd 2 Stunden pro Tag
- ☐ 2 bis annähernd 4 Stunden pro Tag
- ☐ 4 bis annähernd 6 Stunden pro Tag
- ☐ 6 oder mehr Stunden pro Tag

31 Bei der Arbeit schnell gehen und dabei nichts tragen

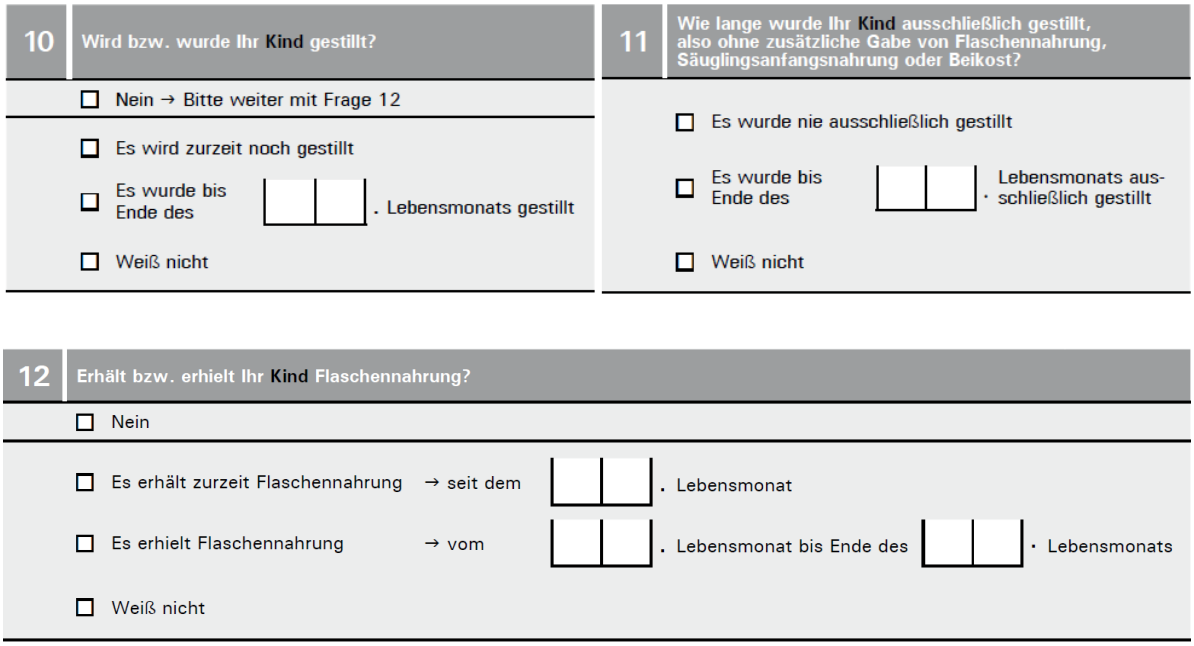
- ☐ Keine
- ☐ Weniger als ½ Stunde pro Tag
- ☐ ½ bis annähernd 2 Stunden pro Tag
- ☐ 2 bis annähernd 4 Stunden pro Tag
- ☐ 4 bis annähernd 6 Stunden pro Tag
- ☐ 6 oder mehr Stunden pro Tag

32 In der Arbeit schnell gehen und dabei Dinge tragen (schwerer als 4 kg = 4 Flaschen Wasser oder 4 Kartons Milch)

- ☐ Keine
- ☐ Weniger als ½ Stunde pro Tag
- ☐ ½ bis annähernd 2 Stunden pro Tag
- ☐ 2 bis annähernd 4 Stunden pro Tag
- ☐ 4 bis annähernd 6 Stunden pro Tag
- ☐ 6 oder mehr Stunden pro Tag

Quelle: modifiziert nach Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and Validation of a Pregnancy Physical Activity Questionnaire. Med Sci Sports Exer 2004 36(10):1750-1760.

A2 – Questions related to breastfeeding behaviour – adapted from the KIGGS study
(Lippe et al. 2014)



10 Wird bzw. wurde Ihr **Kind** gestillt?

- ☐ Nein → Bitte weiter mit Frage 12
- ☐ Es wird zurzeit noch gestillt
- ☐ Es wurde bis Ende des ☐☐. Lebensmonats gestillt
- ☐ Weiß nicht

11 Wie lange wurde Ihr **Kind** ausschließlich gestillt, also ohne zusätzliche Gabe von Flaschennahrung, Säuglingsanfangsnahrung oder Beikost?

- ☐ Es wurde nie ausschließlich gestillt
- ☐ Es wurde bis Ende des ☐☐. Lebensmonats ausschließlich gestillt
- ☐ Weiß nicht

12 Erhält bzw. erhielt Ihr **Kind** Flaschennahrung?

- ☐ Nein
- ☐ Es erhält zurzeit Flaschennahrung → seit dem ☐☐. Lebensmonat
- ☐ Es erhielt Flaschennahrung → vom ☐☐. Lebensmonat bis Ende des ☐☐. Lebensmonats
- ☐ Weiß nicht

A3 – Letter for the acceptance for publication of the manuscript entitled

"Effects of a lifestyle intervention in routine care on prenatal physical activity – findings from the cluster-randomised GeliS trial"

Date: 01 Oct 2019
To: "Hans Hauner" hans.hauner@tum.de
From: "BMC Pregnancy and Childbirth Editorial Office" arvin.estrellado@biomedcentral.com
Subject: Decision on your Submission to BMC Pregnancy and Childbirth - PRCH-D-19-00259R3

PRCH-D-19-00259R3
Effects of a lifestyle intervention in routine care on prenatal physical activity – findings from the cluster-randomised GeliS trial
Julia Hoffmann; Julia Günther; Kristina Geyer; Lynne Stecher; Kathrin Rauh; Julia Kunath; Dorothy Meyer; Christina Sitzberger; Monika Spies; Eva Rosenfeld; Luzia Kick; Renate Oberhoffer; Hans Hauner
BMC Pregnancy and Childbirth

Dear Prof. Dr. Hauner,

I am pleased to inform you that your manuscript "Effects of a lifestyle intervention in routine care on prenatal physical activity – findings from the cluster-randomised GeliS trial" (PRCH-D-19-00259R3) has been accepted for publication in BMC Pregnancy and Childbirth.

If any final comments have been submitted from our reviewers or editors, these can be found at the foot of this email for your consideration.

Before publication, our production team will also check the format of your manuscript to ensure that it conforms to the standards of the journal. They will be in touch shortly to request any necessary changes, or to confirm that none are needed.

Articles in this journal may be held for a short period of time prior to publication. If you have any concerns please contact the journal.

Please do not hesitate to contact us if you have any questions regarding your manuscript and I hope that you will consider BMC Pregnancy and Childbirth again in the future.

If you wish to co-submit a data note to be published in BMC Research Notes (https://bmcresnotes.biomedcentral.com/about/introducing-data-notes) you can do so by visiting our submission portal http://www.editorialmanager.com/resn/. Data notes support open data (https://www.springernature.com/gp/open-research/open-data) and help authors to comply with funder policies on data sharing. Please note that this additional service is entirely optional.

Best wishes,

Lauren McMillan
BMC Pregnancy and Childbirth
https://bmcpregnancychildbirth.biomedcentral.com/

Comments:

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Please also take a moment to check our website at https://bmcpregnancychildbirth.biomedcentral.com/

BMC Pregnancy and Childbirth operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

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A4 – Approval for a publication-based dissertation

Einverständniserklärung zur publikationsbasierten Promotion[1]

Anlage 6 (für § 6 Abs. 2)

Hiermit erkläre ich mein Einverständnis, dass die Dissertation von

Frau/~~Herrn~~ Julia Rebecca HOFFMANN

als publikationsbasierte Dissertation eingereicht wird. Sie erfüllt die nachfolgenden Kriterien:

1. Einleitungs- und Methodenteil (20 Seiten). Ein themenübergreifender Diskussionsteil mit Reflexion zur bestehenden Literatur.
2. Kumulative Einbindung von mindestens zwei akzeptierten Erstautorenveröffentlichungen (full paper in einem englischsprachigen, international verbreiteten Publikationsorgan, peer reviewed)
3. Die eingebundenen Veröffentlichungen müssen federführend vom Doktoranden abgefasst sein.
4. Eingebunden muss sein: je eine einseitige Zusammenfassung der jeweiligen Veröffentlichungen unter Hervorhebung der individuellen Leistungsbeiträge des Kandidaten.
5. Einbindung von ausgewählten Originalveröffentlichungen nur mit einem separaten schriftlichen „Erlaubnisschreiben des jeweiligen Verlags". Alle anderen Originalveröffentlichungen werden unter Nennung der bibliografischen Angaben aufgelistet. In den Exemplaren für die Mitglieder der Prüfungskommission sind alle Originalveröffentlichungen separat dazu abzugeben.

17. Juli 2019
Datum

Unterschrift betreuender Prof.

[1] Zur Vorlage bei der Einreichung der Dissertation.

Acknowledgment

First of all I would like to give my sincere thanks to my supervisor Univ.-Prof. Dr. med. Hans Hauner, head of the Institute, for the opportunity to realise my Ph.D. thesis in the wonderful GeliS study, for his faith in me concerning analyses and the responsibility for the follow-up.

Further, I would like to thank Prof. Dr. Renate Oberhoffer, chair of Preventive Pediatrics for evaluating the thesis as the second examiner, and Prof. Dr. Martin Klingenspor, chair of Molecular Nutritional Medicine, for being the chairman.

Moreover, I would like to thank all members and alumni of the GeliS study team and cooperation partners for designing, conducting, or establishing the GeliS study and the pleasant working atmosphere. Participating women together with their infants have become dear to me and are sincerely acknowledged for their engagement, for sharing personal information and for their confidence in the GeliS team.

In particular, I would like to thank my colleague Julia Günther for the always unconditional, outstanding, trustful teamwork, the inspiring and constructive ‘GeiliS’ booster meetings and for being far more than a colleague. Moreover, I sincerely thank Dr. Lynne Stecher (and Anton) for her exceptional statistical support and for being available no matter from where and when. Further, my thank goes to Monika Spies, Dora Meyer, and the sweeties Kristina Geyer and Roxana Raab for their support and contributions on the professional level, the lovely working atmosphere and for not hesitating to join new ‘GeiliS’ challenges.

Moreover, I sincerely thank Dr. Christina Holzapfel for being more than my mentor by providing excellent advice and for her inexhaustible support and interest in my work and me as a person.

I thank all colleagues and alumni from the Institute for their support in every matter, for the pleasant teamwork, inspiring coffee and lunch breaks, the ‘fast foodie’ runs and all other events that made the time at the Institute unforgettable.

Furthermore, I thank all of my friends for their patient support, motivation, and proofreading as well as for sharing a healthy work-life-balance.

I am very grateful for the unconditional support and limitless advice of my family and Martin. They never lost confidence, were always there for me and supported me in every way, from strategic brainstorming to critical research questions through to mind opening cycling tours, inspiring sailing days and enjoyable Ammersee weekends.

Curriculum vitae

Persönliche Daten

Name	**Julia Rebecca Hoffmann**
Geburtsdatum	**18.10.1988 in München**
Nationalität	**Deutsch**

Promotion

seit 04/2015	**Technische Universität München (TUM)** Promotion am Else Kröner-Fresenius-Zentrum für Ernährungsmedizin, Lehrstuhl für Klinische Ernährungsmedizin *Thema der Doktorarbeit*: "'Healthy living in pregnancy (GeliS)' – Effects of a lifestyle intervention in the antenatal routine care setting on physical activity and breastfeeding behaviour and maternal weight development"

Studium

09/2012 – 12/2014	**Technische Universität München** Abschluss: Master of Science (M.Sc.) Nutrition and Biomedicine *Thema der Masterarbeit*: "GeliS (Healthy living in pregnancy) – Evaluation of a lifestyle intervention programme – Implementation of counselling sessions into standard antenatal care"
10/2008 – 09/2011	**Justus-Liebig-Universität Gießen** Abschluss: Bachelor of Science (B.Sc.) Ernährungswissenschaften *Thema der Bachelorarbeit*: „In vitro- und in vivo – Untersuchungen zur Regulation der Sterol Regulatory Element-binding Proteins (SREBPs) in der Schilddrüse durch Cholesterol und Peroxisome Proliferator-Activated Receptor Alpha (PPARα) – Agonisten"

Allgemeine Hochschulreife

09/1999 – 06/2008	Rhabanus-Maurus-Gymnasium, St.Ottilien

List of publications and congress contributions

Publications

J. Kunath* & J. Günther*, K. Rauh, **J. Hoffmann**, L. Stecher, E. Rosenfeld, L. Kick, L. Ulm, H. Hauner. Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care - the cluster-randomised GeliS trial. BMC medicine 2019, 17, 5. [*both authors contributed equally to the manuscript].

J. Günther* & **J. Hoffmann***, M. Spies, H. Hauner. Lebensstil und Gewichtszunahme in der Schwangerschaft – Bedeutung für die Gesundheit von Mutter und Kind. Ernährung & Medizin 2019; 34: 20-25. [*both authors contributed equally to the manuscript].

J. Hoffmann* & J. Günther*, K. Geyer, L. Stecher, K. Rauh, J. Kunath, D. Meyer, C. Sitzberger, M. Spies, E. Rosenfeld, L. Kick, R. Oberhoffer, H. Hauner. Effects of a lifestyle intervention in routine care on prenatal physical activity – findings from the cluster-randomised GeliS trial. BMC Pregnancy and Childbirth 2019 [*both authors contributed equally to the manuscript; article accepted for publication].

J. Hoffmann, J. Günther, K. Geyer, L. Stecher, J. Kunath, D. Meyer, M. Spies, E. Rosenfeld, L. Kick, K. Rauh, Hans Hauner. Associations between prenatal physical activity and neonatal and obstetric outcomes—a secondary analysis of the cluster-randomised GeliS trial. J. Clin. Med. 2019 [under review].

J. Hoffmann, J. Günther, L. Stecher, M. Spies, D. Meyer, J. Kunath, R. Raab, K. Rauh, H. Hauner. Effects of a Lifestyle Intervention in Routine Care on Short- and Long-Term Maternal Weight Retention and Breastfeeding Behavior—12 Months Follow-up of the Cluster-Randomized GeliS Trial. J. Clin. Med. 2019, 8(6), 876.

J. Günther, **J. Hoffmann**, J. Kunath, M. Spies, D. Meyer, L. Stecher, E. Rosenfeld, L. Kick, K. Rauh, H. Hauner. Effects of a Lifestyle Intervention in Routine Care on Prenatal Dietary Behavior—Findings from the Cluster-Randomized GeliS Trial. J. Clin. Med. 2019, 8(7), 960.

J. Günther, **J. Hoffmann**, M. Spies, D. Meyer, J. Kunath, L. Stecher, E. Rosenfeld, L. Kick, K. Rauh, H. Hauner. Associations between the Prenatal Diet and Neonatal Outcomes—A Secondary Analysis of the Cluster-Randomised GeliS Trial. Nutrients 2019, 11(8), 1889.

Talks / Congress contributions

J. Hoffmann. Kann Lebensstilintervention in der Schwangerschaft Gestationsdiabetes und exzessive Gewichtszunahme verhindern? Ergebnisse der GeliS Studie. 12. Diabetes Herbsttagung der Deutschen Diabetes Gesellschaft (DDG) und 34. Jahrestagung der Deutschen Adipositas-Gesellschaft (DAG) e.V., 09.11.-10.11.2018 in Wiesbaden, Germany.

J. Günther, **J. Hoffmann**, J. Kunath, K. Rauh, M. Spies, L. Kick, E. Rosenfeld, L. Stecher, H. Hauner. „Gesund leben in der Schwangerschaft" – Ergebnisse der GeliS-Lebensstilinterventionsstudie in zehn bayrischen Regionen. 56. Wissenschaftlicher Kongress der DGE (Deutsche Gesellschaft für Ernährung e.V.), 19.-21.03.2019 in Gießen, Germany.

Posters

K. Rauh, **J. Hoffmann**, J. Kunath, J. Günther, L. Kick, E. Rosenfeld, H. Hauner. Evaluation der Beratungsgespräche des Lebensstilinterventions-Programms „Gesund leben in der Schwangerschaft" (GeliS). 53. Wissenschaftlicher Kongress der DGE (Deutsche Gesellschaft für Ernährung e.V.), 02.-04.03.2016 in Fulda, Germany.

J. Hoffmann, J. Günther, J. Kunath, K. Rauh, L. Bär, M. Spies, L. Kick, E. Rosenfeld, L. Stecher, H. Hauner. „Gesund leben in der Schwangerschaft" – Evaluation der GeliS-Lebensstilintervention. 56. Wissenschaftlicher Kongress der DGE (Deutsche Gesellschaft für Ernährung e.V.), 19.-21.03.2019 in Gießen, Germany.

J. Günther, **J. Hoffmann**, K. Rauh, J. Kunath, E. Rosenfeld, L. Kick, L. Stecher, H. Hauner. The effect of lifestyle counselling on dietary behavior of pregnant women – secondary results of the randomised controlled GeliS trial. 26th European Congress on Obesity, 28.04.–01.05.2019, Glasgow, Scotland.

J. Hoffmann, J. Günther, K. Rauh, J. Kunath, E. Rosenfeld, L. Kick, L. Stecher, H. Hauner. Effect of prenatal lifestyle counselling in routine care on gestational weight gain and the risk of gestational diabetes - results of the cluster-randomised GeliS trial. DIP 2019 – 10th International Symposium on Diabetes, Hypertension, Metabolic Syndrome and Pregnancy, 29.05.–01.06.2019, Florence, Italy.

J. Hoffmann, J. Günther, J. Kunath, K. Rauh, L. Stecher, E. Rosenfeld, L. Kick, K. Geyer, M. Spies, D. Meyer, H. Hauner. Effects of prenatal lifestyle counselling on diet and physical activity in the cluster-randomised controlled GeliS ("Gesund leben in der Schwangerschaft"/Healthy living in pregnancy) trial. International Society for Developmental

Origins of Health and Disease – World Congress 2019, 20.10.–23.10.2019, Melbourne, Australia.

J. Günther, J. Kunath, K. Rauh, **J. Hoffmann**, L. Stecher, E. Rosenfeld, L. Kick, H. Hauner. The Healthy living in pregnancy (GeliS) trial – a large-scaled public health approach for the prevention of excessive gestational weight gain and pregnancy complications. International Society for Developmental Origins of Health and Disease – World Congress 2019, 20.10.–23.10.2019, Melbourne, Australia.