Lehrstuhl für Ernährungsmedizin

Lifestyle intervention for pregnant women to prevent excessive gestational weight gain: a cluster-randomized study in ten Bavarian regions.

Julia Kunath

Vollständiger Abdruck der von der Fakultät Wissenschaftszentrum Weihenstephan für Ernährung, Landnutzung und Umwelt der Technischen Universität München zur Erlangung des akademischen Grades eines

Doktors der Naturwissenschaften

genehmigten Dissertation.

Vorsitzender:	Prof. Dr. Martin Klingenspor
Prüfer der Dissertation:	1. Prof. Dr. Johann J. Hauner
	2. Prof. Dr. Heiko Witt

Die Dissertation wurde am 06.11.2018 bei der Technischen Universität München eingereicht und durch die Fakultät Wissenschaftszentrum Weihenstephan für Ernährung, Landnutzung und Umwelt am 11.02.2019 angenommen.

TABLE OF CONTENTS

LIST OF FIGURES ..... **i**

LIST OF TABLES ..... **ii**

LIST OF STUDY DOCUMENTS ..... **iii**

ABBREVIATIONS ..... **iv**

SUMMARY **1**

ZUSAMMENFASSUNG **3**

1. INTRODUCTION **5**

1.1 Maternal Pre-pregnancy overweight/obesity and its consequences 6

1.2 The concept of fetal programming 10

1.3 Characteristics of weight gain in singleton pregnancy 12

1.4 Recommendations for weight gain in pregnancy 14

1.5 Excessive gestational weight gain and its consequences 16

1.6 Knowledge about weight gain in pregnancy among expectant mothers and healthcare providers 19

1.7 Trends in gestational weight gain in Germany 20

1.8 Current lifestyle interventions to optimize pregnancy and obstetric outcomes 21

2. GELIS – A LIFESTYLE INTERVENTION STUDY DURING PREGNANCY **33**

2.1 Study Endpoints 33

2.2 Study design and setting 34

2.2.1 The cluster randomization 35

2.2.2 Recruitment of gynecological and midwife practices and counselors 35

2.2.3 Qualification of counselors 35

2.2.4 Recruitment of participants 39

2.2.5 The GeliS lifestyle intervention program (Visit V1-Visit V4) 40

2.2.6 Study documents and materials 43

2.2.7 Follow-Up 45

2.2.8 Drop-out criteria 46

2.3 Outcome measures and data collection 46

2.4 Data management 48

2.5 Power calculation 48

2.6 Datasets for analyses 49

2.7 Statistical analyses 50

3 RESULTS **52**

3.1 Participating practices, counselors and pregnant women 52

3.2 Characterization of the study population 53

3.3 Primary outcome – Gestational weight gain 60
3.3.1 Adherence to IOM guidelines 61
3.3.2 Mean total gestational weight gain 64
3.3.3 Weight gain at different time points during pregnancy 65
3.4 Secondary outcomes 66
3.4.1 Maternal Pregnancy and birth related outcomes 66
3.4.2 Birth related outcomes in infants 72
3.4.3 Postpartum weight retention 74
3.5 Correlations between gestational weight gain and pre-pregnancy BMI and secondary outcomes in the whole study population 75
3.6 Correlations between compliance and gestational weight gain 77
4. DISCUSSION 80
4.1 Recruitment process 80
4.2 Study population 82
4.3 Primary outcome analyses – A comparison with literature and national data 83
4.4 Secondary outcome analyses 88
4.4.1 Gestational diabetes mellitus 88
4.4.2 Birth weight 92
4.4.3 Maternal and obstetric outcomes 92
4.5 Implementation of the study into practice 93
4.6 Why the intervention was not successful - Possible explanations 96
4.7 General strengths and limitations of the trial 97
5. CONCLUSION AND OUTLOOK 100
REFERENCES 105
APPENDIX 132
1. Study documents 132
2. Supplemental tables 177
ACKNOWLEDGEMENTS 180
LIST OF PUBLICATIONS AND CONGRESS CONTRIBUTIONS 182
EIDESSTATTLICHE ERKLÄRUNG 184

LIST OF FIGURES

Figure 1: The vicious circle of obesity and metabolic disorders. 12
Figure 2: GeliS study regions. 34
Figure 3: GeliS study scheme. 41
Figure 4: Flow chart of the GeliS trial. 55
Figure 5: Adherence to IOM guidelines by study participants depending on pre-pregnancy BMI. 61
Figure 6: Proportion of women with excessive, adequate and inadequate GWG in the intervention and the control group. 62
Figure 7: Birth weight (including preterm births) of infants between study groups. 72
Figure 8: Correlations of GWG with different secondary outcomes. 75
Figure 9: Correlations of pre-pregnancy BMI with different secondary outcomes. 76
Figure 10: Mean total GWG of participants classified by profession of healthcare providers. 79
Figure 11: Possible influencing factors of blood sugar levels. 91
Figure 12: Different surveys for evaluating the lifestyle intervention program 94
Figure 13: Recommendations for future approaches 101

LIST OF TABLES

Table 1: Consequences of maternal pre-pregnancy overweight/obesity. 6
Table 2: Components of weight gain during pregnancy. 13
Table 3: The 2009 US Institute of Medicine (IOM) recommendations for GWG for singleton pregnancies ... 14
Table 4: Consequences of excessive GWG. 16
Table 5: Lifestyle intervention studies during pregnancy targeting GWG. 23
Table 6: Inclusion and exclusion criteria 40
Table 7: Documents and materials used in the GeliS trial. 43
Table 8: Thresholds in venous plasma after a 75-g-oGTT for diagnosis of GDM. 47
Table 9: Gynecological and midwife practices participating in the GeliS study. 52
Table 10: Qualified counselors in the GeliS study. 52
Table 11: Numbers of participants in the GeliS study. 53
Table 12: Comparison of baseline characteristics between GeliS study participants and rejecters. 56
Table 13: Baseline characteristics of the GeliS study population. 57
Table 14: Anamnestic characteristics of GeliS participants. 59
Table 15: Study participants with excessive GWG. 63
Table 16: Mean total GWG in control versus intervention group. 64
Table 17: Weight gain at different time points during pregnancy. 65
Table 18: Women with diagnosed GDM and results of fasting glucose concentrations. 67
Table 19: Results of HbA_{1c} measurements in the intervention versus the control group. 68
Table 20: Pregnancy complications in the intervention versus the control group. 69
Table 21: Obstetric outcomes among study participants. 70
Table 22: Birth related outcomes in infants in the intervention versus the control group. 73
Table 23: Maternal weight retention (6-8 weeks postpartum). 74
Table 24: Outcomes of women with excessive versus not excessive GWG 76
Table 25: Quantitative evaluation of lifestyle counseling sessions. 77
Table 26: Mean total GWG of women attended all lifestyle counseling sessions during pregnancy versus women attended not all sessions during pregnancy. 78
Table 27: Mean total GWG and proportion of women exceeding IOM guidelines compared to the GeliS study 85
Table 28: GWG among study participants according the IOM recommendations. 177
Table 29: Mean total GWG among all study participants. 177
Table 30: Maternal blood pressure. 178
Table 31: Qualitative evaluation of lifestyle counseling sessions. 178
Table 32: Experiences of GeliS counselors with study procedures. 179

LIST OF STUDY DOCUMENTS

Study document 1: Participant information and written informed consent (Intervention)……132
Study document 2: Participant information and declaration of consent (Control)……140
Study document 3: Screening questionnaire……148
Study document 4: Detail of the Case Report Form……149
Study document 5: Folder with presentation boards for parental counseling……163
Study document 6: Weight gain charts……163
Study document 7: Instructions……165
Study document 8: Checklists……170
Study document 9: Sticker for maternity card……177

ABBREVIATIONS

AOK	Allgemeine Ortskrankenkasse
AR	Adipose Rebound
AQUA	Institut für Angewandte Qualitätsförderung und Forschung im Gesundheitswesen
BAQ	Bayerische Arbeitsgemeinschaft für Qualitätssicherung (Bavarian working group on quality assurance in outpatient medical care)
BMI	Body Mass Index
BZgA	Bundeszentrale für gesundheitliche Aufklärung
CIAPSE	Le Congrès International sur l'Activité Physique et le Sport chez l'enfant (The International Congress on children's Physical Activity and Sport)
CRF	Case Report Form
DAG	Deutsche Adipositas Gesellschaft e.V.
DASH	Dietary Approaches to Stop Hypertension
DEGS	Studie zur Gesundheit Erwachsener in Deutschland (German health Interview and examination survey for adults)
DGE	Deutsche Gesellschaft für Ernährung e.V.
EDTA	Ethylenediaminetetraacetic acid
EKFS	Else Kröner-Fresenius-Stiftung
EPDS	Edinburgh Postnatal Depression Scale
EPHR	European Perinatal Health Report
FeLIPO	Feasibility of a Lifestyle Intervention in Pregnancy to Optimize maternal weight development
FFQ	Food Frequency Questionnaire
g	Gram
GCT	Glucose Challenge Test
GDM	Gestational Diabetes Mellitus
GEE	Generalized Estimating Equations
GeliS	Gesund leben in der Schwangerschaft (Healthy living in pregnancy)
GWG	Gestational Weight Gain
HTA	Health Technology Assessment
ICC	Intraclass Correlation Coefficient
IOM	Institute of Medicine
IPD	Individual Participant Data
IQTIG	Institut für Qualitätssicherung und Transparenz im Gesundheitswesen

i-WIP Collaborative Group	International Weight Management in Pregnancy Collaborative Group
KErn	Kompetenzzentrum für Ernährung (Competence Center for Nutrition)
kcal	Kilocalorie
kg	Kilogram
KiGGS	Kinder- und Jugendgesundheitssurvey (German Health Interview and Examination Survey for Children and Adolescents)
KORA	Kooperative Gesundheitsforschung in der Region Augsburg (Cooperative health research in the region Augsburg)
KVB	Kassenärztliche Vereinigung Bayerns (Bavarian Association of Statutory Health Insurance Physicians)
l	Liter
LGA	Large for Gestational Age
LIMIT	Limiting weight gain in overweight and obese women during pregnancy to improve health outcomes
MRI	Max-Rubner-Institut
m	Meter
mmHg	Millimeters mercury
mol	Mole
NaF	Sodium fluoride
NIHR	The UK National Institute for Health Research
NRC	National Research Council
oGTT	Oral Glucose Tolerance Test
OR	Odds Ratio
PEPO	Perinatal Prevention of Obesity
PHQ	Patient Health Questionnaire
PPAQ	Pregnancy Physical Activity Questionnaire
PPWR	Postpartum Weight Retention
RCT	Randomized Controlled Trial
SGA	Small for Gestational Age
TUM	Technical University of Munich
UPBEAT	UK Better Eating and Activity Trial
WBCB	Well Baby Check-up Booklet (Kinderuntersuchungsheft)
WHO	World Health Organization

SUMMARY

The worldwide prevalence of overweight and obesity has dramatically increased in the past decades. In Germany, every second person currently has a body mass index (BMI) over 25 kg/m^2 including women of childbearing age. Comparable to a high BMI at the beginning of pregnancy, excessive gestational weight gain is associated with short- and long-term adverse effects in mothers and their children. Women who gain weight in excess during pregnancy retain more weight after birth than women showing a healthy weight gain. As known from literature, lifestyle behavior of expectant mothers can influence the metabolism of infants, leading to obesity or chronic diseases such as cardiovascular diseases or diabetes mellitus in later life.

The cluster-randomized lifestyle intervention study GeliS (acronym for "Gesund leben in der Schwangerschaft") developed by the Technical University of Munich (TUM) in cooperation with the Competence Center for Nutrition (KErn) was performed in ten Bavarian regions. The program was intended to encourage healthy dietary and physical activity behavior in pregnant women. Designed as a public health project, the lifestyle program was attached to routine antenatal and postnatal visits. Women in the intervention group received three comprehensive counseling sessions on diet, physical behavior and adequate weight gain during pregnancy and one session after birth. Sessions were performed by trained midwives, medical assistants and gynecologists. The aim of the study was to limit the proportion of pregnant women exceeding gestational weight gain recommendations of the Institute of Medicine (IOM) and furthermore, to prevent maternal and infant risks of complications. Women in the control group received standard antenatal care without additional lifestyle advice.

2286 women, 71 gynecological practices and 62 active lifestyle counselors took part in the GeliS study. 11 % of all participating women dropped out of the study. The intervention was not successful in reducing the proportion of women exceeding the IOM guidelines. 45.1 % of women in the intervention group and 45.7 % of women in the control group gained more weight than recommended by the IOM. Especially overweight and obese women frequently exceeded these guidelines. Mean gestational weight gain (GWG) was 14.1 kg in both groups. Lifestyle advice did not result in significantly less pregnancy and obstetric complications. Gestational diabetes mellitus (GDM) was diagnosed in 11 % of women in both groups. The average long-term blood glucose parameter HbA_{1c} was 5.1 % with no difference between groups. The rate of cesarean sections was 30 % (intervention group) and 28 % (control group). There was a small but significant

reduction in birth weight of 50 g on average in the intervention group (intervention group: 3313 g; control group: 3363 g; p=0.02). Children of mothers in the intervention group were also less tall at birth (intervention group: 51.1 cm; control group: 51.6 cm; p=0.001).

In the setting of routine prenatal care, lifestyle advice for pregnant women given by trained gynecologists, midwives and medical assistants was not successful in limiting GWG and pregnancy complications such as gestational diabetes mellitus. Further analyses will provide information on dietary and physical activity behavior, women's well-being, the intake of dietary supplements and the prevalence of breastfeeding. In a five year follow-up observation, the development of weight, health as well as dietary and lifestyle behavior factors of mothers and their children will be analyzed to assess potential long-term effects of the intervention.

ZUSAMMENFASSUNG

Die weltweite Prävalenz von Übergewicht und Adipositas ist in den letzten Jahrzehnten dramatisch angestiegen. In Deutschland hat derzeit jeder zweite Erwachsene einen Body-Mass-Index (BMI) über 25 kg/m^2. Auch Frauen im gebärfähigen Alter sind betroffen. Ähnlich wie das Gewicht zu Beginn einer Schwangerschaft kann auch die Gewichtszunahme während der Schwangerschaft mit kurz- und langfristigen negativen Folgen für Mutter und Kind einhergehen. Frauen, die übermäßig in der Schwangerschaft zunehmen, behalten nach der Geburt mehr Gewicht als Frauen mit einer gesunden Gewichtszunahme in der Schwangerschaft. Wissenschaftliche Studien bestätigen, dass der Lebensstil der Schwangeren darüber hinaus auch auf den Stoffwechsel des Kindes einwirken und ihn für sein weiteres Leben prägen kann. So gibt es Hinweise, dass Kinder von übergewichtigen Müttern ein erhöhtes Risiko haben, selbst übergewichtig zu werden und an chronischen Krankheiten wie Herz-Kreislauf-Erkrankungen oder Diabetes zu erkranken.

Die vor diesem Hintergrund entwickelte cluster-randomisierte Lebensstil-Interventionsstudie GeliS („Gesund leben in der Schwangerschaft“) der Technischen Universität München (TUM) wurde in Kooperation mit dem Kompetenzzentrum für Ernährung (KErn) in zehn bayerischen Studienregionen durchgeführt. Die GeliS-Intervention sollte Schwangere ermutigen, sich ausgewogen zu ernähren und regelmäßig zu bewegen. Als Public Health Projekt konzipiert, wurde das Lebensstilprogramm an die routinemäßigen Termine der Schwangerenvorsorge angebunden. Frauen der Interventionsgruppe erhielten während der Schwangerschaft drei ausführliche Beratungsgespräche zu den Themen Ernährung, Bewegung und angemessene Gewichtszunahme in der Schwangerschaft sowie ein Gespräch nach der Geburt. Die Beratungen wurden durch speziell geschulte Hebammen und medizinische Fachangestellte sowie Gynäkologen durchgeführt. Ein zusätzliches Beratungsgespräch erfolgte nach der Geburt des Kindes. Ziel der Intervention war es, eine übermäßige Gewichtszunahme während der Schwangerschaft (oberhalb der Empfehlungen des amerikanischen Institute of Medicine (IOM)) zu begrenzen und gesundheitliche Risiken für Mutter und Kind zu minimieren. Frauen in der Vergleichsgruppe erhielten die routinemäßige Schwangerschaftsbetreuung ohne zusätzliches Beratungsangebot.

2286 rekrutierte Studienteilnehmerinnen, 71 gynäkologische Praxen und 62 aktive Lebensstilberater nahmen an der GeliS-Studie teil. 11 % der rekrutierten Studienteilnehmerinnen schieden im Laufe der Studie aus.

Die GeliS-Intervention konnte den Anteil an Frauen mit exzessiver Gewichtszunahme (oberhalb der IOM-Kriterien) nicht beeinflussen. In der Interventionsgruppe nahmen 45,1 % und in der Kontrollgruppe 45,7 % mehr Gewicht zu als vom IOM empfohlen. Besonders unter den übergewichtigen und adipösen Frauen wurden die Empfehlungen zur Gewichtszunahme in beiden Gruppen häufig überschritten. Die mittlere Gewichtszunahme betrug in der Interventions- und Kontrollgruppe jeweils 14,1 kg. Die Lebensstilberatung führte zu keiner signifikanten Reduktion von Schwangerschafts- und Geburtskomplikationen. Sowohl in den Interventions- als auch den Kontrollregionen wurde insgesamt bei rund 11 % der Frauen ein Gestationsdiabetes diagnostiziert. Der Langzeitblutzuckerparameter HbA_{1c} beider Gruppen betrug im Mittel 5,1 % Prozent. Die Kaiserschnittrate betrug jeweils 30 % (Interventionsgruppe) und 28 % (Kontrollgruppe). Beim Geburtsgewicht zeigte sich eine signifikante, wenn auch geringe Reduktion in der Interventionsgruppe um durchschnittlich 50 g (Intervention: 3313 g; Vergleich: 3363 g; p=0,02). Kinder von Müttern der Interventionsgruppe wiesen außerdem eine geringere Körperlänge bei der Geburt auf (Intervention: 51,1 cm; Vergleich: 51,6 cm; p=0,001).

Die Lebensstilberatung von schwangeren Frauen durch geschulte Gynäkologen, Hebammen und medizinische Fachangestellte war im Rahmen der routinemäßigen Schwangerschaftsvorsorge nicht erfolgreich bei der Begrenzung einer übermäßigen Gewichtszunahme und Schwangerschaftskomplikationen wie Gestationsdiabetes. In weiteren Analysen werden Daten zu Ernährung, Bewegung, Wohlbefinden, Nahrungsergänzungsmittel-Einnahme in der Schwangerschaft und Stillraten ausgewertet. Im Follow-Up der GeliS-Studie werden die langfristige Gewichtsentwicklung, die gesundheitliche Entwicklung sowie Ernährungs- und Lebensstilfaktoren bei Müttern und Kindern bis zu fünf Jahre nach der Geburt weiter beobachtet, um mögliche langfristige Effekte der Intervention zu untersuchen.

1. INTRODUCTION

Overweight and obesity are described as one of the major public health concerns worldwide resulting in a shorter life expectancy through the occurrence of several diseases like cardiovascular diseases, diabetes and cancer (WHO 2016). The worldwide prevalence of obesity has more than doubled between 1980 and 2014 (WHO 2016). In 2014, more than 1.9 billion adults were overweight and over 600 million of these were obese (WHO 2016). According to a pooled analysis of population-based studies with 19.2 million participants in 200 countries, the mean body mass index (BMI) in women increased from 22.1 kg/m^2 in 1975 to 24.4 kg/m^2 in 2014 (NCD Risk Factor Collaboration 2016).

The alarming trend of obesity has led to an increasing number of women being obese at the beginning of pregnancy. In Germany, almost every third pregnant woman is overweight and every seventh is obese (Max Rubner-Institut 2008, AQUA 2014, IQTIG 2017). According to the latest European Perinatal Health Report (EPHR) 22.6 % of German women are overweight and 13.7 % are obese at the onset of pregnancy and, thus, Germany ranks second among all countries in Europe (EPHR 2010), which is a concern for the health of at least two generations. The risk of short- and long-term metabolic dysfunction in the mother and her offspring resulting from maternal overweight or obesity are well documented and increase with increasing BMI (Dodd et al. 2011).

In addition to a high pre-pregnancy body mass index (BMI), gestational weight gain (GWG) in excess may result in a similar risk profile for mothers and their infants, particularly in an increased risk of developing childhood obesity and its later consequences hypothesized to result from a malprogramming process during pregnancy and early postnatal life (Dabelea & Crume 2011, Gillman 2016). As described in the second wave of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS Wave 2, 2014-2017), 15.4 % of children and adolescents in the age between three and 17 years are overweight (including obesity) and 5.9 % are obese (Schienkiewitz et al. 2018). Unfortunately, obese children often remain obese during adolescence and adulthood, resulting in increased demands on the healthcare system (Sonntag et al. 2015, Sonntag et al. 2016). In Germany, individuals who were overweight or obese during childhood cause 3-5 times higher lifetime costs than individuals who were normal weight as child (Sonntag et al. 2016). An early start of primary prevention strategies can provide a meaningful contribution to stop the worrying development in obesity among children and adolescents.

Pregnancy and the early postnatal phase are probably critical periods for long-term health, but can also be considered as a “window of opportunity” for positive lifestyle changes of pregnant women (Phelan 2016). Women are in regular contact with health care professionals and seem to be more motivated to adopt healthy behaviors than at any other time (Phelan 2010). Therefore, there is an urgent need for cost-effective strategies, which can be integrated into routine antenatal care.

The alarming trend in maternal obesity and excessive GWG has led to an increase in interventions designed to attenuate the potential adverse effects on the mother and offspring. The following survey of current literature provides an overview of the consequences of maternal pre-pregnancy overweight/obesity for mothers and their infants. In addition to the concept of fetal programming, trends and recommendations in the field of GWG are illustrated. After describing the short- and long-term consequences of weight gain in excess during pregnancy, existing lifestyle intervention studies targeting to optimize pregnancy outcomes, especially maternal weight gain, are reviewed.

1.1 MATERNAL PRE-PREGNANCY OVERWEIGHT/OBESITY AND ITS CONSEQUENCES

Reviews and meta-analyses have shown that overweight and obesity in women who enter pregnancy carrie the risk of numerous potential short- and long-term adverse health outcomes (Sebire et al. 2001, Cedergren 2004, Catalano & Ehrenberg 2006, Guelinckx et al. 2008, Heslehurst et al. 2008, Adamo et al. 2012, Marchi et al. 2015, Poston et al. 2016). Table 1 summarizes the described consequences for mothers and their offspring.

Table 1: Consequences of maternal pre-pregnancy overweight/obesity.

	Short-term outcomes	**Long-term outcomes**
Maternal consequences	Fertility impairment GDM Preeclampsia/ gestational hypertension Complications during labor and delivery Adversely affected breastfeeding behavior	Obesity Diabetes Cardiac and endocrine diseases
Offspring consequences	Fetal defects & congenital anomalies Macrosomia, LGA Preterm birth	Obesity Diabetes

Consequences for the mother

Complications related to overweight and obesity may already occur before and at the time of conception. Obesity is clearly associated with the risk of fertility disorders in women including menstrual disorders, a longer time to conceive, and infertility (Hassan & Killick 2004, Gesink Law et al. 2007, Wise et al. 2010, Fontana & Della Torre 2016).

Authors stated a substantially higher risk of developing gestational diabetes mellitus (GDM) among obese women and pointed out that the risk of developing GDM increases with the degree of obesity (Chu et al. 2007b, Torloni et al. 2009). As described by Chu et al. (2007b), the risk of developing GDM is two, four and even nine times higher respectively among overweight, obese, and severely obese women compared to women who enter pregnancy with normal weight. GDM, in turn, can increase the risk for developing subsequent diabetes later in life in the mother (Lee et al. 2007, Torloni et al. 2009).

Furthermore, there is an increased risk of pregnancy-induced hypertension and preeclampsia in obese pregnant women (Marchi et al. 2015, Kim et al. 2016). The review by Salihu and colleagues (2012) indicates that the risk of pregnancy-induced hypertension was shown to be 4.5–8.7 times higher and the risk of preeclampsia 3-10 times higher in obese pregnant women compared with normal weight women.

Obese women are more likely to experience complications during labor and delivery. In contrast with normal weight pregnant women, the risk of cesarean delivery is more than doubled for obese women (Chu et al. 2007a, Heslehurst et al. 2008, Poobalan et al. 2009). Maternal obesity can also be linked to the following various adverse outcomes: increased risk of birth over 41-42 weeks of gestation, increased rates of induction of labor, more frequent use of oxytocin augmentation, and higher incidence of failure to progress in labor (Sebire et al. 2001, Heslehurst et al. 2008).

Postpartum, obese women are more likely to experience postpartum hemorrhage, infection, a longer duration of hospital stay, increased neonatal intensive care requirements, and have an increased risk of venous thromboembolism and depression (Sebire et al. 2001, Duhl et al. 2007, Heslehurst et al. 2008, Molyneaux et al. 2014, Marchi et al. 2015).

Systematic reviews have suggested that maternal obesity also adversely affects breastfeeding behavior (Amir & Donath 2007, Turcksin et al. 2014). It is associated with a delayed onset of lactogenesis and with a decreased intention of breastfeeding (Nommsen-Rivers et al. 2010). Furthermore, obese women show a shorter duration of breastfeeding and lower rates of exclusive

breastfeeding than women with a healthy weight (Amir & Donath 2007, Turcksin et al. 2014, Bever Babendure et al. 2015).

Weight change between one pregnancy and the next may influence risk of complications in the next pregnancy. Findings of a cohort study of more than 150,000 Swedish women with two births support a relationship between the inter-pregnancy weight change and the risk of adverse pregnancy outcomes including preeclampsia, cesarean delivery, stillbirth, and large for gestational age (LGA) birth (birth weight above 90th percentile) (Villamor & Cnattingius 2006). This indicates an association between an increase in BMI and adverse outcomes and, moreover, a dose-response effect. Even a modest gain of 1-2 BMI units between pregnancies in overweight/obese women but also in normal weight women resulted in a higher risk of obesity-related pregnancy outcomes and perinatal complications (e.g. gestational hypertension and GDM) in the next pregnancy (Villamor & Cnattingius 2006). Importantly, postpartum weight reduction in overweight and obese women was shown to lower the risks of disorders in the next pregnancy (Villamor & Cnattingius 2006, Mostello et al. 2010, Ehrlich et al. 2011, Jain et al. 2013).

Complications occurring during pregnancy in overweight mothers might result in several diseases in later life. A large Swedish retrospective cohort study indicated that women with a BMI above 25 kg/m^2 at the beginning of pregnancy have an increased risk of developing obesity (OR 21.9), a six-fold increase in the risk of developing diabetes and more than a two-fold increase in the risk for cardiac and endocrine diseases at 10-17 years after first registered delivery (Moll et al. 2017).

Consequences for the offspring

Adverse impacts of maternal overweight or obesity on the offspring may appear in early or late pregnancy but also during the period around birth and later in life (Adamo et al. 2012). Maternal obesity is linked to fetal defects (malformation) or congenital anomalies including neural tube defects, spina bifida, limb reduction anomalies, cardiovascular anomalies or cleft lips and palate (Ray et al. 2005, Stothard et al. 2009). As potential explanations for an association between maternal overweight and obesity and congenital anomaly, research groups offer the possibility of undiagnosed diabetes and hyperglycemia in obese pregnant women or nutritional deficiencies (especially reduced folate levels) as well as more difficulties in ultrasound visualization of fetal anatomy and decreased sensitivity in ultrasound for cardiac anatomy in obese women (Hendler et al. 2004, Stothard et al. 2009).

Analyses show that premature delivery is more likely to occur in pregnant women with obesity (Marchi et al. 2015). In addition, there is an increased risk of fetal death, stillbirth, neonatal, and infant death (Aune et al. 2014). The risk of early pregnancy loss is assumed to be 30 % higher in women with obesity than in those of normal weight (Marchi et al. 2015).

In addition, fetal macrosomia (infant birth weight ≥4000 g or ≥4500 g) and LGA babies are more common among pregnant women with obesity (Ehrenberg et al. 2004, Sewell et al. 2006, Yu et al. 2013, Marchi et al. 2015). The risk of macrosomia is more than doubled in obese women and is even more than 3-fold higher in morbidly obese (BMI >40 kg/m^2) women (Cedergren 2004).

Furthermore, it has been reported that maternal overweight/obesity in early pregnancy is a risk factor for long-term consequences, especially for infant and childhood obesity. It is supposed that overweight/obesity in early pregnancy more than doubles the risk of obesity in offspring between the ages of 2 and 4 (Whitaker 2004) and, moreover, it is associated with type 2 diabetes in youth, independent of developing diabetes during pregnancy (Dabelea et al. 2008). Finally, Catalano and colleagues (2009) are convinced that maternal pregravid obesity is one of the strongest predictors of childhood obesity and metabolic dysfunction. Few years later, these findings were reinforced by a systematic review and meta-analysis by Yu and collaborators (2013).

The development of BMI during growth follows a typical pattern. A rapid increase of the BMI occurs during the first year of life. Then, BMI subsequently declines and reaches a minimum around the age between 5 and 7 years, before beginning a sustained increase up to the end of growth. The lowest point of the BMI curve is suggested as the start of the adipose rebound (AR) (Rolland-Cachera et al. 2006). In 1984, Rolland-Cachera and colleagues observed that the age at the AR was significantly associated with BMI at later ages. Three years later, they found the earlier the AR occurs the higher the BMI at 21 years of age (Rolland-Cachera et al. 1987). Current literature (Linares et al. 2016) suggests that a higher pre-pregnancy BMI is an independent risk factor of early adipose rebound in the offspring, regardless of the nutritional status of the child. Such observations underline findings showing that the early life represents a critical window for later health (Linares et al. 2016).

1.2 THE CONCEPT OF FETAL PROGRAMMING

Evidence from epidemiological data and experimental models have revealed that nutritional and environmental exposures presented during the intrauterine and early postnatal period may have important implications for the future health of the infant. It is assumed that these conditions can lead to permanent programmed alterations in physiological systems (Godfrey & Barker 2000, Plagemann 2004, Alfaradhi & Ozanne 2011, Lau et al. 2011, Geraghty et al. 2015).

First analyses that were conducted to support the concept of fetal programming, especially the Dutch famine study, have shown the impact of maternal nutrition on various and often harmful effects on the offspring, for example the development of offspring obesity. Epidemiological data from the Dutch Hunger Winter during World War Ⅱ in 1944/45 demonstrated that the offspring of women exposed to famine in the first trimester of gestation were more likely to be obese in later life (Ravelli et al. 1976, Ravelli et al. 1999, Roseboom et al. 2001). However, undernutrition in late pregnancy was associated with a decreased risk of obesity (Roseboom et al. 2001).

The birth weight of newborns is commonly used as an accessible indicator to detect such alterations caused by maternal under- or overnutrition. First studies initially focused on the relationship between low birth weight and risk of obesity and metabolic syndrome in later life. In the early 1990s, Barker and colleagues observed that individuals with low birth weight were at increased risk of cardiovascular diseases (Barker & Osmond 1986), glucose intolerance/type 2 diabetes (Hales et al. 1991) and metabolic syndrome. They postulated the “small-baby-syndrome” and explained it by the “thrifty phenotype” hypothesis in which early growth restriction is seen as an adaptation to poor fetal nutrition to maximize the chances of survival in conditions of ongoing environmental deprivation (Hales & Barker 1992, Alfaradhi & Ozanne 2011). As a consequence of a postnatal plentiful nutrient supply the risk of obesity and developing type 2 diabetes is increased (Hales & Barker 1992, Alfaradhi & Ozanne 2011).

A systematic review involving 980,450 persons from 16 countries of four different continents shows a positive linear relationship in 89 % of the included studies between birth weight and the risk of offspring overweight/obesity in later life (Harder et al. 2007b). Also in the study by Oken et al. (2008), a linear relationship was suggested. Several years later, Schellong and colleagues (2012) performed a large systematic review and a meta-analysis including 643,902 persons from 66 studies and 26 countries globally. The authors concluded that low birth weight is followed by decreased long-term risk of overweight, while high birth weight predisposes for later overweight (Schellong et al. 2012). Only three studies in the mentioned review by Harder et al. (2007b)

provide indications of a relationship between low birth weight and an increased risk of later overweight or obesity, as supposed in the “small-baby-syndrome” hypothesis. These three studies described a similar increase of risk in both underweight and macrosomic newborns, which indicates a U-shape relationship between birth weight and the risk of later overweight or obesity.

Moreover, the meta-analysis of Harder et al. (2007a) indicates that both high birth weight and low birth weight are linked to an increased risk of diabetes mellitus type 2. So there seems to be a U-shape relation between birth weight and the risk of later-life diabetes mellitus type 2 (Plagemann & Harder 2005, Harder et al. 2007a). Metabolic diseases in later life thus seem to occur in both underweight and overweight infants.

With the regard of the rising prevalence of obesity in pregnancy and the association with GDM, recent studies have also linked maternal overnutrition (overweight and obesity) and excessive GWG to the risk of the metabolic syndrome in the offspring. The underlying mechanisms for such long-term effects are still hypothetical. However, insights into the possible mechanisms contributing to the programming of physiological systems in the offspring including metabolic, hormonal and neuronal alterations as well as epigenetic modifications or impaired placental function are starting to emerge, especially through animal models (Plagemann 2004, Alfaradhi & Ozanne 2011, Li et al. 2011). Potential mechanisms explaining the relationship between excessive GWG (and accreted fat mass) and offspring BMI or childhood overweight may refer to fetal hyperleptinemia and hyperinsulinemia. These may lead to alterations in gene expressions of developing fetal hypothalamic structures and induce abnormal persistent changes in energy regulation and obesity in adult life (Poston 2010, Ensenauer et al. 2013).

In literature (Dabelea & Crume 2011), an intergenerational vicious circle of obesity and metabolic disorders is used to illustrate the effects of environmental and nutritional imbalances *in utero* (Figure 1). Overweight and/or diabetes during pregnancy can lead to fetal overnutrition. Fetal overnutrition is often followed by increased birth weight, a high fat mass and macrosomia at birth. Following the explanations above, daughters are consequently at increased risk of becoming obese or diabetic themselves in their reproductive age if their mothers were overweight/obese, diabetic or gained weight in excess during pregnancy.

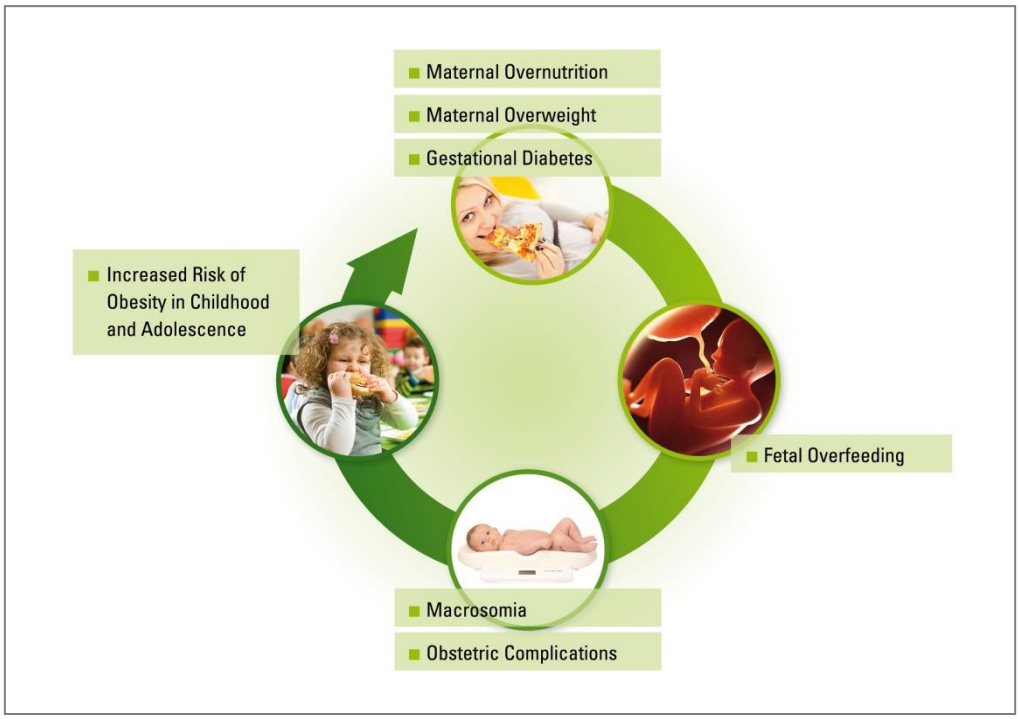


Figure 1: The vicious circle of obesity and metabolic disorders.

(Photo credits: vitapix/istockphoto.com (figure no. 22332751), henrik5000/istockphoto.com (figure no. 16437508), istockphoto.com (figure no. 5275976), fatihhoca/istockphoto.com (figure no. 12292607)).

However, prevention appears possible. With regard to the global obesity epidemic, adequate prevention and intervention strategies which can interrupt this vicious circle are urgently required. Especially pregnancy is a sensitive and powerful period in which women are concerned about the health of their growing infants and may be especially motivated to change behavior (Phelan 2010). In addition, interventions started during pregnancy could be continued after birth. Consequently, mothers would become a role model for their infant (Phelan 2010). Thus, the time of pregnancy provides a "teachable moment" for promoting healthy lifestyle habits which could be adopted even in the time after birth (Phelan 2010). Consequently, pregnancy is a crucial time providing the opportunity for obesity prevention in this and the next generation (Kaar et al. 2014).

1.3 CHARACTERISTICS OF WEIGHT GAIN IN SINGLETON PREGNANCY

GWG is the total amount of weight gained during pregnancy and depends on the BMI of women before conception (Rasmussen & Yaktine 2009). The total amount of weight gain during pregnancy varies considerably among women and is inversely related to weight before pregnancy (Lederman et al. 1997, Rasmussen & Yaktine 2009). An examination of different studies revealed

that the mean total GWG of normal weight women giving birth to term infants ranged from 10.0 to 16.7 kg (Rasmussen & Yaktine 2009). However, some generalizations regarding the patterns of average GWG can be made. Usually, there is a minimal gain of 1-2 kg during the first trimester (Rasmussen & Yaktine 2009). A progressive gain in weight of approximately 0.45 kg per week occurs during the second trimester and 0.40 kg per week during the third trimester in order to support the functions of growth and development of the fetus (Institute of Medicine 1990).

The components of GWG can be divided into the products of conception and maternal tissue accretion (Institute of Medicine 1990). Table 2 illustrates maternal and fetal components contributing to weight gain over the course of a singleton pregnancy.

Table 2: Components of weight gain during pregnancy adapted from Hytten and Leitch (1971).

Body component		Percentage (%) of total weight gain
Products of conception	Fetus	27.2
	Placenta	5.2
	Amniotic fluid	6.4
Maternal tissues	Uterus	7.8
	Mammary gland	3.3
	Blood	10.0
	Extracellular fluid	13.4
	Assumed fat deposition	26.8

The products of conception including fetus, placenta and amniotic fluid, account for approximately one third of the total amount of GWG. On the average, the fetus represents approximately 25 % of the total gain, the placenta about 5 %, and the amniotic fluid about 6 % (Hytten & Leitch 1971). The remainder of weight gain in pregnancy is due to an increase of maternal tissues including uterus, mammary gland, blood, extracellular fluid and maternal fat deposition. Different studies found a positive correlation between GWG and fat gain (Lederman et al. 1997, Butte et al. 2003, Berggren et al. 2016). An accretion of maternal fat deposition provides a source of energy for supporting the development and growth of the fetus, and buffers short or medium-term changes in energy supply (Nelson et al. 2010). Moreover, an appropriate weight gain over the course of pregnancy provides sufficient postpartum maternal fat stores to support lactation (Lederman et al. 1997).

1.4 RECOMMENDATIONS FOR WEIGHT GAIN IN PREGNANCY

Although maternal weight and GWG is a worldwide concern there is no global consensus in guidelines policies (Alavi et al. 2013, Scott et al. 2014). Many countries around the world have provided a wide variety of recommendations to manage obesity during pregnancy but only very few countries have clear guidelines for appropriate GWG (Alavi et al. 2013, Scott et al. 2014). Less than 10 % of national policies addressed healthy maternal weight across the entire spectrum of childbearing including the time before, during and after pregnancy (Scott et al. 2014). The majority of national guidelines recommend counseling for overweight and obese women before conception to begin pregnancy with a healthy weight. As can be seen in most national guidelines, health care providers should determine women's BMI and discuss appropriate weight gain at the first prenatal visit (Scott et al. 2014).

In 1990, the IOM released recommendations for weight gain during pregnancy based on maternal BMI before conception, with the aim of improving the birth weight of infants. With regard to alarming changes in demographics of women of childbearing age, the IOM revised their guidelines in 2009 (Table 3) (Rasmussen & Yaktine 2009). For women with a normal pre-pregnancy weight, a weight gain of 11.5 kg to 16 kg for a full-term singleton pregnancy of 40 weeks has been shown to be associated with the lowest risk of complications during pregnancy and birth.

Table 3: The 2009 US Institute of Medicine (IOM) recommendations for GWG for singleton pregnancies (Rasmussen & Yaktine 2009).

Pre-pregnancy BMI		GWG [kg]
Underweight	<18,5 kg/m^2	12.5 – 18.0
Normal weight	18.5 – 24.9 kg/m^2	11.5 – 16.0
Overweight	25.0 – 29.9 kg/m^2	7.0 – 11.5
Obesity	≥30 kg/m^2	5.0 - 9.0

Compared to 1990, women are now heavier, tend to be older when they become pregnant, are entering pregnancy overweight/obese or with chronic conditions such as hypertension or diabetes more often, are having more twin and triplet pregnancies and many are gaining too much weight during pregnancy (The American College of Obstetricans and Gynecologists 2013, Rasmussen & Yaktine 2009). While the 1990 guidelines only considered the welfare of the infant, the 2009 re-examined guidelines were developed to limit excessive GWG to support optimal

outcomes of both mothers and infants. The primarily considered outcomes used to develop GWG ranges were: infants born small or large for gestational age, the mother`s risk for an unplanned cesarean delivery, excessive (≥5 kg) weight retention, preterm birth, and childhood obesity. The 2009 IOM revision differs from the previous one in two important ways. First, they refer to pre-pregnancy BMI ranges for underweight, normal weight, overweight, and obese women developed by the World Health Organization (WHO) rather than the previous used categories from the Metropolitan Life Insurance tables. Second, a relatively narrow range of weight gain with an upper limit is recommended for obese women. This differs from previous recommendations of at least 6.8 kg. However, concerns have been raised that the weight gain targets are too high, especially for overweight and obese women. Beyerlein and colleagues (2010) stated that especially in overweight and obese women, weight gain within the IOM recommendations has not only been associated with beneficial but also with adverse pregnancy outcomes. Moreover, the new guidelines do not differentiate degrees of obesity, especially for morbidly obese women (The American College of Obstetricans and Gynecologists 2013, Kominiarek et al. 2013, Faucher & Barger 2015). The 2009 committee points out that the guidelines are intended for the use among women in the United States. Nonetheless, they may be applicable to women in other developed countries but not in areas of the world where women are substantially shorter or thinner than American women (Rasmussen & Yaktine 2009). Even if the IOM guidelines are often criticized (Beyerlein et al. 2009b, Beyerlein et al. 2010, Kominiarek et al. 2013, Hamad et al. 2016), the updated recommendations provide clinicians with a basis for practice and offer opportunities for gynecologists and other health care providers to manage excessive weight gain in pregnancy.

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) recommends starting pregnancy at a healthy BMI and counseling on healthy lifestyle but concludes that there is insufficient evidence that addressing GWG will lead to improved birth outcomes (National Institute for Health and Care Excellence 2010). Therefore, NICE (2010) does not recommend any GWG guideline and to weigh women repeatedly during pregnancy, except for obese and other high risk women.

The current practical recommendations for pregnant women in Germany that were developed with and are supported by the German professional associations and scientific societies for obstetricians and gynecologists, midwives and pediatricians recommend to approach a normal body weight before becoming pregnant and an appropriate gestational weight gain between 10 and 16 kg for normal weight women (Koletzko et al. 2018). In the case of overweight and obese women, a lower weight gain in pregnancy is desirable. Moreover, it is recommended that in

underweight women, it should be ensured that there is sufficient weight gain during pregnancy (Koletzko et al. 2018). Referring to the practical recommendations energy needs in the last few months of pregnancy are only slightly higher (up to about 10 %) than before pregnancy (Koletzko et al. 2018). The guidelines of the Nutrition Societies of Germany ("Reference Values for Nutrient Intake") recommend an additional energy intake of 250 kcal/day during the second trimester and 500 kcal/day during the third trimester (Deutsche Gesellschaft für Ernährung e.V. 2015). These guidelines refer only to normal weight women with a GWG of 12 kg over the total duration of pregnancy and unabated physical activity.

1.5 EXCESSIVE GESTATIONAL WEIGHT GAIN AND ITS CONSEQUENCES

As already described, maternal overweight or obesity is associated with a variety of pregnancy and obstetric complications. Likewise, recent data suggest that excessive GWG may result in a similar risk profile of adverse maternal and fetal outcomes (Table 4). It appears to adversely affect the course of pregnancy and birth on the one hand and maternal and offspring health development over short and long terms on the other hand (Rasmussen & Yaktine 2009). Risks do not only affect overweight and obese women, but also women entering pregnancy with a normal pre-pregnancy BMI (Crane et al. 2009, Rode et al. 2012, Brunner et al. 2015).

Table 4: Consequences of excessive GWG.

	Short-term outcomes	Long-term outcomes
Maternal consequences	Cesarean delivery, Preeclampsia GDM	Postpartum weight retention
Offspring consequences	Macrosomia, LGA Preterm birth	Obesity

Consequences for the mother

The most consistent adverse outcome for mothers with excessive GWG is maternal short- and long-term postpartum weight retention, independent of pre-pregnancy BMI (Nohr et al. 2008, Rasmussen & Yaktine 2009, Margerison Zilko et al. 2010, Nehring et al. 2011, Mannan et al. 2013). Nehring et al. (2011) showed in their meta-analysis that women with GWG above the IOM recommendations retained an additional of 3 kg after 3 years and 4.7 kg on average after 15 years postpartum compared to women who gained within the guidelines. This, in turn, becomes a

significant risk factor for maternal pregravid obesity in a subsequent pregnancy as well as obesity and related metabolic disorders in later life (Rooney & Schauberger 2002, Rooney et al. 2005, Mamun et al. 2010, Fraser et al. 2011, Catalano & deMouzon 2015).

In addition to postpartum weight retention, excessive GWG is a clear risk factor for cesarean delivery (particularly in overweight and obese women) and is associated with gestational hypertension or preeclampsia, whereby the evidence for this association is more limited (Nohr et al. 2008, Rasmussen & Yaktine 2009, Margerison Zilko et al. 2010, Li et al. 2013, Haugen et al. 2014, Goldstein et al. 2017).

Moreover, few studies indicate a possible relationship between greater GWG and GDM, particularly among overweight or obese women (Herring et al. 2009, Hedderson et al. 2010, Gibson et al. 2012). Diabetes during pregnancy is a concern because it can result in short- and long-term complications for both the mother and the offspring, such as macrosomia (Neiger 1992) and an elevated risk for the mother with a history of GDM and their offspring of developing manifest type 2 diabetes mellitus in later life (Hedderson et al. 2010). Especially children of mothers with diagnosed GDM show a significant higher birth weight and dramatically higher risks of macrosomia (Jovanovic-Peterson et al. 1991, Langer et al. 2005, Kwik et al. 2007). However, the results of a randomized intervention study by Crowther et al. (2005) indicate that infants born to mothers receiving intensive GDM therapy were significantly less likely to be LGA and macrosomic. These findings emphasize the importance of a general screening for GDM and its subsequent adequate therapeutic treatment. There is also a positive association between maternal GDM and offspring overweight/obesity but it might attenuate after adjustment for pre-pregnancy BMI (Philipps et al. 2011, Kim et al. 2012, Nehring et al. 2013). A possible reason for the influence of higher GWG on the development of GDM, especially early in pregnancy, is seen in the greater maternal fat accretion, which may impair insulin sensitivity (Rasmussen & Yaktine 2009, Hedderson et al. 2010). However, as described in the review by Viswanathan et al. (2008), there is only a weak association between GWG and the development of abnormal glucose metabolism (either GDM or impaired glucose tolerance). A methodological limitation in most of studies was the use of total weight gain over the entire duration of pregnancy and the heterogeneity of diagnosis and treatment (Viswanathan et al. 2008, Goldstein et al. 2017). Focusing on weight gain before GDM diagnosis may prevent confounding by therapeutic interventions to manage GDM such as dietary counseling to control GWG. As shown in a meta-analysis of Brunner et al. (2015), excessive GWG measuring prior to GDM screening increases the risk of GDM by a factor of 1.4 in both normal and overweight/obese women.

Consequences for the offspring

Referring to fetal growth, observational data described by the IOM report (1990) indicate a quite strong association between lower GWG and increased risk of small for gestational age infants (SGA), especially in underweight and normal weight women, and between higher GWG and increased risk of LGA (Nohr et al. 2008, Rasmussen & Yaktine 2009). Goldstein et al. (2017) reported the greatest risk of LGA in underweight women with weight gain above the guidelines. Moreover, different studies have shown that women who gain weight in excess have a 2- to 3-fold increased risk of fetal macrosomia (Bergmann et al. 2003, Hedderson et al. 2006, Helms et al. 2006, Dietz et al. 2009, Ludwig & Currie 2010, Alberico et al. 2014, Tian et al. 2016, Goldstein et al. 2017). Macrosomia is again linked to further health consequences for both mothers and offspring including delivery complications such as shoulder dystocia, cesarean delivery or maternal death (Institute of Medicine 1990, Boulet et al. 2004, Stotland et al. 2004, Weissmann-Brenner et al. 2012). Moreover, high birth weight subsequently is associated with the risk of childhood overweight and obesity (Oken & Gillman 2003, Schellong et al. 2012).

According to the report by the IOM and the National Research Council (Rasmussen & Yaktine 2009), there are indications of a U-shape association between GWG and preterm birth (defined as < 37 weeks' completed gestation). An increased risk of preterm birth among women was reported in both the lowest and the highest GWG categories (Viswanathan et al. 2008). In contrast, McDonald and colleagues (2011b) as well as Goldstein et al. (2017) described a lower risk of preterm birth in women showing high weight gain.

In recent years, several studies have demonstrated a growing interest in GWG with an emphasis on the relationship between excessive GWG and an increased risk of offspring overweight or obesity in childhood (Moreira et al. 2007, Oken et al. 2007, Wrotniak et al. 2008, Olson et al. 2009, Kries et al. 2011, Margerison Zilko et al. 2010, Poston 2012, Ensenauer et al. 2013, Nehring et al. 2013, Kaar et al. 2014, Tie et al. 2014, van Rossem et al. 2015, Hivert et al. 2016), in adolescence (Oken et al. 2008, Laitinen et al. 2012) and even persisting in adulthood (Mamun et al. 2009, Reynolds et al. 2010, Schack-Nielsen et al. 2010, Mamun et al. 2014). Lau et al. (2014) reflected the existing evidence on the associations of GWG and offspring's body weight in a systematic review. They referred to 23 observational cohort studies including data about children aged between two and 18.9 years. The findings of the review also support the hypothesis that high rates of GWG, especially in early- and mid-pregnancy, are a potential risk factor for childhood obesity (Lau et al. 2014). Moreover, the meta-analysis by Mamun et al. (2014) has shown that women who gained excessive weight during pregnancy had a 40 % increased risk of offspring

obesity. However, Lau et al. (2014) pointed out that potential confounding effects of shared familial characteristics like genetics and maternal and child lifestyle factors need to be measured and adjusted in future studies (Lau et al. 2014). Moreover, different working groups have confirmed that the adjustment of maternal BMI can significantly attenuate the influence of excessive GWG on childhood overweight/obesity (Oken et al. 2007, Wrotniak et al. 2008, Tie et al. 2014).

1.6 KNOWLEDGE ABOUT WEIGHT GAIN IN PREGNANCY AMONG EXPECTANT MOTHERS AND HEALTHCARE PROVIDERS

As described in a systematic review by Vanstone et al. (2016) women do not seem to be aware of recommendations for a healthy weight gain during pregnancy. Different studies have indicated that a considerable proportion of overweight as well as obese women overestimate their optimal target weight gain during pregnancy (Stotland et al. 2005, Shub et al. 2013). As demonstrated by McDonald et al. (2011a), 37 % of women were planning to gain weight within the 2009 IOM guidelines whereas 39 % of women were planning to gain weight above the guidelines. Moreover, women are highly motivated to change their behavior to improve fetal health, but their knowledge about the risks and consequences of excessive GWG as well as effective methods of weight management seems to be poor (Shub et al. 2013, Vanstone et al. 2016, Willcox et al. 2016). More than half of the women are seeking information about GWG using information sources besides their health care provider (McDonald et al. 2011a, Willcox et al. 2015). According to Willcox et al. (2015), pregnant women are more likely to consult non-clinician sources including the internet, books, friends and family members (Willcox et al. 2015). Many pregnant women reported that they did not achieve weight gain recommendations in adherence with the 2009 guidelines or even receive no weight gain advice from their prenatal care provider (Stotland et al. 2005, McDonald et al. 2011a, Olander et al. 2011, Stewart et al. 2012, Deputy et al. 2018).

Physicians seem to be aware of the importance of healthy GWG as well as maternal and child health complications resulting from excess GWG (Power et al. 2009, van der Pligt et al. 2011, Wilkinson & Stapleton 2012). As described by van der Pligt et al. (2011), healthcare providers have suggested a multidisciplinary approach including input from allied health professionals as the most useful support. Nevertheless, they highlighted multiple barriers, primarily cost barriers, to achieve an appropriate management of excessive GWG. Further barriers include the need to improve their communication skills, lack of time, beliefs that pregnant women will have negative

reactions to weight-related discussions, and a lack of weight management knowledge (Olander et al. 2011, Heslehurst et al. 2014a). 79 % of obstetric and midwifery staff believe their training and education regarding GWG and lifestyle behavior change methods is inadequate (Stewart et al. 2012). In addition, midwives noted concern about the sensitive issue weight (Willcox et al. 2012). The aspects of such observations support the need for adequate GWG guidance and, moreover, it indicates that further research is needed to identify effective approaches to support healthcare professionals to implement weight management into practice (Olander et al. 2011, Heslehurst et al. 2014b).

1.7 TRENDS IN GESTATIONAL WEIGHT GAIN IN GERMANY

Unfortunately, in many countries including Germany, an increasing proportion of pregnant women exceed the IOM guidelines with clear tendency towards a sustained increase (Rasmussen & Yaktine 2009, Schiessl et al. 2009, Kries et al. 2011, Ensenauer et al. 2013, Johnson et al. 2015). In response to the modern lifestyle and the increased prevalence of obesity in women of reproductive age, mean weight gain during pregnancy has increased significantly by 2 kg within two decades (1986-2005) as indicated by the German KiGGS study (Bergmann et al. 2007). Correspondingly, the mean birth weight has increased significantly by an average of 50 g. Ferrari et al. (2014) have shown in a German retrospective analysis of 11,771 women that the proportion of women who exceed the IOM thresholds has increased from 34 % in 2005 to 43 % in 2012. Overweight and obese women are more likely to gain excessive weight than women who began their pregnancy at a normal BMI (Kaar et al. 2014). According to Ferrari et al. (2014), 29 % of normal weight women, 55 % of overweight women and 58 % of obese women gained weight in excess (Ferrari et al. 2014). These dramatic trends were also shown by Dudenhausen et al. (2015). They compared the adherence to GWG recommendations in the United States and Germany. United State data for the analysis were based on CDC birth certificate data from nulliparous births (N=2,082,279). German data were used from the German BabyCare Program as well as available medical records at delivery (N=1656). Overall, only 34 % of German pregnancies and a similar proportion of 32 % of American women gained weight within the IOM recommendations (Dudenhausen et al. 2015). According to the German KiGGS study, the highest increase in weight gain during pregnancy is observed among women living in large cities and among women with a lower social status (Bergmann et al. 2007).

1.8 CURRENT LIFESTYLE INTERVENTIONS TO OPTIMIZE PREGNANCY AND OBSTETRIC OUTCOMES

In recent years, plenty of research groups have investigated a variety of different approaches during pregnancy to promote healthy GWG to minimize adverse outcomes for mother and infant. An increasing number of published studies, with at least 10 trials published each year since 2011, and 16 published in 2016, reflect the importance and high priority of preventing obesity and excessive weight gain in pregnancy (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). While several randomized controlled trials (RCTs) could show favorable results in reducing the risk of excessive GWG and/or in reducing total GWG (Polley et al. 2002, Wolff et al. 2008, Asbee et al. 2009, Thornton et al. 2009, Haakstad & Bo 2011, Huang et al. 2011, Phelan et al. 2011, Quinlivan et al. 2011, Vinter et al. 2011, Ruchat et al. 2012, Walsh et al. 2012, Bogaerts et al. 2013, Harrison et al. 2013, Rauh et al. 2013, Renault et al. 2014, Vesco et al. 2014, Ronnberg et al. 2015, Herring et al. 2016, Sagedal et al. 2016, Daly et al. 2017, Nobles et al. 2017, Redman et al. 2017, Simmons et al. 2017, Willcox et al. 2017, Yeo et al. 2017) or in improving other health outcomes like GDM (Koivusalo et al. 2015) other RCTs reported no convincing effects on weight gain during pregnancy (Clapp et al. 2000, Guelinckx et al. 2010, Jackson et al. 2011, Barakat et al. 2012, Althuizen et al. 2013, Dodd et al. 2014a, Brownfoot et al. 2015, Skouteris et al. 2016, Garnaes et al. 2016) or other maternal and neonatal outcomes (Polley et al. 2002, Moses et al. 2014). Table 5 summarizes the intervention strategies and main outcomes of current RCTs during pregnancy targeting GWG and other health variables in mothers and their offspring.

The Finnish RADIEL trial reduced the incidence of GDM by 39 % in high-risk women by attending a moderate lifestyle intervention including individualized counseling on diet, physical activity, and weight control (Koivusalo et al. 2015). Regarding GDM, positive results were also seen in the study by Quinlivan et al. (2011) in overweight and obese women, which could not be confirmed in the study of Guelinckx et al. (2010) and Luoto et al. (2011).

Similarly inconsistent findings can be described for postpartum weight retention. Ronnberg et al. (2016) could detect significant lower mean weight retention at ≤16 weeks postpartum but no significant difference in weight retention after one year. Rauh et al. (2015) concluded favorable effects on weight retention at month four postpartum but a rather modest effect on maternal weight retention at 12 months postpartum. Even if positive effects regarding limiting GWG are apparent, the effect on outcomes beyond the immediate postpartum period is less known. For example, Vesco and colleagues (2016) demonstrated a reduction in GWG, but there was no

difference between the intervention and control groups in maternal weight or in the infant weight-for-length at one year postpartum.

The results of the largest randomized trials carried out so far – Limiting weight gain in overweight and obese women during pregnancy to improve health outcomes (LIMIT) and the UK Pregnancies Better Eating and Activity Trial (UPBEAT) – are of modest success and show the limitations of diet and lifestyle interventions during pregnancy (Dodd et al. 2014a, Poston et al. 2015).

The multicenter LIMIT trial involved over 2000 overweight and obese women between 2008 and 2011 in Australia. The intervention included a combination of dietary, exercise and behavioral strategies at six time points during pregnancy through a mixture of face-to-face and telephone contacts delivered by a research dietician and trained research assistants. Differently from smaller trails and systematic reviews, the LIMIT trial did not find differences in mean GWG. Moreover, the intervention did not achieve the primary endpoint of reducing the risk of infants born large for gestational age. Nevertheless, the intervention resulted in a significant risk reduction in the risk of an infant being born with birth weight above 4 kg as well as significant improvements in the quality of diet and increased physical activity (Dodd et al. 2014a, Dodd et al. 2014c, Dodd et al. 2014b).

UPBEAT was a trial of relatively intensive behavioral support for diet and lifestyle improvement in 1555 obese women. The complex intervention was offered once a week through eight health trainer-led group or individual sessions delivered face-to-face or via phone. Women in the intervention group were supported to problem-solve, set goals, self-monitor, and enlist social support in attempting to develop a healthier pattern of eating (Briley et al. 2014). There were no effects on the primary outcomes either the incidence of GDM or LGA-infants, despite improvements in some secondary outcomes in the intervention group, including reduced dietary glycemic load, energy intake, carbohydrate and total fat intake, increased protein and fiber intake, and increased physical activity (Poston et al. 2015). Moreover, women in the intervention group have shown a modest but significant 0.6 kg reduced GWG (Poston et al. 2015). Recently, Patel and colleagues (Patel et al. 2017) found that the intervention reduced infant adiposity and led to a sustained improvement in maternal diet at six months postpartum.

Studies done so far were mostly carried out in high-income countries and it is not clear whether the results are applicable to lower income settings.

Table 5: Lifestyle intervention studies during pregnancy targeting GWG.

Study	Population	Intervention	Main Outcomes
LIMIT **Dodd et al. 2014,** **Dodd et al. 2014,** **Grivell et al. 2015** **Australia**	**N=2212** n(I)=1018 n(C)=1104 BMI ≥25	**Diet & PA** 3 face-to-face sessions + 3 sessions via telephone with research dieticians and research assistants (combination of dietary, exercise and behavioral strategies, GWG advice)	↔LGA ↓BW ≥4000 g (p=0.04), BW ≥4500 g (p=0.04) ↔Maternal pregnancy and birth outcomes **↔GWG (9.39 vs. 9.44 kg, p=0.89), excessive GWG (42 vs. 42 %, p=0.85)** ↑Fetal mid-thigh fat mass (p=0.02) ↓Fetal subscapular adipose tissue deposition (p=0.02) Diet and PA improvements
UPBEAT **Poston et al. 2015,** **Flynn et al. 2015,** **Patel et al. 2017** **UK**	**N=1555** n(I)=783 n(C)=772 BMI ≥30	**Diet & PA** Initial individual interview with a health trainer; 8 further weekly group or individual sessions (SMART goals and review of previous week's goals); Informative handbook, DVD on exercise regimen, pedometer, log book for recording weekly SMART goals	↔GDM, LGA **↓GWG (7.19 vs. 7.76 kg; -0.55 kg, p=0.04)** ↓Infant adiposity at 6 months pp Diet and PA improvements Sustained improvement in maternal diet at 6 months pp
The Fit for Delivery Study **Phelan et al. 2011,** **Phelan et al. 2014** **USA**	**N=401** n(I)=201 n(C)=200 50 % nw, 50 % ow/ob	**Diet & PA** 1 face-to-face session; weekly mailed materials that promoted appropriate GWG, healthy eating, and exercise; telephone based feedback	**↓Excessive GWG in nw (40.2 vs. 52.1 %, p=0.003)** ↑Proportion of nw and ow/ob women achieving pregravid weight or below at 6 months pp (30.7 vs. 18.7 %, p=0.01) ↑Proportion of women achieving pregravid weight or below at 12 months pp ↑Dietary restraint through 6 months pp
The Norwegian Fit for Delivery Study **Sagedal et al. 2016,** **Sagedal et al. 2017a** **Sagedal et al. 2017b** **Norway**	**N=606** n(I)=303 n(C)=303	**Diet & PA** 2 dietary counseling sessions with appropriate GWG advice by phone; twice-weekly supervised exercise sessions and encouragement to PA on three additional days per week; booklets, interactive website, cooking classes and evening meetings	**↓Total GWG (14.4 vs. 15.8 kg; -1.3 kg, p=0.01)** **↓GWG per week (0.36 vs. 0.39 kg/week, p=0.01)** **↔Excessive GWG (41.6 vs. 50.0 %, p=0.06)** ↔BW, LGA ↔Obstetrical and neonatal outcomes ↔GDM ↓12-month PPWR
Ronnberg et al. 2015, **Ronnberg et al. 2016** **Sweden**	**N=445** n(I)=221 n(C)=224 BMI ≥19	**Weighing & Exercise** Personalized weight graph, education on recommended GWG, prescription of exercise, and regular monitoring of GWG	**↓GWG (14.2 vs. 15.3 kg, p=0.03)** **↔Excessive GWG (41.1 vs. 50.0 %, p=0.23)** ↓16-week PPWR (p=0.02), 1-year PPWR

BMI=body mass index; BW=birth weight; C=control group; GDM=gestational diabetes mellitus; GWG=gestational weight gain; I= intervention group; IOM=Institute of Medicine; LGA=large for gestational age; nw=normal weight; ob=obese; ow=overweight; PA=physical activity; PPWR=postpartum weight retention; SGA=short for gestational age; ↑=increase; ↔=no difference; ↓=decrease

Table 5: Continued.

Study	Population	Intervention	Main Outcomes
TOP **Renault et al. 2014** **Denmark**	**N=389** n=(PA+D)=130 n(PA)=125 n(C)=134 BMI ≥30	**Diet & PA** 11-13 contacts with dietitian every 2 weeks; initial dietary counseling session and advice to limit GWG to <5 kg (all participants); PA intervention (PA): encouragement to increase PA aiming at a daily step count of 11,000; Dietary intervention (D): hypocaloric Mediterranean-style diet	**↓GWG (PA+D: 8.6 kg, PA: 9.4 kg vs. C: 10.9 kg, p[PA+D vs. C]=0.01; p[PA vs. C]=0.04);** **↓Excessive GWG** ↔BW ↔Neonatal and obstetric outcomes
ROLO **Walsh et al. 2012, McGowan et al. 2013, Horan et al. 2014** **Ireland**	**N=800** n(I)=394 n(C)=406 Infant with BW >4 kg	**Low glycemic index diet** 1 dietary education group session with research dietitian; 2 meetings for reinforcement	↔BW **↓GWG (12.2 vs.13.7 kg, p=0.01), excessive GWG (38 vs 48 %, p=0.01)** ↓Glucose intolerance (p=0.02) ↓Maternal glycemic index, energy intake ↑Protein intake, dietary fiber intake ↑Weight loss from prepregnancy to 3 months pp (p=0.02)
RADIEL **Koivusalo et al. 2015** **Finland**	**N=293** n(I)=155 n(C)=138 History of GDM and/or BMI ≥30	**Diet & PA** Individualized counseling on diet, PA, and weight control by trained study nurses; 1 group meeting with dietitian	↓GDM (13.9 vs. 21.6 %, p=0.04) **↓GWG (-0.58 kg, p=0.04)** Diet and PA improvements
Jeffries et al. 2009 **Australia**	**N=286** n(I)=148 n(C)=138	**Weight monitoring** Personalized weight measurement card, providing of optimal GWG range with the intention to self-monitor weight over the course of pregnancy	**↓GWG in whole sample (0.44 vs. 0.46 kg/week, p=0.28)** **↓GWG in ow women (0.42 vs 0.54 kg/week, p=0.01)** **↔Excessive GWG (18 vs. 23 %, p=0.42)**
Hui et al. 2012 **Canada**	**N=224** n(I)=112 n(C)=112	**Diet & PA** Community-based group exercise sessions, instructed home exercise (total of 3–5 ×/week); 2 dietary counseling sessions	**↓Excessive GWG (36 vs. 48 %, p=0.01)** **↔GWG (15.2 vs. 14.1 kg, p=0.28)** ↔BW, LGA, GDM, cesarean delivery Diet and PA improvements after 2 months enrolment
NELLI **Luoto et al. 2011** **Finland**	**N=442** n(I)=246 n(C)=196 ≥1 GDM risk factor	**Diet & PA** Individualized counseling on PA, diet, and GWG at 5 antenatal visits	↔GDM **↔GWG (13.8 vs 14.2 kg; -0.43 kg, p=0.44)** ↓BW (p=0.01), LGA (p=0.04) Diet and PA improvements

BMI=body mass index; BW=birth weight; C=control group; GDM=gestational diabetes mellitus; GWG=gestational weight gain; I= intervention group; IOM=Institute of Medicine; LGA=large for gestational age; nw=normal weight; ob=obese; ow=overweight; PA=physical activity; PPWR=postpartum weight retention; SGA=short for gestational age; ↑=increase; ↔=no difference; ↓=decrease

Table 5: Continued.

Study	Population	Intervention	Main Outcomes
LIP Vinter et al. 2011 Denmark	N=360 n(I)=180 n(C)=180 BMI 30–45	Diet & PA 4 individual dietary counseling sessions with dietitian; free fitness center membership, physical training, personal coaching	↓GWG (7.0 vs. 8.6 kg, p=0.01) ↓Excessive GWG (35 vs. 47 %, p = 0.06) ↑BW (p=0.04) ↔Obstetric outcomes
FeLIPO Rauh et al. 2013, Rauh et al. 2015 Germany	N=250 n(I)=167 n(C)=83	Diet, PA & weight monitoring 2 individualized counseling sessions; personalized feedback on nutrition and PA habits; Weight gain chart according to IOM guidelines	↓Excessive GWG (38 vs. 60 %, p=0.03) ↓GWG (14.1 vs. 15.6 kg, p=0.05) ↓4-month PPWR (p=0.03) ↓12-month PPWR (p=0.03) ↔Obstetric and neonatal outcomes
HeLP-her Harrison et al. 2013, Harrison et al. 2014 Australia	N=228 n(I)=121 n(C)=107 ow/ob; History of GDM	Diet & PA 4 individual sessions by health coach; pregnancy-specific dietary advice, simple healthy eating and PA messages; simple behavioral change strategies to identify short-term goals, and increase self-efficacy and self-monitoring	↓GWG by 28 weeks (6.0 vs. 6.9 kg; -0.9 kg, p<0.05) ↓GWG in ow women(6.0 vs. 7.8 kg, p<0.05) ↔GWG in ob women (5.2 vs. 5.9 kg, p=0.32) ↓GDM PA improvements ↓6-week PPWR (p<0.05)
New Life(style) Study Althuizen et al. 2013 Netherlands	N=246 n(I)=123 n(C)=123	Diet, PA & weight 4 face-to-face counseling sessions about weight, PA and diet; 1 session by telephone after delivery	↔GWG (11.6 vs. 11.1 kg, B=-0.05) ↔Excessive GWG (70.4 vs. 72.4 %, OR=0.92) ↔52-week PPWR
Brownfoot et al. 2015 Australia	N=782 n(I)=386 n(C)=396	Weighing At each antenatal clinic appointment followed by counseling according to IOM guidelines	↔GWG (0.54 vs. 0.53 kg/week, p= 0.63) ↔Excessive GWG (75 vs. 71 %, p=0.21)
Wang et al. 2017 China	N=300 n(I)=150 n(C)=150 ow/ob	PA 3 times per week via a cycling program until 37 weeks of gestation	↓GDM (22.0 vs. 40.6 %, p<0.001) ↓GWG at 25 weeks (4.08 vs. 5.92 kg, p<0.001) ↓GWG at the end (8.38 vs. 10.47 kg, p<0.001) ↓BW (p=0.05)
Thornton et al. 2009 USA	N=257 n(I)=124 n(C)=133 BMI ≥30	Diet At least 1 session with dietician regarding conventional prenatal nutrition guidelines; Calorie-appropriate nutritional regimen, monitored at each prenatal visit by physician; Encouragement to engage in 30 minutes of walking per day	↓GWG (5.0 vs. 14.1 kg, p<0.001) ↓Gestational hypertension (p<0.05) ↓6-week PPWR (p<0.001) ↔ Preeclampsia, caesarean delivery, GDM, BW, macrosomia, APGAR

BMI=body mass index; BW=birth weight; C=control group; GDM=gestational diabetes mellitus; GWG=gestational weight gain; I= intervention group; IOM=Institute of Medicine; LGA=large for gestational age; nw=normal weight; ob=obese; ow=overweight; PA=physical activity; PPWR=postpartum weight retention; SGA=short for gestational age; ↑=increase; ↔=no difference; ↓=decrease

Table 5: Continued.

Study	Population	Intervention	Main Outcomes
Keep Fit Jackson et al. 2011 USA	N=321 n(I)=158 n(C)=163	Diet & PA Brief messages about diet, exercise, and weight gain; Delivered by an computerized actor-portrayed Video Doctor counseling tool twice during pregnancy	Diet and PA improvements ↔ GWG (15.15 vs. 15.24 kg, p=0.95) ↔Excessive GWG
The DALI Lifestyle Study Simmons et al. 2017 9 European Countries	N=436 n(HE+PA)=108 n(HE)=113 n(PA)=110 n(C)=105 BMI ≥29	Diet & PA 5 face-to-face and ≤4 telephone coaching sessions or contacts using e-mail with advice on healthy eating (HE) and physical activity (PA); GWG targeting <5 kg;	↓GWG (HE+PA vs. C: -2.02 kg, p<0.05) ↔GWG (HE vs. C: -0.28; PA vs. C: 0.01, p≥0.05) ↔GDM ↔BW, SGA, LGA
The B.A.B.Y. Study Nobles et al. 2017 USA	N=290 n(I)=143 n(C)=147 History of GDM or BMI ≥25	PA 12-week individually tailored, motivationally matched program designed to increase the compliance with guidelines for exercise during pregnancy (30 min/day)	↔GWG (12.9 vs. 13.8 kg; -0.97 kg, p=0.39) ↔Excessive GWG (64.4 % vs. 69.1 %, p=0.59)

BMI=body mass index; BW=birth weight; C=control group; GDM=gestational diabetes mellitus; GWG=gestational weight gain; I= intervention group; IOM=Institute of Medicine; LGA=large for gestational age; nw=normal weight; ob=obese; ow=overweight; PA=physical activity; PPWR=postpartum weight retention; SGA=short for gestational age; ↑=increase; ↔=no difference; ↓=decrease

Results of current meta-analyses and systematic reviews

Even meta-analyses and systematic reviews of lifestyle interventions reported inconsistent results (Dodd et al. 2008, Guelinckx et al. 2008, Streuling et al. 2010, Dodd et al. 2010, Campbell et al. 2011, Gardner et al. 2011, Streuling et al. 2011, Tanentsapf et al. 2011, Brown et al. 2012, Oteng-Ntim et al. 2012, Sui et al. 2012, Thangaratinam et al. 2012a, Thangaratinam et al. 2012b, Choi et al. 2013, Hill et al. 2013, Agha et al. 2014, Elliott-Sale et al. 2015, Muktabhant et al. 2015, O'Brien et al. 2016, Sanabria-Martinez et al. 2015, Flynn et al. 2016, Song et al. 2016, Fealy et al. 2017, Rogozińska et al. 2017, Zhang et al. 2018).

A recent published systematic review demonstrated that normal weight women who received a dietary and lifestyle intervention during pregnancy have shown significantly reduced total GWG (mean difference of 1.25 kg) and were less likely to experience weight gain above the IOM guidelines and hypertension compared to women who received standard antenatal care (O'Brien et al. 2016). Similar results were shown in previous literature (Streuling et al. 2010, Gardner et al. 2011, Thangaratinam et al. 2012a, Thangaratinam et al. 2012b). The meta-analysis of Thangaratinam et al. (2012a) found that weight management interventions resulted in a reduction in weight gain in the intervention group of 1.42 kg compared with the control group, and in a reduction in the incidence of preeclampsia and shoulder dystocia. In contrast, Campbell et al. (2011) found no clear evidence of interventions to prevent excessive weight gain during pregnancy.

Focusing on overweight and obese women, Dodd et al. (2010) found no significant effect of an antenatal dietary intervention on mean GWG and any other maternal and infant health outcomes. In turn, Oteng-Ntim and colleagues (2012) suggested that a modest restriction of GWG is possible in overweight and obese pregnant women if they receive an antenatal lifestyle intervention. Even if they have not seen any beneficial effects in other outcomes such as cesarean delivery, LGA, birth weight or macrosomia, they have shown a trend towards a reduced prevalence of GDM (Oteng-Ntim et al. 2012). Interventions seem to be more successful in meeting GWG targets in overweight and obese pregnant women if they are delivered by prenatal health care providers (Yeo et al. 2017). Agha et al. (2014) concluded that behavioral interventions in pregnancy may be effective in reducing GWG in obese women, but not in overweight or morbidly obese women.

Thangaratinam et al. (2012a) stated in their meta-analysis that interventions which concentrate on diet control are the most effective type of interventions during pregnancy in reducing GWG. Beneficial effects of diet only interventions were also seen in the systematic review by Tanentsapf et al. (2011). According to this review, dietary advice during pregnancy significantly reduced total

GWG, weight retention at six months postpartum and incidence of cesarean delivery, but had no significant effect on birth weight, preeclampsia, GDM and preterm birth (Tanentsapf et al. 2011). Similar to the results of the meta-analysis by Streuling et al. (2011), Sui et al. (2012) have shown that also exercise only interventions have a positive impact on pregnancy outcomes. Here, the provision of a supervised antenatal exercise intervention was associated with significantly less weight during pregnancy in overweight and obese women when compared with standard antenatal care. The review by Elliott-Sale et al. (2015) has shown that exercise during pregnancy significantly reduced GWG but did not significantly enhance weight loss in the postpartum period. Besides positive effects with regard to GWG, Sanabria-Martínez et al. (2015) found that physical exercise programs during pregnancy decreased the risk of GDM. Fortunately, a Cochrane review of diet, exercise or both for preventing excessive weight gain in pregnancy found that these interventions reduced the average risk of excessive GWG by 20 % (Muktabhant et al. 2015) and confirmed the results of Choi et al. (Choi et al. 2013) that physical activity plus dietary interventions are effective for weight management in pregnancy.

The International Weight Management in Pregnancy (i-WIP) Collaborative Group has currently evaluated the efficacy of lifestyle interventions, including diet, physical activity and mixed interventions in pregnancy on maternal, fetal, and neonatal outcomes in women according to their BMI, age, ethnicity, parity, and underlying medical conditions (Ruifrok et al. 2014). The network is funded by the UK National Institute for Health Research (NIHR) and Health Technology Assessment (HTA) and comprises researchers, clinicians, nutritionists, dieticians, physiotherapists, exercise physiologists, midwives, nurses, and consumers from 17 countries (Ruifrok et al. 2014, Dodd & Thangaratinam 2016). The individual participant data (IPD) meta-analysis of randomized trials also aims to quantify the relationship between the amount of weight gained in pregnancy and the risk of adverse maternal and fetal outcomes, to assess whether adherence to IOM recommendations on GWG improves pregnancy outcomes, to identify the prognostic factors for GWG, to identify the most effective components of lifestyle interventions, and to assess the cost effectiveness of interventions (Ruifrok et al. 2014). First results of the meta-analysis of IPD obtained from 36 randomized trials including 12,343 women displayed positive effects of diet- and physical activity-based interventions on weight gain during pregnancy. Researchers of the i-WIP Collaborative Group detected less weight gain in the intervention group than in the control group (mean difference −0.70 kg), irrespective of maternal BMI, age, parity, ethnicity, or pre-existing medical condition (Rogozińska et al. 2017). Interventions also reduced the risk of cesarean sections but there was no significant beneficial effect identified in other maternal and offspring outcomes (Rogozińska et al. 2017). Addition of study level data from non-IPD studies to

the IPD meta-analysis resulted in stronger evidence of benefit for gestational diabetes. Unfortunately, diet- and physical activity-based interventions in pregnancy do not seem to be cost-effective compared with usual care (Rogozińska et al. 2017).

Diversity of interventions applied during pregnancy – What makes it difficult to derive clinical practice guidelines from current intervention studies?

Due to the considerable heterogeneity of interventions and their methodological insufficiencies, it remains difficult to recommend any specific and effective intervention program for limiting excessive GWG in pregnant women. Studies conducted so far show a wide variation in the characteristics of the population, number of participants, design and intensity of the intervention and also in their outcomes. Commonly, there is a lack of information about the control group. Standard care differs between countries and, thus, may affect the effectiveness of the different interventions (Flynn et al. 2016). Moreover, the effects of lifestyle interventions in different groups of women based on BMI category, age, ethnicity, parity and risk status in pregnancy is not clear (Goldstein et al. 2016) which complicates the comparability between studies.

While some trials focused on optimizing GWG and health outcomes in women of all BMI categories (Phelan et al. 2011, Barakat et al. 2012, Rauh et al. 2013, Ronnberg et al. 2015, Sagedal et al. 2016, Skouteris et al. 2016), others included certain population groups like overweight or obese women (Wolff et al. 2008, Thornton et al. 2009, Guelinckx et al. 2010, Dodd et al. 2014a, Renault et al. 2014, Poston et al. 2015, Okesene-Gafa et al. 2016, Daly et al. 2017, Simmons et al. 2017) or even women at risk of developing GDM (Korpi-Hyovalti et al. 2011, Luoto et al. 2011, Harrison et al. 2013, Nobles et al. 2017).

Weight management strategies during pregnancy can be divided into those that are diet-based, physical-activity-based, and a mixture of diet-based and physical-activity-based. Especially, dietary interventions apply a wide range of advisory strategies. Typical dietary approaches provide healthy eating advice based on national recommendations or nutrition guidelines targeting a balanced diet aiming to limit total energy intake (Bogaerts et al. 2013, Dodd et al. 2014a, Guelinckx et al. 2010, Vinter et al. 2011, Wolff et al. 2008). Some include advice to follow a particular eating pattern such as a Mediterranean or DASH diet (Dietary Approaches to Stop Hypertension) (Renault et al. 2014, Vesco et al. 2014) to decrease consumption of certain nutrient components such as food of high glycemic index and glycemic load (Walsh et al. 2012, Moses et al. 2014). Others have used probiotic interventions because of their potential beneficial effects on

the gut microbiome, resulting in modification of lipopolysaccharides and insulin sensitivity (Luoto et al. 2010, Nitert et al. 2013, Lindsay et al. 2013, Dolatkhah et al. 2015, Halkjaer et al. 2016, Okesene-Gafa et al. 2016). Being physically active is also an important part of a healthy lifestyle. Typical physical activity based interventions are of moderate intensity (<70 % heart rate maximum; <140 beats per minute; 12-14 on the 6-20 Borg Scale) and comprise predominately aerobic-exercise, some resistance exercises, stretching and strengthening and walking for 30 minutes or for a set number of steps (Streuling et al. 2011, Thangaratinam et al. 2012b, Muktabhant et al. 2015, Elliott-Sale et al. 2015, WHO 2016).

Lifestyle advices are provided in various intensities, frequencies and time frames during pregnancy and in the postpartum period (Flynn et al. 2016, O'Brien et al. 2016). Also the beginning of the intervention differs between trials (Flynn et al. 2016, O'Brien et al. 2016). Lifestyle advices were either given via informative materials and brochures, via emailing, the Internet, video and DVD messages, telephone calls, group sessions or even in individual face-to-face meetings. Interventions were delivered through health care providers with different background knowledge like midwives, dieticians, medical or research assistants, nurses as well as physicians. Goal setting, regular weight monitoring, use of weight-gain graphs according to IOM guidelines, verbal feedback on success toward goals, and self-monitoring of diet and physical activity through the use of food and/or physical activity records, pedometers, and food scales are commonly utilized supporting strategies in effective studies and appear to be helpful to achieve optimal weight gain during pregnancy (Brown et al. 2012).

The German FeLIPO trial – a pilot study

Only few trials have tried to integrate lifestyle programs into routine antenatal care and were also modestly effective in reducing excessive GWG (Kinnunen et al. 2008, Harrison et al. 2013, Daley et al. 2015, Daley et al. 2016). Thus, there remains a clear need to establish feasible and effective strategies in order to limit GWG to appropriate levels. The German FeLIPO trial (acronym for “Feasibility of a lifestyle intervention in pregnancy to optimize maternal weight development”) provided knowledge regarding the feasibility of a low intensity lifestyle program in optimizing weight gain and health outcomes in pregnancy within the framework of the German health care system. The study was performed as a cluster-randomized controlled intervention trial in eight gynecological practices in the Munich area. 250 pregnant women of all BMI categories were recruited. The intervention comprised two counseling sessions with trained researchers focusing on diet, physical activity and weight monitoring. Women in the intervention group gained

significantly less weight than women in the control group receiving routine prenatal care (14.1 kg vs. 15.6 kg; $p<0.05$). Moreover, the intervention resulted in a significantly smaller proportion of women exceeding the IOM guidelines (38 % vs. 60 %; $p<0.05$) and the study detected a trend for a decreased risk of developing GDM and less cesarean deliveries among women in the intervention group (Rauh et al. 2013).

The GeliS study and the aim of the present work

The GeliS study (acronym for "Gesund leben in der Schwangerschaft"/healthy living in pregnancy) is a cluster-randomized, controlled intervention trial conducted in the federal state of Bavaria and represents the worldwide largest lifestyle intervention study during pregnancy so far. It is based on the positive experiences of the pilot study FeLIPO and aims to explore the concept of a comprehensive lifestyle intervention in the routine health care system. As a true public health approach, it is adapted to the well-established German pre- and postnatal care system used by almost every pregnant woman. The GeliS project aims to complement this health care system by a lifestyle program combining a balanced diet, regular physical activity, and self-monitoring of body weight to primarily avoid excessive GWG and associated adverse maternal and infant health outcomes. Furthermore, a five year follow-up observation will investigate the long-term effects of the intervention in mothers and their children. Weight development in the children will be followed utilizing the unique German health check-up system for children. In order to stop the increasing trend of pregnant women showing weight gain in excess, promoting healthy lifestyle in pregnancy is an urgent demand. Several interventions done in this field show inconsistent results and it remains difficult to derive the most successful way to prevent excessive GWG and its consequences. If the GeliS trial is shown to be effective and a benefit for both mother and child can be demonstrated, the program may provide a basis for implementation in the well-established health care system for pregnant women in Germany and, hence, become a valuable strategy for the primary prevention of early childhood obesity.

The present work wants to clarify if a lifestyle intervention program which is attached to the German routine health care system for pregnant women is able to reduce the proportion of expectant mothers showing excessive GWG according to the criteria of the IOM (Rasmussen & Yaktine 2009). Moreover, it will be assessed if lifestyle counseling results in decreased absolute amounts of GWG in pregnant women compared to women who receive standard antenatal care. Subgroup analyses will detect the effects of the intervention on GWG and GDM among normal weight, overweight and obese women. Based on the evaluation of maternity cards and birth

records of participating women, short-term effects of the intervention regarding obstetric and neonatal outcomes like GDM, birth weight for gestational age or mode of delivery will be comprehensively investigated. Moreover, associations between GWG and selected secondary outcomes will be examined. Due to the performance of the trial in five different study regions distributed throughout Bavaria, the effects of the intervention within the randomized clusters will be analyzed.

Finally, the results of the present work will provide information on the feasibility of the GeliS intervention program in routine heath care by considering the recruitment process of the trial and its implementation into practice.

2. GELIS – A LIFESTYLE INTERVENTION STUDY DURING PREGNANCY

The GeliS study is a lifestyle intervention study for pregnant women to promote maternal and fetal health through antenatal dietary and physical activity advice and self-monitoring of body weight. As a multicenter and multidisciplinary public health project the trial was conducted in ten regions of Bavaria, a federal state of Germany. The primary hypothesis being tested in the study is that an antenatal intervention prevents gestational weight gain (GWG) in excess which has been linked to numerous adverse maternal and fetal outcomes. The study was developed and conducted by the Else Kröner-Fresenius-Center for Nutritional Medicine of the Technical University of Munich (TUM) in cooperation with the Competence Center for Nutrition (KErn). The trial is supported by the Bavarian State Ministry of Food, Agriculture and Forestry, the Bavarian State Ministry of Health and Care, the AOK Bayern, and the Else Kröner-Fresenius- Stiftung (EKFS). The GeliS study protocol as well as study related materials were approved by the ethics committee of the Technical University of Munich. The protocol was registered in the ClinicalTrials.gov Protocol Registration System (NCT01958307). The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice guidelines and the declaration of Helsinki as well as with current local regulatory requirements and laws.

2.1 STUDY ENDPOINTS

Primary outcome

The primary objective tested in the GeliS trial was to examine whether the intervention compared to standard antenatal care leads to a smaller proportion of participating women with excessive GWG as defined by the Institute of Medicine (IOM) (Rasmussen & Yaktine 2009).

Secondary outcomes

Secondary outcome parameters include:

- Incidence of gestational diabetes mellitus (GDM)
- Other pregnancy complications such as preeclampsia

- Anthropometric measures and health status of the newborns (birth weight, height, head circumference, large for gestational age (LGA), small for gestational age (SGA), APGAR-Score, pH)
- Obstetric complications such as mode of delivery, induction of labor, rate of cesarean deliveries
- Maternal body weight after delivery (6-8 weeks postpartum)
- Maternal dietary habits during pregnancy and after delivery
- Maternal physical activity habits during pregnancy and after delivery
- Maternal mental health
- Postnatal depression at 6-8 weeks after delivery

2.2 STUDY DESIGN AND SETTING

The GeliS trial was designed as a prospective, cluster-randomized, controlled, open intervention trial in Bavaria, a federal state in south eastern Germany. Five Bavarian administrative regions were chosen as study setting: Oberbayern, Oberpfalz, Oberfranken, Mittelfranken and Unterfranken. An overview of the geographic location of selected regions in Bavaria is shown in Figure 2.

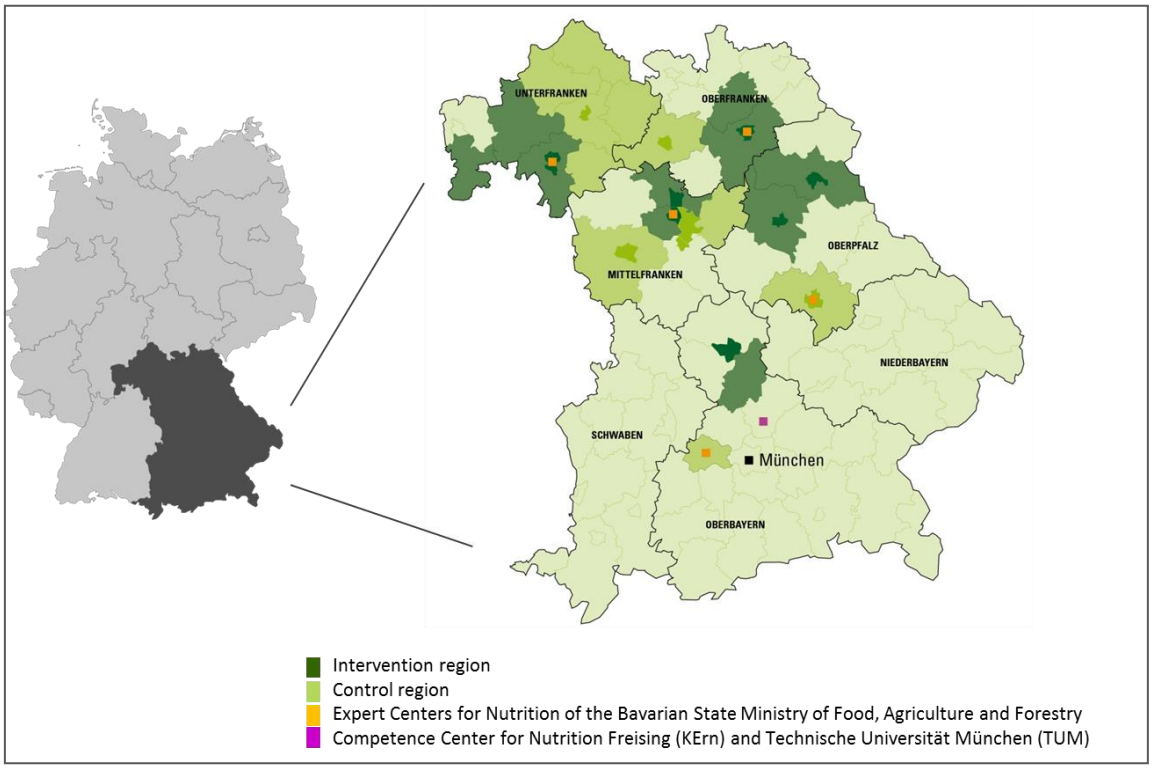


Figure 2: GeliS study regions.

2.2.1 THE CLUSTER RANDOMIZATION

The study is a cluster-randomized trial conducted in gynecological and midwife practices in the "real-life" setting of routine care in ten selected urban and rural districts in Bavaria. The level of randomization was rural and urban districts. Within each of the five participating Bavarian administrative regions, two (urban as well as rural) districts were first pairwise matched with regard to annual number of birth as well as sociodemographic and geographic criteria. Randomization into defined intervention and control region was then carried out within these pairs by computer. The rationale for using cluster randomization was to avoid contamination or spillover effects between trial arms, which would have occurred if individuals or practices were randomized.

2.2.2 RECRUITMENT OF GYNECOLOGICAL AND MIDWIFE PRACTICES AND COUNSELORS

Each pair of an intervention and control region was supervised by local project managers employed by expert centers for nutrition run by the Bavarian State Ministry of Food, Agriculture and Forestry. Project managers searched for potential practices on various levels using the internet, telephone book, and family brochures of respective districts. Contact details of practices and midwives were partly listed by the professional association of gynecologists, the Kassenärztliche Vereinigung Bayerns (KVB – Bavarian Association of Statutory Health Insurance Physicians) and the Bavarian Association of Midwives. Moreover, regional quality circles of gynecologists and homepages of health insurances were used to find potential gynecological practices and midwives. Project managers initially contacted eligible gynecological and midwife practices via information leaflets and afterwards, they asked for participation by phone and in informal meetings in which detailed information on the background, procedures and organization of the GeliS study were presented.

2.2.3 QUALIFICATION OF COUNSELORS

Gynecologists, their medical staff and midwives in the intervention regions acted as health care providers and key communicators by conducting lifestyle counseling sessions for participating pregnant women in the "real-life" setting of routine care. As a precondition for participation as a counselor in the GeliS study they had to attend two standardized qualifying seminars with a total of approximately 10 hours of structured teaching. Seminars provide sufficient background

information in order to ensure competency in lifestyle counseling and standardization of the intervention. They were organized by project managers from the expert centers for nutrition and members of the GeliS study team from the Technical University of Munich and the Competence Center for Nutrition. Seminar contents and information material for the counselors were developed in cooperation with the Healthy Start - Young Family Network, a project of IN FORM, which is funded by the German Federal Ministry of Food and Agriculture. Presentations slides and the manual for further training on nutrition and physical activity during pregnancy can be downloaded free of charge (Healthy Start - Young Family Network 2018). Overall, 21 qualifying seminars took place in all five study regions with 81 potential GeliS counselors (53 medical assistants, 20 midwives, seven gynecologists, and one student trainee) at the first whole-day seminar and 68 participants (43 medical assistants, 18 midwives, five gynecologists, and two student trainees) at the second seminar. In the following, the contents of seminars are described in detail.

First day seminar

The first day seminar consisted of five units including background information on the GeliS trial and detailed facts about a healthy lifestyle during pregnancy.

Unit 1: GeliS study

In the first unit, background information and the rational of the GeliS trial were explained. Counselors were introduced to the study design, essential procedures and relevant study documents. A standardized schedule of each lifestyle counseling session of the trial was given and the mode of data collection was described.

Unit 2: Basic information

In the second unit, the importance of a healthy lifestyle during pregnancy including a balanced diet and regular physical activity as well as abstaining from alcohol and smoking were illustrated with regard to the hypothesis of fetal programming. In this context, the influence of maternal pre-pregnancy weight and GWG on maternal and fetal adverse outcomes and long-term health consequences were discussed. It was pointed out that counselors may play a fundamental role in helping women to escape the hypothesized intergenerational circle of obesity by offering ways to achieve a healthy lifestyle. Participants learned about the IOM recommendations for GWG and the distribution of this weight across different tissues. They also were informed about the

relatively small increase in energy demand (200-300 kcal/day) but substantial higher macro- and micronutrient requirements during pregnancy. It was emphasized that the quality rather than the quantity of food should be taken into account, which means that it is not necessary to "eat for two".

Unit 3: Nutrition in pregnancy

The third unit informed counselors about the principles of a balanced diet during pregnancy according to practice guidelines developed by the Healthy Start - Young Family Network in consensus with most medical, scientific and professional institutes in Germany (Koletzko et al. 2013a). Recommended portions for daily consumption of different food groups and beverages were visualized by the German „Ernährungspyramide“ (aid infodienst Ernährung, Landwirtschaft, Verbraucherschutz e.V. 2012), which is based on the recommendations of the Deutsche Gesellschaft für Ernährung (DGE, German Nutrition Society) (Deutsche Gesellschaft für Ernährung, Österreichische Gesellschaft für Ernährung, Schweizerische Gesellschaft für Ernährungsforschung, Schweizerische Vereinigung für Ernährung 2012). Critical micronutrients during pregnancy such as folic acid, iodine and iron were particularly highlighted. Vegetarian and vegan diet during pregnancy and their limitations as well as favorable aspects of breastfeeding were discussed.

Unit 4: Physical activity in pregnancy

The central issue of this unit was to demonstrate the health benefits of an active pregnancy. The importance of moderate exercises and sports as well as daily physical activity was explained. The following recommendations on frequency, intensity, time and type of physical activity were presented: 30 min of moderate intensity activity on most days of the week or 150 min of moderate intensity activity per week, both in an appropriate heart rate zone. A list of appropriate and inappropriate sports was given. In addition, counselors were encouraged to motivate pregnant women to a physically active lifestyle in everyday life, e.g. by walking instead of driving for transportation or by using the stairs instead of the lift.

Unit 5: Potential risks during pregnancy

Different risks including alcohol consumption and smoking can have harmful effects on the fetus during pregnancy. In this unit, it was emphasized that pregnant women should completely avoid alcohol consumption and smoking during pregnancy. It was also elucidated that pregnant women should not smoke and should not stay in rooms where people smoke or have been smoked. Moreover, the procedures of GDM diagnosis and therapy were shown. Finally, appropriate food

selection and preparation was explained to avoid food poisoning such as toxoplasmosis and listeriosis.

Second day seminar

The second seminar focused on information given in the last lifestyle counseling session within the GeliS project (6-8 weeks postpartum). It was designed for half a day.

Unit 1: Exchange of counselors` experiences

The second seminar started with an exchange of experiences between participating GeliS counselors. They reported about their first experiences in counseling sessions and any problems they may have had with study documents and materials.

Unit 2: Breastfeeding and infant formula

The following session highlighted the importance of breastfeeding for the best development of newborns. Project managers presented various aspects about breastfeeding, e.g. components of breast milk and an appropriate maternal diet during the breastfeeding period. Counselors were encouraged to motivate pregnant women to breastfed, in particular by highlighting the benefits for mothers and their newborns. The recommendations on breastfeeding duration correspond to the practice guidelines of the Healthy Start - Young Family Network (Koletzko et al. 2013b) and were presented as follows: Exclusive breastfeeding is recommended until the end of the 4th month or the beginning of the 5th month of life. Depending on maturity of the infants, the introduction of complementary food can start between the beginning of the 5th and the 7th month postpartum but can individually differ. It is recommended to continue breastfeeding during this time. The total duration of breastfeeding is determined by mothers and their infants themselves.
In addition, participants learned about various types of formula nutrition and their preparation if mothers refuse breastfeeding or being unable to breastfeed their child.

Unit 3: Physical activity after pregnancy

In the third unit, counselors were informed on possibilities of supporting physical activity behavior of infants in the first year of life. Moreover, opportunities were shown to be active as a mother and as a family.

Unit 4: Complementary feeding

The last session comprised complementary feeding including the recommended time to start and practical tips on feeding. Understanding signals from infants as well as basic principles about the components and preparation of different baby foods are further aspects of this unit.

Evaluation of seminars

At the beginning of both seminars, the counselors´ level of knowledge regarding a healthy lifestyle in pregnancy was examined by a knowledge test. Seminar participants had to answer brief multiple choice or open questions about central issues concerning a healthy lifestyle of pregnant women. At the end of the seminar, the level of knowledge was re-tested. In addition, participants completed a brief evaluation questionnaire. The knowledge test and evaluation questionnaire were developed in cooperation with the Healthy Start - Young Family Network and the Competence Center for Nutrition. Both, results of the knowledge test and evaluation questionnaire can be considered for developing future qualifying seminars for health care providers.

2.2.4 RECRUITMENT OF PARTICIPANTS

The recruitment process of participants in the GeliS study was based on experiences of the FeLIPO pilot trial (Rauh et al. 2013).

After attending qualifying seminars, gynecologists and medical assistants as well as midwives were responsible for recruiting pregnant women in selected study regions. It was planned to continuously inform all expectant mothers in participating practices about the GeliS project using leaflets and study posters in waiting rooms or in a one-to-one conversation. All women before the end of the 12th week of gestation were invited to take part in the study and were encouraged to complete a short screening questionnaire including demographic and anamnestic data relevant to the study as well as possible reasons for refusal. Aim of the screening questionnaire was on the one hand to check inclusion and exclusion criteria and on the other hand to obtain basic information about participating and non-participating women.

Screening and consent to study participation (Visit V0: ≤12th week of gestation)

If women were interested to participate in the study, following inclusion and exclusion criteria (Table 6) were checked:

Table 6: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Gestational age ≤12th week of gestation • Age: 18 years - 43 years • Pre-pregnancy BMI ≥18,5 and ≤40,0 kg/m^2 • Sufficient German language skills • Written informed consent	• Multiple pregnancy • High risk pregnancy (contraindications to exercise) • Uncontrolled chronic diseases (e.g. thyroid dysfunction, diabetes mellitus) • Psychiatric or psychosomatic diseases

In order to represent the general healthy population, underweight and severely obese women were excluded. Eligible women received detailed study information and provided their written informed consent. Each participant in both, intervention and control regions, obtained the first questionnaire containing questions about dietary and physical activity habits, intake of supplements as well as about maternal mental health. Moreover, women in intervention regions received a pedometer (Beurer GmbH, Ulm, Germany) with adequate instructions used to monitor and motivate walking. A subgroup of women in the intervention and the control group (region Oberbayern) documented their daily steps in a personal diary.

2.2.5 THE GELIS LIFESTYLE INTERVENTION PROGRAM (VISIT V1-VISIT V4)

Offering lifestyle counseling to pregnant women within the routine health care, the GeliS study aims to encourage women to comply with recommendations for GWG according to the IOM criteria and to promote a healthy lifestyle over the course of pregnancy. Women in the intervention group were encouraged to a healthy pattern of eating, to be physical active in daily life and to self-monitor their weight gain during the course of pregnancy. The intervention was conducted by specifically trained and certified gynecologists, medical assistants and midwives in participating gynecological practices. Figure 3 illustrates the study scheme of the GeliS project including all visits, examinations performed as well as data assessed throughout the whole trial.

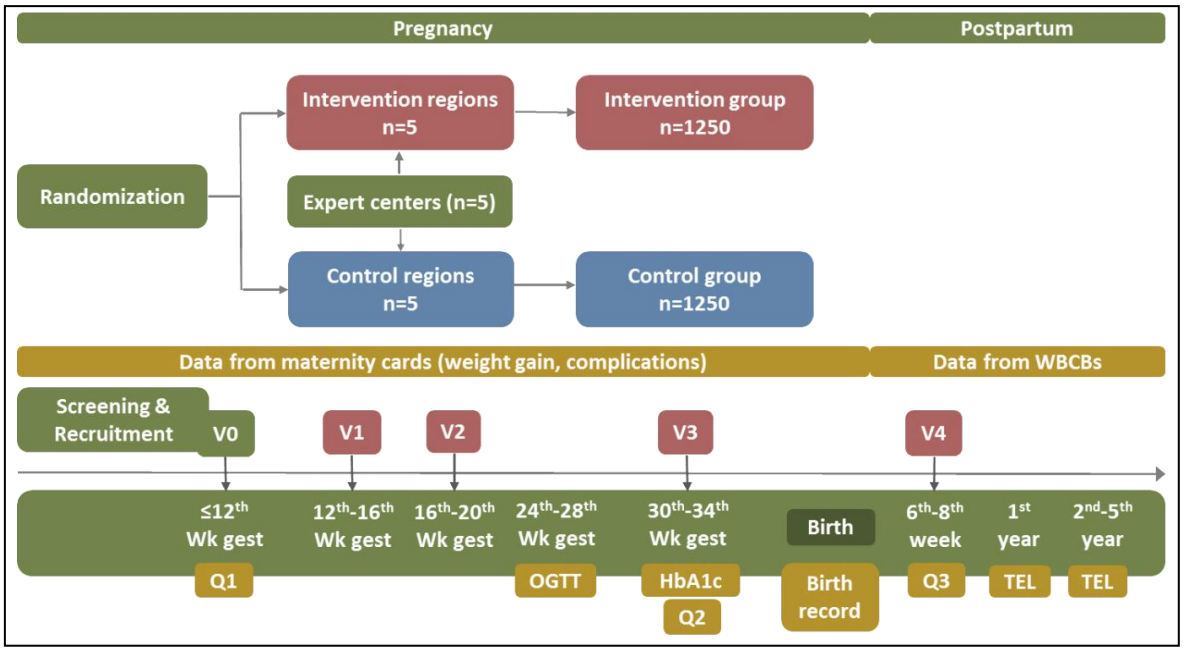


Figure 3: GeliS study scheme.

V: visit, Wk gest: weeks of gestation, Q: questionnaire, OGTT: oral glucose tolerance test, TEL: telephone call, WBCB: well baby check-up booklet, Data source: Rauh et al. (2014).

Expectant mothers in the intervention regions received three structured and individualized face-to-face counseling sessions during pregnancy and one session after delivery, each lasting 30-45 minutes. The counseling sessions were attached to routine pre- and postnatal visits (visit 1: 12^{th}-16^{th}, visit 2: 16^{th}-20^{th}, and visit 3: 30^{th}-34^{th} week of gestation and visit 4: 6^{th}-8^{th} week postpartum) and followed a predefined curriculum. The recommendations of dietary and physical activity advice were in accordance with the practical guidelines developed by the Healthy Start - Young Family Network (Koletzko et al. 2013a).

To ensure consistency in counseling processes and contents, lifestyle counselors obtained a presentation folder including 24 easily understandable predefined slides for every session as well as checklists for scheduling and documentation of sessions.

Participants in both, intervention and control group, received a questionnaire at visits 0, 3 and 4 including questions about dietary and physical activity habits, intake of supplements as well as about maternal mental health. In addition, the third questionnaire contained questions about postnatal depression as well as an evaluation form to assess the acceptance of the lifestyle program in the intervention group. The following section describes the contents of visits in detail.

Visit 1 (12^{th}-16^{th} week of gestation)

In the first visit, the importance of a healthy lifestyle during pregnancy and its determining factors were addressed. In this context, women received first information on a balanced diet containing carbohydrates, fat and protein consistent with current German dietary recommendations (Deutsche Gesellschaft für Ernährung, Österreichische Gesellschaft für Ernährung, Schweizerische Gesellschaft für Ernährungsforschung, Schweizerische Vereinigung für Ernährung 2012). The additional demand of energy and nutrients were illustrated while critical nutrients, especially folic acid, iodine and iron were highlighted. Women learned to understand the risks of alcohol, smoking and foodborne infections during pregnancy. Physical activity advice focused on encouraging women to adopt a more active lifestyle. A chart for adequate weight gain according to pre-pregnancy BMI category was introduced to self-monitor weight development as proposed by the IOM (Rasmussen & Yaktine 2009). Women's weight was measured at each visit and documented in maternity cards. Moreover, brochures including examples for adequate exercise and a list of local prenatal physical exercise programs as well as a brochure with recommendations for a balanced diet in pregnancy were handed out. The first questionnaire which was distributed in visit 0 was collected by counselors.

Visit 2 (16^{th}-20^{th} week of gestation, 4 weeks distance to visit 1)

At the second appointment, pregnant women received more detailed and specific advice on diet and physical activity as well as an individual feedback based on information from the first collected questionnaire. Furthermore, they learned about possibilities for integrating an active lifestyle into daily routine. Counselors addressed GWG again by discussing personal weight gain charts. Women were encouraged to attend a standardized two hour oral glucose tolerance test (oGTT) which was recommended to perform between the 24^{th} and 28^{th} week of gestation.

Visit 3 (30^{th}-34^{th} week of gestation)

Contents from the previous visits were repeated and consolidated. Expectant mothers were informed on prenatal and postnatal exercise classes. Counselors addressed specific problems that might occur in pregnancy, such as water retention or back complaints. Beneficial aspects of breastfeeding were highlighted. Once again, weight gain was monitored and discussed and the second questionnaire was handed out. Between the 30^{th} and 34^{th} week of gestation, a venous EDTA blood sample was collected for measurement of glycosylated hemoglobin (HbA_{1c}).

Visit 4 (6th-8th week postpartum)

In the last lifestyle counseling session, the importance of breastfeeding for mothers and their newborns was discussed and counselors provided information on appropriate maternal diet and physical activity during breastfeeding as well as infant feeding practices.
The second questionnaire was collected and the third questionnaire was handed out with a free envelope to send the questionnaire back to the study team. The third questionnaire included questions about maternal dietary and physical activity habits, intake of supplements, postnatal depression, breastfeeding behavior as well as questions for the evaluation of the project.

Control Group

Women in the control group received routine prenatal care. They obtained leaflets about a healthy lifestyle in pregnancy, but no specific individual advice on diet, physical activity or weight gain in pregnancy. Weight measurements, data collection, and distribution of questionnaires took place within routine prenatal care visits at the same time periods as in the intervention group.

2.2.6 STUDY DOCUMENTS AND MATERIALS

All documents and materials utilized in the trial are summarized in Table 7.

Table 7: Documents and materials used in the GeliS trial.

Study documents and materials	Utilization and purpose
Documents for data collection	
Screening questionnaire *) 1)	To record baseline characteristics from participants and non-participants and to check inclusion and exclusion criteria.
Questionnaire part 1, part 2 and part 3	To evaluate maternal dietary and physical behavior, and intake of dietary supplements during pregnancy and 6-8 weeks after delivery. Maternal dietary behavior: Food Frequency Questionnaire (FFQ) according to the DEGS-Study (German Health Interview and Examination Survey for Adults) 2) with added questions on the intake of dietary supplements. Maternal physical activity behavior: validated Pregnancy Physical Activity Questionnaire (PPAQ), modestly adjusted to German habits .3) Maternal mental health: questionnaire with validated elements (WHO-5; PHQ-4; questions from the KORA study - a research platform that is used by national and international research teams. 4) Postnatal depression 6-8 weeks after delivery: German version of the

	Edinburgh Postnatal Depression Scale (EPDS) validated by Bergant et al. (1998). Evaluation of study procedures by study participants. [1)] Pedometer diary: Seven-day diary to assess the total number of steps as measurerd by pedometers. Diary is only used in a subgroup (region Oberbayern).[1)]
Maternity card	Copies of study relevant pages from maternity cards to evaluate pregnancy outcomes.
Birth record	Copies of birth records to evaluate obstetric and birth outcomes.
Organizational documents	
Instructions [*) 1)]	Leaflet with study related instructions for project managers, practices in intervention and control regions and for counselors with pre specified contents and a list of supplemental material for every visit.
Checklists [*) 1)]	List with annotations to measurements, provision and collection of questionnaires, provision of supplemental materials, organization of appointments. Signature of participants to acknowledge that counseling was given.
Sticker for maternity card [1)]	Recording study relevant information (postpartum weight, blood glucose concentrations, HbA_{1c}) which is not yet part of maternity cards.
Case Report Forms [*) 1)]	Contain data obtained during women's participation.
Participant information and written informed consent [1)]	Precondition for study participation.
Documents for qualifying seminars	
Manual & slides [5)]	The manual provides a detailed and clear summary of the contents of the qualifying seminars.
Counseling documents	
Presentation folder [*) 6)]	Folder with numbered presentation boards that contain information about: Healthy lifestyle in pregnancy, adequate GWG, recommended dietary principles, supplementation of micronutrients, alcohol and smoking in pregnancy, allergy prevention, GDM Binder had to be used in every visit. Number and type of slides are predefined for V1, V2, V3 and V4.
Explanatory notes for presentation slides [6)]	Background information for the counselor about every slide of the binder. Notes are to be used during counseling sessions.
Weight gain chart [*) 1)]	Chart with range of adequate GWG dependent on pre-pregnancy BMI (according to IOM criteria [7)]) for self-monitoring of GWG. Three different charts for normal, overweight or obese pre-pregnancy body weight.
Pedometer [8)]	Portable device counting every step for self-monitoring of walking activity and motivation for increasing physical activity in daily life.
Feedback table [1)]	Supporting table to analyze individual dietary patterns assessed by questionnaires.

Supplemental material	
Flyer „Fit durch die Schwangerschaft“ [9)]	Flyer with basic information about a healthy lifestyle in pregnancy.
Leaflet „Das beste Essen in der Schwangerschaft“ [10)]	Brochure with detailed information about a healthy diet in pregnancy.
Leaflet „Bewegt durch die Schwangerschaft“ [1)]	Leaflet with different gymnastic exercises for pregnant women.
Leaflet with local sport opportunities [1)]	List with local sport opportunities.
Leaflet diet/physical activity in the first year of life	Brochure with information for a healthy diet and physical activity in the first year of the infants.
AOK health-program [11)]	Sport and lifestyle courses offered and paid by the AOK Bayern.
Flyer „Stillen – was sonst?“ [12)]	Flyer with advantages of breastfeeding.
Sticker for well baby check-up booklet [13)]	Sticker shows important facts for a healthy first year of infants.
Sticker for maternity card [14)]	Sticker shows important facts for a healthy lifestyle during pregnancy.

[*)] Documents are presented in the appendix.
[1)] Created by the GeliS study team
[2)] Haftenberger et al. (2010)
[3)] Chasan-Taber et al. (2004)
[4)] Helmholtz Zentrum München - Deutsches Forschungszentrum für Gesundheit und Umwelt
[5)] Created by Healthy Start - Young Family Network (2014a)
[6)] Created by Healthy Start - Young Family Network (2014b)
[7)] Rasmussen & Yaktine (2009)
[8)] Beurer GmbH (Ulm, Germany)
[9)] Created by Healthy Start - Young Family Network (2012a)
[10)] Created aid infodienst Ernährung, Landwirtschaft, Verbraucherschutz e.V. (2013)
[11)] AOK Bayern – Die Gesundheitskasse (2017)
[12)] Created by Healthy Start - Young Family Network (2012b)
[13)] Created by Healthy Start - Young Family Network (2011a)
[14)] Created by Healthy Start - Young Family Network (2011b)

2.2.7 FOLLOW-UP

To determine whether the intervention has led to sustained change in maternal dietary and physical activity behaviors and to address the influence of the intervention on the long-term health of mother and child, a follow-up observation program is conducted after one, three and five years after delivery. Information on breastfeeding and infant feeding practices, growth development, maternal weight development as well as dietary and physical activity behavior of mothers and children is collected by questionnaires. The infant anthropometrics and health status are obtained from the German well baby check-up booklet. This booklet is offered to all mothers in Germany at birth to enhance regular health examinations by the family pediatricians.

2.2.8 DROP-OUT CRITERIA

Following reasons were considered as drop-out criteria and were documented in Case Report Forms (CRFs):

- Insufficient compliance according to the study protocol
- Decline of further study visits
- Change of practice or residence
- Participants were no longer reachable
- Miscarriage/ late loss of pregnancy
- Complications during pregnancy that interfere with the study protocol
- Others.

2.3 OUTCOME MEASURES AND DATA COLLECTION

Pregnancy and obstetric outcomes

Pregnancy and obstetric data are routinely documented in maternity cards at every prenatal visit. In Germany, pregnant woman obtain maternity cards at their first gynecological visit as soon as pregnancy is confirmed. It includes data about fetal and maternal health and the expected date of birth as well as data of the follow up checkup postpartum.

Detailed obstetric outcomes were obtained from birth records including mode of birth, induction of labor, fetal position at delivery, potential maternal and newborns complications, birth related injuries, type of anesthesia, APGAR-Score, and anthropometrics of the newborn.

Weight measurements

Pre-pregnancy BMI calculation was based on self-reported pre-pregnancy weight at the time of recruitment. Weight was routinely measured at every antenatal visit and documented in the maternity card. To obtain standardized weight data, a detailed standard operation procedure of weight measurement was offered to participating practices. GWG as the primary outcome parameter of the project was calculated as the weight change between the measured weight at the first (V0) and the last prenatal visit (G). If weight was not measured at the first visit, the self-reported pre-pregnancy weight was used instead. Moreover, maternal weight retention was measured between 6 and 8 weeks postpartum (V4).

Oral glucose tolerance test

To test for GDM, all study participants were encouraged to attend a standardized 75-g two-hour oral glucose tolerance test between the 24th and 28th week of gestation. Tests were performed according to the guidelines of the German Diabetes Society (DDG) and the German Society of Gynecology and Obstetrics (DGGG) (Kleinwechter et al. 2016), which comply with the guidelines of the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) (Metzger et al. 2010). After an overnight fast for at least eight hours, plasma glucose level was measured before, one and two hours after intake of 75 grams glucose. Table 8 presents the diagnostic thresholds for fasting, 1-h, and 2-h plasma glucose concentrations. According to the IADPSG, GDM was diagnosed if at least one of these thresholds was equaled or exceeded. Measured glucose values were documented in maternity cards. Depending on the severity, women with GDM diagnosis partly received specific treatment (dietary counseling or insulin treatment). This was done by the treating gynecologist at his/her own discretion. However, every participating center received information on the current national guidelines for the management of gestational diabetes.

Table 8: Thresholds in venous plasma after a 75-g-oGTT for diagnosis of GDM according to DDG and DGGG (Kleinwechter et al. 2016).

	Glucose thresholds in venous plasma	
	(mg/dl)	(mmol/l)
Fasting glucose	92	5,1
1-hour-glucose	180	10,0
2-hour-glucose	153	8,5

Measurement of glycosylated hemoglobin concentration (HbA_{1c})

Additional information about the presence and severity of diagnosed GDM was obtained by determining the HbA_{1c}. Therefore, EDTA blood was collected between the 30th and 34th week of gestation. Results were documented in maternity cards.

Assessment of SGA and LGA infants

Infants classified as SGA are born with a birth weight lower than the 10th percentile for their gestational age. LGA infants are generally defined as those with a birth weight greater than the

90th percentile for gestational age (Lee et al. 2013). The assessment of SGA and LGA born infants were based on the German perinatal data from 1995-2000 (Voigt et al. 2006).

Demographic data

Demographic data were obtained from the screening questionnaire. Participants as well as rejecters were asked for the following data:

- Age
- Height (cm); pregravid weight (kg)
- Parity
- Nationality; native country; native language
- Marital status; living together with a partner
- Educational level
- Professional level
- Working status

2.4 DATA MANAGEMENT

Practice staff in intervention and control regions sent relevant pages of maternity cards, birth records and questionnaires to local project managers in respective regions. All data were pseudonymized and transferred to CRFs by project managers before they were sent to data management at the Münchner Studienzentrum for database entry and retention.

Adherence to the study protocol as well as data documentation was regularly monitored by the Münchner Studienzentrum in cooperation with research assistants from the Technical University of Munich.

2.5 POWER CALCULATION

The primary outcome of the study is the proportion of women showing excessive GWG according to the IOM guidelines. As hypothesized, a lifestyle intervention focusing on diet, physical activity and weight monitoring will prevent gaining weight in excess. The sample size of the study was calculated based on the proportion of women exceeding weight gain recommendations according to the IOM guidelines and the results of the previous conducted pilot study (Rauh et al. 2013).

According to the Bavarian perinatal register, at least 40 % of the women (BMI ≥18.5 kg/m^2) were expected to exceed the recommended IOM levels in the control group (Beyerlein 2009a, personal communication based on the Bavarian perinatal data from 2007). It was assumed that the intervention would lead to a decrease to 30 %. 1900 pregnant women (Donner & Klar 2000b) were needed to detect this difference in proportions with 90 % power using a significance level (alpha) of 5 % and an intraclass correlation coefficient (ICC) of 0.5 % (Hannan et al. 1994). With regard to a possible imbalance in the sample size between groups as well as a drop-out rate of up to 20 % until delivery, 2500 participants had to be recruited for the trial.

2.6 DATASETS FOR ANALYSES

The **rejecter set** contains women who were assessed for eligibility but declined to participate.

The **baseline set** contains all women who provided written consent with the exception of women who were not eligible when reassessed.

The **primary analysis set** contains all women in the baseline set with the exception of:

- Women with miscarriages or late loss of pregnancy
- Women who had terminations
- Women with pregnancy complications that interfere with the intervention
- Maternal deaths during pregnancy
- Women with preterm birth (<37 week of gestation)

The **per-protocol set for the primary outcome** contains all women in the primary analysis set with the exception of:

- Women with a missing measured weight value at V0 or G
- Women in the intervention group who missed a lifestyle counseling session during pregnancy
- Women in the intervention group who had a lifestyle counseling session more than two weeks later than planned during pregnancy
- Women who violated the inclusion/exclusion criteria in terms of gestational age at entry, age and pre-pregnancy BMI

2.7 STATISTICAL ANALYSES

Data were cleaned and checked for missing values prior to analyses. The intervention and control arms were compared and tested for superiority in terms of the proportion of women with excessive GWG.

The null and alternative hypotheses are:
H_0: There is no difference in the proportion of women with excessive GWG between the intervention and control groups.
H_A: There is a difference in the proportion of women with excessive GWG between the intervention and control groups.
H_0 was rejected if the p value for the "group" coefficient in the primary analysis model was less than 0.05.

For the primary analysis, a generalized estimating equations (GEE) logistic regression model with excessive GWG as the dependent variable and group (intervention/control) as an independent variable were used (Donner & Klar 2000a). Unadjusted and adjusted analyses were conducted. Pre-pregnancy BMI category, age, parity and gestational age at the first prenatal visit (V0) were adjusted for in the model. The GEE approach was used to adjust for the clusters, assuming an exchangeable correlation structure (Donner & Klar 2000a).

The presented results correspond to complete case analysis including all participants for whom primary outcome data were available, apart from those women who had a preterm delivery (<37th week of gestation). Women with preterm delivery were excluded from the analysis in order to present the proportion of women with excessive GWG in a full-length pregnancy. In addition, an intention to treat approach was taken for the primary analysis including all participants in the primary analysis set. If the primary outcome was missing for some participants, multiple imputation using fully conditional specification was used to create ten imputed datasets with results pooled across these datasets (Berglund & Heeringa 2014). The data were imputed based upon all weight data recorded during pregnancy (at V0, V1, V2 and V3), pre-pregnancy BMI category, age, parity, gestational age at the first and last prenatal visits, study group and cluster. Further, a pre-specified per-protocol analysis was performed excluding those participants who missed a measured weight at screening or last visit prior to birth, who violated inclusion/exclusion criteria, or, for those in the intervention group, missed a lifestyle counseling session or had a counseling session more than two weeks later than planned.

Subgroup analyses were conducted to assess the effect of the intervention separately by pre-pregnancy BMI category, educational level, and region.

Patient demographics and other baseline characteristics were summarized by study group for the baseline set. The characteristics of participants between the baseline and rejecter sets were compared in exploratory analyses.

GEE linear, logistics and multinomial models were similarly used to compare the secondary endpoints between the intervention and control groups and fit for the continuous, binary and categorical outcome variables, respectively.

All analyses were performed using SAS software, version 9.4 for Windows, Copyright 2002-2015, SAS Institute Inc., Cary, NC, USA.

3 RESULTS

The GeliS lifestyle intervention program was intended to limit excessive weight gain in pregnancy and to support maternal and fetal health. This section shows the numbers of recruited practices, counselors and pregnant women, the flow of participants through the trial as well as baseline characteristics of participants and rejecters. Afterwards, results of the primary outcome gestational weight gain (GWG) and secondary outcomes are presented.

3.1 PARTICIPATING PRACTICES, COUNSELORS AND PREGNANT WOMEN

The project was conducted in five administrative regions of Bavaria (Oberbayern, Oberpfalz, Oberfranken, Mittelfranken, Unterfranken). In these regions, 71 gynecological and midwife practices took part in the trial (Table 9).

Table 9: Gynecological and midwife practices participating in the GeliS study.

	All regions	Oberbayern	Oberpfalz	Oberfranken	Mittelfranken	Unterfranken
Intervention	**39**	8	9	9	8	5
Control	**32**	9	8	6	7	2
Total	**71**	**17**	**17**	**15**	**15**	**7**

It was planned to recruit a total of 100 practices with 50 practices each in the intervention and control regions. Despite a second recruitment period in Mittelfranken and Unterfranken it was not possible to achieve the planned amounts of practices. 39 practices in the intervention regions and 32 practices in the control regions participated in the trial.

62 counselors (gynecologists, midwives and medical assistants) were recruited for the study (Table 10). They completed qualifying seminars and recruited at least one pregnant woman.

Table 10: Qualified counselors in the GeliS study.

All regions	Oberbayern	Oberpfalz	Oberfranken	Mittelfranken	Unterfranken
62	13	13	11	14	11

From July 2013 to December 2015, participating practices assessed pregnant women for inclusion. 2286 pregnant women took part in the project equally distributed to the intervention and control group (Table 11).

Table 11: Numbers of participants in the GeliS study.

	All regions	Oberbayern	Oberpfalz	Oberfranken	Mittelfranken	Unterfranken
Intervention	**1152**	124	322	284	262	160
Control	**1134**	212	280	461	146	35
Total	**2286**	**336**	**602**	**745**	**408**	**195**

Due to the small number of participating practices and counselors in Unterfranken only 35 pregnant women were recruited in the control region. Most women were recruited in Oberfranken (n=745).

3.2 CHARACTERIZATION OF THE STUDY POPULATION

Flow of participants

Figure 4 displays the flow of participants through the GeliS trial. 2641 pregnant women were initially screened for study participation. 311 (11.8 %) of them declined study participation. Main reasons for declining were lack of time (n=46), no interest (n=22), fear about data protection (n=18), belief in own experiences or competences (n=17), too high effort (n=6) and study participation in previous pregnancy (n=2). 204 women did not specify their reasons for refusal. Multiple answers were possible. 44 (1.7 %) women were interested to participate in the trial but were excluded because 35 (1.3 %) did not meet eligibility criteria, six (0.2 %) had a miscarriage and three (0.1 %) could not be reached anymore for giving written informed consent. Of 2286 women who provided their consent, 25 (1.1 %) were not eligible when reassessed. Finally, 1139 women formed the intervention group and got detailed counseling about healthy weight and lifestyle during pregnancy. 1122 women were assigned to receive standard antenatal care.

For 2017 (89.2 %) women, primary outcome data were available. Reasons for missing outcome data were miscarriage (n=73), termination (n=9) or severe pregnancy complications (n=4). Further 158 (7.0 %) women dropped out in both groups and were excluded from the analysis due to the following main reasons (multiple reasons were possible): change of practice or residence (n=65), decline of further study visits (n=59), participants were no longer reachable (n=31).

It was planned to recruit a total of 2500 pregnant women. The actual drop-out rate of 10.8 % (intervention group: 10.6 %, control group: 11.0 %) was lower than the estimated drop-out rate of 20 %. Moreover, the number of women included was balanced with 1152 women included in the intervention group and 1134 women included in the control group. Both conditions made it possible to stop the recruitment with a lower number of participants than originally planned.

1885 (83.4 %) women were included in complete-case analysis of the primary outcome. 132 (5.8 %) women had a preterm birth and were excluded from analysis of GWG. For the per-protocol analysis of the primary outcome 97 (4.3 %) additional women in both groups were excluded for the following reasons (multiple reasons were possible): 43 (1.9 %) had a pre-pregnancy BMI slightly lower (n=38) or higher (n=5) than defined in the study protocol. From 22 women (1.0 %) weight measured at entry was missing. 20 women in the intervention group (0.9 %) missed at least one counseling session. 18 women in the intervention group (0.8 %) were counseled more than two weeks before or after the planned time frame. After all, 1788 (79.1 %) women remained for the per-protocol GWG analysis.

2018 (89.3 %) infants (including premature births) were included in the complete-case analysis at birth and 1911 (84.5 %) women were analysed with regard to short-term postpartum weight retention (PPWR).

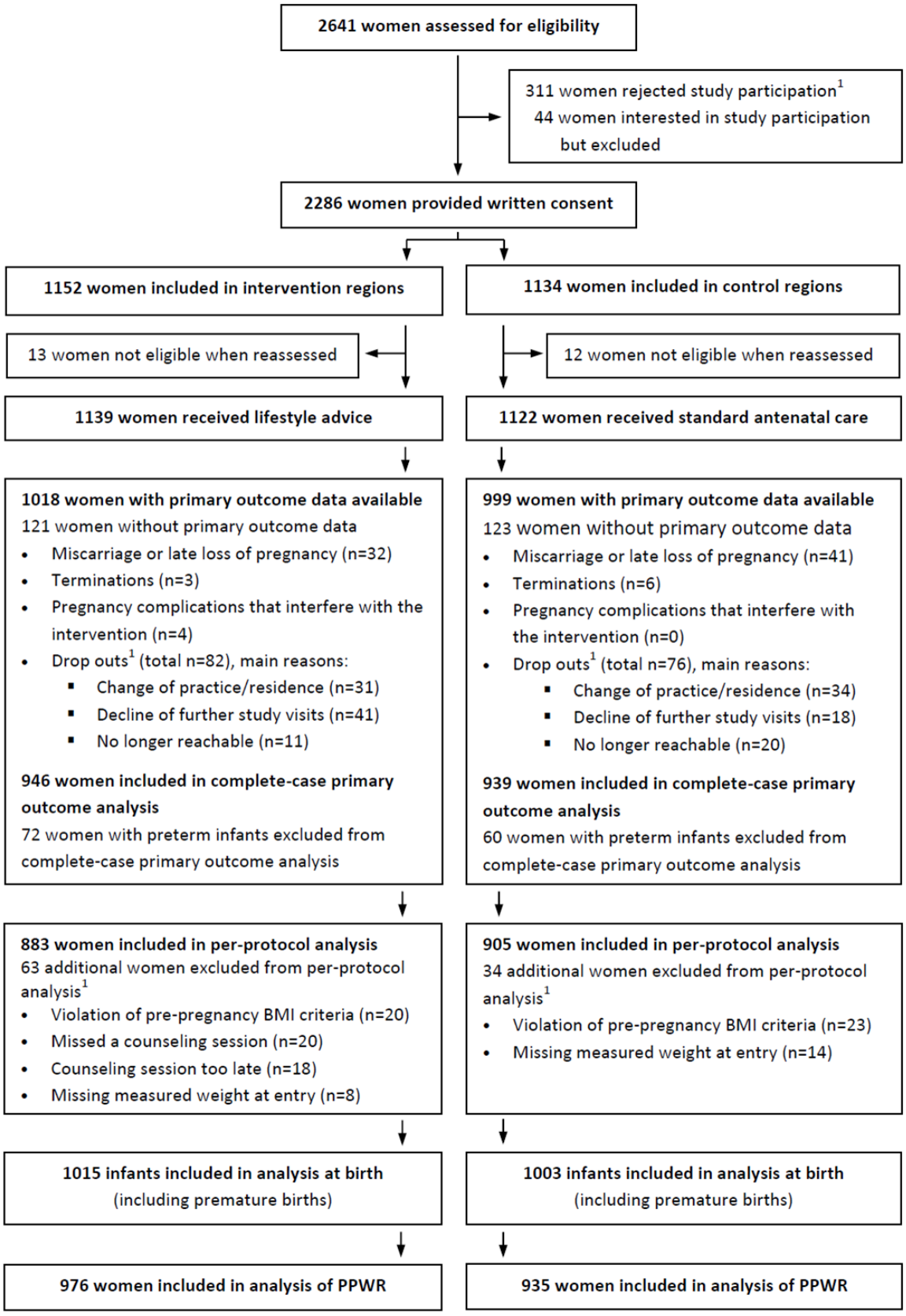


Figure 4: Flow chart of the GeliS trial.
BMI= body mass index; GWG= gestational weight gain; PPWR=postpartum weight retention. [1]Multiple reasons possible.

Baseline characteristics of participants and rejecters

A comparison of baseline characteristics between participants and rejecters is shown in Table 12.

Table 12: Comparison of baseline characteristics between GeliS study participants and rejecters.

	Participants (n=2261)	**Rejecters (n=311)**
Age (years)	30.3 ± 4.5	29.9 ± 4.4
Height (cm)[a)]	167.3 ± 6.0	167.2 ±6.2
Pre-pregnancy weight (kg)[a)]	68.2 ± 13.4	66.2 ± 13.4
Pre-pregnancy BMI (kg/m^2)	24.4 ± 4.5	23.6 ± 4.5
Pre-pregnancy BMI category		
Underweight	48/2261 (2.1)	21/311 (6.8)
Normal weight	1419/2261 (62.8)	204/311 (65.6)
Overweight	520/2261 (23.0)	57/311 (18.3)
Obese	274/2261 (12.1)	29/311 (9.3)
Parity		
0	1299/2258 (57.5)	152/307 (49.5)
1	759/2258 (33.6)	115/307 (37.5)
≥2	200/2258 (8.9)	40/307 (13.0)
Nationality		
German	2167/2257 (96.0)	297/309 (96.1)
Others	90/2257 (4.0)	14/309 (4.5)
Country of birth		
Germany	2002/2256 (88.7)	254/309 (82.2)
Others	254/2256 (11.3)	55/309 (17.8)
Native Language		
German	2117/2255 (93.9)	275/309 (89.0)
Others	138/2255 (6.1)	44/309 (14.2)
Marital Status		
Married	1453/2250 (64.6)	200/307 (65.2)
Single/divorced	797/2250 (35.4)	107/307 (34.9)
Living with a partner	2158/2252 (95.8)	287/309 (92.9)
Educational level		
None	6/2253 (0.3)	1/308 (0.3)
General secondary school	354/2253 (15.7)	96/308 (31.2)
Intermediate secondary school	952/2253 (42.3)	156/308 (50.7)
High school	9941/2253 (41.8)	55/308 (17.9)
Professional level		
Apprentice/student	61/2237 (2.7)	7/306 (2.3)
No professional qualification	52/2237 (2.3)	13/306 (4.3)
Completed vocational training (apprenticeship, college)	1531 /2237 (68.4)	214/306 (69.9)
University degree	593/2237 (26.5)	67/306 (22.0)
Others	-	6/306 (2.0)
Working status		
Full-time job	1160/2235 (51.9)	144/309 (46.6)
Part-time job	560/2235 (25.1)	78/309 (25.2)

Marginal employment	136/2235 (6.1)	22/309 (7.1)
Serve an apprenticeship	59/2235 (2.6)	9/309 (2.9)
Not working	55/2235 (2.5)	10/309 (3.2)
Parental leave/housewife	265/2235 (11.9)	50/309 (16.2)

Data are given as mean ± standard deviation or number (%)
[a)] Self-reported
BMI=Body Mass Index

Study participants tended to be slightly older than study rejecters (30.3 years vs. 29.9 years). They had a higher mean weight and BMI at the beginning of pregnancy with a lower percentage of women being normal weight (62.8 % vs. 65.9 %) and higher percentage of overweight (23.0 % vs. 18.3 %) and obese women (12.1 % vs. 9.3 %) than rejecters. A higher percentage of participating women expected their first child (57.5 % vs. 49.5 %) whereas a higher percentage of study rejecters gave birth to one, two or more children. A higher percentage of study rejecters reported being not born in Germany and that German is not their native language, respectively. Participating women were well educated including 41.8 % of women completed high school and 42.3 % completed intermediate secondary school. In contrast, only 17.9 % of rejecters completed high school but almost one third completed only general secondary school. There is a higher proportion of rejecters who had no professional qualification and a smaller proportion with university degree.

Baseline characteristics of participants

Table 13 outlines the anthropometric, sociodemographic and lifestyle characteristics of participants in the control and intervention group at trial entry.

Table 13: Baseline characteristics of the GeliS study population.

	Intervention (n=1139)	**Control (n=1122)**	**Total (n=2261)**
Age (years)	30.2 ± 4.4	30.4 ± 4.7	30.3 ± 4.5
Height (cm)[a)]	167.4 ± 6.0	167.2 ± 6.0	167.3 ± 6.0
Pre-pregnancy weight (kg)[a)]	68.4 ± 13.1	68.0 ± 13.7	68.2 ± 13.4
Pre-pregnancy BMI (kg/m^2)	24.4 ± 4.4	24.3 ± 4.6	24.4 ± 4.5
Pre-pregnancy BMI category			
Underweight	24/1139 (2.1)	24/1122 (2.1)	48/2261 (2.1)
Normal weight (including underweight)	732/1139 (64.3)	735/1122 (65.5)	1467/2261 (64.9)
Overweight	271/1139 (23.8)	249/1122 (22.2)	520/2261 (23.0)
Obese	136/1139 (11.9)	138/1122 (12.3)	274/2261 (12.1)
Gestational age at entry (week)	8.1 ± 2.1	8.4 ± 2.2	8.3 ± 2.2
Gravidity			
1	558/1053 (53.0)	478/1032 (46.3)	1036/2085 (49.7)

2	315/1053 (29.9)	347/1032 (33.6)	662/2085 (31.8)
3	120/1053 (11.4)	135/1032 (13.1)	255/2085 (12.2)
≥4	60/1053 (5.7)	72/1032 (7.0)	132/2085 (6.3)
Parity			
0	706/1139 (62.0)	593/1119 (53.0)	1299/2258 (57.5)
1	358/1139 (31.4)	401/1119 (35.8)	759/2258 (33.6)
≥2	75/1139 (6.6)	125/1119 (11.2)	200/2258 (8.9)
Smoking			
Yes, regular smoking	36/1061 (3.4)	42/1044 (4.0)	78/2105 (3.7)
Yes, occasional smoking (<1 cigarette per day)	24/1061 (2.3)	22/1044 (2.1)	46/2105 (2.2)
Not anymore	441/1061 (41.6)	460/1044 (44.1)	901/2105 (42.8)
Never smoked	560/1061 (52.8)	520/1044 (49.8)	1080/2105 (51.3)
How many cigarettes per day?	4.6 ± 3.1	6.2 ± 4.4	5.4 ± 3.9
Nationality			
German	1092/1139 (95.9)	1075/1118 (96.2)	2167/2257 (96.0)
Others	47/1139 (4.1)	43/1118 (3.9)	90/2257 (4.0)
Country of birth			
Germany	1001/1138 (88.0)	1001/1118 (89.5)	2002/2256 (88.7)
Others	137/1138 (12.0)	117/1118 (10.5)	254/2256 (11.3)
Native Language			
German	1067/1137 (93.8)	1050/1118 (93.9)	2117/2255 (93.9)
Others	70/1137 (6.2)	68/1118 (6.1)	138/2255 (6.1)
Marital Status			
Married	766/1136 (67.4)	687/1114 (61.7)	1453/2250 (64.6)
Single/divorced	370/1136 (32.6)	427/1114 (38.3)	797/2250 (35.4)
Living with a partner	1093/1134 (96.4)	1065/1118 (95.3)	2158/2252 (95.8)
Educational level			
None	2/1138 (0.2)	4/1115 (0.4)	6/2253 (0.3)
General secondary school	172/1138 (15.1)	182/1115 (16.3)	354/2253 (15.7)
Intermediate secondary school	486/1138 (42.7)	466/1115 (41.8)	952/2253 (42.3)
High school	478/1138 (42.0)	463/1115 (41.5)	9941/2253 (41.8)
Professional level			
Apprentice/student	33/1132 (2.9)	28/1105 (2.5)	61/2237 (2.7)
No professional qualification	20/1132 (1.8)	32/1105 (2.9)	52/2237 (2.3)
Completed vocational training (apprenticeship, college)	782/1132 (69.1)	749/1105 (67.8)	1531 /2237 (68.4)
University degree	297/1132 (26.2)	296/1105 (26.8)	593/2237 (26.5)
Working status			
Full-time job	613/1124 (54.5)	547/1111 (49.2)	1160/2235 (51.9)
Part-time job	267/1124 (23.8)	293/1111 (26.4)	560/2235 (25.1)
Marginal employment	62/1124 (5.5)	74/1111 (6.7)	136/2235 (6.1)
Serve an apprenticeship	33/1124 (2.9)	26/1111 (2.3)	59/2235 (2.6)
Not working	27/1124 (2.4)	28/1111 (2.5)	55/2235 (2.5)
Parental leave/housewife	122/1124 (10.9)	143/1111 (12.9)	265/2235 (11.9)

Data are given as mean ± standard deviation or number (%)
a) Self-reported
BMI=Body Mass Index

Baseline characteristics were generally balanced across the trial groups. Women in the lifestyle intervention group had almost the same median age as women who received standard antenatal care during the GeliS trial (30.2 years vs. 30.4 years). Mean self-reported weight and pre-pregnancy BMI was similar in the intervention and control group (68.4 kg and 68.0 kg; 24.4 kg/m^2 and 24.3 kg/m^2) with nearly two thirds of women being normal weight and one third of women being overweight and obese. 48 participants with a pre-pregnancy BMI slightly lower than 18.5 kg/m^2 (inclusion failures; 24 intervention and 24 control participants) were included in the normal weight BMI category for statistical analyses. Women in both groups were in the 9th week of gestation at trial entry. A higher percentage of women in the intervention group were nulliparous (62.0 % vs. 53.0 %) and were never pregnant before the study (53.0 % vs. 46.3 %) compared to women in the control group. 124 (5.9 %) participating women reported that they currently smoke with no relevant difference between study groups (5.7 % vs. 6.1 %). 5.4 cigarettes were smoked per day. Most of study participants were born in Germany and lived together with a partner. Women in both groups were well educated with high percentage having a university degree (26.2 % vs. 26.8 %). Half of the participating women in each of the groups had a full-time job.

Anamnestic characteristics

Data on anamnestic characteristics were documented in maternity cards by practice staff or gynecologists at the beginning of pregnancy. Data were available for 1027 participants in the intervention group and 1013 participants in the control group (Table 14). Of these, 851 in the intervention group and 856 in the control had at least one of the presented medical findings at the screening visit. Familiar predispositions include diabetes, hypertension, abnormalities, hereditary diseases, and psychological diseases.

Table 14: Anamnestic characteristics of GeliS participants.

	Intervention (n=1027)	**Control (n=1013)**	**Total (n=2040)**
Familiar predisposition	467 (45.5)	491 (48.5)	958 (47.0)
Own serious diseases	226 (22.0)	262 (25.9)	488 (23.9)
Tendency to bleeding or thrombosis	30 (2.9)	36 (3.6)	66 (3.2)
Allergies	378 (36.8)	413 (40.8)	791 (38.8)
Former blood transfusion	14 (1.4)	8 (0.8)	22 (1.1)
Specific psycholgical stress	44 (4.3)	21 (2.1)	65 (3.2)
Specific social burden	4 (0.4)	5 (0.5)	9 (0.4)
Rhesus incompatibility (in previous	5 (0.5)	4 (0.4)	9 (0.4)

pregnancies)			
Dwarfism	2 (0.2)	2 (0.2)	4 (0.2)
Skeletal abnormality	39 (3.8)	51 (5.0)	90 (4.4)
Pregnant women above 35 years	159 (15.5)	180 (17.8)	339 (16.6)
Many previous births (more than 4 children)	2 (0.2)	1 (0.1)	3 (0.1)
Status after infertility treatment	43 (4.2)	28 (2.8)	71 (3.5)
Status after preterm birth	26 (2.5)	30 (3.0)	56 (2.7)
Status after deficiency birth	4 (0.4)	12 (1.2)	16 (0.8)
Status after 2 or more miscarriages/abortions	49 (4.8)	37 (3.7)	86 (4.2)
Dead/injured fetus in anamnesis	9 (0.9)	9 (0.9)	18 (0.9)
Complications of previous deliveries	57 (5.6)	67 (6.6)	124 (6.1)
Post partum complications	13 (1.3)	28 (2.8)	41 (2.0)
Status after cesarean section	105 (10.2)	117 (11.5)	222 (10.9)
Status after uterus surgery	33 (3.2)	42 (4.1)	75 (3.7)
Rapid pregnancy sequence (less than 1 year)	44 (4.3)	32 (3.2)	76 (3.7)
Other specific characteristics	103 (10.0)	73/1013 (7.2)	176 (8.6)
High risk pregnancy	122 (11.9)	178 (17.6)	300 (14.7)

Data are given as number (%)

Women in both groups are comparable in their anamnestic data. 2.7 % of study participants had a preterm birth and 10.9 % of women had a cesarean delivery in a previous pregnancy. According to participating gynecologists, 14.7 % of study participants had a high risk pregnancy. Women in the intervention group (11.9 %) were less likely to be at high risk than women in the control group (17.6 %).

3.3 PRIMARY OUTCOME – GESTATIONAL WEIGHT GAIN

Results concerning gestational weight gain are shown in the whole study population and grouped by intervention and control. Intervention effects are presented in terms of an estimated odds ratio comparing the odds of the outcome in the intervention group with the control group. An odds ratio <1 would be in favor of the intervention. Unadjusted and adjusted analyses, adjusting for pre-pregnancy BMI category, age, parity and gestational age at the first prenatal visit, were conducted.

3.3.1 ADHERENCE TO IOM GUIDELINES

Gestational weight gain according to the IOM guidelines in the whole study population

Figure 5 demonstrates the adherence to the IOM guidelines among all GeliS-participants and shows differences between normal weight, overweight and obese women.

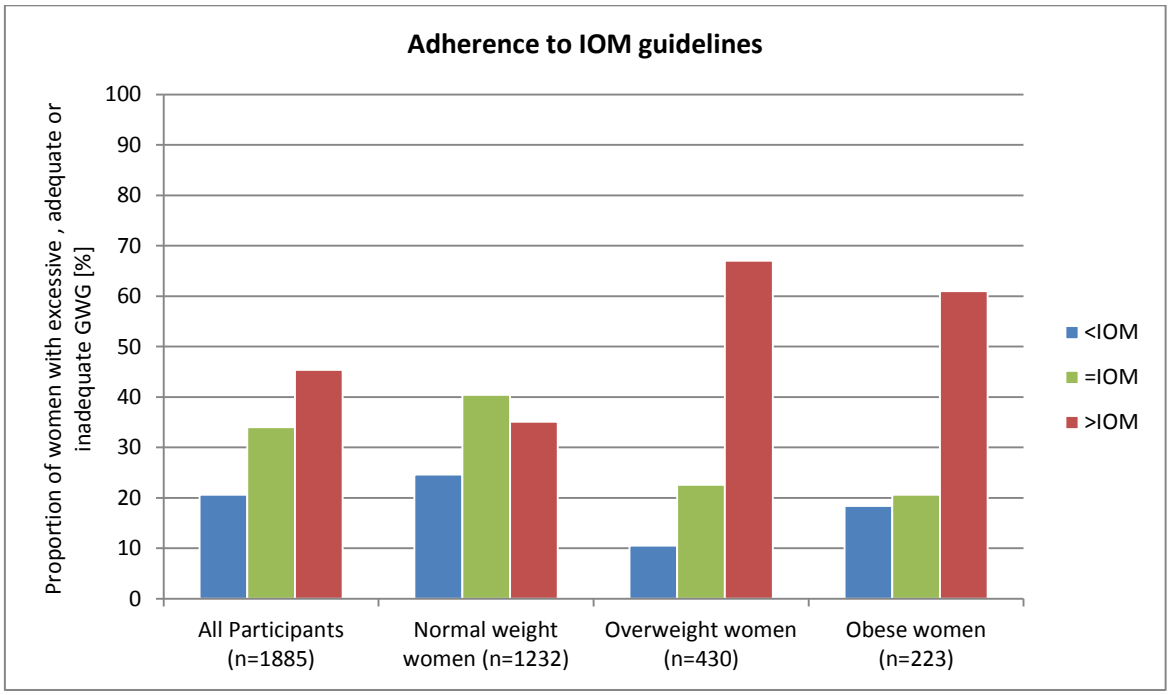


Figure 5: Adherence to IOM guidelines by study participants depending on pre-pregnancy BMI.

Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit; Inadequate, adequate and excessive GWG is defined according to the criteria provided by the U.S. Institute of Medicine (Rasmussen & Yaktine 2009); GWG=gestational weight gain; IOM=Institute of Medicine

34.0 % of all women showed adequate weight gain (Figure 5). 45.4 % of all participants exceeded the IOM guidelines whereas 20.6 % of women gained less than recommended. Among normal weight women, 40.4 % adhered to the IOM recommendations and gained up to 16 kg in pregnancy. 24.6 % of normal weight women gained less than the recommended range and 35.1 % exceeded the recommendations. Excessive GWG was more frequent among overweight and obese women compared to normal weight participants. Two thirds of overweight (67.0 %) and obese (61.0 %) women exceeded the recommended ranges. Only one-fifth of overweight (22.6 %) and obese (20.6 %) women complied with the recommendations.

Gestational weight gain according to the IOM guidelines between study groups

No considerable differences were seen between study groups regarding adherence to the IOM guidelines (Figure 6). Analyses of excessive GWG resulted in no evidence for different effects between the intervention and control group (Figure 6, Table 15, Appendix: Table 28). Weight gain recommendations were exceeded by 45.1 % of women in the intervention group and 45.7 % of women in the control group. There was no statistically significant difference between groups (adjusted OR: 0.95; 95 % CI: 0.66 to 1.38; p=0.79). 21.4 % in the intervention and 19.9 % in the control group gained weight below IOM recommendations (p=0.002) (Appendix: Table 28). The intraclass correlation coefficient (ICC), reflecting potential systematic differences between the clustered study regions, was low (0.8 %).

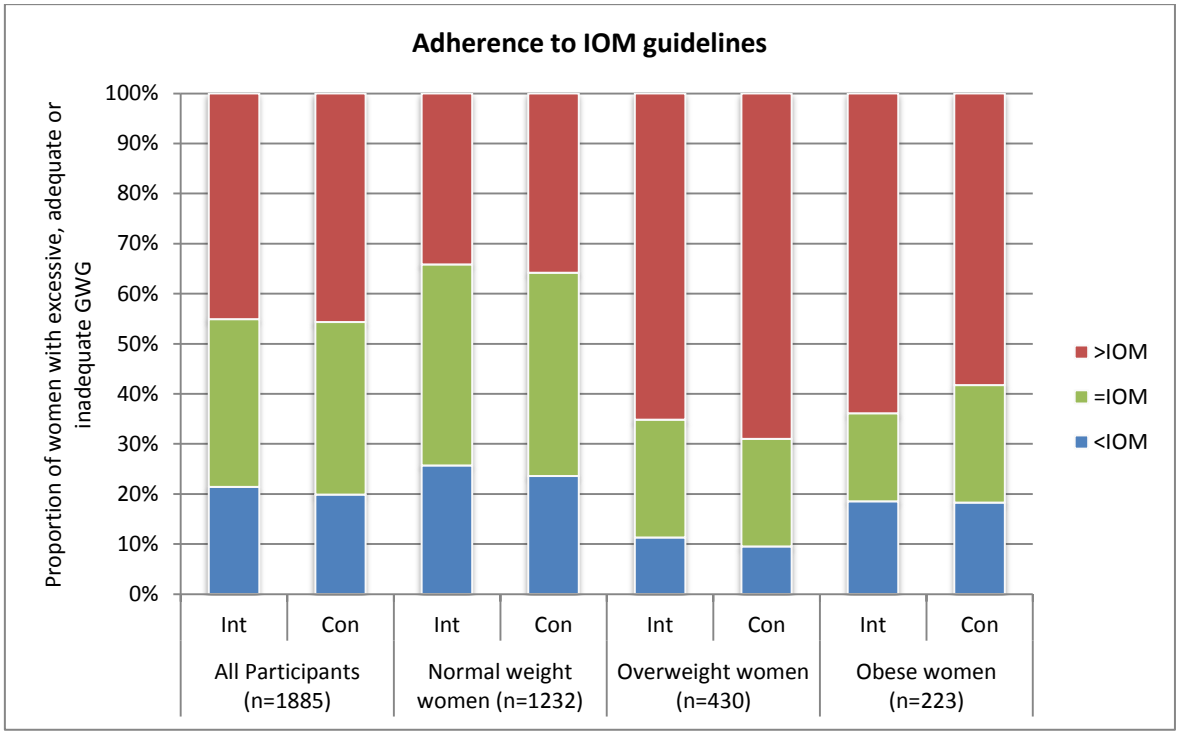


Figure 6: Proportion of women with excessive, adequate and inadequate GWG in the intervention and the control group.

Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit; Inadequate, adequate and excessive GWG is defined according to the criteria provided by the U.S. Institute of Medicine (Rasmussen & Yaktine 2009); GWG=gestational weight gain; IOM=Institute of Medicine; Int=intervention group; Con=control group

Similar results for the primary outcome were obtained in the per-protocol and the multiple imputation analysis (Table 15). According to the per-protocol analysis, 45.4 % of women who received three counseling sessions about a healthy lifestyle during pregnancy and monitored their

weight in this period gained weight in excess whereas 46.5 % of women who received standard antenatal care exceeded the IOM recommendations. Similarly, there was no statistically significant difference between groups (adjusted OR: 0.92; 95% CI: 0.65 to 1.29; p=0.63).

The effect of the intervention was also analyzed according to the initial BMI category (Figure 6, Table 15). The intervention showed no effect in all BMI categories. Among the normal weight BMI category, 34.2 % of women in the intervention group and 35.9 % of women in the control group exceeded IOM guidelines. Less overweight women in the intervention group gained weight in excess (65.2 % vs. 69.0 %; p=0.38) with no significant effect of the intervention. Among obese women, the intervention resulted in a higher percentage of women who gained weight in excess (63.9 % vs. 58.3 %; p=0.79), which was not statistically significant.

Table 15: Study participants with excessive GWG.

Women gaining more weight than recommended by IOM guidelines						
			Effect of intervention (95 % CI)			
	Intervention	**Control**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Complete-case	427/946 (45.1)	429/939 (45.7)	1.05 (0.76-1.43)	0.78	0.95 (0.66-1.38)	0.79
Multiple Imputation			1.03 (0.77-1.39)	0.82	0.95 (0.68-1.33)	0.75
Per-protocol	401/883 (45.4)	421/905 (46.5)	1.02 (0.75-1.37)	0.92	0.92 (0.65-1.29)	0.63
Excessive GWG by pre-pregnancy BMI category						
Normal weight	208/608 (34.2)	224/624 (35.9)	1.00 (0.68-1.47)	0.99	0.92 (0.61-1.38)	0.67
Overweight	150/230 (65.2)	138/200 (69.0)	0.85 (0.55-1.33)	0.48	0.81 (0.51-1.29)	0.38
Obese	69/108 (63.9)	67/115 (58.3)	1.27 (0.75-2.14)	0.38	1.08 (0.62-1.87)	0.79
Excessive GWG by region						
Oberbayern	46/106 (43.4)	72/182 (39.6)	1.17 (0.72-1.90)	0.52	1.05 (0.61-1.83)	0.86
Oberpfalz	112/262 (42.8)	113/222 (50.9)	0.72 (0.50-1.03)	0.07	0.57 (0.38-0.85)	**0.01**
Oberfranken	101/236 (42.8)	191/392 (48.7)	0.79 (0.57-1.09)	0.15	0.60 (0.42-0.85)	**0.01**
Mittelfranken	119/218 (54.6)	49/115 (42.6)	1.62 (1.03-2.55)	**0.04**	1.54 (0.95-2.51)	0.08
Unterfranken	49/124 (39.5)	4/28 (14.3)	3.92 (1.28-11.99)	**0.02**	6.01 (1.64-21.96)	**0.01**
Excessive GWG by education level						
General secondary school	77/137 (56.2)	74/155 (47.7)	1.43 (1.17-1.75)	**<0.001**	1.38 (1.05-1.81)	**0.02**
Intermediate secondary school	194/415 (46.8)	200/388 (51.6)	0.83 (0.62-1.11)	0.20	0.78 (0.55-1.10)	0.16
High school	156/391 (39.9)	151/390 (38.7)	1.07 (0.72-1.60)	0.74	0.92 (0.60-1.41)	0.71

Data are given as n (%), effect sizes as odds ratios and 95 % CIs
Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age, parity and gestational age at 1st visit

Looking at different study regions (Table 15), highly variable results were obtained. After adjustment, the intervention resulted in significantly less women with excessive weight gain in Oberpfalz (p=0.01) and Oberfranken (p=0.01). In contrast, among the other regions (Oberbayern,

Mittelfranken, Unterfranken) more women in the intervention group gained weight in excess than women in the control group. Analyses resulted in significant effects in Mittelfranken before adjustment (p=0.04) and in Unterfranken before (p=0.02) as well as after adjustment (p=0.01).

Among low educated women in the trial (Table 15), a significant higher percentage exceeded IOM recommendations in the intervention group (56.2 % vs. 47.7 %; p=0.02). In contrast, there were no differences in women with a higher educational level (39.9 % vs. 38.7 %; p=0.71).

3.3.2 MEAN TOTAL GESTATIONAL WEIGHT GAIN

Participating women in the intervention and control group had a mean total GWG of 14.1 kg during pregnancy showing no differences between groups (Table 16, Appendix: Table 29).

Table 16: Mean total GWG in control versus intervention group.

Mean total GWG (kg)						
			Estimated mean difference			
	Intervention (n=946)	**Control (n=939)**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Complete-case	14.1 ± 5.3	14.1 ± 5.2	0.28 (-0.61-1.17)	0.54	0.09 (-0.79-0.97)	0.84
Mean total GWG by pre-pregnancy BMI category						
Normal weight	14.6 ± 4.5	14.8 ± 4.6	0.06 (-0.79-0.90)	0.90	-0.10 (-0.93-0.72)	0.81
Overweight	14.0 ± 6.0	14.1 ± 5.5	-0.02 (-0.90-0.86)	0.96	-0.26 (-1.14-0.63)	0.57
Obese	11.5 ± 6.8	10.6 ± 6.5	1.00 (-0.90-2.90)	0.30	0.52 (-1.05-2.09)	0.51
Mean total GWG by region						
Oberbayern	14.3 ± 4.5	13.6 ± 4.3	0.7 (-0.3-1.8)	0.19	0.3 (-0.7-1.4)	0.52
Oberpfalz	13.9 ± 4.9	14.7 ± 5.1	-0.8 (-1.7-0.1)	0.08	-1.1 (-2.0-(-0.2))	**0.02**
Oberfranken	13.7 ± 5.3	14.5 ± 5.4	-0.8 (-1.7-0.1)	0.07	-1.0 (-1.8-(-0.1))	**0.03**
Mittelfranken	14.8 ± 6.0	13.3 ± 5.8	1.5 (0.2-2.8)	**0.03**	1.1 (-0.2-2.4)	0.11
Unterfranken	13.7 ± 5.1	10.1 ± 5.7	3.5 (1.4-5.7)	**0.002**	4.0 (1.6-6.3)	**0.001**

Data are given as means ± standard deviation, effect sizes as marginal mean difference and 95 % CIs
Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age, parity and gestational age at 1st visit

Mean total gestational weight gain was 14.6 kg in normal weight, 14.0 kg in overweight and 11.0 kg in obese women (Appendix: Table 29) and did not differ between intervention and routine care group (Table 16).

Moreover, results of analyses by region are similar to those of excessive GWG (Table 16). Whereas lifestyle counseling lead to significantly less mean total GWG after adjustment in Oberpfalz (adjusted mean estimated difference: -1.1; 95 % CI: -2.0 to -0.2; p=0.02) and

Oberfranken (adjusted mean estimated difference: -1.0; 95 % CI: -1.8 to -0.1; p=0.03), women in the intervention regions in Oberbayern, Mittelfranken and Unterfranken gained more weight during pregnancy than women in the control regions with significant results in Mittelfranken before adjustment (p=0.03) and in Unterfranken before (p=0.002) as well as after adjustment (p=0.001).

3.3.3 WEIGHT GAIN AT DIFFERENT TIME POINTS DURING PREGNANCY

Table 17 shows the mean average weight gain at different time points during pregnancy.

Table 17: Weight gain at different time points during pregnancy.

	Intervention (n=946)	Control (n=939)	Total (n=1885)
Mean average weekly weight gain by pre-pregnancy BMI category (kg)	0.5 ± 0.2	0.5 ± 0.2	0.5 ± 0.2
Normal weight	0.5 ± 0.1	0.5 ± 0.2	0.5 ± 0.1
Overweight	0.5 ± 0.2	0.5 ± 0.2	0.5 ± 0.2
Obese	0.4 ± 0.2	0.4 ± 0.2	0.4 ± 0.2
Weight gain between visits (kg)			
V1 minus first measured (V0)	1.0 ± 1.8	1.1 ± 1.8	1.0 ± 1.8
V2 minus V0	2.8 ± 2.4	2.9 ± 2.4	2.9 ± 2.4
V3 minus V0	9.9 ± 4.1	10.2 ± 4.1	10.1 ± 4.1
Weight gain from first antenatal visit until oGTT			
Normal weight	3.1 ± 2.1	3.2 ± 2.2	3.2 ± 2.2
Overweight	2.6 ± 2.6	2.8 ± 2.6	2.7 ± 2.6
Obese	1.3 ± 3.0	1.5 ± 2.7	1.4 ± 2.8

Data are given as means ± standard deviation

Women participated in the GeliS trial, gained on average 0.5 kg per week over the entire time of pregnancy (Table 17). There was no difference between the intervention and control group. The 0.5 kg per week also applies for the subgroups of normal weight and overweight women with no differences between the intervention and control group. Obese women in both groups gained on average 0.4 kg per week.

In order to examine the influence of counseling sessions, weight was measured at same time points at visit 1, visit 2 and visit 3 (Table 17). At visit 1 (12^{th}-16^{th} week of gestation), pregnant women gained on average 1.0 kg. Between the beginning of pregnancy and visit 2 (16^{th}-20^{th} week of gestation) women gained on average 2.9 kg. Until the last counseling session during pregnancy (30^{th}-34^{th} week of gestation) women gained on average 10.1 kg with a slight difference between

groups (9.9 kg vs. 10.2 kg). Before oGTT measurements (16th-20th week of gestation), normal weight women gained more weight (3.2 kg) than overweight (2.7 kg) and obese women (1.4 kg) with small differences in favor of the intervention group (Table 17).

3.4 SECONDARY OUTCOMES

Secondary outcome variables comprise the comparison of pregnancy and birth related outcomes between study groups including results of the oral glucose tolerance test (oGTT) as well as maternal and fetal complications during pregnancy and birth, birth related anthropometrics and short-term postpartum weight retention (PPWR).

3.4.1 MATERNAL PREGNANCY AND BIRTH RELATED OUTCOMES

Gestational diabetes mellitus

2h-oGTT and fasting glucose concentration

In order to test for gestational diabetes mellitus (GDM), a 2h-oGTT was conducted between the 24th and 28th week of gestation. GDM was diagnosed if at least one of the three thresholds according to the guidelines of the German Diabetes Society (DDG) and the German Society of Gynecology and Obstetrics (DGGG) (Kleinwechter et al. 2016) was exceeded. Six participants who were diagnosed as “No GDM” were excluded from GDM analyses because they were tested before the 20th week of gestation. All participants who were considered for the primary analysis set were analyzed but also including those women who had a premature birth.

1008 (88.5 %) women in the intervention group and 954 (85.0 %) women in the standard care group had an oGTT and could be assessed for the analyses of GDM. 109 (10.8 %) women in the intervention group and 106 (11.1 %) women in the control group developed GDM (Table 18). However, this difference was not statistically significant before and after adjustment for potential confounders (adjusted OR: 0.84; 95 % CI: 0.41 to 1.71; p=0.62).

While in 215 of all women GDM was diagnosed, only 82 women were treated. 3.5 % of women in the intervention and 4.9 % in the control group received GDM treatment. 2.9 % of these women have been urged to undergo a change of diet and 1.8 % of women were treated with insulin. Some women received both insulin and dietary treatment.

Whereas the rate of diagnosed GDM tended to be lower in normal weight (6.9 % vs. 7.9 %; p=0.25) and obese women (27.5 % vs. 30.3 %; p=0.56) who received the intervention, the rate of GDM was slightly higher in overweight women (13.0 % vs. 9.4 %; p=0.82) with no statistical significance.

In contrast to the results for excessive GWG, there were less women in the intervention regions of Oberbayern (5.2 % vs. 20.3; p=0.001) and Mittelfranken (10.5 % vs. 25.4 %; p=0.001) who developed GDM compared to women in the control regions (Table 18). In contrast, a higher percentage of women in intervention regions of Oberpfalz (10.3 % vs. 5.7 %; p=0.08) and Oberfranken (14.6 % vs. 6.3 %; p=0.001) developed GDM compared to women of control groups in these two regions.

Table 18: Women with diagnosed GDM and results of fasting glucose concentrations.

			Effect of intervention (95 % CI)			
	Intervention	**Control**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Diagnosed GDM						
Complete-case	109/1008 (10.8)	106/954 (11.1)	0.74 (0.37-1.47)	0.38	0.84 (0.41-1.71)	0.62
Treated GDM	35/1008 (3.5)	47/954 (4.9)	0.68 (0.33-1.39)	0.29	0.76 (0.43-1.37)	0.36
Dietary treatment	24/1008 (2.4)	33/954 (3.5)				
Insulin treatment	19/1008 (1.8)	17/954 (1.8)				
Diagnosed GDM by pre-pregnancy BMI category						
Normal weight	45/649 (6.9)	49/620 (7.9)	0.75 (0.38-1.46)	0.39	0.67 (0.35-1.31)	0.25
Overweight	31/239 (13.0)	20/212 (9.4)	1.13 (0.40-3.19)	0.82	1.12 (0.43-2.92)	0.82
Obese	33/120 (27.5)	37/122 (30.3)	0.73 (0.33-1.63)	0.44	0.79 (0.36-1.75)	0.56
Diagnosed GDM by region						
Oberbayern	6/115 (5.2)	33/163 (20.3)	0.22 (0.09-0.54)	**0.001**	0.21 (0.08-0.54)	**0.001**
Oberpfalz	30/292 (10.3)	13/227 (5.7)	1.89 (0.96-3.70)	0.07	1.84 (0.92-3.69)	0.08
Oberfranken	36/247 (14.6)	26/412 (6.3)	2.53 (1.49-4.31)	**0.001**	2.51 (1.45-4.35)	**0.001**
Mittelfranken	25/230 (10.5)	31/122 (25.4)	0.36 (0.20-0.64)	**0.001**	0.33 (0.18-0.63)	**0.001**
Unterfranken	12/124 (9.7)	3/30 (10.0)	0.96 (0.25-3.66)	0.96	1.06 (0.24-4.65)	0.94
Fasting glucose concentration (mg/dl)						
Complete-case	79.5 ± 9.2	77.4 ± 12.4	1.2 (-3.9-6.4)	0.64	1.2 (-3.7, 6.2)	0.62
Fasting glucose concentration by pre-pregnancy BMI category (mg/dl)						
Normal weight	78.6 ± 8.9	75.9 ± 11.8	1.7 (-3.1-6.5)	0.49	1.6 (-3.1-6.4)	0.51
Overweight	80.3 ± 8.7	78.3 ± 12.5	1.3 (-4.5-7.1)	0.67	1.1 (-4.6-6.8)	0.70
Obese	83.3 ± 10.6	83.6 ± 13.0	-0.8 (-5.9-4.2)	0.74	-0.7 (-5.6-4.1)	0.76
Fasting glucose concentration by region (mg/dl)						
Oberbayern	77.4 ± 10.3	82.2 ± 12.4	-4.8 (-7.6-(-2.0))	**0.001**	-4.7 (-7.5-(-1.8))	**0.001**
Oberpfalz	80.4 ± 8.2	69.9 ± 13.0	10.6 (8.7-12.4)	**<0.001**	10.3 (8.5-12.1)	**<0.001**
Oberfranken	80.3 ± 9.9	77.5 ± 9.8	2.8 (1.3-4.4)	**<0.001**	2.6 (1.1-4.2)	**0.001**

Mittelfranken	79.6 ± 9.1	85.7 ± 10.9	-6.1 (-8.3-(-4.0))	**<0.001**	-6.3 (-8.5-(-4.2)	**<0.001**
Unterfranken	77.9 ± 8.7	73.8 ± 10.3	4.1 (0.5-7.7)	**0.03**	4.1 (0.6-7.6)	**0.02**

Data are given as number (%) or mean ± standard deviation
Effect sizes: Continuous variables as estimated marginal mean difference (95 % CIs) and categorized variables as odds ratios (95 % CIs)
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity

Fasting glucose concentration was higher in the intervention group compared to the control group (79.5 mg/dl vs. 77.4 mg/dl; p=0.62) with different results by analyses in regions (Table 18). Women in intervention regions in Oberbayern and Mittelfranken had significantly lower concentrations before starting the oGTT than women in control regions. In contrast, women in intervention regions in Oberpfalz, Oberfranken and Unterfranken had significantly higher fasting glucose concentrations than women in control regions.

Hemoglobin A_{1c} (HbA_{1c})

In order to obtain additional information on the presence and severity of diagnosed GDM, glycosylated hemoglobin concentrations were measured between the 30th and 34th week of gestation. Mean HbA_{1c} in late pregnancy was 5.1 % in both groups (intervention group: 32.2 mmol/mol; control group: 32.1 mmol/mol) (Table 19). Obese women in the intervention group had a slightly lower mean HbA_{1c} (33.3 mmol/mol vs. 33.6 mmol/mol; p=0.007). Negligible differences were also seen regarding study regions. The intervention resulted in slightly higher HbA_{1c} values in Oberbayern and Oberfranken but slightly lower HbA_{1c} values in Oberpfalz, Mittelfranken and Unterfranken.

Table 19: Results of HbA_{1c} measurements in the intervention versus the control group.

			Effect of intervention (95 % CI)			
	Intervention	**Control**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
HbA_{1c} (%)						
Complete-case	5.1 ± 0.3	5.1 ± 0.3	0.01 (-0.00-0.03)	0.13	0.02 (-0.01-0.05)	0.12
HbA_{1c} (%) by pre-pregnancy BMI						
Normal weight	5.1 ± 0.3	5.0 ± 0.3	0.02 (-0.01-0.04)	0.24	0.02 (-0.00-0.05)	0.08
Overweight	5.1 ± 0.4	5.1 ± 0.3	0.04 (-0.01-0.09)	0.10	0.04 (-0.02-0.09)	0.20
Obese	5.2 ± 0.3	5.2 ± 0.3	-0.05 (-0.09-(-0.02))	**0.003**	-0.05 (-0.09-(-0.02))	**0.005**
HbA_{1c} (%) by region						
Oberbayern	5.1 ± 0.3	5.1 ± 0.3	0.08 (0.00-0.16)	**0.04**	0.12 (0.04-0.20)	**0.004**
Oberpfalz	5.1 ± 0.3	5.1 ± 0.4	-0.00 (-0.07-0.06)	0.88	0.01 (-0.06-0.07)	0.85
Oberfranken	5.1 ± 0.4	5.1 ± 0.3	0.01 (-0.04- 0.07)	0.66	0.01 (-0.05-0.06)	0.82
Mittelfranken	5.1 ± 0.3	5.1 ± 0.4	-0.01 (-0.09-0.07)	0.77	0.00 (-0.08-0.08)	0.96
Unterfranken	5.1 ± 0.3	5.1 ± 0.2	-0.01 (-0.12-0.13)	0.94	-0.00 (-0.14-0.14)	0.96

HbA_{1c} (mmol/mol)						
Complete-case	32.2 ± 3.7	32.1 ± 3.5	0.15 (-0.45-0.74)	0.63	0.24 (-0.40, 0.87)	0.47
HbA_{1c} (mmol/mol) by pre-pregnancy BMI						
Normal weight	31.8 ± 3.5	31.7 ± 3.5	0.21(-0.56-0.97)	0.60	0.29 (-0.47-1.04)	0.46
Overweight	32.6 ± 3.9	32.4 ± 3.1	0.25 (-0.641.14)	0.58	0.25 (-0.691.19)	0.60
Obese	33.3 ± 3.7	33.6 ± 3.7	-0.28 (-0.54-(-0.02))	**0.04**	-0.32 (-0.56-(-0.09))	**0.007**
HbA_{1c} (mmol/mol) by region						
Oberbayern	33.0 ± 3.3	31.7 ± 3.3	1.30 (0.41-2.19)	**0.004**	1.68 (0.79-2.58)	**<0.001**
Oberpfalz	31.6 ± 3.8	32.6 ± 3.8	-1.05 (-1.77-(-0.32))	**0.005**	-0.95 (-1.68-(-0.22))	**0.01**
Oberfranken	32.8 ± 3.6	31.9 ± 3.4	0.83 (0.22-1.44)	**0.008**	0.75 (0.15-1.35)	**0.01**
Mittelfranken	31.7 ± 3.7	31.9 ± 3.9	-0.12 (-1.01-0.76)	0.78	-0.03 (-0.91-0.86)	0.95
Unterfranken	32.5 ± 3.8	32.7 ± 2.1	-0.25 (-1.79-1.29)	0.75	-0.24 (-1.80-1.32)	0.76

Data are given as mean ± standard deviation, effect sizes as marginal mean difference and 95 % CIs
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity

Pregnancy complications

The intervention did not increase complications such as vaginal bleeding (3.2 % vs. 4.4 %; p=0.22). Among women in the intervention group, preterm labor was less frequently reported (1.6 % vs. 2.9 %; p=0.003) (Table 20). Maternal blood pressure was measured at each visit. Hypertension was defined as high blood pressure (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg) on at least two visits. Elevated blood pressure was reported more often in the intervention group (9.5 % vs. 6.4 %; p=0.02; Table 20, Appendix: Table 30). Anemia was less frequently identified in the intervention group than in the control group (2.3 % vs. 6.6 %; p=0.12).

Table 20: Pregnancy complications in the intervention versus the control group.

			Effect of intervention (95 % CI)			
	Intervention (n=956)	**Control (n=893)**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Bleeding	31 (3.2)	39 (4.4)	0.69 (0.35-1.34)	0.27	0.65 (0.32-1.29)	0.22
Placenta previa	12 (1.3)	7 (0.8)	[2]		[2]	
Hydramnios	1 (0.1)	6 (0.7)	[2]		[2]	
Oligohydramnios	11 (1.2)	15 (1.7)	[2]		[2]	
Placental insufficiency	4 (0.4)	14 (1.6)	[2]		[2]	
Cervical insufficiency	16 (1.7)	22 (2.5)	[2]		[2]	
Preterm labor	15 (1.6)	26 (2.9)	0.54 (0.35-0.84)	**0.01**	0.51 (0.33-0.79)	**0.003**
Anemia	22 (2.3)	59 (6.6)	0.39 (0.13-1.15)	0.09	0.41 (0.14-1.24)	0.12
Proteinuria	1 (0.1)	1 (0.1)	[2]		[2]	
Preeclampsia/ HELLP syndrome	14/1006 (1.4)	13 (1.3)	[2]		[2]	

Moderate or heavy edemas	5 (0.5)	8 (0.9)	[2]		[2]	
Hypertension	99/1041 (9.5)	66/1039 (6.4)	1.56 (0.98-2.49)	0.06	1.64 (1.09-2.45)	**0.02**

Data are given as n (%), effect sizes as odds ratios and 95 % CIs
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity
[2]No statistic testing due to small number of cases

Obstetric outcomes

Results concerning obstetric outcomes in control and intervention group are shown in Table 21. Almost two thirds of children were born spontaneous with no differences between the intervention and control group. Elective cesarean section rates were higher among women in the intervention group (15.5 % vs. 11.6 %; p=0.02). Emergency cesarean section rates were 14.8 % in the intervention group and 15.9 % in the control group (p=0.26). Labor was induced more often in women in the control group (17.3 % vs. 23.5 %; p=0.04). Anesthesia (76.8 % vs. 80.1 %; p=0.47) and obstetric complications (75.8 % vs. 76.7 %; p=0.54) were similarly frequent among groups.

Table 21: Obstetric outcomes among study participants.

			Effect of intervention (95 % CI)			
	Intervention	**Control**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Mode of delivery (including preterm births)						
Spontaneous birth	615/1016 (60.5)	628/1003 (62.6)	Reference		Reference	
Elective cesarean section	157/1016 (15.5)	117/1003 (11.6)	1.37 (1.05-1.78)	**0.02**	1.41 (1.08-1.85)	**0.02**
Emergency cesarean section	150/1016 (14.8)	159/1003 (15.9)	0.96 (0.75-1.24)	0.77	0.86 (0.67-1.12)	0.26
Instrumental vaginal delivery	94/1016 (9.3)	99/1003 (9.9)	0.97 (0.72-1.31)	0.84	0.83 (0.61-1.14)	0.25
Induction of labor	174/1007 (17.3)	233/992 (23.5)	0.71 (0.48-1.06)	0.10	0.65 (0.43-0.98)	**0.04**
Fetal position at delivery						
Cephalic presentation	952/1014 (93.9)	937/999 (93.8)	Reference		Reference	
Breech presentation	60/1014 (5.9)	55/999 (5.5)	0.99 (0.68-1.44)	0.94	0.93 (0.65-1.35)	0.72
Transverse presentation	2/1014 (0.2)	7/999 (0.7)				
Birth related injuries	574/1012 (56.7)	592/996 (59.4)	0.93 (0.70-1.23)	0.60	0.86 (0.65-1.13)	0.27
Vaginal laceration	225/1012 (22.2)	285/996 (28.6)				
Perineal tear (first-/second-degree)	237/1012 (23.4)	271/996 (27.2)				
Perineal tear (third-/fourth-degree)	15/1012 (1.5)	14/996 (1.4)				
Episiotomy	206/1012 (20.4)	146/996 (14.7)				
Others	55/1012 (5.4)	109/996 (10.9)				
Anesthesia	769/1001 (76.8)	787/982 (80.1)	1.05 (0.55-2.00)	0.87	1.23 (0.69-2.19)	0.47
Local	248/1001 (24.8)	300/982 (30.5)				
Epidural/peridual	319/1001 (31.9)	282/982 (28.7)				

Spinal	180/1001 (18.0)	142/982 (14.5)				
General/ endotracheal	45/1001 (4.5)	48/982 (4.9)				
Others	17/1001 (1.7)	21/982 (2.1)				
Obstetric complications	767/1012 (75.8)	767/999 (76.7)	1.31 (0.79-2.19)	0.30	1.18 (0.70-1.99)	0.54
Premature rupture of membranes	228/1012 (22.5)	257/999 (25.7)				
Exceeded date of birth	144/1012 (14.2)	161/999 (16.1)				
Pathological cardiotocography	204/1012 (20.2)	193/999 (19.3)				
Prolonged first or second stage of labor	148/1012 (14.6)	155/999 (15.5)				
Disproportion	50/1012 (4.9)	22/999 (2.2)				
Meconium-tainted amniotic fluid	78/1012 (7.7)	107/999 (10.7)				
Umbilical cord anomalies	134/1012 (13.2)	139/999 (13.9)				
Others	419/1012 (41.4)	494/999 (49.4)				

Data are given as n (%), effect sizes as odds ratios and 95 % CIs
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity

3.4.2 BIRTH RELATED OUTCOMES IN INFANTS

Birth related outcomes in infants are summarized in Table 22. Newborns of women who received counseling sessions during pregnancy had a slightly lower birth weight compared to newborns of women in the control group (3313 g vs. 3363 g; p=0.02) (Figure 7). The unadjusted mean difference was lower if preterm births were excluded from birth weight analysis (unadjusted mean difference: -33.6 g; 95 % CI: -60.8 to -6.5; p=0.02).

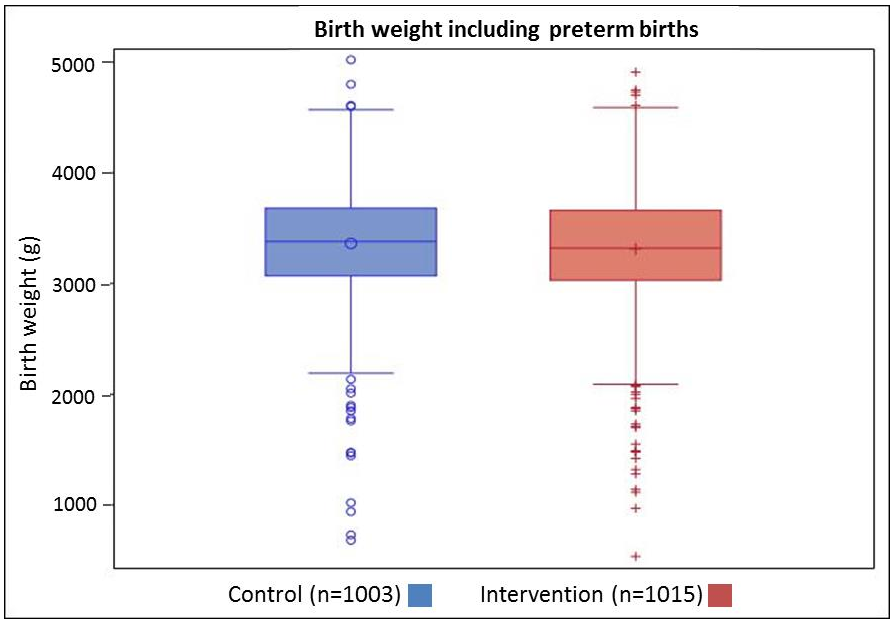


Figure 7: Birth weight (including preterm births) of infants between study groups.

Birth weight of infants in the intervention group was 3313 g (± 536 g) and birth weight of infants in the control group was 3363 g (± 498 g) (Unadjusted marginal mean difference: -50.2; 95 % CI: -80.6 to -19.7; p=0.001; adjusted marginal mean difference: -44.0; 95 % CI: -81.0 to -7.01; p=0.02).

Mean birth length was also lower in the intervention group (51.1 ± 2.7 cm vs. 51.6 ± 2.5 cm, adjusted mean difference -0.5; 95 % CI: -0.7 to -0.2; p=0.001). No differences were identified in the proportion of children born large for gestational age (LGA) and small for gestational age (SGA). There were slightly more children with birth weight above or equaling 4500 g in the intervention group compared to the control group (1.3 % vs. 0.6 %; p=0.20). No differences between groups were detected for the number of children with weight above or equaling 4000 g at birth (8.5 % vs. 8.3 %; p=0.66). The rate of preterm born infants was low in both groups (7.1 % vs. 6.0 %; p=0.44). One stillbirth was observed in the intervention group and one neonatal death per group. Head circumference and APGAR-Scores were similar between groups. Male and female newborns were equally distributed between groups with a slight tendency of less male newborns in the

intervention group (50.5 % vs. 54.5 %). The intervention did not lead to a significant increase in infant complications at birth (10.0 % vs. 8.2 %; p=0.31).

Table 22: Birth related outcomes in infants in the intervention versus the control group.

			Effect of intervention (95 % CI)			
	Intervention	**Control**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Birth weight (g)						
Including preterm births	3313 ± 536	3363 ± 498	-50.2 (-80.6-(-19.7))	**0.001**	-44.0 (-81.0-(-7.0))	**0.02**
Excluding preterm births	3391 ± 444	3419 ± 427	-33.6 (-60.8-(-6.5))	**0.02**	-26.4 (-59.0-6.3)	0.11
Large for gestational age	73/1013 (7.2)	75/1003 (7.5)	0.99 (0.87-1.12)	0.87	1.01 (0.86-1.20)	0.86
Small for gestational age	88/1013 (8.7)	84/1003 (8.4)	1.06 (0.83-1.34)	0.65	1.03 (0.82-1.31)	0.78
Birth weight ≥4000 g	86/1015 (8.5)	83/1003 (8.3)	1.02 (0.87-1.22)	0.78	1.04 (0.88-1.23)	0.66
Birth weight ≥4500 g	13/1015 (1.3)	6/1003 (0.6)	2.01 (0.58-6.89)	0.27	2.28 (0.66-7.90)	0.20
Preterm birth	72/1014 (7.1)	60/1004 (6.0)	1.21 (0.83-1.77)	0.32	1.18 (0.78-1.79)	0.44
APGAR-Score (0 min)	8.8 ± 1.1	8.7 ±1.3	0.09 (-0.10-0.27)	0.35	0.11 (-0.07-0.29)	0.22
APGAR-Score (5 min)	9.7 ± 0.7	9.7 ± 0.6	-0.01 (-0.09-0.06)	0.73	-0.00 (-0.07-0.07)	0.97
APGAR-Score (10 min)	9.9 ± 0.9	9.9 ± 0.5	0.02 (-0.05-0.09)	0.55	0.02 (0.04-0.09)	0.51
Head circum-ference (cm)	34.6 ± 1.7	34.8 ± 1.5	-0.2 (-0.4-0.0)	0.07	-0.2 (-0.4-0.0)	0.09
Birth length (cm)	51.1 ± 2.7	51.6 ± 2.5	-0.5 (-0.7-(-0.2))	**<0.001**	-0.5 (-0.7-(-0.2))	**0.001**
pH level	7.3 ± 0.1	7.3 ± 0.1	-0.00 (0.02-0.02)	0.85	0.00 (-0.02-0.02)	0.88
Gender						
male	513/1015 (50.5)	547/1004 (54.5)				
female	502/1015 (49.5)	457/1004 (45.5)				
Complications	101/1014 (10.0)	82/1001 (8.2)	1.23 (0.90-1.68)	0.19	1.18 (0.86-1.61)	0.31
Infections	12/1014 (1.2)	8/1001 (0.8)				
Fetal hypoxia/ respiratory dysfunction	15/1014 (1.5)	7/1001 (0.7)				
Malformation	7/1014 (0.7)	7/1001 (0.7)				
Others	77/1014 (7.6)	67/1001 (6.7)				

Data are given as number (%) or mean ± standard deviation
Effect sizes: Continuous variables as estimated marginal mean difference (95 % CIs) and categorized variables as odds ratios (95 % CIs)
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity
Birth weight data were available for 1015 infants in intervention group and 1003 infants in control group.
Birth length data were available for 1011 infants in intervention group and 992 infants in control group.
Data for head circumference were available for 1008 infants in intervention group and 973 infants in control group.

3.4.3 POSTPARTUM WEIGHT RETENTION

Women in the intervention group weighed 73.8 kg between six and eight weeks after giving birth (V4) which did not differ from weight measured among women in the control group with 73.0 kg at this time (Table 23). As shown in Table 23, mean short-term weight retention defined as maternal weight measured between six and eight weeks after giving birth (V4) minus weight measured at first antenatal visit (V0) was similar between both groups (4.0 kg vs. 4.3 kg; p=0.65). There were also no differences in maternal weight retention when subgroup analyses according to pre-pregnancy BMI category were performed.

Table 23: Maternal weight retention (6-8 weeks postpartum).

			Effect of intervention (95 % CI)			
	Intervention (n=976)	**Control (n=935)**	**Unadjusted**	**p value**	**Adjusted[1]**	**p value[1]**
Weight measured 6-8 weeks postpartum (kg)	73.8 ± 13.4	73.0 ± 13.7	0.62 (-1.12-2.35)	0.48	0.62 (-0.27-1.51)	0.17
Normal weight	67.2 ± 8.6	66.3 ± 8.4	0.91 (0.03-1.80)	0.04	0.93 (0.04-1.81)	0.04
Overweight	81.3 ± 9.2	80.5 ± 8.8	0.44 (-1.59-2.48)	0.67	0.38 (-1.46-2.21)	0.69
Obese	95.4 ± 11.9	96.0 ± 11.8	-0.73 (-2.56-1.12)	0.44	-0.83 (-2.74-1.07)	0.39
Weight retention (kg) (6-8 weeks postpartum)	4.0 ± 4.8	4.3 ± 4.8	-0.13 (-0.95-0.69)	0.76	-0.19 (-1.01-0.63)	0.65
Normal weight	4.4 ± 4.1	4.8 ± 4.0	-0.32 (-0.96-0.32)	0.33	-0.34 (-0.97-0.30)	0.30
Overweight	4.0 ± 5.2	4.5 ± 5.3	-0.45 (-1.23-0.34)	0.26	-0.42 (-1.25-0.42)	0.33
Obese	1.4 ± 6.5	1.2 ± 6.1	0.56 (-1.65-2.77)	0.62	0.34 (-1.68-2.36)	0.74

Data are given as mean ± standard deviation, effect sizes as marginal mean difference and 95 % CIs
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age and parity
Weight retention=Weight measured between 6 and 8 weeks postpartum (V4) minus weight measured at V0

3.5 CORRELATIONS BETWEEN GESTATIONAL WEIGHT GAIN AND PRE-PREGNANCY BMI AND SECONDARY OUTCOMES IN THE WHOLE STUDY POPULATION

The following part shows associations between GWG as well as pre-pregnancy BMI and different outcome parameters including birth weight, HbA_{1c} and cesarean delivery in the whole study sample independent of the intervention.

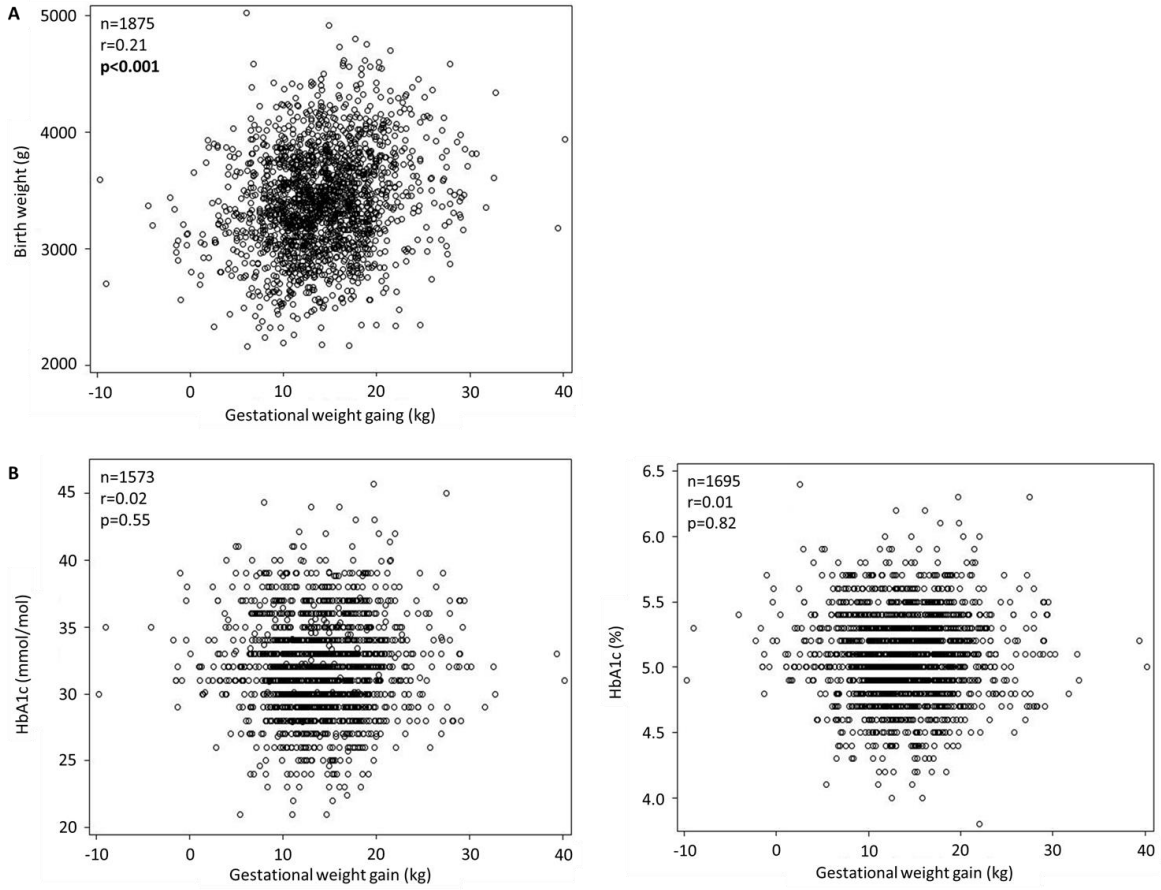


Figure 8: Correlations of GWG with different secondary outcomes.

Gestational weight change=weight change between the weight measured at the first visit (V0) and the weight measured at the last prenatal visit (G); correlation of GWG with birth weight (A) and HbA_{1c} (B) in the whole study population.

There was significant evidence (p<0.001) of a weak positive association between GWG and birth weight (r = 0.21) (A; Figure 8). No significant evidence of an association between GWG and HbA_{1c} was found (B; Figure 8).

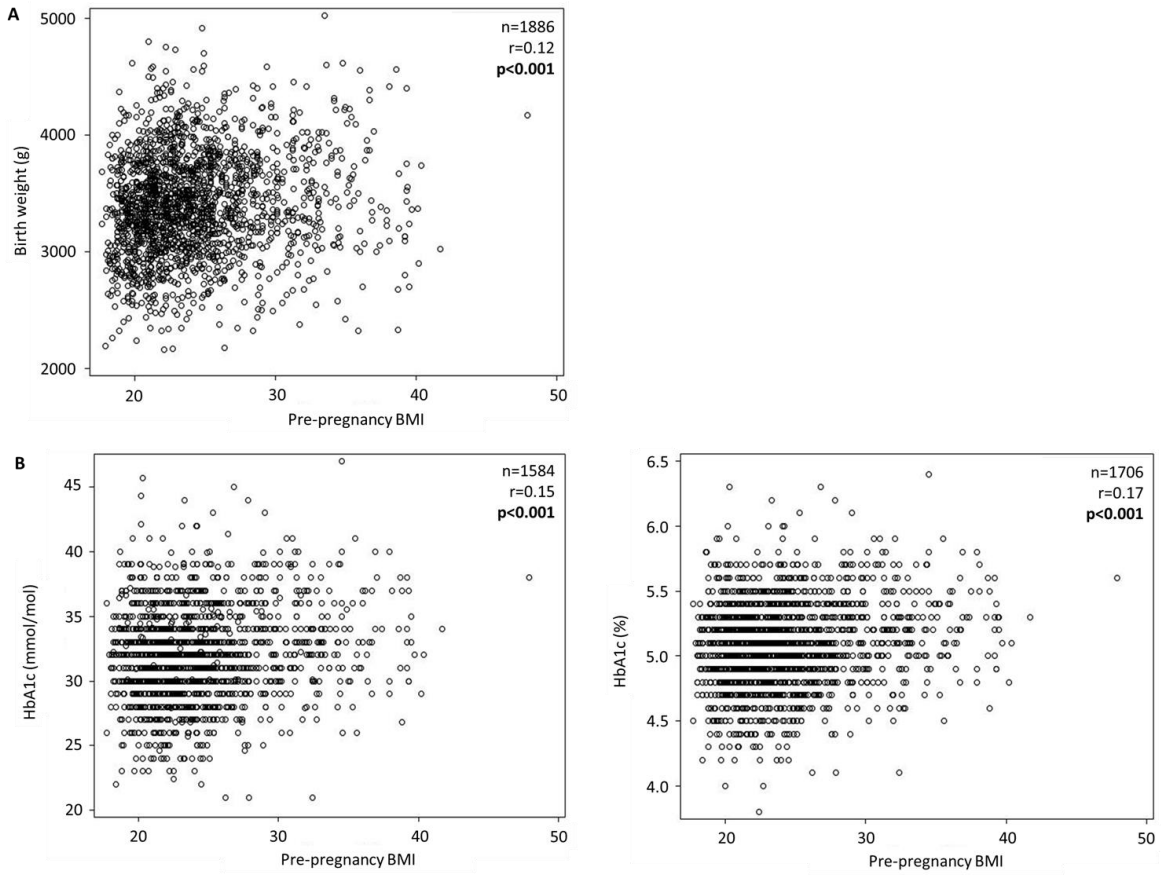


Figure 9: Correlations of pre-pregnancy BMI with different secondary outcomes.

Correlation of pre-pregnancy BMI with birth weight (A) and HbA_{1c} (B) in the whole study population.

There was significant evidence (p<0.001) of a weak positive association between pre-pregnancy BMI and birth weight (r = 0.12) (A; Figure 9) and significant evidence (p<0.001) of a weak positive association between pre-pregnancy BMI and HbA_{1c} (B; Figure 9).

Moreover, outcomes between women who gained weight in excess versus women who gained weight according to IOM recommendations are compared in Table 24.

Table 24: Outcomes of women with excessive versus not excessive GWG

	Excessive GWG	**Not excessive GWG**	**p value**
Cesarean section	272/850 (32.0)	249/1026 (24.3)	**<0.001**
LGA	86/849 (10.1)	54/1024 (5.3)	**<0.001**
Birth weight >4000g	114/850 (13.4)	57/1025 (5.6)	**<0.001**
GDM	67/817 (8.2)	126/988 (12.8)	**0.002**
HbA_{1c} (mmol/mol)	32.4 ± 3.6	31.8 ± 3.6	**0.001**

Data are given as number (%) or mean ± standard deviation
Chi-square tests were used for comparisons of rates, and t-test for HbA_{1c} comparison of means.

Cesarean deliveries were more frequent among women with excessive GWG (32.0 % vs. 24.3 %; p<0.001). Infants born to women who have gained weight in excess were more likely to have a high birth weight above 4000 g (13.4 % vs. 5.6 %; p<0.001) and were more likely to be large for their gestational age (10.1 % vs. 5.3 %; p<0.001). Moreover, women who have gained weight above the recommended IOM ranges had higher HbA_{1c} values than women who have gained weight according to the IOM recommendations (32.4 mmol/mol vs. 31.8 mmol/mol; p=0.001). Results for gestational diabetes were converse. Women who have gained above the IOM recommendations developed significantly less frequent GDM compared to women who have gained within healthy ranges (8.2 % vs. 12.8 %; p=0.002).

3.6 CORRELATIONS BETWEEN COMPLIANCE AND GESTATIONAL WEIGHT GAIN

Compliance with the intervention

Compliance with the intervention program in terms of attending the scheduled sessions was good. Detailed information is presented in Table 25. The first planned lifestyle intervention session (12^{th}-16^{th} week of gestation) was received by 98.3 % of women in the intervention group, the second (16^{th}-20^{th} week of gestation) by 97.6 %, the third (30^{th}-34^{th} week of gestation) by 95.9 % and the postpartum session by 93.7 % (Table 25). While 87.6 % of women attended all four counseling sessions, 2.7% did not attend any of the four sessions. The mean number of attended sessions was 3.7. During pregnancy, 2.8 sessions were attended on average. The large majority of sessions were performed in the correct time intervals (Table 25).

Table 25: Quantitative evaluation of lifestyle counseling sessions.

	Number of women	Correct time interval
Lifestyle counseling sessions		
Session 1: 12^{th}-16^{th} week of gestation	1069/1087[1] (**98.3 %**)	953/1069 (**89.1 %**)
Session 2: 16^{th}-20^{th} week of gestation	1047/1073[1] (**97.6 %**)	957/1047 (**91.4 %**)
Session 3: 30^{th}-34^{th} week of gestation	1006/1049[1] (**95.9 %**)	855/1006 (**85.0 %**)
Session 4: 6-8 weeks postpartum	974/1039[1] (**93.7 %**)	759/974 (**77.9 %)**
Number of counseling sessions		
No session	30/1099[2] (**2.7 %**)	
One session	21/1099[2] (**1.9 %**)	
Two sessions	32/1099[2] (**2.9 %**)	
Three sessions	54/1099[2] (**4.9 %**)	
Four sessions	963/1099[2] (**87.6 %**)	

[1]number of women in the intervention group at the time of the respective session
[2]number of women in the intervention group excluding women with major pregnancy complications

As shown in Table 26, there was no significant evidence of a difference in mean total GWG between women who attended all sessions during pregnancy and those who did not (p=0.53). This confirms the results of the per-protocol analysis.

Table 26: Mean total GWG of women attended all lifestyle counseling sessions during pregnancy versus women attended not all sessions during pregnancy.

	Mean total GWG [kg]	p value
Women attended not all sessions during pregnancy	13.3 ± 6.4	0.53
Women attended all sessions during pregnancy	14.1 ± 5.2	

Data are given as mean ± standard deviation
T-test was used for comparison of means.

Protocol violations

A further marker of compliance is the rate of protocol violations. The rate of severe protocol violations and the total number of violations per participant in one practice were analyzed. Severe protocol violations mainly include missing counseling sessions or a missing oGTT. Light violations were recorded if for example sessions or tests occurred too early or late. There is some evidence of a positive association between the rate of severe protocol violations per participant in one practice and mean GWG: estimated Spearman coefficient is 0.35 (p=0.04). A note of caution is needed though because some of the more extreme points (high rate with high mean, low rate with low mean) are from practices with relatively few participants. Similarly, a positive association was estimated for severe and light violations pooled, but this was not statistically significant: 0.28 (p=0.11).

Profession of counselors

The women in the complete-case set were counseled by 43 medical assistants (762 participants), 13 midwives (122 participants) and five gynecologists (57 participants). The mean (SD) weight change by profession was 14.2 kg (5.2), 13.4 kg (5.6) and 14.1 kg (5.7), respectively (Figure 10). ANOVA does not provide significant evidence of a difference (p=0.30).

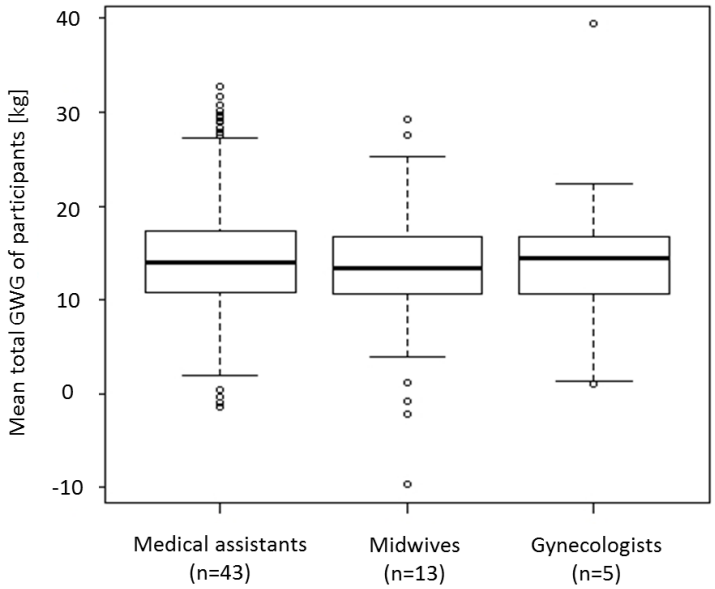


Figure 10: Mean total GWG of participants classified by profession of healthcare providers.

Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit.

4. DISCUSSION

The GeliS lifestyle study was conducted as a public health approach designed to limit the proportion of women with excessive gestational weight gain (GWG) and, moreover, to reduce maternal and fetal adverse pregnancy and obstetric outcomes in the "real-life" setting of routine care. Three counseling sessions focusing on diet, physical activity and monitoring of weight gain were given during pregnancy. One session regarding breastfeeding, infant feeding practices and physical activity for the young family followed between six and eight weeks postpartum. Study procedures were adapted to the daily routine work of gynecological and midwife practices to allow an implementation of the intervention into the German maternity health care system after successful evaluation.

The recruitment process and the implementation of the trial into practice are reflected in the following section. Primary and secondary outcomes of the study are discussed critically and put into the context of the existing literature. Strengths and limitations of the work are indicated.

4.1 RECRUITMENT PROCESS

As planned, pregnant women were recruited before the end of the 12th week of gestation (on average in the 9th week of gestation). To intervene early in pregnancy is important as many women gain much of their pregnancy weight in the first trimester (Jersey et al. 2012, Hill et al. 2016) and high early GWG appears to be predictive for total excessive GWG (Carreno et al. 2012, Knabl et al. 2014) and adverse pregnancy outcomes (Brown et al. 2002, Carreno et al. 2012, Campbell et al. 2016, Cho et al. 2015, Gaillard et al. 2015, MacDonald et al. 2017, Zhong et al. 2017). GeliS counselors were encouraged to include expectant mothers as early as possible in order to start with the intervention preferably at the beginning of the second trimester. Nevertheless, recruiting women at this early time of pregnancy increase the risk to include a higher proportion of women with miscarriages or even terminations and adding a risk of distress for these women (Hill et al. 2017). Among GeliS study participants 73 women (3.2 %) had a miscarriage or late loss of pregnancy.

The recruitment of practices differed between study regions and strongly depended on the motivation of gynecologists and their medical staff in both intervention and control regions. While some gynecologists were convinced of the aim and background of the study and were highly

motivated to participate, others raised concerns about the compatibility of study procedures with daily practice. Some physicians feared that the study would be too time-consuming and interfere with their daily work. Frequently, it was not possible to reach physicians by telephone. Either they had no time or practice staff blocked a telephone call before, making a conversation with the physician impossible. In contrast, midwives were frequently open-minded towards study participation but some gynecological practices preferred their own practice staff as counselors and even rejected the cooperation with midwives. The cooperation with midwives could have compensated the lack of time of own practice staff and, thus, more interested pregnant women could have been recruited. Unfortunately, freelance midwives had only little chance to recruit pregnant women before the end of the 12th week of gestation. Generally, study participation depended on willingness of practice staff. If medical assistants were highly motivated to engage they often convinced physicians to take part in the study. Otherwise, if medical assistants were unwilling to participate, physicians had no chance even if they were motivated. For future work, an intensive cooperation with the medical association or the professional association of gynecologists might be helpful to reach a maximum of physicians and to demonstrate the scientific demand of such trials. Not only the recruitment of practices but also the recruitment of pregnant women depended more on organizational structures within practices than on the amount of pregnant women within a practice. The area of practices (rural versus urban regions) did also not provide conclusions about the efficiency of recruitment.

In two study regions (Mittelfranken and Unterfranken) the recruitment of practices and pregnant women proceeded very slowly. In Unterfranken there were gynecological practices with high amounts of patients in both control and intervention regions. Most of them rejected study participation because of limited time. Other practices had only few patients and set other priorities like laboratory or reproductive medicine. Moreover, in Unterfranken there was no quality circle of gynecologists which made the recruitment even more difficult. In December 2014, study regions in Mittelfranken and Unterfranken were extended and further practices were recruited in order to limit imbalances between numbers of women recruited across study regions. Selection process and cluster randomization of extended regions followed the GeliS study protocol and was approved by the ethics committee of the Technical University of Munich.

4.2 STUDY POPULATION

The 2286 women included in the GeliS study were equally distributed into intervention and control arms. Baseline characteristics were comparable between groups, showing the effectiveness of the randomization process.

Characteristics of women participating in the GeliS study were comparable to available Bavarian and also German data. The average age of study participants and rejecters was 30. As known from national data, about one third of pregnant women in Germany are aged between 30 and 34 (AQUA 2014, IQTIG 2017). One third of study participants of the GeliS trial were overweight (35.1 %) with 12.1 % being obese. These proportions were in line with obstetric data of Bavaria (BAQ 2016) and Germany (AQUA 2014). Weight prior or rather at the beginning of pregnancy is the most predictive factor for GWG above IOM recommendations (Deputy et al. 2015, Samura et al. 2016).

57.5 % of all pregnant women in the GeliS trial expected their first child which is in line with Bavarian (BAQ 2016) and national obstetric data (AQUA 2014, IQTIG 2017). As known from literature (Schiessl et al. 2009, Kominiarek & Peaceman 2017, Rogozińska et al. 2017), nulliparous and primiparous women are at higher risk of exceeding weight gain recommendations compared to multiparous women. Half of rejecters reported to have already one or more than one child which may cause the main reasons for declining study participation: lack of time and belief in own experiences or competences. 11.3 % of study participants were born in foreign countries. Most study participants (84.1 %) have intermediate and high levels of education. In contrast, most rejecters (81.9 %) have low and intermediate levels of education. It is known that people with a low level of education often have a lower level of competence in dealing with health-related services, such as prevention programs (Robert Koch-Institut 2009). A potential hypothesis is that highly educated women may be more interested in or be aware of healthy lifestyle strategies and may be more willing to take action to prevent excessive GWG. Education is an important social determinant of many health outcomes but the accessibility to educationally disadvantaged women and those who have greatest need should be targeted in future projects.

Smoking during pregnancy is a well-known risk factor for adverse fetal outcomes including low birth weight, preterm birth and stillbirth (Rogers 2008, Deutsches Krebsforschungszentrum 2010, Dietz et al. 2010). 5.9 % of participating pregnant women of the GeliS trial reported to smoke regularly or occasionally with no big differences between groups (5.7 % vs. 6.1 %). This was a lower or quite similar percentage as known from national data of about 6.8 % (AQUA 2014) or 5.4 % (IQTIG 2017) but a higher percentage as known from Bavarian data of 3.6 % (BAQ 2016).

According to the German Perinatal Survey for the years 2007–2011, data on 3.187.920 singleton pregnancies demonstrated that 11.2 % pregnant women were smokers (Scholz et al. 2013). These results were confirmed by the results of the second wave of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS Wave 2, 2014-2017), which have shown that 10.9 % of expectant mothers smoked during pregnancy (Kuntz et al. 2018). It is noteworthy that the proportion of mothers who smoked during pregnancy decreased from 19.9 % since the KiGGS baseline study (2003-2007) to 10.9 % (Kuntz et al. 2018). 42.8 % of GeliS participants stated to not smoke anymore. Among others, Lindberg et al. (2016) analyzed the relationship between smoking status and GWG and found that former smokers are at increased risk of excess GWG. Similar results were shown by Deputy et al. (2015) who observed that smoking cessation was associated with excessive weight gain among normal weight and obese women. However, the information of the response option “not anymore” was not clearly defined in the GeliS study. It was not known if pregnant women stopped smoking at the beginning of pregnancy or long time ago. Analyses of participants' smoking status should be interpreted with caution, as they are based on self-reported data.

In summary, participants were found to be representative of the target population for age, pre-pregnancy BMI, smoking status and parity compared to available national data. However, the results of the study may not be completely applicable to the overall population of Germany because women of the GeliS trial predominantly had a high educational level above average, belonged to the white Caucasian population and, moreover, almost none of them came from an ethnic minority.

4.3 PRIMARY OUTCOME ANALYSES – A COMPARISON WITH LITERATURE AND NATIONAL DATA

Our findings suggest that provision of lifestyle advice within routine care during pregnancy addressing diet, physical activity and weight monitoring is not effective in avoiding excessive GWG or at reducing total GWG. Unfortunately, the promising results of the pilot study FeLIPO could not be repeated by the GeliS intervention. While the proportion of women who exceeded the Institute of Medicine (IOM) guidelines could be significantly reduced in FeLIPO (38.2 % vs. 59.5 %; p=0.03) (Rauh et al. 2013), there was no difference between the intervention and control group in the GeliS study (45.1 % vs. 45.7 %; p=0.79). Consistent results were observed regarding absolute amounts of weight gain (14.1 kg vs. 14.1 kg; p=0.84).

The lack of intervention effect for our primary outcome GWG is comparable with current research that demonstrated low evidence and inconsistent findings (Dodd et al. 2010, Skouteris et al. 2010, Campbell et al. 2011, Catalano & deMouzon 2015, Dodd et al. 2014a, Poston et al. 2015, Flynn et al. 2016, Poston 2017, The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). A large meta-analysis including individual participant data (IPD) of more than 12,000 women came to similar conclusions (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). According to the i-WIP Collaborative Group (2017), lifestyle interventions consistently reduce GWG but the effect was quite small (-0.7 kg) and 37 % of women still had weight gain that exceeded the guidelines. Except for a reduction of the risk of cesarean delivery, the i-WIP consortium did not report any further significant effects for mothers and their children including birth weight (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017).

Regarding the study design, it has to be mentioned that the large majority of previously conducted lifestyle intervention studies were performed by trained experts within academic study centers. In contrast to the GeliS approach this only poorly reflects the “real-life” situation. Controlled studies involving exercise groups, objective monitoring of physical activity and constant observation of dietary behavior may be more likely to achieve effects in the prevention of excessive GWG. However, there is an urgent need for the development and evaluation of effective strategies in the “real-life” setting of routine prenatal care in order to be applicable at the population level. The GeliS trial was designed based on the FeLIPO trial and was comparable in terms of the trial setting and counseling contents (Rauh et al. 2013). However, there was one major difference between the two trials. In the FeLIPO trial, counseling was provided by a trained dietary expert, while practice personnel delivered the sessions in the GeliS study. This considerable difference may substantially contribute to the discrepancy in the results of the two studies. Apart from the pilot trial FeLIPO (Rauh et al. 2013), two identified completed studies have integrated lifestyle interventions into prenatal care (Kinnunen et al. 2008, Harrison et al. 2013), but only one of them was successful in reducing GWG (Harrison et al. 2013). Although the study was integrated into routine care, counseling was performed by a qualified expert instead of trained practice staff as done in the GeliS study (Harrison et al. 2013).

Nevertheless, Muktabhant et al. (2015) highlighted in their Cochrane review that the included weight management (diet and physical activity) interventions reduced the number of women gaining weight in excess by 20 % and also other meta-analyses and systematic reviews of previous

studies reported a reduction in GWG (Streuling et al. 2010, Gardner et al. 2011, Tanentsapf et al. 2011, Oteng-Ntim et al. 2012, Thangaratinam et al. 2012a, Choi et al. 2013, O'Brien et al. 2016).

A comparison with national data

Data of the GeliS trial concerning the primary outcome are comparable to German and Bavarian data (Table 27).

Table 27: Mean total GWG and proportion of women exceeding IOM guidelines compared to the GeliS study

Study	Mean total GWG [kg]	Women exceeding IOM guidelines [%]
GeliS	14.1	45.4
Ferrari et al. 2014	13.7	42.9
Schiessl et al. 2009	14.1	-
Beyerlein et al. 2009a	14.0	41
Ensenauer et al. 2013	14.9	53.6

Survey data obtained from 11,771 women at a regional university hospital in Cologne (Ferrari et al. 2014) fit the primary outcome data of GeliS participants. In 2012, 42.9 % of women examined in Cologne exceeded the guidelines of the IOM and a total GWG of 13.7 kg was measured (Ferrari et al. 2014). Also data from the BAQ, the Bavarian working group on clinical quality assessment, are comparable to the data of GeliS participants. Maternal data were analyzed for 695,707 mature singleton deliveries in obstetric units in Bavaria, Southern Germany, from 2000 to 2007 (Schiessl et al. 2009). A mean GWG of 14.1 kg was observed calculated as last weight prior to delivery minus maternal weight at booking (Schiessl et al. 2009). Regarding weight gain according to the IOM guidelines, Beyerlein (2009a) reported a comparable pattern looking at the BAQ data mentioned above. 22 % of pregnant women gained weight below the IOM recommendations (GeliS: 21 %), 37 % within the recommendations (GeliS: 34 %) and 41 % exceeded the guidelines (GeliS: 45 %). In a retrospective cohort study (PEPO - Perinatal Prevention of Obesity Development), data of 6837 mother-child dyads were collected during the mandatory school entry health examinations in six regions of Bavaria (Ensenauer et al. 2013). Ensenauer et al. (2013) obtained a proportion of 53.6 % of women showing GWG above the recommended guidelines which was higher than the proportion in the GeliS study. 6837 women in six Bavarian regions had a mean total GWG of 14.9 kg which was also slightly higher than the results of mean total GWG in

GeliS. Finally, the results of the GeliS study confirm the high percentage of women who exceed the IOM recommendations and, thus, suggest an urgent need for action.

Primary outcome in study regions

Results of the primary outcome in the five study regions were highly heterogeneous. In Oberpfalz and Oberfranken the intervention led to a significantly smaller proportion of women exceeding the IOM criteria and reduced the mean total GWG after adjustment. In contrast, more women in the intervention groups in Oberbayern and Mittelfranken exceeded the IOM guidelines and had higher mean total GWG compared to the control groups. This was also seen in Unterfranken but here, results need to be interpreted with caution due to the low amount of participants in the control group. Differences in the primary outcome among study regions may be a result of a different provision of the intervention in practices or even at the level of counselors. Each GeliS counselor received a standardized two day seminar as well as detailed instructions and materials for counseling. However, conditions in the practices, especially limited time and suitable locations, as well as a various levels of commitment regarding the trial and finally, a different educational background of counselors may have contributed to a different quality of the intervention delivered and, thus, may be reasons for different results in study regions. As described above, the recruitment of practices and pregnant women in Oberpfalz and Oberfranken was more efficient than in the other three regions. This indicates that gynecologists, midwives and medical assistants in these regions were more motivated and strongly committed which may contribute to better results regarding the primary endpoint.

Generally, the study was not designed and adequately powered to evaluate the effects of the intervention in single study regions. Therefore, the results concerning study regions need to be interpreted with caution.

Primary outcome in subgroups

In general, more overweight and obese women exceed the IOM GWG guidelines than healthy weight women (Rasmussen & Yaktine 2009, Ferrari et al. 2014, Goldstein et al. 2016, Rogozińska et al. 2017) and lifestyle interventions often showed no effect in the subgroups of overweight and obese women (Dodd et al. 2010, Poston & Chappell 2012, Dodd et al. 2014a). In the GeliS study, 35 % of all participating normal weight women gained weight above the IOM recommendations,

whereas 67 % of overweight and 61 % of obese women exceeded the IOM criteria. No influence of the BMI subgroup on the intervention effects was observed.

Focusing on women with normal BMI at the beginning of pregnancy, a systematic review by O'Brien (2016) has shown only a slight positive impact of interventions. In particular, Phelan et al. (2011) have detected in the US-American *Fit for Delivery Study* that a single face-to-face counseling session targeting weight gain, healthy eating and exercise was effective in reducing the proportion of normal weight women who gained weight in excess. Similar positive effects were described by Polley et al. (2002) who demonstrated reduced excessive GWG among normal weight women in the intervention group.

With regard to overweight and obese women, no significant improvements were seen in both studies (Polley et al. 2002, Phelan et al. 2011). Rauh et al. (2013) have also detected that the effect of the intervention was generally more pronounced among normal weight women and had no effect on overweight/obese women. Similarly, the Australian LIMIT intervention did not succeed in a better adherence to IOM guidelines in overweight and obese women (Dodd et al. 2014a). Despite an intensive intervention program as tested throughout the UPBEAT trial in obese women, the effects regarding GWG were only small (-0.55 kg) (Poston et al. 2015). As Ruchat et al. (2012) mentioned, overweight and obese women tend to have unhealthy eating habits and a sedentary lifestyle before becoming pregnant. Thus, behavior changes may be even more challenging than in their healthy weight counterparts. Moreover, overweight and obese women may have body weight issues and low self-esteem. For those reasons, this subgroup of pregnant women may need more support and encouragement than healthy weight women in order to be able to overcome crucial barriers (Ruchat & Mottola 2012). Accordingly, lifestyle interventions which were based on frequent counseling sessions for women with a BMI about 30 kg/m^2 (Wolff et al. 2008, Vinter et al. 2011, Renault et al. 2014, Poston et al. 2015) seem to be more effective than those which were less frequent (Polley et al. 2002, Phelan et al. 2011). Nevertheless, such high intensity lifestyle programs limit the ability to integrate them in clinical practice.

Next to BMI subgroups, primary outcome data of the GeliS trial were also analyzed according to the educational background of the pregnant women. Women in the intervention group who had a low level of education (general secondary school) exceeded the IOM criteria more often than women who received no additional lifestyle advice (56.2 % vs. 47.7 %; p=0.02). No effects were seen among women who completed intermediate secondary school and among higher educated women (high school). It cannot be excluded that the design of the GeliS intervention may not be suitable for lower educated women in terms of intensity, materials or complexity. However,

counselors were instructed to give simple and practical recommendations. In general, women with low educational level are more likely to gain weight outside the IOM recommendations (Bogaerts et al. 2012, O'Brien et al. 2017). However, there is inconsistent evidence in literature regarding the effect of maternal educational level (O'Brien et al. 2017). Even if the GeliS intervention did not show favorable results in women with a low educational attainment, targeted, individualized healthcare interventions are necessary, especially for lowly educated women, in order to increase their chances of gaining weight in accordance with the GWG recommendations (O'Brien et al. 2017).

4.4 SECONDARY OUTCOME ANALYSES

Taken together, the GeliS antenatal intervention failed in demonstrating notable changes regarding pregnancy complications as well as obstetric and neonatal outcomes. No beneficial effects were seen regarding the prevalence of gestational diabetes mellitus (GDM), cesarean sections, large for gestational age (LGA) born infants or short-term maternal weight retention. There was a weak favorable trend towards a lower birth weight as well as a lower birth length in the intervention group. However, it has to be mentioned that the GeliS trial was not adequately powered for such outcomes. In the following, the intervention effects on GDM and birth weight will be discussed in detail and will be compared with current literature.

4.4.1 GESTATIONAL DIABETES MELLITUS

Prevalence of gestational diabetes mellitus in the whole study sample

11.0 % of study participants tested exceeded at least one of the threshold values of a 75-g-oGTT (oral glucose tolerance test) for diagnosis of GDM according to DDG and DGGG (Kleinwechter et al. 2016). This proportion was slightly lower than population-based representative data for Germany showing an overall prevalence of 13.2 % (Melchior et al. 2017). However, these data were obtained from pregnant women who received mainly only the pretest that is based on a single measurement of plasma glucose concentration one hour after a 50 g glucose intake. According to the German Maternity Directive (Gemeinsamer Bundesausschuss 2016), GDM screening shall be offered to all pregnant women not suffering from preexisting manifest diabetes mellitus. The screening comprises a pretest (one hour 50-g-GCT) and a diagnostic test (two hour 75-g-oGTT) if results from the pretest exceed the cutoff values (≥135 mg/dl (7.5 mmol/l) after one

hour). However, it should be considered that the glucose challenge test (GCT) is conducted independent of food intake and time of day (Kleinwechter et al. 2016). In the GeliS study, gynecologists were instructed to directly perform the 75-g-oGTT and to conduct it according to DDG and DGGG (Kleinwechter et al. 2016). According to the population-based, nationwide analysis of the screening coverage by Melchior and colleagues (2017), 80.8 % of pregnant women were screened for GDM with most of them (63.3%) receiving only the pretest, while 12.7 % received both the pretest and the diagnostic test, and 4.8 % received only the diagnostic test.

Prevalence of gestational diabetes mellitus in women who have received lifestyle advice

The GeliS intervention did not prevent GDM given that 10.8 % of women in the intervention group and 11.1 % of women in the control group were diagnosed. Several randomized controlled trials (RCTs) (Polley et al. 2002, Wolff et al. 2008, Asbee et al. 2009, Thornton et al. 2009, Guelinckx et al. 2010, Korpi-Hyovalti et al. 2011, Luoto et al. 2011, Vinter et al. 2011, Hui et al. 2012, Hawkins et al. 2015, Poston et al. 2015), meta-analyses and reviews (Tanentsapf et al. 2011, Han et al. 2012, Thangaratinam et al. 2012a, Yin et al. 2014, Bain et al. 2015, The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017) have also reported no significant benefits of interventions during pregnancy regarding the prevention of GDM. In a Cochrane review including 13 RCTs (involving 4983 women) no clear difference was observed in the risk of developing GDM for women receiving a combined diet and exercise intervention compared with women receiving no intervention (Bain et al. 2015). The working group pointed out that included trials varied in the quality, characteristics of the interventions, study populations and outcome definitions (Bain et al. 2015). In addition, they highlighted that there is currently no conclusive evidence as to which types of intervention are the most suitable for preventing GDM (Bain et al. 2015). However, there seems to be a trend towards a reduction in GDM for women receiving dietary advice compared with standard care with a greater treatment effect for overweight and obese women (Rogozińska et al. 2015, Tieu et al. 2017). Rogozińska and colleagues (2015) have shown that diet-based interventions reduced the risk of GDM even by 33 %, but similar to the Cochrane review they found no effect on GDM through interventions based on diet and lifestyle. Nevertheless, there are individual RCTs (Quinlivan et al. 2011, Walsh et al. 2012, Koivusalo et al. 2015, Wang et al. 2015, Wang et al. 2017) and meta-analyses or reviews of these RCTs (Sanabria-Martinez et al. 2015, Song et al. 2016, Shepherd et al. 2017, Bennett et al. 2018) indicating positive effects of lifestyle interventions regarding the prevention of GDM. Song and colleagues (2016) analyzed 29 RCTs with 11,487 pregnant women and demonstrated that either diet or

physical activity interventions can achieve an 18 % reduction in the risk of GDM, especially if initiated before the 15th week of gestation. In addition, a positive trend regarding GDM was also achieved in the pilot study FeLIPO (Rauh et al. 2013). If study level data from non-IPD studies were added to the IPD meta-analysis from the i-WIP Collaborative Group (2017), beneficial results for GDM were also seen.

A further indicator of GDM was the analysis of HbA_{1c} measurements. The glycosylated hemoglobin concentration is not suitable as a parameter for GDM diagnosis alone. However, if diabetes was diagnosed by oGTT, measurement of HbA_{1c} could be helpful to quantify the extent of preceding hyperglycemia. Moreover, Ensenauer et al. (2015) have found that a high HbA_{1c} value (≥5.7 % (39 mmol/mol)) at delivery indicated gestational dysglycemia in obese women negative for GDM. Moreover, it is associated with an increased offspring risk for being born LGA, having higher average birth weights, and with adverse long-term effects on maternal outcomes several years postpartum. Mean HbA_{1c} value measured in late pregnancy was not increased among GeliS participants and no differences between the study groups were observed. Obese women showed slightly higher levels of $HbA1_c$ than normal and overweight women. In addition, the values of obese women in the intervention group were slightly lower than those of obese women in the control group. Further subgroup analyses of $HbA1_c$ in women with GDM or in women who have infants born LGA will be conducted in order to examine these relationships also in the GeliS trial.

Prevalence of gestational diabetes mellitus with regard to the study regions

Similar to the results of the primary outcome, there were differences when performing the analysis separately for the five GeliS study regions. In contrast and that is questionable, analysis are oppositional to the findings regarding excessive GWG. The intervention resulted in a lower prevalence of GDM in Oberbayern (p=0.001) and Mittelfranken (p=0.001) and in a higher prevalence in Oberpfalz (p=0.08) and in Oberfranken (p=0.001). However, results for the prevalence of GDM need to be interpreted with caution. Possible reasons for the huge differences in the prevalence of GDM could be variances in measurement techniques between practices (Figure 11). Therefore, practice staff was contacted by phone and asked about detailed measurement procedures of GDM in their practice.

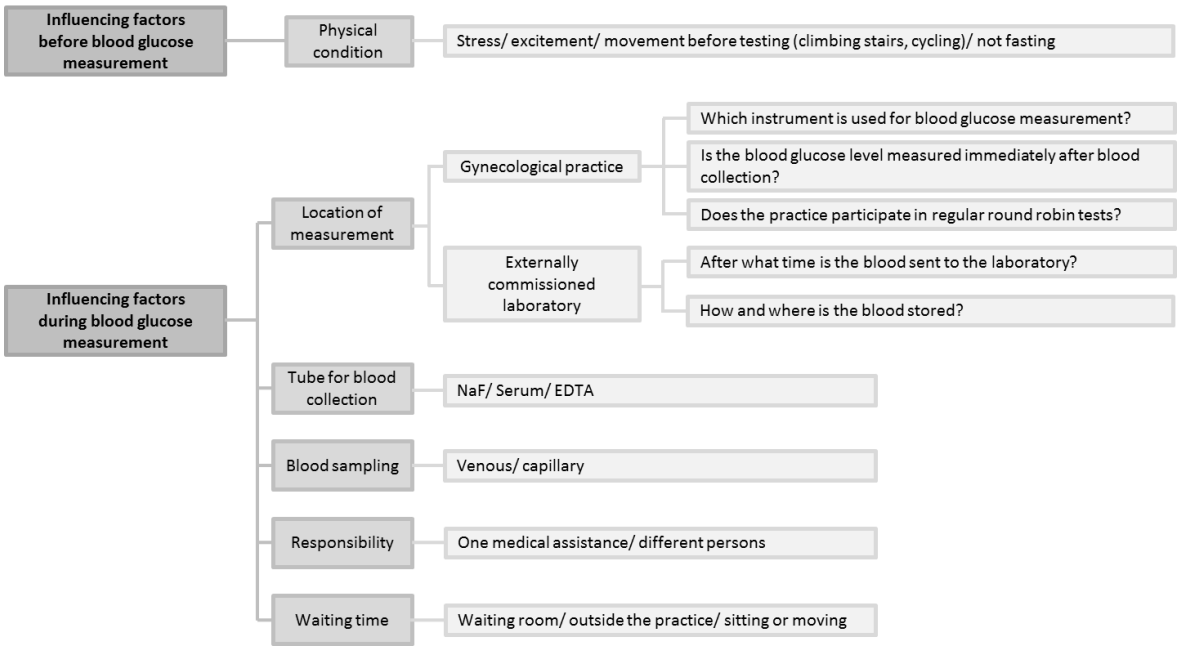


Figure 11: Possible influencing factors of blood sugar levels.

NaF=Sodium fluoride; EDTA=Ethylenediaminetetraacetic acid.

As expected there was a high variance in measurement procedures between practices. However, no systematic errors could be detected. As the study was not designed and adequately powered to evaluate the effects of the intervention in single study regions, the results concerning study regions need to be interpreted with caution.

The GDM diagnosis was conducted by the study team following strict adherence to the defined blood glucose thresholds (Metzger et al. 2010, Kleinwechter et al. 2016). In many cases, GDM was diagnosed if only the fasting value was equaled or exceeded but the other two values were physiological. However, slightly higher fasting values can also occur if women have not completely refrained from eating or due to hectic/stress/excitement (way into the practice, examination, etc.). The strict evaluation of blood glucose thresholds by the study team was reflected in the analysis of women treated. Only 38 % of women with diagnosed GDM received either insulin or dietary treatment or both.

Further large studies of high quality are needed to assess possible benefits of lifestyle advice on glycemic outcomes.

4.4.2 BIRTH WEIGHT

Birth weight data in the GeliS study were in the range of representative data from Germany and Bavaria. The mean birth weight of newborns of GeliS participants was 3338 g which is comparable with 3330 g observed in the KiGGS study. 8.4 % of GeliS infants had a birth weight above or equaling 4000 g and 0.9 % above or equal 4500 g. Knowing from BAQ (2016) data, 7.8 % of infants born in Bavaria had birth weight above or equaling 4000 g and 1.0 % above or equaling 4500 g, respectively.

The intervention resulted in a significant trend towards a lower mean birth weight, even if the difference between the intervention and control group was only small (3313 g vs. 3363 g; p=0.02). The difference observed in birth length in the intervention group of the GeliS study may be the explanation for the difference in birth weight. Similar to the pilot study FeLIPO, the intervention resulted in no significant differences regarding infants born LGA and infants with birth weight above or equaling 4000 g and above or equaling 4500 g. Also meta-analyses and systematic reviews reported no evidence concerning an effect of lifestyle interventions on birth weight (Dodd et al. 2010, Tanentsapf et al. 2011, Oteng-Ntim et al. 2012, Thangaratinam et al. 2012a, Flynn et al. 2016, O'Brien et al. 2016). According to Thangaratinam et al. (2012a), there were no significant differences in birth weight and the incidence of LGA babies between the groups. Similar observations were made by the i-WIP Collaborative Group (2017).

4.4.3 MATERNAL AND OBSTETRIC OUTCOMES

Although most other maternal and obstetric outcomes were not affected by the intervention, several differences were observed. Elective caesarean section was more frequently reported in the lifestyle counseling group. As the mode of delivery was not addressed during lifestyle counseling, a specific effect of the intervention seems to be unlikely. Due to the cluster randomization, one possible explanation could be differences in procedures between hospitals in performing cesarean sections, which is underpinned by a high variance in the cesarean section rate between regions (Kolpik et al. 2012). Among women in the control group, labor had to be induced more often than in the counseling group. Labor is induced frequently, especially after the estimated due date, but as gestation week at birth was comparable between groups, the difference in the rate of labor induction could again relate to clinic-specific procedures. Concerning hypertension, the intervention program itself is unlikely to explain the group difference. Blood pressure was measured routinely in medical practices. Differences in blood

pressure measurement procedures between the single practices cannot be excluded and may be one possible explanation. Another difference between groups was the proportion of women with preterm labor which was slightly higher in the control group. This parameter was evaluated as safety factor in order to ensure that encouraging women to be physically active during pregnancy would not lead to premature contractions. The circumstance that the proportion was not higher and even lower in the intervention group supports the safety of the physical activity component.

In summary, correlation analyses of GWG or pre-pregnancy BMI with different secondary outcomes in the whole study sample confirmed results from literature. Weight gain during pregnancy above the recommended range by the IOM as well as a high pre-pregnancy BMI were associated with adverse outcomes for mothers and infants including high birth weight, LGA infants and cesarean section. These findings of the GeliS trial support the importance of this target group with regard to lifelong health.

4.5 IMPLEMENTATION OF THE STUDY INTO PRACTICE

To date, the prenatal care provided by gynecologists and midwives mainly focuses on fetal growth parameters and potential maternal and fetal complications but does usually not include lifestyle advice. The GeliS intervention program was carried out as a public health approach in the “real-life” setting of routine care for pregnant women which constitutes the main strength of the study. It comprised a lifestyle intervention program with comprehensive contents mediated in four counseling sessions in order to promote a healthy lifestyle among pregnant women and to limit the proportion of women with excessive GWG.

Different surveys were conducted in order to evaluate if the intervention could be implemented in the practice of routine antenatal care for pregnant women (Figure 12). First, counselors gave feedback about their first experiences with the intervention within qualifying seminars. Second, counseling sessions were monitored by a master’s degree student. Finally, personal feedback of counselors and participants about the intervention program was collected by questionnaires after the study.

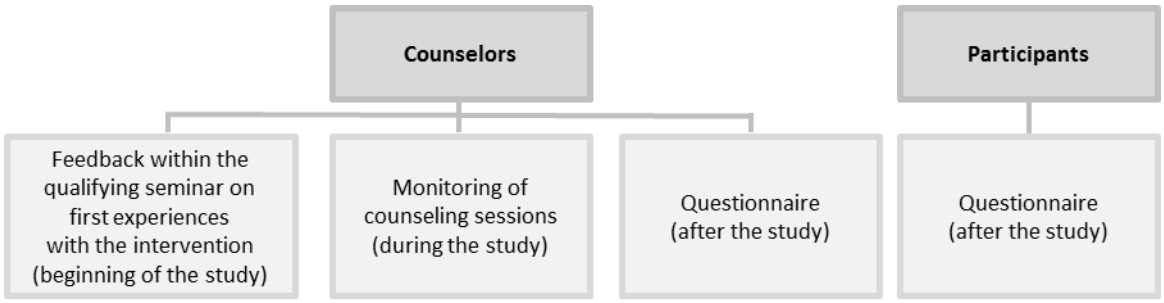


Figure 12: Different surveys for evaluating the lifestyle intervention program

Evaluation of the lifestyle intervention program by counselors

Due to the specific characteristics of the study designed as a public health approach, it was not possible to extensively check whether the sessions were consistently implemented as intended by the gynecologists, midwives and medical assistants. However, the adherence to study protocol and the quality of these counseling sessions as well as the feasibility of the program within routine care were evaluated by a master's degree student at the Chair of Nutritional Medicine of the Technical University of Munich (Hoffmann 2014). For that purpose, a sample of lifestyle counseling sessions was supervised by the student assessing duration, contents delivered in the sessions as well as the utilization of the study materials. Selected results are presented in the Appendix (Table 31). Nevertheless, it is important to note that only a small group of 20 counselors were monitored in this thesis. While the master's thesis was performed during the course of study, the experiences of GeliS counselors with study procedures were recorded at the end of the study using an evaluation questionnaire (Appendix: Table 32). The results of these surveys are broadly comparable. Most counselors reported that pregnant women were highly motivated to attend the GeliS program which is an urgent condition to realize modifications in lifestyle behavior. Moreover, counselors reported feeling competent regarding the contents and procedures of the program by attending qualifying seminars before giving intervention sessions and utilizing study documents and materials provided.

As reported in literature, from the health care providers' perspective there is often a lack of time, training, skills, self-efficacy and concerns about discussing weight with pregnant women (Schmied et al. 2011, Heslehurst et al. 2014a, Furness et al. 2015). In addition, obese women reported that they feel judged by health care professionals raising the topic of their weight (Lindhardt et al. 2013). Although counseling sessions in the GeliS trial followed a predefined curriculum, differences in the quality of the intervention delivered were possible. Unfortunately, medical assistants which represent the largest group of counselors did not use weight gain charts regularly

(Hoffmann 2014). It seemed that they partially felt uncomfortable to discuss weight with participating women and were concerned about fostering anxiety. These findings support previous results from research conducted with health professionals concluding that weight issues may need to be discussed with great care and that training should be provided for health professionals regarding discussing GWG (Heslehurst et al. 2011, Olander et al. 2011, Schmied et al. 2011, Heslehurst et al. 2014a). Application of charts was a central tool of the GeliS intervention in order to promote appropriate weight gain. In future projects the handling of weight gain charts should be trained to a larger extend.

In addition, individual feedback on dietary and activity behavior based on information from the first questionnaire collected was not given as regularly as it was intended (Hoffmann 2014). Therefore, a suboptimal quality of the lifestyle counseling may also explain the missing effectiveness of the intervention program. Even if counselors reported feeling well prepared through training sessions, a two day seminar may not be adequate to qualify gynecologists, medical assistants and midwives for high-quality lifestyle coaching. This was emphasized as GeliS counselors considered cooperation with nutritional and physical activity experts as helpful (Appendix: Table 32) which is in line with a survey of practitioners regarding the management and assessment of GWG conducted by van der Pligt et al. (2011). Correspondingly, the pilot study FeLIPO demonstrated that a lifestyle intervention provided by experienced nutritionists was successful in preventing excessive GWG (Rauh et al. 2013). Fortunately, most of participating counselors in the GeliS trial would appreciate a lifestyle intervention as part of routine care and would still participate in similar programs (Appendix: Table 32). A systematic review by Heslehurst et al. (2014a) identified that healthcare professionals appear to be motivated to address weight management with pregnant women and to overcome barriers to practice through improving their knowledge and skills. In future qualifying seminars, it is planned to add a unit on motivational interviewing to provide sufficient communication skills (Healthy Start - Young Family Network 2014a). It is supposed to address the basics of communication and counseling and the importance of pregnant women's motivation for counseling. The concept of motivational interviewing is particularly suitable for conversations with pregnant women who have a low or ambivalent willingness to change their behavior as the consultant supports women in developing their own motivation to change their behavior.

Evaluation of the lifestyle intervention program by participants

The evaluation of the intervention by participating women has been analyzed in a bachelor's thesis (data are not presented in the current work). Lifestyle advice was experienced as helpful by most of the women. Half of the women reported that the intervention has partially contributed to changes in their dietary and physical activity behavior. Moreover, recommendations on GWG were also reported as helpful by most of the participants in the intervention group. Similar to the statements of counselors, women in the intervention group have requested lifestyle advice as part of routine care during pregnancy. These findings were supported by a high participation rate, high proportion of women attending all lifestyle sessions during pregnancy and in the postpartum period as well as a low drop-out rate of 11 % which was lower than the expected rate of 20 % reflecting the applicability of the program. Moreover, it indicates – indirectly – that expectant mothers are highly interested in a healthy lifestyle in order to promote the healthy development of their infants. This was similarly observed in other studies (Willcox et al. 2015, Vanstone et al. 2016, Nikolopoulos et al. 2017). Especially first-time mothers seek information about GWG (Szwajcer et al. 2005, Willcox et al. 2015). Together with high rates of excessive GWG, this emphasizes the gap between the current situation in prenatal care and the need for information and support.

4.6 WHY THE INTERVENTION WAS NOT SUCCESSFUL - POSSIBLE EXPLANATIONS

Pregnancy reflects a time of many changes in life including financial, relationship, social and physical conditions and there are circumstances which can make it difficult to concentrate on diet or physical activity changes. Morning sickness, food aversions and fatigue or indigestion could be some of them. Moreover, there are competing demands such as primary care and/or specialist appointments, screening tests and potential complications which can interfere with the compliance to intervention strategies (Hill et al. 2017). However, as described above, women seem to be open for behavior changes during the time of pregnancy in order to ensure a healthy development of their child. Nevertheless, current intervention strategies show only small effects (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). Regardless of the good accessibility of pregnant women in gynecology and midwife practices due to frequent clinical visits it appears that there are different barriers to overcome bad habits and form new positive habits (Dodd & Briley 2017, Hill et al. 2017). It was found that the formation of new habits needs on average 66 days of repetition. Depending on complexity of behaviors it can take up to 254 days to be realized (Lally et al. 2010). In the context of the GeliS intervention, it is

possible that desired weight results were not achieved because the short window of gestation for new habit formation was even too short and behavioral changes could not be stabilized during the time of intervention.

As discussed in previous works, intervention programs have often been initiated too late (Gardner et al. 2011, Catalano & deMouzon 2015, Hill et al. 2017). Catelano and deMouzon (2015) have investigated possible explanations for not achieving desired outcomes (e.g. fetal overgrowth, GDM or preeclampsia) through current lifestyle interventions in obese women. They suggested that the metabolic condition of mothers before pregnancy and in early pregnancy affects early placental function and gene expression (Catalano & deMouzon 2015). Furthermore, they argued that these alterations in maternal/placental function occur in the first trimester of pregnancy prior to when most intervention trials are initiated (Catalano & deMouzon 2015). Despite the early recruitment of pregnant women in the GeliS trial, the first counseling session took place at the beginning of the second trimester.

Given that more than 50 % of overweight and obese women exceed the recommended weight ranges but almost one third of normal weight women also do, women of all BMI classifications between 18.5 kg/m^2 and 40 kg/m^2 were included and analyzed in the present GeliS study in order to reach the broadest possible range of women. Similarly, women were included independent of parity, independent of cultural background and independent of age as well as independent of educational level. As Hill and colleagues (2017) mentioned, it is possible that a one-size-fits-all approach may not be appropriate to consider individual differences in knowledge, exposure to information, skills, resources, and motivation. Nevertheless, as concluded in the work of the i-WIP Collaborative Group (2017), all women could benefit from lifestyle interventions including diet and physical activity, irrespective of maternal characteristics including BMI, ethnicity, age, and underlying medical conditions.

4.7 GENERAL STRENGTHS AND LIMITATIONS OF THE TRIAL

Although the GeliS intervention showed no major effects on GWG and pregnancy complications, the trial has several strengths next to some limitations. The GeliS trial used robust methods including prospectively measured weight and BMI in all participants and a cluster-randomized design which counteracted spillover effects of lifestyle counseling contents from women of the intervention to the control group. A further strength of the trial was the large sample size, the inclusion of normal weight as well as overweight and obese women, the low drop-out rate, only

few missing data in the complete-case analysis, pre-specified primary and secondary outcomes with practical relevance during prenatal care, and a pre-specified analysis plan. As intended, the trial could be scheduled in combination with pre- and postnatal visits within the setting of routine care for pregnant women.

Nevertheless, the intensity of the GeliS intervention comprising three counseling sessions during pregnancy may not be sufficient to promote significant lifestyle changes and differences in GWG. Otherwise, increasing the intensity of the intervention might have affected compliance of pregnant women and also of health care providers because of their limited resources. Implementing the program into routine care may require the support of specifically trained dieticians or lifestyle coaches in a quieter surrounding than a busy practice office. Separated rooms exclusively intended for counseling sessions could contribute to an increased quality of the lifestyle intervention.

Moreover, a limitation of the lifestyle intervention program was that counseling was not extensively based on concepts of behavior change. Lifestyle counseling included methods such as self-monitoring and feedback on behavior. An extension with additional methods such as motivational interviewing was not possible, but could enhance the quality.

The safety of the intervention is a crucial aspect when dealing with pregnant women. The rate of preterm born infants was low in women participating in the GeliS trial and there was no adverse intervention effect regarding preterm births. This was also true for infants being born small for gestational age (SGA). As concluded by the i-WIP Collaborative Group (2017), pregnant women should be encouraged to engage in physical activity, as the meta-analysis found that preterm birth was not associated with physical activity during pregnancy. Moreover, among GeliS participants the intervention did not lead to an increase of further pregnancy and obstetric complications such as preterm labor or bleedings or to an increase in infant complications at birth such as adjustment disorders, cardiac irregularities or hypoglycemia. There was a small but significant difference between intervention and control groups in the proportion of women who gained weight below the recommended guidelines (19.9 % vs. 21.4 %; p=0.002; Appendix: Table 28). 21.4 % of women in the intervention group have shown weight gain below recommendation levels, which was lower than 29.1 % of women in the meta-analysis of the i-WIP Collaborative Group (2017).

Pre-pregnancy BMI was calculated by self-reported weight and height which may have led to an underestimation or underreporting of pre-pregnancy BMI in overweight and obese women and, thus, to an overestimated proportion of women with excessive GWG. As described in literature, this aspect is a well-known problem that exists throughout pregnancy and non-pregnancy

research (Connor Gorber et al. 2007, Mandujano et al. 2012). However, it has also been shown that self-reported pre-pregnancy weight and weight measured at the first prenatal visit resulted in identical classification of pre-pregnancy BMI (Holland et al. 2013, Bannon et al. 2017) and that reporting errors have no large influence on the associations between pregnancy-related weight and birth outcomes (Headen et al. 2017). Within the GeliS trial, weight was reassessed at the beginning of pregnancy by practice staff in participating gynecological practices using standardized methods which were given by the study team. Finally, the calculation of GWG was based on weight measured by practice staff.

As a further common problem in intervention studies, selection bias also occurred in the GeliS trial. Women participating in the GeliS trial had a higher than average level of education, belonged to the white Caucasian population and only a small proportion of them came from ethnic minorities, as sufficient language skills were a prerequisite for participation. Therefore, results may not be generalizable to the overall population of Germany.

Furthermore, women in the control group were aware of participating in a study assessing their diet and physical activity behavior and GWG in pregnancy although a cluster-randomized design was chosen to avoid spill-over effects. Both groups received study material including questionnaires on dietary behavior and physical activity, which could have led to increased awareness and behavior adaptions among women in the control group. Therefore, intervention effects could be underestimated by a possible influence on behavior.

A further limitation was the imbalance of recruitment rates in different study regions, which may be related to unmotivated gynecologists and practice staff or to lower numbers of pregnant patients during the recruitment phase among practices.

5. CONCLUSION AND OUTLOOK

There is an urgent demand for successful lifestyle interventions in pregnancy as more than 40 % of pregnant women in Germany exceed the recommended guidelines for gestational weight gain (GWG) resulting in short- and long-term negative consequences. Results of the primary outcome of the GeliS study highlight the difficulties in limiting GWG at a population level, with 45.1 % of women in the intervention group gaining weight in excess. As literature has shown, lifestyle interventions during pregnancy can improve health outcomes for mothers and their offspring but up to now, the effects of such interventions are rather small and are not sufficient to give any specific recommendations for interventions to prevent excessive GWG (Poston & Chappell 2012, Thangaratinam et al. 2012a, Muktabhant et al. 2015, Dodd & Briley 2017, Hanson et al. 2017, The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017, van der Pligt et al. 2017). Nevertheless, researchers underline the importance of recommending regular physical activity and balanced diet during pregnancy and highlighting the benefits of a healthy lifestyle of expectant mothers (The International Weight Management in Pregnancy (i-WIP) Collaborative Group 2017). Researchers concluded that there is no need for concern about the safety of the IOM recommendations for weight gain and also about the safety of lifestyle interventions, particularly with regard to physical activity in pregnancy. Positive effects of a healthy lifestyle during pregnancy should be elucidated to expectant mothers by emphasizing the benefits and lack of harm (Thangaratinam et al. 2012a, Poston 2017).

The GeliS lifestyle program did not yield in favorable effects on GWG (primary outcome) or any other secondary outcomes, except for a small trend towards a decreased birth weight and length. Based on the process and the results of the GeliS study, recommendations for future approaches can be derived (Figure 13).

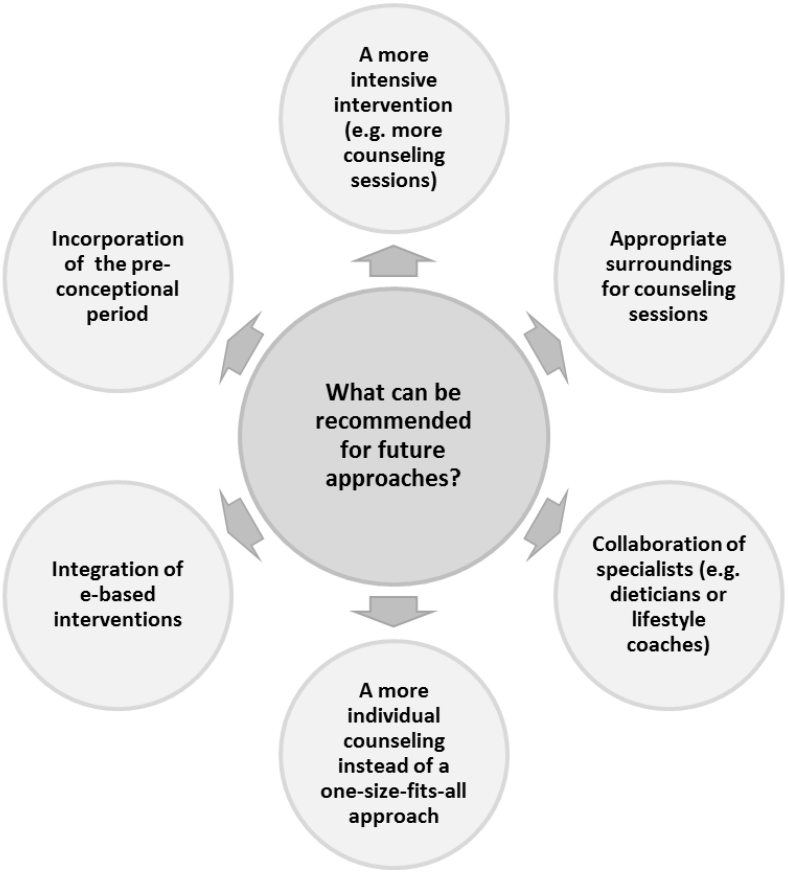


Figure 13: Recommendations for future approaches

As researchers have previously suggested (Muktabhant et al. 2015, Goldstein et al. 2016, Hill et al. 2017), study procedures were adapted to the daily routine work of gynecological and midwife practices in order to allow an implementation of the intervention into the German maternity health care system. To date, no other trial has investigated the compatibility of an additional lifestyle advisory component within routine health care for pregnant women to such a large extent. Interviews with participating gynecologists, medical assistants and midwives have supported the feasibility of attaching the intervention to antenatal care. As it is a major goal to implement programs that were previously successful in academic settings into routine care, in future, qualifying seminars could be intensified. However, it remains questionable if an appropriate lifestyle intervention regarding weight management as well as diet and physical activity behavior can be delivered adequately through gynecological practice staff and if it is achievable within the current standard care capacity. The integration of a program such as GeliS into daily work and the combination of counseling sessions with routine care visits may also require cooperation with specifically trained and experienced dieticians or lifestyle coaches. This could lead to an improvement of the quality of lifestyle counseling and might thus, reduce the

proportion of women with excessive GWG and associated health consequences. Although the GeliS study was not successful in limiting the rate of excessive GWG, the implementation of weight management strategies into routine care is a promising approach to deliver knowledge about healthy lifestyle and weight gain.

As the GeliS trial was supported by the Bavarian State ministry for nutrition, agriculture and forestry, the Bavarian State ministry for health and care as well as by a large German health statutory insurance fund, there was a chance to address concerns and awareness of policy makers. Promoting political will and advocacy of important stakeholders is an essential step in order to implement such a program into the standard care for pregnant women and, moreover, to raise public awareness for the topic. In this context, the GeliS study was a favorable approach connecting science and policy and translating scientific knowledge into the “real-life” situation of routine care for pregnant women. However, the integration of an effective and efficient lifestyle intervention program into daily work and combination of counseling sessions with pre- and postnatal visits remains a challenge.

As an alternative to traditional face-to-face counseling, interventions can be provided electronically-based (e-based), which has already been tested by different working groups (Nicholson et al. 2016, Graham et al. 2017, Hayman et al. 2017, Lau et al. 2017, Willcox et al. 2017, van den Heuvel 2018). E-based platforms are websites, internet, mobile phone applications (Apps), SMS, email, computers and interactive videos and combinations of these delivery formats with in-person and phone sessions (Lau et al. 2017). They provide an opportunity to deliver trusted source information through a low-cost method during pregnancy (Redman et al. 2017) as every second expectant mother reported to use pregnancy-related Apps before, during and after pregnancy (Forschungsgruppe g/d/p 2015). Therefore, it is conceivable that e-based interventions could easily be integrated into standard health care. Nevertheless, the evidence on effectiveness is limited and needs further investigation (Lau et al. 2017, Overdijkink et al. 2018, van den Heuvel et al. 2018).

There is a current app-trilogy which was developed by the Competence Centre for Nutrition (KErn) in cooperation with the Healthy Start - Young Family Network and the “Stiftung Kindergesundheit” in order to support women with the desire of having children, during pregnancy as well as during the breastfeeding period and the beginning of complementary feeding till the third year of life (KErn – Kompetenzzentrum für Ernährung & Stiftung Kindergesundheit 2018). The trilogy comprises information about healthy diet and physical activity which are based on the practice guidelines developed by the Healthy Start - Young Family

Network (Koletzko et al. 2013a) and includes weight monitoring as well as further interactive tools. It is conceivable that this app could be developed as a tool for a future e-based intervention concept.

Recently published e-based intervention trials demonstrated several potential benefits during pregnancy (O'Brien et al. 2014, Lau et al. 2017) and in the postpartum period (Sherifali et al. 2017). In particular, Willcox and colleagues (2017) found out that a mobile health intervention promoting healthy diet, physical activity and GWG was able to significantly reduce GWG and maintain physical activity in overweight and obese women. Similarly, Redman et al. (2017) have shown in a parallel-arm randomized controlled trial (RCT) that an intensive lifestyle intervention via a mobile phone was effective in reducing the proportion of overweight and obese women exceeding the Institute of Medicine (IOM) guidelines. Additionally, the intervention was cost-effective and resulted in increased intervention adherence (Redman et al. 2017). Nevertheless, Lau et al. (2017) concluded that there is currently inadequate evidence to suggest the use of e-based lifestyle interventions for improving maternal and neonatal outcomes. More research is necessary regarding the use and acceptance of such e-based interventions (Sherifali et al. 2017).

A healthy pre-pregnancy body weight is associated with better pregnancy and childhood outcomes (MacInnis et al. 2016) but the limited time of pregnancy may not be sufficient to realize new dietary and physical activity behavior changes in order to affect these outcomes. Thus, this “window of opportunity” may be overestimated as a life phase to induce rapid and sustained lifestyle changes. Therefore, it might be useful to incorporate the pre-conceptional period into intervention strategies in order to prevent and manage obesity and related adverse health outcomes already before conception and, moreover, to have a long-term chance of behavior formation and to enter pregnancy with healthy lifestyle habits (Goldstein et al. 2016, Poston et al. 2016, Samura et al. 2016, Teede & Moran 2016, Hanson et al. 2017, Hill et al. 2017, Dutton et al. 2018). 69 % of German first-time mothers are going to have additional children (Statistisches Bundesamt 2013). Therefore, using the inter-conceptional time could be a further aspect of pre-conceptional interventions. It could be a chance to reduce maternal weight prior to a subsequent pregnancy and, hence, to minimize the risk of excessive GWG and associated adverse outcomes (van der Pligt et al. 2013, Hill et al. 2017). Nevertheless, it remains difficult to recruit women in the pre-conceptional period as half of all pregnancies are unplanned (Bundeszentrale für gesundheitliche Aufklärung (BZgA) 1996, Sedgh et al. 2014). Starting interventions already in the postpartum period and continuing until the next pregnancy provides an opportunity to overcome the barrier of reaching women in their pre-conceptional period (Bogaerts et al. 2017). Systematic

reviews and meta-analyses have indicated positive effects of lifestyle interventions for weight management among postpartum women (Nascimento et al. 2014, Lim et al. 2015).

Subsequent planned analyses of the GeliS trial will provide information on the dietary and physical activity behavior among study participants during the course of pregnancy as well as about the long-term effects of the intervention. These analyses will ascertain whether the intervention affected dietary and physical activity behavior and, thus, could help to understand the missing intervention effect on maternal and fetal outcomes. Furthermore, they may highlight which components of the counseling need more emphasis in future trials. A follow-up observation is planned up to the 5th year of life in order to extensively evaluate the weight development as well as long-term health of mothers and their infants. The GeliS study provides a large dataset of dietary and physical activity behavior, maternal mental health and postnatal depression, intake of dietary supplements during pregnancy, breastfeeding rates as well as health outcomes of mothers and their children. This dataset is unique for Bavaria and offers the possibility for further comprehensive analyses also independent of the intervention.

REFERENCES

Adamo KB, Ferraro ZM, Brett KE: Can we modify the intrauterine environment to halt the intergenerational cycle of obesity? International journal of environmental research and public health 2012, 9:1263-1307.

Agha M, Agha RA, Sandall J: Interventions to reduce and prevent obesity in pre-conceptual and pregnant women. A systematic review and meta-analysis. PloS one 2014, 9:e95132.

aid infodienst Ernährung, Landwirtschaft, Verbraucherschutz e.V. (2012): Die aid-Ernährungspyramide - Richtig essen lehren und lernen. https://ble-medienservice.de/3899/Die-aid-Ernaehrungspyramide-Richtig-essen-lehren-und-lernen; 11.06.2018

aid infodienst Ernährung, Landwirtschaft, Verbraucherschutz e.V. (2013): Das beste Essen in der Schwangerschaft. https://ble-medienservice.de/1605/das-beste-essen-in-der-schwangerschaft?c=163; 11.06.2018

Alavi N, Haley S, Chow K et al.: Comparison of national gestational weight gain guidelines and energy intake recommendations. Obesity reviews: an official journal of the International Association for the Study of Obesity 2013, 14:68-85.

Alberico S, Montico M, Barresi V et al.: The role of gestational diabetes, pre-pregnancy body mass index and gestational weight gain on the risk of newborn macrosomia: results from a prospective multicentre study. BMC pregnancy and childbirth 2014, 14:23.

Alfaradhi MZ & Ozanne SE: Developmental programming in response to maternal overnutrition. Frontiers in genetics 2011, 2:27.

Althuizen E, van der Wijden CL, van Mechelen W et al.: The effect of a counselling intervention on weight changes during and after pregnancy. A randomised trial. BJOG: an international journal of obstetrics and gynaecology 2013, 120:92-99.

Amir LH & Donath S: A systematic review of maternal obesity and breastfeeding intention, initiation and duration. BMC pregnancy and childbirth 2007, 7:9.

AOK Bayern – Die Gesundheitskasse: Gesundheitsangebote
https://bayern.aok.de/landingpages/gesundheitsangebote/; 13.04.2018

AQUA-Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen GmbH: Bundesauswertung zum Erfassungsjahr 2014. 16/1 – Geburtshilfe 2014.

Asbee SM, Jenkins TR, Butler JR et al.: Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling: a randomized controlled trial. Obstetrics and gynecology 2009, 113:305-312.

Aune D, Saugstad OD, Henriksen T et al.: Maternal body mass index and the risk of fetal death, stillbirth, and infant death: a systematic review and meta-analysis. JAMA 2014, 311:1536-1546.

Bain E, Crane M, Tieu J et al.: Diet and exercise interventions for preventing gestational diabetes mellitus. The Cochrane database of systematic reviews 2015:CD010443.

Bannon AL, Waring ME, Leung K et al.: Comparison of Self-reported and Measured Pre-pregnancy Weight. Implications for Gestational Weight Gain Counseling. Maternal and child health journal 2017, 21:1469-1478.

BAQ-Bayerische Arbeitsgemeinschaft für Qualitätssicherung in der stationären Versorgung: Geburtshilfe, Auswertung 2016, Modul 16/1 2016.

Barakat R, Cordero Y, Coteron J et al.: Exercise during pregnancy improves maternal glucose screen at 24-28 weeks. A randomised controlled trial. British journal of sports medicine 2012, 46:656-661.

Barker DJ & Osmond C: Diet and coronary heart disease in England and Wales during and after the second world war. Journal of epidemiology and community health 1986, 40:37-44.

Bennett JC, Walker ER, Blumfield LM et al.: Interventions designed to reduce excessive gestational weight gain can reduce the incidence of gestational diabetes mellitus: A systematic review and meta-analysis of randomized controlled trials. Diabetes Research and Clinical Practice 2018, 141:69-79.

Bergant AM, Nguyen T, Heim K et al.: Deutschsprachige Fassung und Validierung der "Edinburgh postnatal depression scale". Deutsche medizinische Wochenschrift 1998, 123:35-40.

Berggren EK, Groh-Wargo S, Presley L et al.: Maternal fat, but not lean, mass is increased among overweight/obese women with excess gestational weight gain. American journal of obstetrics and gynecology 2016, 214:745.e1-5.

Berglund PA & Heeringa S: Multiple imputation of missing data using SAS. Cary, N.C.: SAS Institute; 2014.

Bergmann KE, Bergmann RL, Ellert U et al.: Perinatale Einflussfaktoren auf die spätere Gesundheit. Bundesgesundheitsblatt 2007, 50:670-676.

Bergmann RL, Richter R, Bergmann KE et al.: Secular trends in neonatal macrosomia in Berlin: influences of potential determinants. Paediatric and perinatal epidemiology 2003, 17:244-249.

Bever Babendure J, Reifsnider E, Mendias E et al.: Reduced breastfeeding rates among obese mothers. A review of contributing factors, clinical considerations and future directions. International breastfeeding journal 2015, 10:21.

Beyerlein A: BAQ data 2007 – classification of gestational weight gain according to IOM recommendations. E-mail to Kathrin Rauh (2009a).

Beyerlein A, Schiessl B, Lack N et al.: Optimal gestational weight gain ranges for the avoidance of adverse birth weight outcomes. A novel approach. The American journal of clinical nutrition 2009b, 90:1552-1558.

Beyerlein A, Lack N, von Kries R: Within-population average ranges compared with Institute of Medicine recommendations for gestational weight gain. Obstetrics & Gynecology 2010, 116:1111–8.

Bogaerts A, van den Bergh B, Nuyts E et al.: Socio-demographic and obstetrical correlates of pre-pregnancy body mass index and gestational weight gain. Clinical obesity 2012, 2:150-159.

Bogaerts A, Ameye L, Bijlholt M et al.: INTER-ACT. Prevention of pregnancy complications through an e-health driven interpregnancy lifestyle intervention - study protocol of a multicentre randomised controlled trial. BMC pregnancy and childbirth 2017, 17:154.

Bogaerts AFL, Devlieger R, Nuyts E et al.: Effects of lifestyle intervention in obese pregnant women on gestational weight gain and mental health. A randomized controlled trial. International journal of obesity 2013, 37:814-821.

Boulet SL, Salihu HM, Alexander GR: Mode of delivery and birth outcomes of macrosomic infants. Journal of obstetrics and gynaecology: the journal of the Institute of Obstetrics and Gynaecology 2004, 24:622-629.

Briley AL, Barr S, Badger S et al.: A complex intervention to improve pregnancy outcome in obese women; the UPBEAT randomised controlled trial. BMC pregnancy and childbirth 2014, 14:74.

Brownfoot FC, Davey M-A, Kornman L: Routine weighing to reduce excessive antenatal weight gain. A randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2015, 123:254-261.

Brown JE, Murtaugh MA, Jacobs DR et al.: Variation in newborn size according to pregnancy weight change by trimester. The American journal of clinical nutrition 2002, 76:205-209.

Brown MJ, Sinclair M, Liddle D et al.: A systematic review investigating healthy lifestyle interventions incorporating goal setting strategies for preventing excess gestational weight gain. PloS one 2012, 7:e39503.

Brunner S, Stecher L, Ziebarth S et al.: Excessive gestational weight gain prior to glucose screening and the risk of gestational diabetes: a meta-analysis. Diabetologia 2015, 58:2229-2237.

Bundeszentrale für Gesundheitliche Aufklärung (BZgA), Abteilung Sexualaufklärung, Verhütung und Familienplanung (Ed): Kontrazeption, Konzeption, Kinder oder keine: Dokumentation einer Expertentagung. Köln. Volume 6. 1st edition 1996.

Butte NF, Ellis KJ, Wong WW et al.: Composition of gestational weight gain impacts maternal fat retention and infant birth weight. American journal of obstetrics and gynecology 2003, 189:1423-1432.

Campbell EE, Dworatzek PDN, Penava D et al.: Factors that influence excessive gestational weight gain. Moving beyond assessment and counselling. The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 2016, 29:3527-3531.

Campbell F, Johnson M, Messina J et al.: Behavioural interventions for weight management in pregnancy. A systematic review of quantitative and qualitative data. BMC public health 2011, 11:491.

Carreno CA, Clifton RG, Hauth JC et al.: Excessive early gestational weight gain and risk of gestational diabetes mellitus in nulliparous women. Obstetrics and gynecology 2012, 119:1227-1233.

Catalano P & deMouzon SH: Maternal obesity and metabolic risk to the offspring. Why lifestyle interventions may have not achieved the desired outcomes. International journal of obesity 2015, 39:642-649.

Catalano PM & Ehrenberg HM: The short- and long-term implications of maternal obesity on the mother and her offspring. BJOG: an international journal of obstetrics and gynaecology 2006, 113:1126-1133.

Catalano PM, Farrell K, Thomas A et al.: Perinatal risk factors for childhood obesity and metabolic dysregulation. The American journal of clinical nutrition 2009, 90:1303-1313.

Cedergren MI: Maternal morbid obesity and the risk of adverse pregnancy outcome. Obstetrics and gynecology 2004, 103:219-224.

Chasan-Taber L, Schmidt MD, Roberts DE et al.: Development and validation of a Pregnancy Physical Activity Questionnaire. Medicine and science in sports and exercise 2004, 36:1750-1760.

Cho EH, Hur J, Lee KJ: Early Gestational Weight Gain Rate and Adverse Pregnancy Outcomes in Korean Women. PloS one 2015, 10:e0140376.

Choi J, Fukuoka Y, Lee JH: The effects of physical activity and physical activity plus diet interventions on body weight in overweight or obese women who are pregnant or in postpartum. A systematic review and meta-analysis of randomized controlled trials. Preventive medicine 2013, 56:351-364.

Chu SY, Kim SY, Schmid CH et al.: Maternal obesity and risk of cesarean delivery: a meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2007a, 8:385-394.

Chu SY, Callaghan WM, Kim SY et al.: Maternal obesity and risk of gestational diabetes mellitus. Diabetes care 2007b, 30:2070-2076.

Clapp JF3, Kim H, Burciu B et al.: Beginning regular exercise in early pregnancy. Effect on fetoplacental growth. American journal of obstetrics and gynecology 2000, 183:1484-1488.

Connor Gorber S, Tremblay M, Moher D et al.: A comparison of direct vs. self-report measures for assessing height, weight and body mass index. A systematic review. Obesity reviews: an official journal of the International Association for the Study of Obesity 2007, 8:307-326.

Crane JM, White J, Murphy P et al.: The effect of gestational weight gain by body mass index on maternal and neonatal outcomes. Journal of Obstetrics and Gynaecology Canada 2009, 31:28-35.

Crowther CA, Hiller JE, Moss JR et al.: Effect of Treatment of Gestational Diabetes Mellitus on Pregnancy Outcomes. Obstetrics & Gynecology 2005, 106:635-636.

Dabelea D, Mayer-Davis EJ, Lamichhane AP et al.: Association of intrauterine exposure to maternal diabetes and obesity with type 2 diabetes in youth: the SEARCH Case-Control Study. Diabetes care 2008, 31:1422-1426.

Dabelea D & Crume T: Maternal environment and the transgenerational cycle of obesity and diabetes. Diabetes 2011, 60:1849-1855.

Daley AJ, Jolly K, Jebb SA et al.: Feasibility and acceptability of regular weighing, setting weight gain limits and providing feedback by community midwives to prevent excess weight gain during pregnancy. Randomised controlled trial and qualitative study. BMC obesity 2015, 2:35.

Daley AJ, Jolly K, Jebb SA et al.: Effectiveness of regular weighing, weight target setting and feedback by community midwives within routine antenatal care in preventing excessive gestational weight gain. Randomised controlled trial. BMC obesity 2016, 3:7.

Daly N, Farren M, McKeating A et al.: A Medically Supervised Pregnancy Exercise Intervention in Obese Women. A Randomized Controlled Trial. Obstetrics and gynecology 2017, 130:1001-1010.

Deputy NP, Sharma AJ, Kim SY et al.: Prevalence and characteristics associated with gestational weight gain adequacy. Obstetrics and gynecology 2015, 125:773-781.

Deputy NP, Sharma AJ, Kim SY et al.: Achieving Appropriate Gestational Weight Gain. The Role of Healthcare Provider Advice. Journal of women's health 2018, 27:552-560.

Deutsche Gesellschaft für Ernährung e.V.: http://www.dge.de/presse/pm/wie-viel-energie-braucht-der-mensch/; 13.04.2018

Deutsche Gesellschaft für Ernährung, Österreichische Gesellschaft für Ernährung, Schweizerische Gesellschaft für Ernährungsforschung, Schweizerische Vereinigung für Ernährung: Referenzwerte für die Nährstoffzufuhr. 2nd edition. Bonn: Neuer Umschau Buchverlag; 2012.

Deutsches Krebsforschungszentrum: Schutz der Familie vor Tabakrauch. 2010.

Dietz PM, Callaghan WM, Sharma AJ: High pregnancy weight gain and risk of excessive fetal growth. American journal of obstetrics and gynecology 2009, 201:51.e1-6.

Dietz PM, England LJ, Shapiro-Mendoza CK et al.: Infant morbidity and mortality attributable to prenatal smoking in the U.S. American journal of preventive medicine 2010, 39:45-52.

Dodd J & Thangaratinam S: Researchers' position statement on tackling obesity in pregnancy: the International Weight Management in Pregnancy (i-WIP) collaboration pleads for public health intervention. BJOG: an international journal of obstetrics and gynaecology 2016, 123:163-164.

Dodd JM, Crowther CA, Robinson JS: Dietary and lifestyle interventions to limit weight gain during pregnancy for obese or overweight women. A systematic review. Acta obstetricia et gynecologica Scandinavica 2008, 87:702-706.

Dodd JM, Grivell RM, Crowther CA et al.: Antenatal interventions for overweight or obese pregnant women. A systematic review of randomised trials. BJOG: an international journal of obstetrics and gynaecology 2010, 117:1316-1326.

Dodd JM, Grivell RM, Nguyen AM et al.: Maternal and perinatal health outcomes by body mass index category. The Australian & New Zealand journal of obstetrics & gynaecology 2011, 51:136-140.

Dodd JM, Turnbull D, McPhee AJ et al.: Antenatal lifestyle advice for women who are overweight or obese. LIMIT randomised trial. BMJ (Clinical research ed.) 2014a, 348:g1285.

Dodd JM, Cramp C, Sui Z et al.: The effects of antenatal dietary and lifestyle advice for women who are overweight or obese on maternal diet and physical activity. The LIMIT randomised trial. BMC medicine 2014b, 12:161.

Dodd JM, McPhee AJ, Turnbull D et al.: The effects of antenatal dietary and lifestyle advice for women who are overweight or obese on neonatal health outcomes. The LIMIT randomised trial. BMC medicine 2014c, 12:163.

Dodd JM & Briley AL: Managing obesity in pregnancy - An obstetric and midwifery perspective. Midwifery 2017, 49:7-12.

Dolatkhah N, Hajifaraji M, Abbasalizadeh F et al.: Is there a value for probiotic supplements in gestational diabetes mellitus? A randomized clinical trial. Journal of health, population, and nutrition 2015, 33:25.

Donner A & Klar N: Design and analysis of cluster randomization trials in health research. Chichester: Wiley & Sons; 2000a.

Donner A & Klar N: Design and analysis of cluster randomization trials in health research. Chichester: Wiley & Sons; 2000b.

Dudenhausen JW, Grünebaum A, Kirschner W: Prepregnancy body weight and gestational weight gain-recommendations and reality in the USA and in Germany. American journal of obstetrics and gynecology 2015, 213:591-592.

Duhl AJ, Paidas MJ, Ural SH et al.: Antithrombotic therapy and pregnancy. Consensus report and recommendations for prevention and treatment of venous thromboembolism and adverse pregnancy outcomes. American journal of obstetrics and gynecology 2007, 197:457.e1-21.

Dutton H, Borengasser SJ, Gaudet LM et al.: Obesity in Pregnancy. Optimizing Outcomes for Mom and Baby. The Medical clinics of North America 2018, 102:87-106.

Ehrenberg HM, Mercer BM, Catalano PM: The influence of obesity and diabetes on the prevalence of macrosomia. American journal of obstetrics and gynecology 2004, 191:964-968.

Ehrlich SF, Hedderson MM, Feng J et al.: Change in body mass index between pregnancies and the risk of gestational diabetes in a second pregnancy. Obstetrics and gynecology 2011, 117:1323-1330.

Elliott-Sale KJ, Barnett CT, Sale C: Exercise interventions for weight management during pregnancy and up to 1 year postpartum among normal weight, overweight and obese women. A systematic review and meta-analysis. British journal of sports medicine 2015, 49:1336-1342.

Ensenauer R, Chmitorz A, Riedel C et al.: Effects of suboptimal or excessive gestational weight gain on childhood overweight and abdominal adiposity: results from a retrospective cohort study. International journal of obesity 2013, 37:505-512.

Ensenauer R, Brandlhuber L, Burgmann M et al.: Obese Nondiabetic Pregnancies and High Maternal Glycated Hemoglobin at Delivery as an Indicator of Offspring and Maternal Postpartum Risks. The Prospective PEACHES Mother-Child Cohort. Clinical chemistry 2015, 61:1381-1390.

European Perinatal Health Report (2010): Health and Care of Pregnant Women and Babies in Europe in 2010. www.europeristat.com/images/European%20Perinatal%20Health%20Report_2010.pdf; 11.06.2018.

Faucher MA & Barger MK: Gestational weight gain in obese women by class of obesity and select maternal/newborn outcomes. A systematic review. Women and birth: journal of the Australian College of Midwives 2015, 28:e70-9.

Fealy SM, Taylor RM, Foureur M et al.: Weighing as a stand-alone intervention does not reduce excessive gestational weight gain compared to routine antenatal care. A systematic review and meta-analysis of randomised controlled trials. BMC pregnancy and childbirth 2017, 17:36.

Ferrari N, Mallmann P, Brockmeier K et al.: Secular trends in pregnancy weight gain in German women and their influences on foetal outcome: a hospital-based study. BMC pregnancy and childbirth 2014, 14:228.

Flynn AC, Dalrymple K, Barr S et al.: Dietary interventions in overweight and obese pregnant women. A systematic review of the content, delivery, and outcomes of randomized controlled trials. Nutrition reviews 2016, 74:312-328.

Fontana R & Della Torre S: The Deep Correlation between Energy Metabolism and Reproduction. A View on the Effects of Nutrition for Women Fertility. Nutrients 2016, 8:87.

Forschungsgruppe g/d/p: Apps für Mütter! Nutzung vor, während, nach der Schwangerschaft. Online-Mehrthemenbefragung „Baby-Fokus“
http://survey.gdp-group.com/newsletter/ausgabe_1_2015.html; 13.04.2018

Fraser A, Tilling K, Macdonald-Wallis C et al.: Associations of gestational weight gain with maternal body mass index, waist circumference, and blood pressure measured 16 y after pregnancy: the Avon Longitudinal Study of Parents and Children (ALSPAC). The American journal of clinical nutrition 2011, 93:1285-1292.

Furness PJ, Arden MA, Duxbury AMS et al.: Talking about weight in pregnancy. An exploration of practitioners' and women's perceptions. Journal of Nursing Education and Practice 2015, 5.

Gaillard R, Steegers EAP, Franco OH et al.: Maternal weight gain in different periods of pregnancy and childhood cardio-metabolic outcomes. The Generation R Study. International journal of obesity 2015, 39:677-685.

Gardner B, Wardle J, Poston L et al.: Changing diet and physical activity to reduce gestational weight gain. A meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2011, 12:e602-20.

Garnaes KK, Morkved S, Salvesen O et al.: Exercise Training and Weight Gain in Obese Pregnant Women. A Randomized Controlled Trial (ETIP Trial). PLoS medicine 2016, 13:e1002079.

Gemeinsamer Bundesausschuss: Richtlinien des Gemeinsamen Bundesausschusses über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung („Mutterschafts-Richtlinien“) https://www.g-ba.de/downloads/62-492-1223/Mu-RL_2016-04-21_iK-2016-07-20.pdf; 13.04.2018

Geraghty AA, Lindsay KL, Alberdi G et al.: Nutrition During Pregnancy Impacts Offspring's Epigenetic Status-Evidence from Human and Animal Studies. Nutrition and metabolic insights 2015, 8:41-47.

Gesink Law DC, Maclehose RF, Longnecker MP: Obesity and time to pregnancy. Human reproduction (Oxford, England) 2007, 22:414-420.

Gibson KS, Waters TP, Catalano PM: Maternal weight gain in women who develop gestational diabetes mellitus. Obstetrics and gynecology 2012, 119:560-565.

Gillman MW: Interrupting Intergenerational Cycles of Maternal Obesity. Nestlé Nutrition Institute Workshop Series 2016:59-69.

Godfrey KM & Barker DJ: Fetal nutrition and adult disease. The American journal of clinical nutrition 2000, 71:1344S-52S.

Goldstein R, Teede H, Thangaratinam S et al.: Excess Gestational Weight Gain in Pregnancy and the Role of Lifestyle Intervention. Seminars in reproductive medicine 2016, 34:e14-21.

Goldstein RF, Abell SK, Ranasinha S et al.: Association of Gestational Weight Gain With Maternal and Infant Outcomes. A Systematic Review and Meta-analysis. JAMA 2017, 317:2207-2225.

Graham ML, Strawderman MS, Demment M et al.: Does Usage of an eHealth Intervention Reduce the Risk of Excessive Gestational Weight Gain? Secondary Analysis From a Randomized Controlled Trial. Journal of medical Internet research 2017, 19:e6.

Guelinckx I, Devlieger R, Beckers K et al.: Maternal obesity. Pregnancy complications, gestational weight gain and nutrition. Obesity reviews: an official journal of the International Association for the Study of Obesity 2008, 9:140-150.

Guelinckx I, Devlieger R, Mullie P et al.: Effect of lifestyle intervention on dietary habits, physical activity, and gestational weight gain in obese pregnant women. A randomized controlled trial. The American journal of clinical nutrition 2010, 91:373-380.

Haakstad LAH & Bo K: Effect of regular exercise on prevention of excessive weight gain in pregnancy. A randomised controlled trial. The European journal of contraception & reproductive health care: the official journal of the European Society of Contraception 2011, 16:116-125.

Haftenberger M, Heuer T, Heidemann C et al.: Relative validation of a food frequency questionnaire for national health and nutrition monitoring. Nutrition journal 2010, 9:36.

Hales CN, Barker DJ, Clark PM et al.: Fetal and infant growth and impaired glucose tolerance at age 64. BMJ (Clinical research ed.) 1991, 303:1019-1022.

Hales CN & Barker DJ: Type 2 (non-insulin-dependent) diabetes mellitus: the thrifty phenotype hypothesis. Diabetologia 1992, 35:595-601.

Halkjaer SI, Nilas L, Carlsen EM et al.: Effects of probiotics (Vivomixx(R)) in obese pregnant women and their newborn. Study protocol for a randomized controlled trial. Trials 2016, 17:491.

Hamad R, Cohen AK, Rehkopf DH: Changing national guidelines is not enough. The impact of 1990 IOM recommendations on gestational weight gain among US women. International journal of obesity 2016, 40:1529-1534.

Hannan PJ, Murray DM, Jacobs DR, JR et al.: Parameters to aid in the design and analysis of community trials. Intraclass correlations from the Minnesota Heart Health Program. Epidemiology (Cambridge, Mass.) 1994, 5:88-95.

Han S, Middleton P, Crowther CA: Exercise for pregnant women for preventing gestational diabetes mellitus. The Cochrane database of systematic reviews 2012:CD009021.

Hanson M, Barker M, Dodd JM et al.: Interventions to prevent maternal obesity before conception, during pregnancy, and post partum. The Lancet. Diabetes & Endocrinology 2017, 5:65-76.

Harder T, Rodekamp E, Schellong K et al.: Birth weight and subsequent risk of type 2 diabetes: a meta-analysis. American journal of epidemiology 2007a, 165:849-857.

Harder T, Schellong K, Stupin J et al.: Where is the evidence that low birthweight leads to obesity? Lancet (London, England) 2007b, 369:1859.

Harrison CL, Lombard CB, Strauss BJ et al.: Optimizing healthy gestational weight gain in women at high risk of gestational diabetes. A randomized controlled trial. Obesity (Silver Spring, Md.) 2013, 21:904-909.

Hassan MAM & Killick SR: Negative lifestyle is associated with a significant reduction in fecundity. Fertility and sterility 2004, 81:384-392.

Haugen M, Brantsæter AL, Winkvist A et al.: Associations of pre-pregnancy body mass index and gestational weight gain with pregnancy outcome and postpartum weight retention. A prospective observational cohort study. BMC pregnancy and childbirth 2014, 14:201.

Hawkins M, Hosker M, Marcus BH et al.: A pregnancy lifestyle intervention to prevent gestational diabetes risk factors in overweight Hispanic women. A feasibility randomized controlled trial. Diabetic medicine: a journal of the British Diabetic Association 2015, 32:108-115.

Hayman M, Reaburn P, Browne M et al.: Feasibility, acceptability and efficacy of a web-based computer-tailored physical activity intervention for pregnant women - the Fit4Two randomised controlled trial. BMC pregnancy and childbirth 2017, 17:96.

Headen I, Cohen AK, Mujahid M et al.: The accuracy of self-reported pregnancy-related weight. A systematic review. Obesity reviews: an official journal of the International Association for the Study of Obesity 2017, 18:350-369.

Healthy Start - Young Family Network (2011a): Aufkleber: Was Babys brauchen. https://ble-medienservice.de/3805/Was-Babys-brauchen-Kinderuntersuchungsheft-Aufkleber; 13.04.2018.

Healthy Start - Young Family Network (2011b): Mama, das wünsch' ich mir von dir! Aufkleber für den Mutterpass. https://ble-medienservice.de/3330/Mama-das-wuensch-ich-mir-von-Dir-Mutterpass-Aufkleber; 11.06.2018.

Healthy Start - Young Family Network (2012a): Fit durch die Schwangerschaft. Flyer für die Elternberatung. https://gesund-ins-leben.de/fuer-fachkraefte/medien-materialien/schwangerschaft/fit-durch-die-schwangerschaft/; 13.04.2018.

Healthy Start - Young Family Network (2012b): Stillflyer: Stillen - Was sonst? https://ble-medienservice.de/0340/Stillen-was-sonst; 11.06.2018.

Healthy Start - Young Family Network (2014a): Ernährung und Bewegung in der Schwangerschaft – Referentenhandbuch zur Multiplikatorenfortbildung. https://www.gesund-ins-leben.de/_data/files/fortbildung_schwangerschaft_referentenhandbuch.pdf; 11.06.2018.

Healthy Start - Young Family Network (2014b): Ernährung und Bewegung in der Schwangerschaft – Präsentationstafeln für die Elternberatung (2014b). http://ble-medienservice.de/3668/Ernaehrung-und-Bewegung-in-der-Schwangerschaft-Praesentationstafeln-fuer-die-Elternberatung; 11.06.2018.

Healthy Start - Young Family Network (2018): Fortbildungsunterlagen - Ernährung und Bewegung in der Schwangerschaft. https://www.gesund-ins-leben.de/inhalt/fortbildungsunterlagen-29516.html; 11.06.2018

Hedderson MM, Weiss NS, Sacks DA et al.: Pregnancy weight gain and risk of neonatal complications: macrosomia, hypoglycemia, and hyperbilirubinemia. Obstetrics and gynecology 2006, 108:1153-1161.

Hedderson MM, Gunderson EP, Ferrara A: Gestational weight gain and risk of gestational diabetes mellitus. Obstetrics and gynecology 2010, 115:597-604.

Helmholtz Zentrum München - Deutsches Forschungszentrum für Gesundheit und Umwelt: KORA. Kooperative Gesundheitsforschung in der Region Augsburg: KORA Startseite https://www.helmholtz-muenchen.de/kora; 13.04.2018

Helms E, Coulson CC, Galvin SL: Trends in weight gain during pregnancy: a population study across 16 years in North Carolina. American journal of obstetrics and gynecology 2006, 194:e32-4.

Hendler I, Blackwell SC, Bujold E et al.: The impact of maternal obesity on midtrimester sonographic visualization of fetal cardiac and craniospinal structures. International journal of obesity and related metabolic disorders: journal of the International Association for the Study of Obesity 2004, 28:1607-1611.

Herring SJ, Oken E, Rifas-Shiman SL et al.: Weight gain in pregnancy and risk of maternal hyperglycemia. American journal of obstetrics and gynecology 2009, 201:61.e1-7.

Herring SJ, Cruice JF, Bennett GG et al.: Preventing excessive gestational weight gain among African American women. A randomized clinical trial. Obesity (Silver Spring, Md.) 2016, 24:30-36.

Heslehurst N, Simpson H, Ells LJ et al.: The impact of maternal BMI status on pregnancy outcomes with immediate short-term obstetric resource implications: a meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2008, 9:635-683.

Heslehurst N, Moore H, Rankin J et al.: How can maternity services be developed to effectively address maternal obesity? A qualitative study. Midwifery 2011, 27:e170-7.

Heslehurst N, Newham J, Maniatopoulos G et al.: Implementation of pregnancy weight management and obesity guidelines. A meta-synthesis of healthcare professionals' barriers and facilitators using the Theoretical Domains Framework. Obesity reviews: an official journal of the International Association for the Study of Obesity 2014a, 15:462-486.

Heslehurst N, Crowe L, Robalino S et al.: Interventions to change maternity healthcare professionals' behaviours to promote weight-related support for obese pregnant women. A systematic review. Implementation science: IS 2014b, 9:97.

Hill B, Skouteris H, Fuller-Tyszkiewicz M: Interventions designed to limit gestational weight gain. A systematic review of theory and meta-analysis of intervention components. Obesity reviews: an official journal of the International Association for the Study of Obesity 2013, 14:435-450.

Hill B, Skouteris H, Fuller-Tyszkiewicz M et al.: Can a health coaching intervention delivered during pregnancy help prevent excessive gestational weight gain? Journal of behavioral medicine 2016, 39:793-803.

Hill B, McPhie S, Moran LJ et al.: Lifestyle intervention to prevent obesity during pregnancy. Implications and recommendations for research and implementation. Midwifery 2017:13-18.

Hivert M, Rifas-Shiman SL, Gillman MW et al.: Greater early and mid-pregnancy gestational weight gains are associated with excess adiposity in mid-childhood. Obesity (Silver Spring) 2016, 24:1546-1553.

Hoffmann JR: GeliS (Healthy living in pregnancy): Evaluation of a lifestyle intervention programme - Implementation of counselling sessions into standard antenatal care. Master`s Thesis 2014.

Holland E, Moore Simas TA, Doyle Curiale DK et al.: Self-reported pre-pregnancy weight versus weight measured at first prenatal visit. Effects on categorization of pre-pregnancy body mass index. Maternal and child health journal 2013, 17:1872-1878.

Huang TT, Yeh CY, Tsai YC: A diet and physical activity intervention for preventing weight retention among Taiwanese childbearing women. A randomised controlled trial. Midwifery 2011, 27:257-264.

Hui A, Back L, Ludwig S et al.: Lifestyle intervention on diet and exercise reduced excessive gestational weight gain in pregnant women under a randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2012, 119:70-77.

Hytten FE & Leitch I: The physiology of human pregnancy. 2nd edition. Oxford: Blackwell Scientific Publ; 1971.

Institute of Medicine (US) Committee on Nutritional Status During Pregnancy and Lactation: Nutrition during pregnancy: Part I, weight gain: part II, nutrient supplements. Washington, D.C: National Academy Press; 1990.

IQTIG – Institut für Qualitätssicherung und Transparenz im Gesundheitswesen: Bundesauswertung zum Erfassungsjahr 2016. Geburtshilfe 2017.

Jackson RA, Stotland NE, Caughey AB et al.: Improving diet and exercise in pregnancy with Video Doctor counseling. A randomized trial. Patient education and counseling 2011, 83:203-209.

Jain AP, Gavard JA, Rice JJ et al.: The impact of interpregnancy weight change on birthweight in obese women. American journal of obstetrics and gynecology 2013, 208:205.e1-7.

Jersey SJ de, Nicholson JM, Callaway LK et al.: A prospective study of pregnancy weight gain in Australian women. The Australian & New Zealand journal of obstetrics & gynaecology 2012, 52:545-551.

Johnson JL, Farr SL, Dietz PM et al.: Trends in gestational weight gain: the Pregnancy Risk Assessment Monitoring System, 2000-2009. American journal of obstetrics and gynecology 2015, 212:806.e1-8.

Jovanovic-Peterson L, Peterson CM, Reed GF et al.: Maternal postprandial glucose levels and infant birth weight: the Diabetes in Early Pregnancy Study. The National Institute of Child Health and Human Development--Diabetes in Early Pregnancy Study. American journal of obstetrics and gynecology 1991, 164:103-111.

Kaar JL, Crume T, Brinton JT et al.: Maternal obesity, gestational weight gain, and offspring adiposity: the exploring perinatal outcomes among children study. The Journal of pediatrics 2014, 165:509-515.

KErn – Kompetenzzentrum für Ernährung & Stiftung Kindergesundheit (2018): Die App-Trilogie - Für Schwangere und junge Familien zu den Themen gesunde Ernährung und Bewegung. https://www.familie-gesund-ernaehrt.de/; 11.06.2018.

Kim SS, Zhu Y, Grantz KL et al.: Obstetric and Neonatal Risks Among Obese Women Without Chronic Disease. Obstetrics and gynecology 2016, 128:104-112.

Kim SY, Sharma AJ, Callaghan WM: Gestational diabetes and childhood obesity: what is the link? Current opinion in obstetrics & gynecology 2012, 24:376-381.

Kinnunen TI, Aittasalo M, Koponen P et al.: Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care. BMC pregnancy and childbirth 2008, 8:37.

Kleinwechter H, Schäfer-Graf U, Bührer C et al.: Gestationsdiabetes mellitus (GDM) –Diagnostik, Therapie und Nachsorge. Praxisleitlinie der Deutschen Diabetes Gesellschaft (DDG) und der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG). Diabetologie und Stoffwechsel 2016, 11:S182-S194.

Knabl J, Riedel C, Gmach J et al.: Prediction of excessive gestational weight gain from week-specific cutoff values. A cohort study. Journal of perinatology: official journal of the California Perinatal Association 2014, 34:351-356.

Koivusalo SB, Rono K, Klemetti MM et al.: Gestational Diabetes Mellitus Can Be Prevented by Lifestyle Intervention. The Finnish Gestational Diabetes Prevention Study (RADIEL): A Randomized Controlled Trial. Diabetes care 2015, 39:24-30.

Koletzko B, Bauer CP, Bung P et al.: German national consensus recommendations on nutrition and lifestyle in pregnancy by the Healthy Start - Young Family Network. Annals of nutrition & metabolism 2013a, 63:311-322.

Koletzko B, Bauer C-P, Brönstrup A et al.: Säuglingsernährung und Ernährung der stillenden Mutter. Monatsschrift Kinderheilkunde 2013b, 161:237-246.

Koletzko B, Cremer M, Flothkötter M et al.: Diet and Lifestyle Before and During Pregnancy – Practical Recommendations of the Germany-wide Healthy Start – Young Family Network. Geburtshilfe und Frauenheilkunde 2018, 78:1–21.

Kolpik P, Nolting H-D, Zich K.: Faktencheck Gesundheit. Kaiserschnittgeburten – Entwicklung und regionale Verteilung. 1st edition 2012, https://faktencheck-gesundheit.de/de/publikationen/publikation/did/faktencheck-gesundheit-kaiserschnitt. 21.08.2018.

Kominiarek MA, Seligman NS, Dolin C et al.: Gestational weight gain and obesity. Is 20 pounds too much? American journal of obstetrics and gynecology 2013, 209:214.e1-11.

Kominiarek MA & Peaceman AM: Gestational weight gain. American journal of obstetrics and gynecology 2017.

Korpi-Hyovalti EAL, Laaksonen DE, Schwab US et al.: Feasibility of a lifestyle intervention in early pregnancy to prevent deterioration of glucose tolerance. BMC Public Health 2011, 11:179.

Kries R von, **Ensenauer R, Beyerlein A et al.**: Gestational weight gain and overweight in children: Results from the cross-sectional German KiGGS study. International journal of pediatric obesity: IJPO: an official journal of the International Association for the Study of Obesity 2011, 6:45-52.

Kuntz B, Zeiher J, Starker A et al.: Rauchen in der Schwangerschaft – Querschnittergebnisse aus KiGGS Welle 2 und Trends. Journal of Health Monitoring 2018, 3:47-54.

Kwik M, Seeho SKM, Smith C et al.: Outcomes of pregnancies affected by impaired glucose tolerance. Diabetes research and clinical practice 2007, 77:263-268.

Laitinen J, Jaaskelainen A, Hartikainen AL et al.: Maternal weight gain during the first half of pregnancy and offspring obesity at 16 years. A prospective cohort study. BJOG: an international journal of obstetrics and gynaecology 2012, 119:716-723.

Lally P, van Jaarsveld CHM, Potts HWW et al.: How are habits formed. Modelling habit formation in the real world. European Journal of Social Psychology 2010, 40:998-1009.

Langer O, Yogev Y, Xenakis, Elly M J et al.: Overweight and obese in gestational diabetes: the impact on pregnancy outcome. American journal of obstetrics and gynecology 2005, 192:1768-1776.

Lau C, Rogers JM, Desai M et al.: Fetal programming of adult disease: implications for prenatal care. Obstetrics and gynecology 2011, 117:978-985.

Lau EY, Liu J, Archer E et al.: Maternal weight gain in pregnancy and risk of obesity among offspring: a systematic review. Journal of obesity 2014, 2014:524939.

Lau Y, Klainin-Yobas P, Htun TP et al.: Electronic-based lifestyle interventions in overweight or obese perinatal women. A systematic review and meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2017, 18:1071-1087.

Lederman SA, Paxton A, Heymsfield SB et al.: Body fat and water changes during pregnancy in women with different body weight and weight gain. Obstetrics and gynecology 1997, 90:483-488.

Lee ACC, Katz J, Blencowe H et al.: National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. The Lancet. Global health 2013, 1:e26-36.

Lee AJ, Hiscock RJ, Wein P et al.: Gestational diabetes mellitus. Clinical predictors and long-term risk of developing type 2 diabetes: a retrospective cohort study using survival analysis. Diabetes care 2007, 30:878-883.

Li M, Sloboda DM, Vickers MH: Maternal obesity and developmental programming of metabolic disorders in offspring. Evidence from animal models. Experimental diabetes research 2011, 2011:592408.

Lim S, O'Reilly S, Behrens H et al.: Effective strategies for weight loss in post-partum women. A systematic review and meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2015, 16:972-987.

Li N, Liu E, Guo J et al.: Maternal prepregnancy body mass index and gestational weight gain on pregnancy outcomes. PloS one 2013, 8:e82310.

Linares J, Corvalan C, Galleguillos B et al.: The effects of pre-pregnancy BMI and maternal factors on the timing of adiposity rebound in offspring. Obesity (Silver Spring, Md.) 2016, 24:1313-1319.

Lindberg S, Anderson C, Pillai P et al.: Prevalence and Predictors of Unhealthy Weight Gain in Pregnancy. WMJ: official publication of the State Medical Society of Wisconsin 2016, 115:233-237.

Lindhardt CL, Rubak S, Mogensen O et al.: The experience of pregnant women with a body mass index 30 kg/m² of their encounters with healthcare professionals. Acta obstetricia et gynecologica Scandinavica 2013, 92:1101-1107.

Lindsay KL, Walsh CA, Brennan L et al.: Probiotics in pregnancy and maternal outcomes. A systematic review. The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 2013, 26:772-778.

Ludwig DS & Currie J: The association between pregnancy weight gain and birthweight: a within-family comparison. Lancet (London, England) 2010, 376:984-990.

Luoto R, Kinnunen TI, Aittasalo M et al.: Primary prevention of gestational diabetes mellitus and large-for-gestational-age newborns by lifestyle counseling. A cluster-randomized controlled trial. PLoS medicine 2011, 8:e1001036.

Luoto RM, Kinnunen TI, Aittasalo M et al.: Prevention of gestational diabetes: design of a cluster-randomized controlled trial and one-year follow-up. BMC pregnancy and childbirth 2010, 10:39.

MacDonald SC, Bodnar LM, Himes KP et al.: Patterns of Gestational Weight Gain in Early Pregnancy and Risk of Gestational Diabetes Mellitus. Epidemiology (Cambridge, Mass.) 2017, 28:419-427.

MacInnis N, Woolcott CG, McDonald S et al.: Population Attributable Risk Fractions of Maternal Overweight and Obesity for Adverse Perinatal Outcomes. Scientific reports 2016, 6:22895.

Mamun AA, O'Callaghan M, Callaway L et al.: Associations of gestational weight gain with offspring body mass index and blood pressure at 21 years of age: evidence from a birth cohort study. Circulation 2009, 119:1720-1727.

Mamun AA, Kinarivala M, O'Callaghan MJ et al.: Associations of excess weight gain during pregnancy with long-term maternal overweight and obesity: evidence from 21 y postpartum follow-up. The American journal of clinical nutrition 2010, 91:1336-1341.

Mamun AA, Mannan M, Doi SAR: Gestational weight gain in relation to offspring obesity over the life course: a systematic review and bias-adjusted meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2014, 15:338-347.

Mandujano A, Huston-Presley L, Waters TP et al.: Women's reported weight. Is there a discrepancy? The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 2012, 25:1395-1398.

Mannan M, Doi SAR, Mamun AA: Association between weight gain during pregnancy and postpartum weight retention and obesity: a bias-adjusted meta-analysis. Nutrition reviews 2013, 71:343-352.

Marchi J, Berg M, Dencker A et al.: Risks associated with obesity in pregnancy, for the mother and baby: a systematic review of reviews. Obesity reviews: an official journal of the International Association for the Study of Obesity 2015, 16:621-638.

Margerison Zilko CE, Rehkopf D, Abrams B: Association of maternal gestational weight gain with short- and long-term maternal and child health outcomes. American journal of obstetrics and gynecology 2010, 202:574.e1-8.

Max Rubner-Institut - Bundesforschungsinstitut für Ernährung und Lebensmittel: Ergebnisbericht Teil 2 - Nationale Verzehrsstudie 2 2008.

McDonald SD, Pullenayegum E, Taylor VH et al.: Despite 2009 guidelines, few women report being counseled correctly about weight gain during pregnancy. American journal of obstetrics and gynecology 2011a, 205:333.e1-6.

McDonald SD, Han Z, Mulla S et al.: High gestational weight gain and the risk of preterm birth and low birth weight: a systematic review and meta-analysis. Journal of obstetrics and gynaecology Canada 2011b, 33:1223-1233.

Melchior H, Kurch-Bek D, Mund M: The Prevalence of Gestational Diabetes. Deutsches Ärzteblatt international 2017, 114:412-418.

Metzger BE, Gabbe SG, Persson B et al.: International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes care 2010, 33:676-682.

Moll U, Olsson H, Landin-Olsson M: Impact of Pregestational Weight and Weight Gain during Pregnancy on Long-Term Risk for Diseases. PloS one 2017, 12:e0168543.

Molyneaux E, Poston L, Ashurst-Williams S et al.: Obesity and mental disorders during pregnancy and postpartum. A systematic review and meta-analysis. Obstetrics and gynecology 2014, 123:857-867.

Moreira P, Padez C, Mourão-Carvalhal I et al.: Maternal weight gain during pregnancy and overweight in Portuguese children. International journal of obesity 2007, 31:608-614.

Moses RG, Casey SA, Quinn EG et al.: Pregnancy and Glycemic Index Outcomes study. Effects of low glycemic index compared with conventional dietary advice on selected pregnancy outcomes. The American journal of clinical nutrition 2014, 99:517-523.

Mostello D, Jen Chang J, Allen J et al.: Recurrent preeclampsia. The effect of weight change between pregnancies. Obstetrics and gynecology 2010, 116:667-672.

Muktabhant B, Lawrie TA, Lumbiganon P et al.: Diet or exercise, or both, for preventing excessive weight gain in pregnancy. The Cochrane database of systematic reviews 2015:CD007145.

Nascimento SL, Pudwell J, Surita FG et al.: The effect of physical exercise strategies on weight loss in postpartum women. A systematic review and meta-analysis. International journal of obesity 2014, 38:626-635.

National Institute for Health and Care Excellence: Weight management before, during and after pregnancy (PH27) 2010.

NCD Risk Factor Collaboration: Trends in adult body-mass index in 200 countries from 1975 to 2014: a pooled analysis of 1698 population-based measurement studies with 19·2 million participants. Lancet (London, England) 2016, 387:1377-1396.

Nehring I, Schmoll S, Beyerlein A et al.: Gestational weight gain and long-term postpartum weight retention. A meta-analysis. The American journal of clinical nutrition 2011, 94:1225-1231.

Nehring I, Lehmann S, Kries R von: Gestational weight gain in accordance to the IOM/NRC criteria and the risk for childhood overweight: a meta-analysis. Pediatric obesity 2013, 8:218-224.

Neiger R: Fetal macrosomia in the diabetic patient. Clinical obstetrics and gynecology 1992, 35:138-150.

Nelson SM, Matthews P, Poston L: Maternal metabolism and obesity. Modifiable determinants of pregnancy outcome. Human reproduction update 2010, 16:255-275.

Nicholson WK, Beckham AJ, Hatley K et al.: The Gestational Diabetes Management System (GooDMomS). Development, feasibility and lessons learned from a patient-informed, web-based pregnancy and postpartum lifestyle intervention. BMC pregnancy and childbirth 2016, 16:277.

Nikolopoulos H, Mayan M, MacIsaac J et al.: Women's perceptions of discussions about gestational weight gain with health care providers during pregnancy and postpartum. A qualitative study. BMC pregnancy and childbirth 2017, 17:97.

Nitert MD, Barrett HL, Foxcroft K et al.: SPRING. An RCT study of probiotics in the prevention of gestational diabetes mellitus in overweight and obese women. BMC pregnancy and childbirth 2013, 13:50.

Nobles C, Marcus BH, Stanek EJ et al.: The Effect of an Exercise Intervention on Gestational Weight Gain. The Behaviors Affecting Baby and You (B.A.B.Y.) Study: A Randomized Controlled Trial. American journal of health promotion 2017:890117117732409.

Nohr EA, Vaeth M, Baker JL et al.: Combined associations of prepregnancy body mass index and gestational weight gain with the outcome of pregnancy. The American journal of clinical nutrition 2008, 87:1750-1759.

Nommsen-Rivers LA, Chantry CJ, Peerson JM et al.: Delayed onset of lactogenesis among first-time mothers is related to maternal obesity and factors associated with ineffective breastfeeding. The American journal of clinical nutrition 2010, 92:574-584.

O'Brien CM, Grivell RM, Dodd JM: Systematic review of antenatal dietary and lifestyle interventions in women with a normal body mass index. Acta obstetricia et gynecologica Scandinavica 2016, 95:259-269.

O'Brien EC, Alberdi G, McAuliffe FM: The influence of socioeconomic status on gestational weight gain. A systematic review. Journal of public health (Oxford, England) 2017, 40:41-55.

O'Brien OA, McCarthy M, Gibney ER et al.: Technology-supported dietary and lifestyle interventions in healthy pregnant women. A systematic review. European journal of clinical nutrition 2014, 68:760-766.

Oken E & Gillman MW: Fetal origins of obesity. Obesity research 2003, 11:496-506.

Oken E, Taveras EM, Kleinman KP et al.: Gestational weight gain and child adiposity at age 3 years. American journal of obstetrics and gynecology 2007, 196:322.e1-8.

Oken E, Rifas-Shiman SL, Field AE et al.: Maternal gestational weight gain and offspring weight in adolescence. Obstetrics and gynecology 2008, 112:999-1006.

Okesene-Gafa K, Li M, Taylor RS et al.: A randomised controlled demonstration trial of multifaceted nutritional intervention and or probiotics. The healthy mums and babies (HUMBA) trial. BMC pregnancy and childbirth 2016, 16:373.

Olander EK, Atkinson L, Edmunds JK et al.: The views of pre- and post-natal women and health professionals regarding gestational weight gain. An exploratory study. Sexual & reproductive healthcare: official journal of the Swedish Association of Midwives 2011, 2:43-48.

Olson CM, Strawderman MS, Dennison BA: Maternal weight gain during pregnancy and child weight at age 3 years. Maternal and child health journal 2009, 13:839-846.

Oteng-Ntim E, Varma R, Croker H et al.: Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome. Systematic review and meta-analysis. BMC medicine 2012, 10:47.

Overdijkink SB, Velu AV, Rosman AN et al.: The usability and effectiveness of mobile health technology-based lifestyle and medical intervention apps supporting health care during pregnancy: systematic review. Journal of Medical Internet Research mHealth and uHealth 2018, 6:e109.

Patel N, Godfrey KM, Pasupathy D et al.: Infant adiposity following a randomised controlled trial of a behavioural intervention in obese pregnancy. International journal of obesity 2017, 41:1018-1026.

Phelan S: Pregnancy: a "teachable moment" for weight control and obesity prevention. American journal of obstetrics and gynecology 2010, 202:135.e1-8.

Phelan S, Phipps MG, Abrams B et al.: Randomized trial of a behavioral intervention to prevent excessive gestational weight gain. The Fit for Delivery Study. The American journal of clinical nutrition 2011, 93:772-779.

Phelan S: Windows of Opportunity for Lifestyle Interventions to Prevent Gestational Diabetes Mellitus. American journal of perinatology 2016, 33:1291-1299.

Philipps LH, Santhakumaran S, Gale C et al.: The diabetic pregnancy and offspring BMI in childhood: a systematic review and meta-analysis. Diabetologia 2011, 54:1957-1966.

Plagemann A: Fetal programming and functional teratogenesis: on epigenetic mechanisms and prevention of perinatally acquired lasting health risks. Journal of perinatal medicine 2004, 32:297-305.

Plagemann A & Harder T: Premature birth and insulin resistance. The New England journal of medicine 2005, 352:939-40.

Polley BA, Wing RR, Sims CJ: Randomized controlled trial to prevent excessive weight gain in pregnant women. International journal of obesity and related metabolic disorders: journal of the International Association for the Study of Obesity 2002, 26:1494-1502.

Poobalan AS, Aucott LS, Gurung T et al.: Obesity as an independent risk factor for elective and emergency caesarean delivery in nulliparous women--systematic review and meta-analysis of

cohort studies. Obesity reviews: an official journal of the International Association for the Study of Obesity 2009, 10:28-35.

Poston L: Developmental programming and diabetes - The human experience and insight from animal models. Best practice & research. Clinical endocrinology & metabolism 2010, 24:541-552.

Poston L: Gestational weight gain: influences on the long-term health of the child. Current opinion in clinical nutrition and metabolic care 2012, 15:252-257.

Poston L & Chappell LC: How should women be advised on weight management in pregnancy? BMJ (Clinical research ed.) 2012, 344:e2774.

Poston L, Bell R, Croker H et al.: Effect of a behavioural intervention in obese pregnant women (the UPBEAT study). A multicentre, randomised controlled trial. The Lancet Diabetes & Endocrinology 2015, 3:767-777.

Poston L, Caleyachetty R, Cnattingius S et al.: Preconceptional and maternal obesity. Epidemiology and health consequences. The lancet. Diabetes & endocrinology 2016, 4:1025-1036.

Poston L: Obesity in pregnancy; Where are we, where should we go? Midwifery 2017, 49:4-6.

Power ML, Cogswell ME, Schulkin J: US obstetrician-gynaecologist's prevention and management of obesity in pregnancy. Journal of obstetrics and gynaecology: the journal of the Institute of Obstetrics and Gynaecology 2009, 29:373-377.

Quinlivan JA, Lam LT, Fisher J: A randomised trial of a four-step multidisciplinary approach to the antenatal care of obese pregnant women. The Australian & New Zealand journal of obstetrics & gynaecology 2011, 51:141-146.

Rasmussen KM & Yaktine AL. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines: Weight Gain During Pregnancy: Reexamining the Guidelines. Washington, DC: The National Academies Press; 2009.

Rauh K, Gabriel E, Kerschbaum E et al.: Safety and efficacy of a lifestyle intervention for pregnant women to prevent excessive maternal weight gain. A cluster-randomized controlled trial. BMC pregnancy and childbirth 2013, 13:151.

Rauh K, Kunath J, Rosenfeld E et al.: Healthy living in pregnancy. A cluster-randomized controlled trial to prevent excessive gestational weight gain - rationale and design of the GeliS study. BMC pregnancy and childbirth 2014, 14:119.

Rauh K, Guenther J, Kunath J et al.: Lifestyle intervention to prevent excessive maternal weight gain. Mother and infant follow-up at 12 months postpartum. BMC pregnancy and childbirth 2015, 15:265.

Ravelli AC, van der Meulen, J H, **Osmond C et al.**: Obesity at the age of 50 y in men and women exposed to famine prenatally. The American journal of clinical nutrition 1999, 70:811-816.

Ravelli GP, Stein ZA, Susser MW: Obesity in young men after famine exposure in utero and early infancy. The New England journal of medicine 1976, 295:349-353.

Ray JG, Wyatt PR, Vermeulen MJ et al.: Greater maternal weight and the ongoing risk of neural tube defects after folic acid flour fortification. Obstetrics and gynecology 2005, 105:261-265.

Redman LM, Gilmore LA, Breaux J et al.: Effectiveness of SmartMoms, a Novel eHealth Intervention for Management of Gestational Weight Gain. Randomized Controlled Pilot Trial. Journal of Medical Internet Research mHealth and uHealth 2017, 5:e133.

Renault KM, Norgaard K, Nilas L et al.: The Treatment of Obese Pregnant Women (TOP) study. A randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. American journal of obstetrics and gynecology 2014, 210:134.e1-9.

Reynolds RM, Osmond C, Phillips DIW et al.: Maternal BMI, parity, and pregnancy weight gain: influences on offspring adiposity in young adulthood. The Journal of clinical endocrinology and metabolism 2010, 95:5365-5369.

Robert Koch-Institut: Welcher Zusammenhang besteht zwischen der sozialen und gesundheitlichen Lage in den neuen und alten Bundesländern? GBE-Beitrag 2009, www.gbe-bund.de/pdf/Kapitel_7.pdf; 31.05.2018.

Rode L, Kjærgaard H, Ottesen B et al.: Association between gestational weight gain according to body mass index and postpartum weight in a large cohort of Danish women. Maternal and Child Health Journal 2012, 16:406-13.

Rogers JM: Tobacco and pregnancy. Overview of exposures and effects. Birth defects research. Part C, Embryo today: reviews 2008, 84:1-15.

Rogozinska E, Chamillard M, Hitman GA et al.: Nutritional manipulation for the primary prevention of gestational diabetes mellitus. A meta-analysis of randomised studies. PloS one 2015, 10:e0115526.

Rogozińska E, Marlin N, Jackson L et al.: Effects of antenatal diet and physical activity on maternal and fetal outcomes. Individual patient data meta-analysis and health economic evaluation. Health technology assessment (Winchester, England) 2017, 21:1-158.

Rolland-Cachera MF, Deheeger M, Bellisle F et al.: Adiposity rebound in children. A simple indicator for predicting obesity. The American journal of clinical nutrition 1984, 39:129-135.

Rolland-Cachera MF, Deheeger M, Guilloud-Bataille M et al.: Tracking the development of adiposity from one month of age to adulthood. Annals of human biology 1987, 14:219-229.

Rolland-Cachera MF, Deheeger M, Maillot M et al.: Early adiposity rebound. Causes and consequences for obesity in children and adults. International journal of obesity 2006, 30 Suppl 4:S11-7.

Ronnberg A, Hanson U, Ostlund I et al.: Effects on postpartum weight retention after antenatal lifestyle intervention - a secondary analysis of a randomized controlled trial. Acta obstetricia et gynecologica Scandinavica 2016, 95:999-1007.

Ronnberg AK, Ostlund I, Fadl H et al.: Intervention during pregnancy to reduce excessive gestational weight gain-a randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2015, 122:537-544.

Rooney BL & Schauberger CW: Excess pregnancy weight gain and long-term obesity. One decade later. Obstetrics and gynecology 2002, 100:245-252.

Rooney BL, Schauberger CW, Mathiason MA: Impact of perinatal weight change on long-term obesity and obesity-related illnesses. Obstetrics and gynecology 2005, 106:1349-1356.

Roseboom TJ, van der Meulen JH, Ravelli AC et al.: Effects of prenatal exposure to the Dutch famine on adult disease in later life: an overview. Twin research: the official journal of the International Society for Twin Studies 2001, 4:293-298.

Ruchat S-M, Davenport MH, Giroux I et al.: Nutrition and exercise reduce excessive weight gain in normal-weight pregnant women. Medicine & Science in Sports & Exercise 2012, 44:1419-1426.

Ruchat S-M & Mottola MF: Preventing long-term risk of obesity for two generations. Prenatal physical activity is part of the puzzle. Journal of pregnancy 2012, 2012:470247.

Ruifrok AE, Rogozinska E, van Poppel MNM et al.: Study protocol: differential effects of diet and physical activity based interventions in pregnancy on maternal and fetal outcomes--individual patient data (IPD) meta-analysis and health economic evaluation. Systematic reviews 2014, 3:131.

Sagedal LR, Overby NC, Bere E et al.: Lifestyle intervention to limit gestational weight gain. The Norwegian Fit for Delivery randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2016, 124:97-109.

Salihu HM, La Cruz C de, Rahman S et al.: Does maternal obesity cause preeclampsia? A systematic review of the evidence. Minerva ginecologica 2012, 64:259-280.

Samura T, Steer J, Michelis LD et al.: Factors Associated With Excessive Gestational Weight Gain. Review of Current Literature. Global advances in health and medicine 2016, 5:87-93.

Sanabria-Martinez G, Garcia-Hermoso A, Poyatos-Leon R et al.: Effectiveness of physical activity interventions on preventing gestational diabetes mellitus and excessive maternal weight gain. A meta-analysis. BJOG: an international journal of obstetrics and gynaecology 2015, 122:1167-1174.

Schack-Nielsen L, Michaelsen KF, Gamborg M et al.: Gestational weight gain in relation to offspring body mass index and obesity from infancy through adulthood. International journal of obesity and related metabolic disorders 2010, 34:67-74.

Schellong K, Schulz S, Harder T et al.: Birth weight and long-term overweight risk. Systematic review and a meta-analysis including 643,902 persons from 66 studies and 26 countries globally. PloS one 2012, 7:e47776.

Schienkiewitz A, Brettschneider AK, Damerow S et al.: Übergewicht und Adipositas im Kindes- und Jugendalter in Deutschland – Querschnittergebnisse aus KiGGS Welle 2 und Trends. Journal of Health Monitoring 2018, 3:16-23.

Schiessl B, Beyerlein A, Lack N et al.: Temporal trends in pregnancy weight gain and birth weight in Bavaria 2000-2007: slightly decreasing birth weight with increasing weight gain in pregnancy. Journal of perinatal medicine 2009, 37:374-379.

Schmied VA, Duff M, Dahlen HG et al.: Not waving but drowning: a study of the experiences and concerns of midwives and other health professionals caring for obese childbearing women. Midwifery 2011, 27:424-430.

Schneider S, Maul H, Freerksen N et al.: Who smokes during pregnancy? An analysis of the German Perinatal Quality Survey 2005. Public health 2008, 122:1210-1216.

Scholz R, Voigt M, Schneider KTM et al.: Analysis of the German Perinatal Survey of the Years 2007-2011 and Comparison with Data From 1995-1997. Maternal Characteristics. Geburtshilfe und Frauenheilkunde 2013, 73:1247-1251.

Scott C, Andersen CT, Valdez N et al.: No global consensus. A cross-sectional survey of maternal weight policies. BMC pregnancy and childbirth 2014, 14:167.

Sebire NJ, Jolly M, Harris JP et al.: Maternal obesity and pregnancy outcome: a study of 287,213 pregnancies in London. International journal of obesity and related metabolic disorders: journal of the International Association for the Study of Obesity 2001, 25:1175-1182.

Sedgh G, Singh S, Hussain R: Intended and unintended pregnancies worldwide in 2012 and recent trends. Studies in family planning 2014, 45:301-314.

Sewell MF, Huston-Presley L, Super DM et al.: Increased neonatal fat mass, not lean body mass, is associated with maternal obesity. American journal of obstetrics and gynecology 2006, 195:1100-1103.

Shepherd E, Gomersall JC, Tieu J et al.: Combined diet and exercise interventions for preventing gestational diabetes mellitus. The Cochrane database of systematic reviews 2017, 11:CD010443.

Sherifali D, Nerenberg KA, Wilson S et al.: The Effectiveness of eHealth Technologies on Weight Management in Pregnant and Postpartum Women. Systematic Review and Meta-Analysis. Journal of medical Internet research 2017, 19:e337.

Shub A, Huning EYS, Campbell KJ et al.: Pregnant women's knowledge of weight, weight gain, complications of obesity and weight management strategies in pregnancy. BMC research notes 2013, 6:278.

Simmons D, Devlieger R, van Assche A et al.: Effect of Physical Activity and/or Healthy Eating on GDM Risk. The DALI Lifestyle Study. The Journal of clinical endocrinology and metabolism 2017, 102:903-913.

Skouteris H, Hartley-Clark L, McCabe M et al.: Preventing excessive gestational weight gain. A systematic review of interventions. Obesity reviews: an official journal of the International Association for the Study of Obesity 2010, 11:757-768.

Skouteris H, McPhie S, Hill B et al.: Health coaching to prevent excessive gestational weight gain. A randomized-controlled trial. British journal of health psychology 2016, 21:31-51.

Song C, Li J, Leng J et al.: Lifestyle intervention can reduce the risk of gestational diabetes. A meta-analysis of randomized controlled trials. Obesity reviews: an official journal of the International Association for the Study of Obesity 2016, 17:960-969.

Sonntag D, Ali S, Lehnert T et al.: Estimating the lifetime cost of childhood obesity in Germany. Results of a Markov Model. Pediatric obesity 2015, 10:416-422.

Sonntag D, Ali S, Bock F de: Lifetime indirect cost of childhood overweight and obesity. A decision analytic model. Obesity (Silver Spring, Md.) 2016, 24:200-206.

Statistisches Bundesamt (2013): Geburtentrends und Familiensituation in Deutschland 2012. https://www.destatis.de/DE/Publikationen/Thematisch/Bevoelkerung/HaushalteMikrozensus/Geburtentrends5122203129004.pdf?__blob=publicationFile; 11.06.2018

Stewart ZA, Wallace E, Allan C: Weight gain in pregnancy. A survey of current practices in a teaching hospital. The Australian & New Zealand journal of obstetrics & gynaecology 2012, 52:208-210.

Stothard KJ, Tennant, Peter WG, Bell R et al.: Maternal overweight and obesity and the risk of congenital anomalies: a systematic review and meta-analysis. JAMA 2009, 301:636-650.

Stotland NE, Caughey AB, Breed EM et al.: Risk factors and obstetric complications associated with macrosomia. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 2004, 87:220-226.

Stotland NE, Haas JS, Brawarsky P et al.: Body mass index, provider advice, and target gestational weight gain. Obstetrics and gynecology 2005, 105:633-638.

Streuling I, Beyerlein A, Kries R von: Can gestational weight gain be modified by increasing physical activity and diet counseling? A meta-analysis of interventional trials. The American journal of clinical nutrition 2010, 92:678-687.

Streuling I, Beyerlein A, Rosenfeld E et al.: Physical activity and gestational weight gain. A meta-analysis of intervention trials. BJOG: an international journal of obstetrics and gynaecology 2011, 118:278-284.

Sui Z, Grivell RM, Dodd JM: Antenatal exercise to improve outcomes in overweight or obese women. A systematic review. Acta obstetricia et gynecologica Scandinavica 2012, 91:538-545.

Szwajcer EM, Hiddink GJ, Koelen MA et al.: Nutrition-related information-seeking behaviours before and throughout the course of pregnancy. Consequences for nutrition communication. European journal of clinical nutrition 2005, 59 Suppl 1:S57-65.

Tanentsapf I, Heitmann BL, Adegboye ARA: Systematic review of clinical trials on dietary interventions to prevent excessive weight gain during pregnancy among normal weight, overweight and obese women. BMC pregnancy and childbirth 2011, 11:81.

Teede H & Moran L: Lifestyle Factors Focused on Diet and Physical Activity. Recommendations Preconception and During Pregnancy. Seminars in reproductive medicine 2016, 34:65-66.

Thangaratinam S, Rogozinska E, Jolly K et al.: Effects of interventions in pregnancy on maternal weight and obstetric outcomes. Meta-analysis of randomised evidence. BMJ (Clinical research ed.) 2012a, 344:e2088.

Thangaratinam S, Rogozinska E, Jolly K et al.: Interventions to reduce or prevent obesity in pregnant women. A systematic review. Health technology assessment (Winchester, England) 2012b, 16:iii-iv, 1-191.

The American College of Obstetricans and Gynecologists: Committee Opinion No. 548: Weight Gain During Pregnancy. Obstetrics & gynecology 2013, 121:210-212.

The International Weight Management in Pregnancy (i-WIP) Collaborative Group: Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes. Meta-analysis of individual participant data from randomised trials. BMJ (Clinical research ed.) 2017, 358:j3991.

Thornton YS, Smarkola C, Kopacz SM et al.: Perinatal outcomes in nutritionally monitored obese pregnant women. A randomized clinical trial. Journal of the National Medical Association 2009, 101:569-577.

Tian C, Hu C, He X et al.: Excessive weight gain during pregnancy and risk of macrosomia: a meta-analysis. Archives of gynecology and obstetrics 2016, 293:29-35.

Tie HT, Xia YY, Zeng YS et al.: Risk of childhood overweight or obesity associated with excessive weight gain during pregnancy: a meta-analysis. Archives of gynecology and obstetrics 2014, 289:247-257.

Tieu J, Shepherd E, Middleton P et al.: Dietary advice interventions in pregnancy for preventing gestational diabetes mellitus. The Cochrane database of systematic reviews 2017, 1:CD006674.

Torloni MR, Betrán AP, Horta BL et al.: Prepregnancy BMI and the risk of gestational diabetes: a systematic review of the literature with meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2009, 10:194-203.

Turcksin R, Bel S, Galjaard S et al.: Maternal obesity and breastfeeding intention, initiation, intensity and duration: a systematic review. Maternal & child nutrition 2014, 10:166-183.

van den Heuvel JFM, Groenhof TK, Veerbeek JHW et al.: e-Health as the Next-Generation Perinatal Care: An Overview of the Literature. Journal of Medical Internet Research 2018, 20:e202.

van der Pligt P, Campbell K, Willcox J et al.: Opportunities for primary and secondary prevention of excess gestational weight gain: General Practitioners' perspectives. BMC family practice 2011, 12:124.

van der Pligt P, Bick D, Furber C: Tackling maternal obesity. Building an evidence base to reflect the complexity of lifestyle behaviour change. Midwifery 2017, 49:1-3.

van der Pligt P, Willcox J, Hesketh KD et al.: Systematic review of lifestyle interventions to limit postpartum weight retention. Implications for future opportunities to prevent maternal

overweight and obesity following childbirth. Obesity reviews: an official journal of the International Association for the Study of Obesity 2013, 14:792-805.

van Rossem L, Wijga AH, Gehring U et al.: Maternal Gestational and Postdelivery Weight Gain and Child Weight. Pediatrics 2015, 136:e1294-301.

Vanstone M, Kandasamy S, Giacomini M et al.: Pregnant women's perceptions of gestational weight gain. A systematic review and meta-synthesis of qualitative research. Maternal & child nutrition 2016.

Vesco KK, Karanja N, King JC et al.: Efficacy of a group-based dietary intervention for limiting gestational weight gain among obese women. A randomized trial. Obesity (Silver Spring, Md.) 2014, 22:1989-1996.

Vesco KK, Leo MC, Karanja N et al.: One-year postpartum outcomes following a weight management intervention in pregnant women with obesity. Obesity (Silver Spring, Md.) 2016, 24:2042-2049.

Villamor E & Cnattingius S: Interpregnancy weight change and risk of adverse pregnancy outcomes: a population-based study. Lancet (London, England) 2006, 368:1164-1170.

Vinter CA, Jensen DM, Ovesen P et al.: The LiP (Lifestyle in Pregnancy) study. A randomized controlled trial of lifestyle intervention in 360 obese pregnant women. Diabetes care 2011, 34:2502-2507.

Viswanathan M, Siega-Riz AM, Moos MK et al.: Outcomes of maternal weight gain. Evidence report/technology assessment 2008:1-223.

Voigt M, Fusch C, Olbertz D et al.: Analyse des Neugeborenenkollektivs der Bundesrepublik Deutschland. Geburtshilfe und Frauenheilkunde 2006, 66:956-970.

Walsh JM, McGowan CA, Mahony R et al.: Low glycaemic index diet in pregnancy to prevent macrosomia (ROLO study). Randomised control trial. BMJ (Clinical research ed.) 2012, 345:e5605.

Wang C, Wei Y, Zhang X et al.: A randomized clinical trial of exercise during pregnancy to prevent gestational diabetes mellitus and improve pregnancy outcome in overweight and obese pregnant women. American journal of obstetrics and gynecology 2017, 216:340-351.

Wang S, Ma JM, Yang HX: Lifestyle intervention for gestational diabetes mellitus prevention. A cluster-randomized controlled study. Chronic diseases and translational medicine 2015, 1:169-174.

Weissmann-Brenner A, Simchen MJ, Zilberberg E et al.: Maternal and neonatal outcomes of macrosomic pregnancies. Medical science monitor: international medical journal of experimental and clinical research 2012, 18:PH77-81.

Whitaker RC: Predicting preschooler obesity at birth: the role of maternal obesity in early pregnancy. Pediatrics 2004, 114:e29-36.

Wilkinson SA & Stapleton H: Overweight and obesity in pregnancy. The evidence-practice gap in staff knowledge, attitudes and practices. The Australian & New Zealand journal of obstetrics & gynaecology 2012, 52:588-592.

Willcox JC, Campbell KJ, van der Pligt, Paige et al.: Excess gestational weight gain: an exploration of midwives' views and practice. BMC pregnancy and childbirth 2012, 12:102.

Willcox JC, Campbell KJ, McCarthy EA et al.: Gestational weight gain information: seeking and sources among pregnant women. BMC pregnancy and childbirth 2015, 15:164.

Willcox JC, Ball K, Campbell KJ et al.: Correlates of pregnant women's gestational weight gain knowledge. Midwifery 2016.

Willcox JC, Wilkinson SA, Lappas M et al.: A mobile health intervention promoting healthy gestational weight gain for women entering pregnancy at a high body mass index. The txt4two pilot randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2017, 124:1718-1728.

Wise LA, Rothman KJ, Mikkelsen EM et al.: An internet-based prospective study of body size and time-to-pregnancy. Human reproduction (Oxford, England) 2010, 25:253-264.

Wolff S, Legarth J, Vangsgaard K et al.: A randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women. International journal of obesity 2008, 32:495-501.

World Health Organization: Consideration of the evidence on childhood obesity for the Commission on Ending Childhood Obesity: report of the ad hoc working group on science and evidence for ending childhood obesity, Geneva, Switzerland. 2016.

World Health Organization: Fact sheet N°311 – Obesity and overweight
http://www.who.int/mediacentre/factsheets/fs311/en/; 13.04.2018

Wrotniak BH, Shults J, Butts S et al.: Gestational weight gain and risk of overweight in the offspring at age 7 y in a multicenter, multiethnic cohort study. The American journal of clinical nutrition 2008, 87:1818-1824.

Yeo S, Walker JS, Caughey MC et al.: What characteristics of nutrition and physical activity interventions are key to effectively reducing weight gain in obese or overweight pregnant women? A systematic review and meta-analysis. Obesity reviews: an official journal of the International Association for the Study of Obesity 2017, 18:385-399.

Yin YN, Li Xl, Tao TJ et al.: Physical activity during pregnancy and the risk of gestational diabetes mellitus. A systematic review and meta-analysis of randomised controlled trials. British journal of sports medicine 2014, 48:290-295.

Yu Z, Han S, Zhu J et al.: Pre-pregnancy body mass index in relation to infant birth weight and offspring overweight/obesity: a systematic review and meta-analysis. PloS one 2013, 8:e61627.

Zhang R, Han S, Chen GC et al.: Effects of low-glycemic-index diets in pregnancy on maternal and newborn outcomes in pregnant women. A meta-analysis of randomized controlled trials. European journal of nutrition 2018, 57:167-177.

Zhong C, Li X, Chen R et al.: Greater early and mid-pregnancy gestational weight gain are associated with increased risk of gestational diabetes mellitus. A prospective cohort study. Clinical nutrition ESPEN 2017, 22:48-53.

APPENDIX

1. STUDY DOCUMENTS

Study document 1: Participant information and written informed consent (Intervention)

IN

Else Kröner-Fresenius-Zentrum
für Ernährungsmedizin
Lehrstuhl für Ernährungsmedizin

Prof. Dr.
Hans Hauner

Gregor-Mendel-Str. 2
85350 Freising-Weihenstephan
Germany

Tel +49.8161.71.2001
Fax +49.8161.71.2097

hans.hauner@tum.de

Weihenstephan, 30.04.2013

Teilnehmerinformation

zur

GeliS-Studie

„Gesund leben in der Schwangerschaft“

Sehr geehrte Studienteilnehmerin,

Sie sind eingeladen, an der oben genannten Studie teilzunehmen. Sie wurden bereits auf die geplante Studie angesprochen. Der nachfolgende Text soll Ihnen die Ziele und den Ablauf erläutern. Bevor Sie über Ihre Teilnahme entscheiden, bitten wir Sie, dieses Informationsschreiben sorgfältig zu lesen.

1. Warum wird diese Studie durchgeführt?

Übergewicht wird in Deutschland zu einem immer größeren Problem. Die Ursachen sind vor allem zu wenig Bewegung und falsche Ernährung. Häufig geht vor allem starkes Übergewicht mit Folgeerkrankungen wie Bluthochdruck oder Diabetes einher. In Deutschland sind heute rund 30 % aller Frauen im gebärfähigen Alter übergewichtig, wiederum ca. 10 % davon stark übergewichtig. Laut den Ergebnissen des Kinder- und Jugendgesundheitssurveys (KiGGS) bringen zudem ca. 15 % der Kinder in Deutschland bereits zu viel Gewicht auf die Waage. Übergewicht und eine übermäßige Gewichtszunahme in der Schwangerschaft erhöhen das Risiko an einem Schwangerschaftsdiabetes zu erkranken und werden vermehrt mit Schwangerschaftskomplikationen in Verbindung gebracht. Zudem ist eine starke Gewichtszunahme in der Schwangerschaft auch mit einem erhöhten Gewichtsverbleib der Mutter nach der Geburt verbunden. Auch das Risiko des Kindes selbst im späteren Leben an Übergewicht und Diabetes zu erkranken,

kann durch den Lebensstil in der Schwangerschaft beeinflusst werden. Man geht also davon aus, dass diese Risiken bereits im Mutterleib mitgegeben (vorprogrammiert) werden können.
Durch eine geringere Gewichtszunahme in der Schwangerschaft könnte nicht nur das Komplikationsrisiko während der Geburt, sondern auch das langfristige Risiko der Mutter und des Kindes später übergewichtig zu werden, erniedrigt werden. Mit dieser Studie wollen wir nun versuchen zu klären, ob durch eine gezielte Lebensstilberatung während der Schwangerschaft und nach der Geburt zusätzlich zur üblichen Schwangerenvorsorge und Betreuung im Wochenbett die Gesundheit von Mutter und Kind verbessert werden kann.

2. Wie ist der Ablauf der Studie und was muss ich bei einer Teilnahme beachten?

Wenn Sie sich zur Teilnahme entschließen, ist es erforderlich, dass Sie die beiliegende Einverständniserklärung unterschreiben und in Ihrer Frauenarztpraxis/Hebammenpraxis abgeben. Ein weiteres Exemplar der Teilnehmerinformation und der Einverständniserklärung wird Ihnen von der Praxis für Ihre Unterlagen ausgehändigt.
Die Studie wird in 10 bayerischen Regionen (ausgewählte Landkreise und kreisfreie Städte) der Regierungsbezirke Oberbayern, Oberpfalz, Oberfranken, Mittelfranken und Unterfranken durchgeführt.

Beratungsgespräche

Es werden Ihnen drei kostenfreie Beratungstermine (in den Zeiträumen von der 12.-16. Schwangerschaftswoche (SSW), der 16.-20. SSW und der 30.-34. SSW) zu Ernährung und Bewegung und zur richtigen Gewichtszunahme in der Schwangerschaft angeboten. Die Beratungen werden durch speziell geschulte Hebammen oder geschultes Praxispersonal durchgeführt und dauern ca. 30-45 min. Wenn möglich werden die Termine zusammen mit den üblichen Vorsorgeterminen in Ihrer Frauenarztpraxis/bei Ihrer Hebamme kombiniert, so dass es für Sie keine weiteren Extratermine gibt. In der 6.-8. Woche nach der Geburt erhalten Sie ein viertes kostenfreies Beratungsgespräch zu Ernährung und Bewegung in der Stillzeit sowie zur Ernährung des Säuglings. Dieser Termin kann wiederum mit einem Nachsorgetermin in der Praxis oder bei der Hebamme gekoppelt werden.

Datenerhebung

Sollten Sie sich für eine Teilnahme entscheiden, werden Daten zu Ihrem Schwangerschafts-, Geburts- und Wochenbettverlauf, wie z. B. Gewichtszunahme oder etwaige Komplikationen dokumentiert. Hierzu ziehen wir eine Kopie Ihres Mutterpasses und des Protokolls, das bei der Geburt Ihres Kindes erstellt wird, heran. Die Kopien werden vom Praxispersonal Ihrer Frauenarztpraxis erstellt und an uns weitergeleitet.

Zur Erhebung Ihres Lebensstils (Ernährung, Bewegung, Wohlbefinden) bitten wir Sie, zweimal im Verlauf Ihrer Schwangerschaft und einmal nach der Geburt Fragebögen auszufüllen. Die Fragebögen bekommen Sie von Ihrer Frauenarztpraxis/Ihrer Hebamme ausgehändigt.
1, 2 und 3 Jahre nach der Geburt werden Sie noch einmal telefonisch oder per Post nach Ihrem Gewichtsverlauf und Ihrem Lebensstil befragt. Des Weiteren werden zu diesen Zeitpunkten Gewichtsverlauf und Gesundheitsstatus Ihres Kindes anhand der routinemäßigen U-Untersuchungen beim Kinderarzt erfasst sowie Fragen zum Stillverhalten und zur Einführung und Art der Beikost gestellt.

Untersuchung auf Schwangerschaftsdiabetes

Die Untersuchung auf Schwangerschaftsdiabetes gehört seit dem letzten Jahr zu den Routineuntersuchungen in der Schwangerschaft. Allerdings gibt es verschiedene Vorgehensweisen bei diesem Test. Wir bitten Sie im Rahmen der Studie einen zweistündigen Blutzuckerbelastungstest (auch großer Blutzuckertest) zwischen der 24. und 28. SSW gemäß den aktuellsten Leitlinien durchführen zu lassen. Hierbei wird nüchtern und nach dem Trinken einer Zuckerlösung mehrmals der Blutzuckerspiegel anhand einer Blutabnahme aus der Armvene bestimmt. Ihr Frauenarzt ist darüber informiert und wird diesen Test durchführen oder Sie an Ihren Hausarzt weiterleiten. Die Ergebnisse werden im Mutterpass dokumentiert. Des Weiteren bitten wir Sie zwischen der 30. und 34. SSW einer weiteren Blutabnahme zuzustimmen, um den sogenannten Langzeitblutzuckerwert zu bestimmen.

3. Welchen persönlichen Nutzen habe ich von der Teilnahme an der Studie?

Sie erhalten drei kostenfreie Beratungsgespräche zu Ernährung, Bewegung und Gewichtszunahme in der Schwangerschaft sowie ein weiteres kostenfreies Beratungsgespräch nach der Geburt zu Ernährung und Bewegung in der Stillzeit sowie zur Ernährung des Säuglings. Bei den Beratungen bekommen Sie viele nützliche und wissenschaftlich gesicherte Informationsmaterialien rund um das Thema Lebensstil in der Schwangerschaft sowie einen Schrittzähler. Als Dank für Ihre Unterstützung dieser Studie erhalten Sie zudem ein kleines Überraschungspaket.
Durch Ihre Teilnahme können Sie zu einer zukünftig besseren Beratung schwangerer Frauen hinsichtlich Ernährungs- und Bewegungsverhalten und einer angemessenen Gewichtszunahme während der Schwangerschaft beitragen. Dies könnte unter anderem helfen, kindliches und mütterliches Übergewicht zu vermeiden.

4. Welche Risiken sind mit der Teilnahme an der Studie verbunden?

Während dieser Studie werden keine gesundheitsschädlichen Tests durchgeführt und Sie sind keinen besonderen Gesundheitsrisiken ausgesetzt. Bei den Blutabnahmen während der Untersuchung auf Schwangerschaftsdiabetes können an der Einstichstelle gelegentlich leichte Schmerzen, Blutergüsse oder Schwellungen auftreten. Prinzipiell kann es auch zu einer Infektion kommen; allerdings ist die Wahrscheinlichkeit aufgrund der Hygienemaßnahmen sehr gering.

5. Entstehen für mich Kosten durch die Teilnahme an der Studie?

Alle Beratungsgespräche und Untersuchungen, die im Rahmen dieser Studie stattfinden, sind für Sie völlig kostenfrei.

6. Was geschieht mit meinen Daten?

Alle im Rahmen dieser klinischen Studie erhobenen Teilnehmer- und Gesundheitsdaten werden entsprechend den Bestimmungen des Bundesdatenschutzgesetzes und der ärztlichen Schweigepflicht streng vertraulich behandelt. Während der klinischen Prüfung werden medizinische Befunde und persönliche Informationen erhoben und in Ihrer persönlichen Akte niedergeschrieben oder elektronisch gespeichert. Die für die klinische Prüfung wichtigen Daten werden zusätzlich in pseudonymisierter Form gespeichert, ausgewertet und gegebenenfalls weitergegeben.

Pseudonymisiert bedeutet, dass keine Angaben von Namen oder Initialen verwendet werden, sondern nur ein Nummern- und/oder Buchstabencode, evtl. mit Angabe des Geburtsjahres.

Die Einwilligung zur Teilnahme an dieser Studie schließt die Aufzeichnung Ihrer im Rahmen dieser Studie erhobenen medizinischen Daten durch beteiligte Ärzte ein sowie die Weitergabe dieser Daten an den Leiter der klinischen Prüfung, Herrn Prof. Dr. med. Hans Hauner, einschließlich dessen Vertreter und Auftragnehmer sowie die zuständigen Überwachungsbehörden und Ethikkommissionen.

Sie haben das Recht, jegliche Informationen, die sich auf die Teilnahme an dieser Studie beziehen, einzusehen. Dies betrifft Informationen über Ihre allgemeine Gesundheit, jegliche aufgetretene Nebenwirkungen und alle Testergebnisse, die während dieser Studie gesammelt worden sind.

Einzelheiten, insbesondere zur Möglichkeit eines Widerrufs, entnehmen Sie bitte der Einwilligungserklärung, die im Anschluss an diese Teilnehmerinformation abgedruckt ist.

7. Habe ich das Recht auf Information und/oder Rücktritt von der Studie?

Sie haben jederzeit das Recht, Fragen über die Studie zu stellen. Während der Studie werden Ihnen Ihre Frauenarztpraxis oder Ihre Hebamme Fragen zur Studie beantworten. Wenn Sie Fragen zu Ihren Rechten als Teilnehmerin an einem wissenschaftlichen Forschungsprojekt haben, wenden Sie sich bitte an Herrn Professor Dr. Hans Hauner bzw. dessen Vertreter und Mitarbeiter Tel: 08161/71-2788. An diesem Forschungsprojekt nehmen Sie freiwillig teil. Wenn Sie sich zur Teilnahme entschließen, werden Sie gebeten, eine Einverständniserklärung zu unterschreiben. Wenn Sie von der Studie zurücktreten möchten, können Sie Ihr Einverständnis jederzeit und ohne Angabe von Gründen widerrufen, ohne dass für Sie dadurch irgendwelche Nachteile entstehen.

8. Wer entscheidet, ob ich aus der Studie ausscheide?

Der Studienleiter bzw. dessen Vertreter kann Sie auch ohne Ihre Zustimmung auffordern, Ihre Teilnahme an der Studie abzubrechen. Sie werden aus der Studie ausgeschlossen, wenn es Ihnen nicht möglich sein sollte, an der Untersuchung weiter teilzunehmen. Wenn Sie gebeten werden, von der Studie zurückzutreten, werden die Gründe mit Ihnen besprochen.

Falls es Fragen zur Studie gibt, die Ihnen das Praxispersonal oder Ihre Hebamme nicht beantworten können, stehen Ihnen der Studienleiter und das Studienteam jederzeit gerne zur Verfügung.

Sie erreichen uns unter folgenden Telefonnummern:

Kathrin Rauh
Telefon: 08161/71-2788
Mobil: 0152/226 37 381

oder schicken Sie uns eine E-Mail an:
GeliS@KErn.bayern.de

IN

Else Kröner-Fresenius-Zentrum
für Ernährungsmedizin
Lehrstuhl für Ernährungsmedizin

Prof. Dr.
Hans Hauner

Gregor-Mendel-Str. 2
85350 Freising-Weihenstephan
Germany

Tel +49.8161.71.2001
Fax +49.8161.71.2097

hans.hauner@tum.de

Weihenstephan, 30.04.2013

Einverständniserklärung

zur

GeliS-Studie

„Gesund leben in der Schwangerschaft“

Ich wurde über die Art und die Inhalte der Studie eingehend aufgeklärt. Alle meine Fragen zur Studie wurden zu meiner Zufriedenheit beantwortet. Ich habe darüber hinaus den Text der Teilnehmerinformation sowie die hier nachfolgend abgedruckte Datenschutzerklärung gelesen und verstanden. Ich hatte ausreichend Zeit, mich für oder gegen die Teilnahme am Forschungsprojekt zu entscheiden.

Während dieser Studie werden keine gesundheitsschädlichen Tests durchgeführt und ich bin keinen besonderen Gesundheitsrisiken ausgesetzt.
Ich bin damit einverstanden, dass ich für die Studie Fragebögen zu meinem Lebensstil nach bestem Wissen und Gewissen beantworte.

Mir ist bekannt, dass die Teilnahme an der Studie freiwillig ist und dass ich meine Einwilligung jederzeit ohne Angabe von Gründen widerrufen kann.

Datenschutz:
Mir ist bekannt, dass bei dieser klinischen Prüfung personenbezogene Daten, insbesondere medizinische Befunde über mich erhoben, gespeichert und ausgewertet werden. Die Verwendung der Angaben über meine Gesundheit erfolgt nach gesetzlichen Bestimmungen

und setzt vor der Teilnahme an der klinischen Prüfung folgende freiwillig abgegebene Einwilligungserklärung voraus, das heißt ohne die nachfolgende Einwilligung kann ich nicht an der klinischen Prüfung teilnehmen.

1. Ich erkläre mich damit einverstanden, dass im Rahmen dieser klinischen Prüfung personenbezogene Daten, insbesondere Angaben über meine Gesundheit, über mich erhoben und in Papierform sowie auf elektronischen Datenträgern im Münchner Studienzentrum des Klinikums rechts der Isar aufgezeichnet werden. Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:
   a) an den Studienleiter, Herrn Prof. Dr. med. Hans Hauner, einschließlich dessen Vertreter und Auftragnehmer zum Zwecke der wissenschaftlichen Auswertung,
   b) im Falle unerwünschter Ereignisse: an die zuständigen Überwachungsbehörden und Ethikkommissionen.
2. Außerdem erkläre ich mich damit einverstanden, dass autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Auftraggebers sowie die zuständigen Überwachungsbehörden in meine im Prüfzentrum vorhandenen personenbezogenen Daten, insbesondere meine Gesundheitsdaten, Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der Studie notwendig ist. Für diese Maßnahme entbinde ich den Studienarzt von der ärztlichen Schweigepflicht.
3. Ich bin darüber aufgeklärt worden, dass ich jederzeit die Teilnahme an der klinischen Prüfung beenden kann. Im Falle dieses Widerrufs erkläre ich mich damit einverstanden, dass die bis zu diesem Zeitpunkt gespeicherten Daten ohne Namensnennung weiterhin verwendet werden dürfen, soweit dies erforderlich ist.
4. Ich erkläre mich damit einverstanden, dass meine Daten nach Beendigung oder Abbruch der Prüfung mindestens zehn Jahre aufbewahrt werden. Danach werden meine personenbezogenen Daten gelöscht.

Ich erkläre mich bereit, an der oben genannten Studie freiwillig teilzunehmen. Ein Exemplar der Teilnehmerinformation und Einverständniserklärung habe ich erhalten. Ein Exemplar verbleibt im Studienzentrum.

.....

Name der Studienteilnehmerin in Druckbuchstaben

.....	.....
Datum	Unterschrift der ***Studienteilnehmerin***

Ich habe das Aufklärungsgespräch geführt und die Einwilligung der Studienteilnehmerin eingeholt.

.....

Name der aufklärenden Person in Druckbuchstaben

.....

Name/Stempel der Praxis

.....	.....
Datum	Unterschrift der aufklärenden Person

Study document 2: Participant information and declaration of consent (Control)

V

Else Kröner-Fresenius-Zentrum
für Ernährungsmedizin
Lehrstuhl für Ernährungsmedizin

Prof. Dr.
Hans Hauner

Gregor-Mendel-Str. 2
85350 Freising-Weihenstephan
Germany

Tel +49.8161.71.2001
Fax +49.8161.71.2097

hans.hauner@tum.de

Weihenstephan, 30.04.2013

Teilnehmerinformation

zur

GeliS-Studie

„Gesund leben in der Schwangerschaft“

Sehr geehrte Studienteilnehmerin,

Sie sind eingeladen, an der oben genannten Studie teilzunehmen. Sie wurden bereits auf die geplante Studie angesprochen. Der nachfolgende Text soll Ihnen die Ziele und den Ablauf erläutern. Bevor Sie über Ihre Teilnahme entscheiden, bitten wir Sie, dieses Informationsschreiben sorgfältig zu lesen.

1. Warum wird diese Studie durchgeführt?

Übergewicht wird in Deutschland zu einem immer größeren Problem. Die Ursachen sind vor allem zu wenig Bewegung und falsche Ernährung. Häufig geht vor allem starkes Übergewicht mit Folgeerkrankungen wie Bluthochdruck oder Diabetes einher. In Deutschland sind heute rund 30 % aller Frauen im gebärfähigen Alter übergewichtig, wiederum ca. 10 % davon stark übergewichtig. Laut den Ergebnissen des Kinder- und Jugendgesundheitssurveys (KiGGS) bringen zudem ca. 15 % der Kinder in Deutschland bereits zu viel Gewicht auf die Waage. Übergewicht und eine übermäßige Gewichtszunahme in der Schwangerschaft erhöhen das Risiko an einem Schwangerschaftsdiabetes zu erkranken und werden vermehrt mit Schwangerschaftskomplikationen in Verbindung gebracht. Zudem ist eine starke Gewichtszunahme in der Schwangerschaft auch mit einem erhöhten Gewichtsverbleib der Mutter nach der Geburt verbunden. Auch das Risiko des Kindes selbst im späteren Leben an Übergewicht und Diabetes zu erkranken, kann durch den Lebensstil in der Schwangerschaft beeinflusst werden. Man geht also davon

aus, dass diese Risiken bereits im Mutterleib mitgegeben (vorprogrammiert) werden können. Um diese Zusammenhänge besser zu verstehen, ist es wichtig, aktuelle Daten zum Lebensstil und der Gewichtszunahme in der Schwangerschaft sowie zur langfristigen Gesundheit von Mutter und Kind zu sammeln.

2. Wie ist der Ablauf der Studie und was muss ich bei einer Teilnahme beachten?

Wenn Sie sich zur Teilnahme entschließen, ist es erforderlich, dass Sie die beiliegende Einverständniserklärung unterschreiben und in Ihrer Frauenarztpraxis abgeben. Ein weiteres Exemplar der Teilnehmerinformation und der Einverständniserklärung wird Ihnen von der Praxis für Ihre Unterlagen ausgehändigt.
Die Studie wird in 10 bayerischen Regionen (ausgewählte Landkreise und kreisfreie Städte) der Regierungsbezirke Oberbayern, Oberpfalz, Oberfranken, Mittelfranken und Unterfranken durchgeführt.

Datenerhebung

Sollten Sie sich für eine Teilnahme entscheiden, werden Daten zu Ihrem Schwangerschafts-, Geburts- und Wochenbettverlauf, wie z. B. Gewichtszunahme oder etwaige Komplikationen dokumentiert. Hierzu ziehen wir eine Kopie Ihres Mutterpasses und des Protokolls, das bei der Geburt Ihres Kindes erstellt wird, heran. Die Kopien werden vom Praxispersonal Ihrer Frauenarztpraxis erstellt und an uns weitergeleitet.
Zur Erhebung Ihres Lebensstils (Ernährung, Bewegung, Wohlbefinden) bitten wir Sie, zweimal im Verlauf Ihrer Schwangerschaft und einmal nach der Geburt Fragebögen auszufüllen. Die Fragebögen bekommen Sie von Ihrer Frauenarztpraxis ausgehändigt.
1, 2 und 3 Jahre nach der Geburt werden Sie noch einmal telefonisch oder per Post nach Ihrem Gewichtsverlauf und Ihrem Lebensstil befragt. Des Weiteren werden zu diesen Zeitpunkten Gewichtsverlauf und Gesundheitsstatus Ihres Kindes anhand der routinemäßigen U-Untersuchungen beim Kinderarzt erfasst sowie Fragen zum Stillverhalten und zur Einführung und Art der Beikost gestellt.

Untersuchung auf Schwangerschaftsdiabetes

Die Untersuchung auf Schwangerschaftsdiabetes gehört seit dem letzten Jahr zu den Routineuntersuchungen in der Schwangerschaft. Allerdings gibt es verschiedene Vorgehensweisen bei diesem Test. Wir bitten Sie im Rahmen der Studie einen zweistündigen Blutzuckerbelastungstest (auch großer Blutzuckertest) zwischen der 24. und 28. Schwangerschaftswoche (SSW) gemäß den aktuellsten Leitlinien durchführen zu lassen. Hierbei wird nüchtern und nach dem Trinken einer Zuckerlösung mehrmals der Blutzuckerspiegel anhand einer Blutabnahme aus der

Armvene bestimmt. Ihr Frauenarzt ist darüber informiert und wird diesen Test durchführen oder Sie an Ihren Hausarzt weiterleiten. Die Ergebnisse werden im Mutterpass dokumentiert. Des Weiteren bitten wir Sie zwischen der 30. und 34. SSW einer weiteren Blutabnahme zuzustimmen, um den sogenannten Langzeitblutzuckerwert zu bestimmen.

3. Welchen persönlichen Nutzen habe ich von der Teilnahme an der Studie?

Bei Einschluss erhalten Sie eine Teilnehmermappe, in der sich unter anderem Informationen mit den wichtigsten Tipps für einen gesunden Lebensstil für Mutter und Kind befinden. Als Dank für Ihre Unterstützung erhalten Sie ein kleines Überraschungspaket. Unter allen Teilnehmerinnen werden 10 Wochenenden auf dem Bauernhof für Sie und Ihre Familie verlost.
Durch Ihre Teilnahme an dieser Studie können Sie zu einer zukünftig besseren Beratung schwangerer Frauen hinsichtlich Ernährungs- und Bewegungsverhalten und einer angemessenen Gewichtszunahme während der Schwangerschaft beitragen. Dies könnte unter anderem helfen, kindliches und mütterliches Übergewicht zu vermeiden.

4. Welche Risiken sind mit der Teilnahme an der Studie verbunden?

Während dieser Studie werden keine gesundheitsschädlichen Tests durchgeführt und Sie sind keinen besonderen Gesundheitsrisiken ausgesetzt. Bei den Blutabnahmen während der Untersuchung auf Schwangerschaftsdiabetes können an der Einstichstelle gelegentlich leichte Schmerzen, Blutergüsse oder Schwellungen auftreten. Prinzipiell kann es auch zu einer Infektion kommen; allerdings ist die Wahrscheinlichkeit aufgrund der Hygienemaßnahmen sehr gering.

5. Entstehen für mich Kosten durch die Teilnahme an der Studie?

Bei Teilnahme an dieser Studie entstehen für Sie keinerlei Kosten!

6. Was geschieht mit meinen Daten?

Alle im Rahmen dieser klinischen Studie erhobenen Teilnehmer- und Gesundheitsdaten werden entsprechend den Bestimmungen des Bundesdatenschutzgesetzes und der ärztlichen Schweigepflicht streng vertraulich behandelt. Während der klinischen Prüfung werden medizinische Befunde und persönliche Informationen erhoben und in Ihrer persönlichen Akte niedergeschrieben oder elektronisch gespeichert. Die für die klinische Prüfung wichtigen Daten werden zusätzlich in pseudonymisierter Form gespeichert, ausgewertet und gegebenenfalls weitergegeben.

Pseudonymisiert bedeutet, dass keine Angaben von Namen oder Initialen verwendet werden, sondern nur ein Nummern- und/oder Buchstabencode, evtl. mit Angabe des Geburtsjahres.
Die Einwilligung zur Teilnahme an dieser Studie schließt die Aufzeichnung Ihrer im Rahmen dieser Studie erhobenen medizinischen Daten durch beteiligte Ärzte ein sowie die Weitergabe dieser Daten an den Leiter der klinischen Prüfung, Herrn Prof. Dr. med. Hans Hauner, einschließlich dessen Vertreter und Auftragnehmer sowie die zuständigen Überwachungsbehörden und Ethikkommissionen.
Sie haben das Recht, jegliche Informationen, die sich auf die Teilnahme an dieser Studie beziehen, einzusehen. Dies betrifft Informationen über Ihre allgemeine Gesundheit, jegliche aufgetretene Nebenwirkungen und alle Testergebnisse, die während dieser Studie gesammelt worden sind.
Einzelheiten, insbesondere zur Möglichkeit eines Widerrufs, entnehmen Sie bitte der Einwilligungserklärung, die im Anschluss an diese Teilnehmerinformation abgedruckt ist.

7. Habe ich das Recht auf Information und/oder Rücktritt von der Studie?

Sie haben jederzeit das Recht, Fragen über die Studie zu stellen. Während der Studie wird Ihnen Ihre Frauenarztpraxis Fragen zur Studie beantworten. Wenn Sie Fragen zu Ihren Rechten als Teilnehmerin an einem wissenschaftlichen Forschungsprojekt haben, wenden Sie sich bitte an Herrn Professor Dr. Hans Hauner bzw. dessen Vertreter und Mitarbeiter Tel: 08161/71-2788.
An diesem Forschungsprojekt nehmen Sie freiwillig teil. Wenn Sie sich zur Teilnahme entschließen, werden Sie gebeten, eine Einverständniserklärung zu unterschreiben. Wenn Sie von der Studie zurücktreten möchten, können Sie Ihr Einverständnis jederzeit und ohne Angabe von Gründen widerrufen, ohne dass für Sie dadurch irgendwelche Nachteile entstehen.

8. Wer entscheidet, ob ich aus der Studie ausscheide?

Der Studienleiter bzw. dessen Vertreter kann Sie auch ohne Ihre Zustimmung auffordern, Ihre Teilnahme an der Studie abzubrechen. Sie werden aus der Studie ausgeschlossen, wenn es Ihnen nicht möglich sein sollte, an der Untersuchung weiter teilzunehmen. Wenn Sie gebeten werden, von der Studie zurückzutreten, werden die Gründe mit Ihnen besprochen.
Falls es Fragen zur Studie gibt, die Ihnen das Praxispersonal nicht beantworten kann, stehen Ihnen der Studienleiter und das Studienteam jederzeit gerne zur Verfügung.

Sie erreichen uns unter folgenden Telefonnummern:

Kathrin Rauh

Telefon: 08161/71-2788

Mobil: 0152/226 37 381

oder schicken Sie uns eine E-Mail an:

GeliS@KErn.bayern.de

V

Else Kröner-Fresenius-Zentrum
für Ernährungsmedizin
Lehrstuhl für Ernährungsmedizin

Prof. Dr.
Hans Hauner

Gregor-Mendel-Str. 2
85350 Freising-Weihenstephan
Germany

Tel +49.8161.71.2001
Fax +49.8161.71.2097

hans.hauner@tum.de

Weihenstephan, 30.04.2013

Einverständniserklärung

zur

GeliS-Studie

„Gesund leben in der Schwangerschaft"

Ich wurde über die Art und die Inhalte der Studie eingehend aufgeklärt. Alle meine Fragen zur Studie wurden zu meiner Zufriedenheit beantwortet. Ich habe darüber hinaus den Text der Teilnehmerinformation sowie die hier nachfolgend abgedruckte Datenschutzerklärung gelesen und verstanden. Ich hatte ausreichend Zeit, mich für oder gegen die Teilnahme am Forschungsprojekt zu entscheiden.

Während dieser Studie werden keine gesundheitsschädlichen Tests durchgeführt und ich bin keinen besonderen Gesundheitsrisiken ausgesetzt.
Ich bin damit einverstanden, dass ich für die Studie Fragebögen zu meinem Lebensstil nach bestem Wissen und Gewissen beantworte.

Mir ist bekannt, dass die Teilnahme an der Studie freiwillig ist und dass ich meine Einwilligung jederzeit ohne Angabe von Gründen widerrufen kann.

Datenschutz:
Mir ist bekannt, dass bei dieser klinischen Prüfung personenbezogene Daten, insbesondere medizinische Befunde über mich erhoben, gespeichert und ausgewertet werden. Die Verwendung der Angaben über meine Gesundheit erfolgt nach gesetzlichen Bestimmungen und setzt vor der Teilnahme an der klinischen Prüfung folgende freiwillig abgegebene

Einwilligungserklärung voraus, das heißt ohne die nachfolgende Einwilligung kann ich nicht an der klinischen Prüfung teilnehmen.

1. Ich erkläre mich damit einverstanden, dass im Rahmen dieser klinischen Prüfung personenbezogene Daten, insbesondere Angaben über meine Gesundheit, über mich erhoben und in Papierform sowie auf elektronischen Datenträgern im Münchner Studienzentrum des Klinikums rechts der Isar aufgezeichnet werden. Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:
   a) an den Studienleiter, Herrn Prof. Dr. med. Hans Hauner, einschließlich dessen Vertreter und Auftragnehmer zum Zwecke der wissenschaftlichen Auswertung,
   b) im Falle unerwünschter Ereignisse: an die zuständigen Überwachungsbehörden und Ethikkommissionen.
2. Außerdem erkläre ich mich damit einverstanden, dass autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Auftraggebers sowie die zuständigen Überwachungsbehörden in meine im Prüfzentrum vorhandenen personenbezogenen Daten, insbesondere meine Gesundheitsdaten, Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der Studie notwendig ist. Für diese Maßnahme entbinde ich den Studienarzt von der ärztlichen Schweigepflicht.
3. Ich bin darüber aufgeklärt worden, dass ich jederzeit die Teilnahme an der klinischen Prüfung beenden kann. Im Falle dieses Widerrufs erkläre ich mich damit einverstanden, dass die bis zu diesem Zeitpunkt gespeicherten Daten ohne Namensnennung weiterhin verwendet werden dürfen, soweit dies erforderlich ist.
4. Ich erkläre mich damit einverstanden, dass meine Daten nach Beendigung oder Abbruch der Prüfung mindestens zehn Jahre aufbewahrt werden. Danach werden meine personenbezogenen Daten gelöscht.

Ich erkläre mich bereit, an der oben genannten Studie freiwillig teilzunehmen. Ein Exemplar der Teilnehmerinformation und Einverständniserklärung habe ich erhalten. Ein Exemplar verbleibt im Studienzentrum.

.....

Name der Studienteilnehmerin in Druckbuchstaben

.....	.....
Datum	Unterschrift der ***Studienteilnehmerin***

Ich habe das Aufklärungsgespräch geführt und die Einwilligung der Studienteilnehmerin eingeholt.

.....

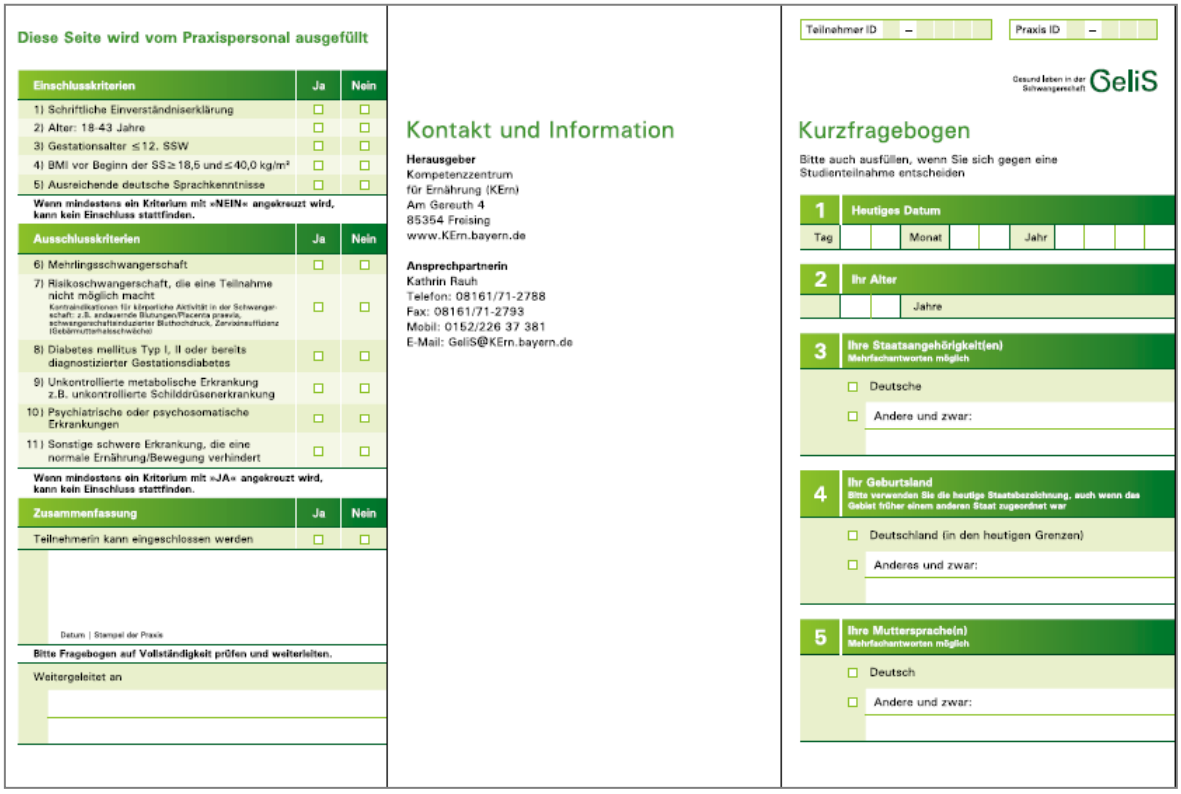
Name der aufklärenden Person in Druckbuchstaben

.....

Name/Stempel der Praxis

.....	.....
Datum	Unterschrift der aufklärenden Person

Study document 3: Screening questionnaire



Diese Seite wird vom Praxispersonal ausgefüllt

Einschlusskriterien	Ja	Nein
1) Schriftliche Einverständniserklärung	☐	☐
2) Alter: 18-43 Jahre	☐	☐
3) Gestationsalter ≤ 12. SSW	☐	☐
4) BMI vor Beginn der SS ≥ 18,5 und ≤ 40,0 kg/m²	☐	☐
5) Ausreichende deutsche Sprachkenntnisse	☐	☐

Wenn mindestens ein Kriterium mit «NEIN» angekreuzt wird, kann kein Einschluss stattfinden.

Ausschlusskriterien	Ja	Nein
6) Mehrlingsschwangerschaft	☐	☐
7) Risikoschwangerschaft, die eine Teilnahme nicht möglich macht (Kontraindikationen für körperliche Aktivität in der Schwangerschaft: z.B. endauernde Blutungen/Placenta praevia, schwangerschaftsinduzierter Bluthochdruck, Zervixinsuffizienz (Gebärmutterhalsschwäche))	☐	☐
8) Diabetes mellitus Typ I, II oder bereits diagnostizierter Gestationsdiabetes	☐	☐
9) Unkontrollierte metabolische Erkrankung z.B. unkontrollierte Schilddrüsenerkrankung	☐	☐
10) Psychiatrische oder psychosomatische Erkrankungen	☐	☐
11) Sonstige schwere Erkrankung, die eine normale Ernährung/Bewegung verhindert	☐	☐

Wenn mindestens ein Kriterium mit «JA» angekreuzt wird, kann kein Einschluss stattfinden.

Zusammenfassung	Ja	Nein
Teilnehmerin kann eingeschlossen werden	☐	☐

Datum | Stempel der Praxis

Bitte Fragebogen auf Vollständigkeit prüfen und weiterleiten.

Weitergeleitet an

Kontakt und Information

Herausgeber
Kompetenzzentrum
für Ernährung (KErn)
Am Gereuth 4
85354 Freising
www.KErn.bayern.de

Ansprechpartnerin
Kathrin Rauh
Telefon: 08161/71-2788
Fax: 08161/71-2793
Mobil: 0152/226 37 381
E-Mail: GeliS@KErn.bayern.de

Teilnehmer ID – Praxis ID –

Gesund leben in der Schwangerschaft GeliS

Kurzfragebogen

Bitte auch ausfüllen, wenn Sie sich gegen eine Studienteilnahme entscheiden

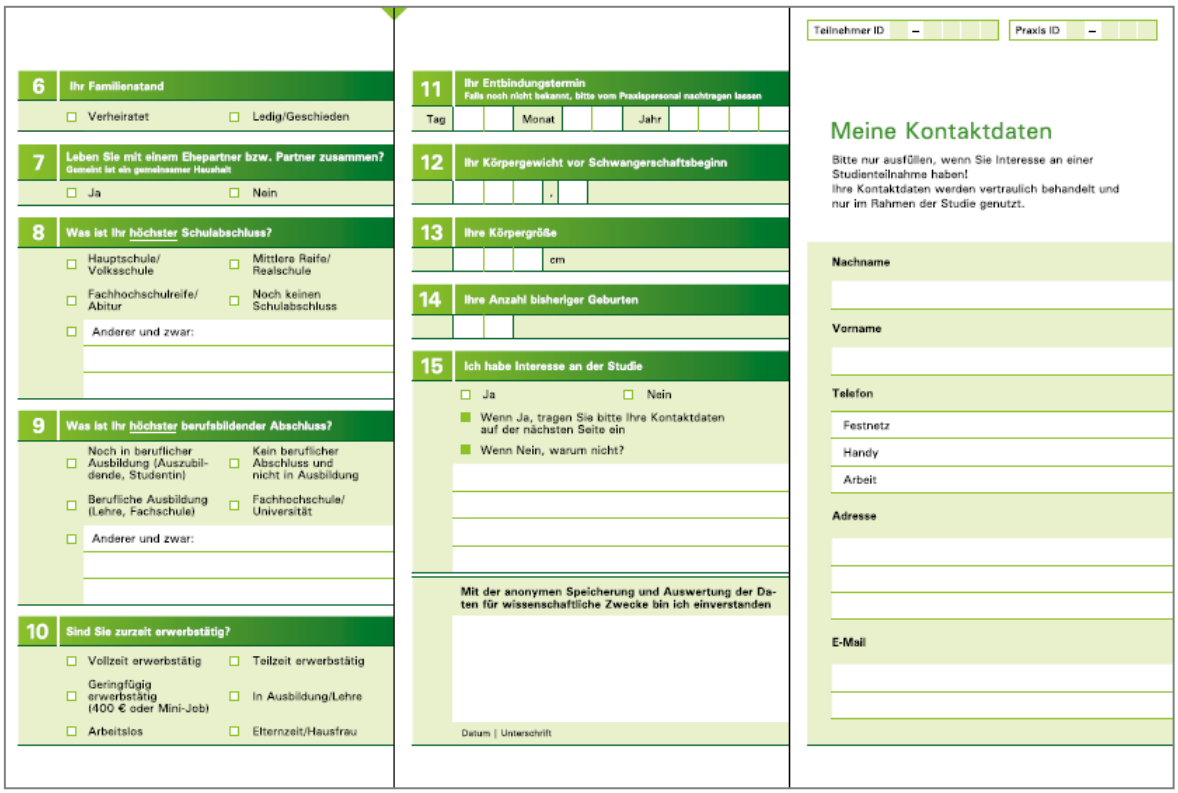
1 Heutiges Datum
Tag Monat Jahr

2 Ihr Alter
Jahre

3 Ihre Staatsangehörigkeit(en)
Mehrfachantworten möglich
☐ Deutsche
☐ Andere und zwar:

4 Ihr Geburtsland
Bitte verwenden Sie die heutige Staatsbezeichnung, auch wenn das Gebiet früher einem anderen Staat zugeordnet war
☐ Deutschland (in den heutigen Grenzen)
☐ Anderes und zwar:

5 Ihre Muttersprache(n)
Mehrfachantworten möglich
☐ Deutsch
☐ Andere und zwar:



6 Ihr Familienstand
☐ Verheiratet ☐ Ledig/Geschieden

7 Leben Sie mit einem Ehepartner bzw. Partner zusammen?
Gemeint ist ein gemeinsamer Haushalt
☐ Ja ☐ Nein

8 Was ist Ihr höchster Schulabschluss?
☐ Hauptschule/ Volksschule
☐ Mittlere Reife/ Realschule
☐ Fachhochschulreife/ Abitur
☐ Noch keinen Schulabschluss
☐ Anderer und zwar:

9 Was ist Ihr höchster berufsbildender Abschluss?
☐ Noch in beruflicher Ausbildung (Auszubildende, Studentin)
☐ Kein beruflicher Abschluss und nicht in Ausbildung
☐ Berufliche Ausbildung (Lehre, Fachschule)
☐ Fachhochschule/ Universität
☐ Anderer und zwar:

10 Sind Sie zurzeit erwerbstätig?
☐ Vollzeit erwerbstätig
☐ Teilzeit erwerbstätig
☐ Geringfügig erwerbstätig (400 € oder Mini-Job)
☐ In Ausbildung/Lehre
☐ Arbeitslos
☐ Elternzeit/Hausfrau

11 Ihr Entbindungstermin
Falls noch nicht bekannt, bitte vom Praxispersonal nachtragen lassen
Tag Monat Jahr

12 Ihr Körpergewicht vor Schwangerschaftsbeginn
, kg

13 Ihre Körpergröße
cm

14 Ihre Anzahl bisheriger Geburten

15 Ich habe Interesse an der Studie
☐ Ja ☐ Nein
■ Wenn Ja, tragen Sie bitte Ihre Kontaktdaten auf der nächsten Seite ein
■ Wenn Nein, warum nicht?

Mit der anonymen Speicherung und Auswertung der Daten für wissenschaftliche Zwecke bin ich einverstanden

Datum | Unterschrift

Teilnehmer ID – Praxis ID –

Meine Kontaktdaten

Bitte nur ausfüllen, wenn Sie Interesse an einer Studienteilnahme haben!
Ihre Kontaktdaten werden vertraulich behandelt und nur im Rahmen der Studie genutzt.

Nachname

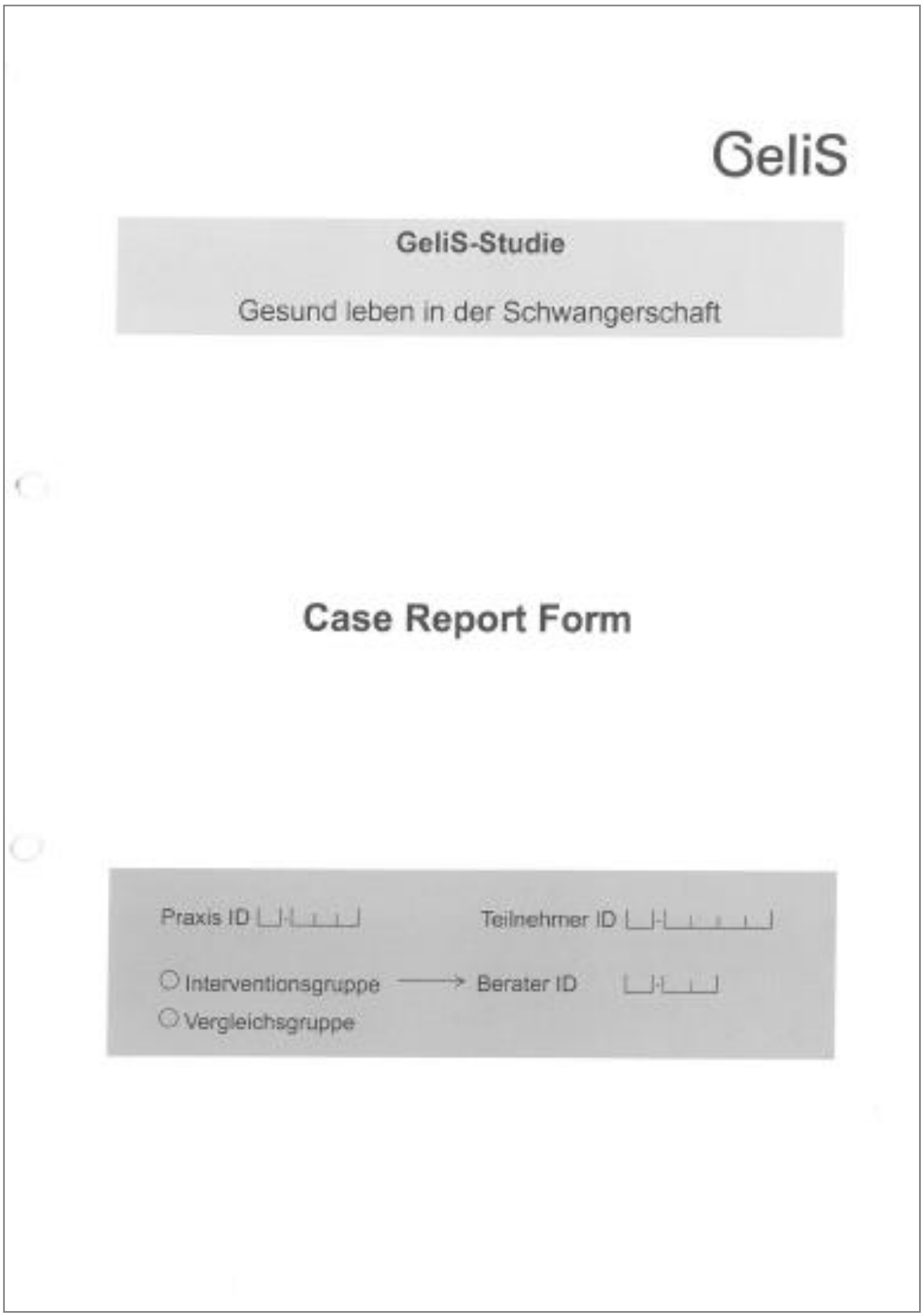
Vorname

Telefon
Festnetz
Handy
Arbeit

Adresse

E-Mail

Study document 4: Detail of the Case Report Form



GeliS

GeliS-Studie

Gesund leben in der Schwangerschaft

Case Report Form

Praxis ID [_]-[_ _ _] Teilnehmer ID [_]-[_ _ _ _]

○ Interventionsgruppe ⟶ Berater ID [_]-[_ _]

○ Vergleichsgruppe

GeliS | **Einschlusskriterien** | **E/A**

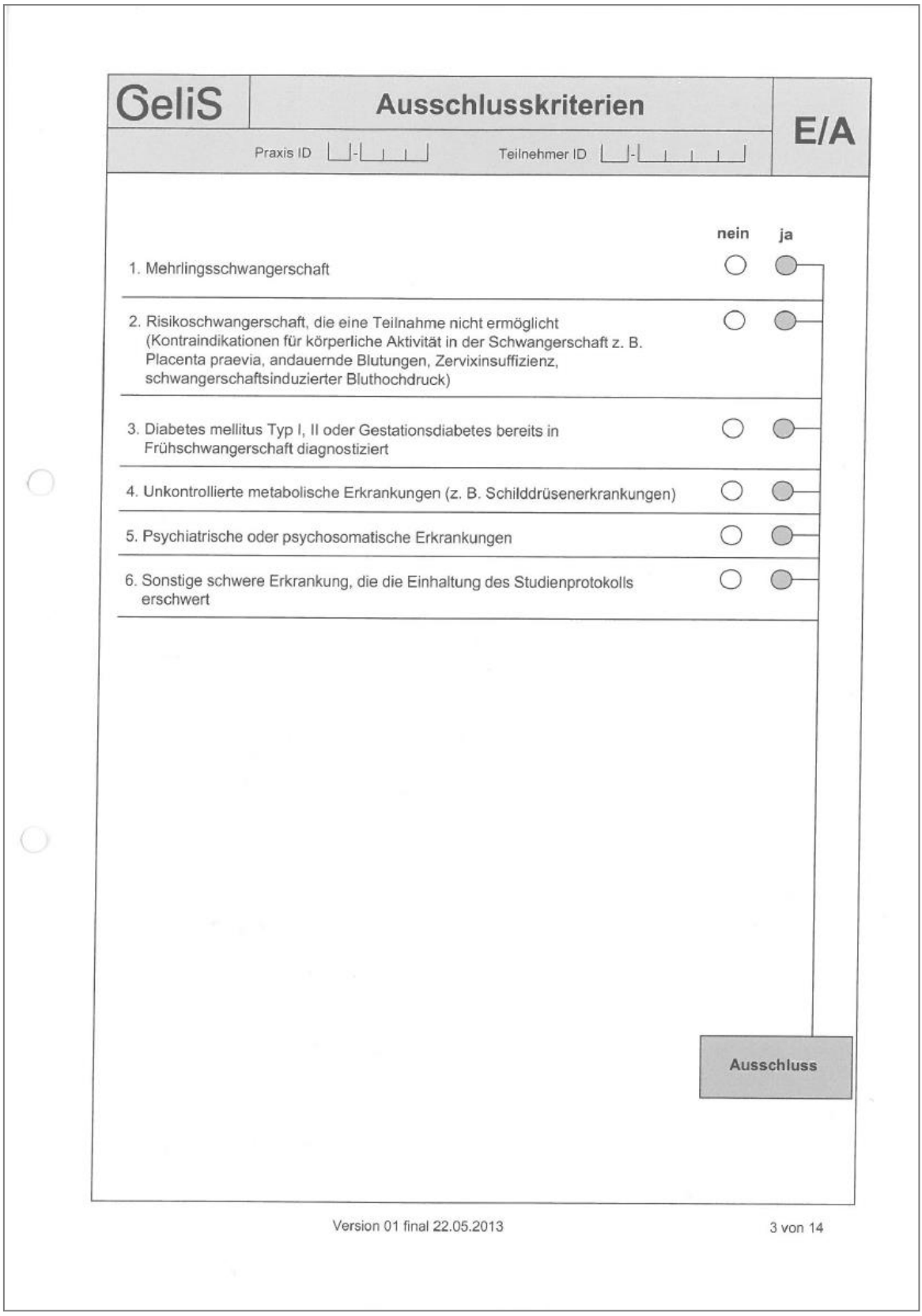
Praxis ID [ ]-[ ] [ ] [ ] Teilnehmer ID [ ]-[ ] [ ] [ ] [ ]

Datum der Einverständniserklärung [ ] [ ] [ ] [ ] [ ] [ ]
T T M M J J

	ja	nein
1. Gestationsalter ≤ 12. Schwangerschaftswoche (SSW)	○	●
2. Alter: 18-43 Jahre	○	●
3. BMI vor Beginn der Schwangerschaft ≥ 18,5 kg/m² und ≤ 40,0 kg/m²	○	●
4. Ausreichende deutsche Sprachkenntnisse	○	●
5. Schriftliche Einverständniserklärung	○	●

Ausschluss

Version 01 final 22.05.2013 2 von 14



GeliS

Ausschlusskriterien

E/A

Praxis ID [ ]-[ ]

Teilnehmer ID [ ]-[ ]

	nein	ja
1. Mehrlingsschwangerschaft	○	●
2. Risikoschwangerschaft, die eine Teilnahme nicht ermöglicht (Kontraindikationen für körperliche Aktivität in der Schwangerschaft z. B. Placenta praevia, andauernde Blutungen, Zervixinsuffizienz, schwangerschaftsinduzierter Bluthochdruck)	○	●
3. Diabetes mellitus Typ I, II oder Gestationsdiabetes bereits in Frühschwangerschaft diagnostiziert	○	●
4. Unkontrollierte metabolische Erkrankungen (z. B. Schilddrüsenerkrankungen)	○	●
5. Psychiatrische oder psychosomatische Erkrankungen	○	●
6. Sonstige schwere Erkrankung, die die Einhaltung des Studienprotokolls erschwert	○	●

Ausschluss

Version 01 final 22.05.2013

3 von 14

GeliS | **Visite 0 (Screening) [≤ 12. SSW]** | **V0**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

Kurzfragebogen vorhanden? ◯ ja ◯ nein

Wenn nein, bitte begründen: _____

Ausfülldatum des Kurzfragebogens |_|_| |_|_| |_|_| (T T M M J J)

ANAMNESTISCHE DATEN

Berechneter Entbindungstermin |_|_| |_|_| |_|_| (T T M M J J)

Korrigierter Entbindungstermin |_|_| |_|_| |_|_| (T T M M J J)

Größe |_|_|_| cm

Gewicht vor Schwangerschaft |_|_|_|,|_| kg

BMI vor Schwangerschaft |_|_|,|_| kg/m²

Anzahl bisheriger Schwangerschaften inkl. dieser (Gravida) *(einschl. Fehl-/ Frühgeburten u. Schwangerschaftsabbrüchen)* |_|

Anzahl bisheriger Geburten (Para) |_|

Erste Vorsorgeuntersuchung

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Gewicht |_|_|_|,|_| kg

Blutdruck |_|_|_| / |_|_|_| mmHg (*systol.* / *diastol.*)

Besonderheiten bei der ersten Vorsorge-untersuchung ◯ ja ◯ nein

↓

Nr.: |_|_|,|_|_|,|_|_|,|_|_|,|_|_|,|_|_| andere: _____

(siehe Mutterpass S. 5 Katalog A)

Nach ärztl. Bewertung des Kataloges A liegt bei der Erstuntersuchung ein Schwangerschaftsrisiko vor ◯ ja ◯ nein

Sonstige Befunde/ Komplikationen ◯ ja ◯ nein

↓

Nr.: |_|_|,|_|_|,|_|_| andere: _____

(siehe Mutterpass S. 6 Katalog B)

GeliS | **Visite 0 (Screening)** [≤ 12. SSW] | **V0**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

FRAGEBOGENPAKET

Fragebogenpaket 1 ausgegeben? ◯ ja ◯ nein

SCHRITTZÄHLER-TAGEBUCH

Nur zutreffend, wenn Probandin in entsprechender Subgruppe ist.

Tagebuch zum Schrittzähler 1 ausgegeben? ◯ ja ◯ nein ◯ nicht zutreffend

GeliS | **Visite 1** [12. – 16. SSW] | **V1**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

LEBENSSTILBERATUNG (Interventionsgruppe)

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Allgemeine Lebensstilberatung durchgeführt? ◯ ja ◯ nein

Wenn nein, bitte begründen: ◯ terminliche Probleme
◯ anderer Grund: _____

VORSORGEUNTERSUCHUNG

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Gewicht |_|_|_|,|_| kg

Blutdruck |_|_|_| / |_|_|_| mmHg (*systol.* / *diastol.*)

Sonstige Befunde/ Komplikationen ◯ ja ◯ nein
↓
Nr.: |_|,|_|,|_| andere: _____
(siehe Mutterpass S. 6 Katalog B)

FRAGEBOGENPAKET

Fragebogenpaket **1** vollständig eingesammelt? ◯ ja ◯ nein
↓
Fehlender Fragebogen:

Wenn ja:

Ausfülldatum des Fragebogenpakets |_|_| |_|_| |_|_| (T T M M J J)

- ☐ Wohlbefinden
- ☐ Bewegung
- ☐ Ernährung
- ☐ Nahrungsergänzungsmittel

SCHRITTZÄHLER-TAGEBUCH

Nur zutreffend, wenn Probandin in entsprechender Subgruppe ist.

Tagebuch zum Schrittzähler 1 eingesammelt? ◯ ja ◯ nein ◯ nicht zutreffend

GeliS | **Visite 2** [16. – 20. SSW] | **V2**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

LEBENSSTILBERATUNG (Interventionsgruppe)

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Individuelle Lebensstilberatung durchgeführt? ◯ ja ◯ nein

Wenn nein, bitte begründen: ◯ terminliche Probleme
◯ anderer Grund: _____

Die individuelle Lebensstilberatung basiert auf der Auswertung des Fragebogenpakets 1.

VORSORGEUNTERSUCHUNG

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Gewicht |_|_|_|,|_| kg

Blutdruck |_|_|_| / |_|_|_| mmHg (*systol.* / *diastol.*)

Sonstige Befunde/ Komplikationen ◯ ja ◯ nein
↓
Nr.: |_|,|_|,|_| andere: _____
(siehe Mutterpass S. 6 Katalog B)

GeliS | **Oraler Glukosetoleranztest** [24. – 28. SSW] | **oGTT**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

SCREENING AUF GESTATIONSDIABETES

Wurde ein 2h–75g-oGTT durchgeführt? ◯ ja ◯ nein

***Wenn ja*:**

Datum des Tests |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Ergebnis des Tests Nüchtern: |_|_|_| mg/dl

1 h: |_|_|_| mg/dl

2 h: |_|_|_| mg/dl

Gestationsdiabetes/ gestörte Glukosetoleranz? ◯ ja ◯ nein

Wenn ja, welche Behandlung? ◯ keine ◯ Ernährungsumstellung ◯ Insulin

Wurde ein Screeningtest durchgeführt? ◯ ja ◯ nein

***Wenn ja*:**

Datum des Tests |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Ergebnis des Tests |_|_|_| mg/dl

GeliS | **Visite 3** [30. – 34. SSW] | **V3**

Praxis ID |_|-|_|_|_| Teilnehmer ID |_|-|_|_|_|_|

LEBENSSTILBERATUNG (Interventionsgruppe)

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Allgemeine Lebensstilberatung durchgeführt? ◯ ja ◯ nein

Wenn nein, bitte begründen: ◯ terminliche Probleme

◯ anderer Grund: _____

VORSORGEUNTERSUCHUNG

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Gewicht |_|_|_|,|_| kg

Blutdruck |_|_|_| / |_|_|_| mmHg (*systol.* / *diastol.*)

Sonstige Befunde/ Komplikationen ◯ ja ◯ nein

↓

Nr.: |_|_|,|_|_|,|_|_| andere: _____

(siehe Mutterpass S. 6 Katalog B)

MESSUNG DES LANGZEIT-BLUTZUCKERWERTS

Datum der Blutabnahme |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

HbA1c |_|_|,|_| % oder: |_|_|_| mmol/mol

FRAGEBOGENPAKET

Fragebogenpaket 2 ausgegeben? ◯ ja ◯ nein

SCHRITTZÄHLER-TAGEBUCH

Nur zutreffend, wenn Probandin in entsprechender Subgruppe ist.

Tagebuch zum Schrittzähler 2 ausgegeben? ◯ ja ◯ nein ◯ nicht zutreffend

GeliS | Geburt | G

Praxis ID |_|_|-|_|_|_| Teilnehmer ID |_|_|-|_|_|_|_|

LETZTE VORSORGEUNTERSUCHUNG VOR GEBURT

Datum |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Gewicht |_|_|_|,|_| kg

Blutdruck |_|_|_| / |_|_|_| mmHg (*systol.* / *diastol.*)

Sonstige Befunde/ Komplikationen ○ ja ○ nein

↓

Nr.: |_|_|,|_|_|,|_|_| andere: _____

(siehe Mutterpass S. 6 Katalog B)

ANGABEN ZUR GEBURT

Datum der Geburt |_|_| |_|_| |_|_| (T T M M J J) Schwangerschaftswoche |_|_|+|_|

Geburtsmodus
- ○ spontan
- ○ Sectio (primär)
- ○ Sectio (sekundär)
- ○ Vaginale Operation

Geburtslage
- ○ Schädellage
- ○ Becken-Endlage
- ○ Querlage

Komplikationen/ Risiken ○ ja ○ nein

↓

- ☐ Vorzeitiger Blasensprung
- ☐ Terminüberschreitung
- ☐ Pathologisches CTG
- ☐ Protrahierte Geburt (EP / AP)
- ☐ Missverhältnis
- ☐ Grünes Fruchtwasser
- ☐ Nabelschnurkomplikation
- ☐ andere: _____

GeliS | **Geburt** | **G**

Praxis ID ⌊_⌋-⌊_ _ _⌋ Teilnehmer ID ⌊_⌋-⌊_ _ _ _⌋

Geburtsverletzungen ○ ja ○ nein

- ☐ Scheiden- / Labienriss
- ☐ Dammriss I. / II. Grades
- ☐ Dammriss III. / IV. Grades
- ☐ Episiotomie
- ☐ andere: _____

Anästhesie ○ ja ○ nein

- ☐ lokal
- ☐ epidural / peridural
- ☐ spinal
- ☐ Allgemeinanästhesie (ITN)
- ☐ andere: _____

Einleitung der Geburt ○ ja ○ nein

pH-Wert (Nabelarterie) ⌊_⌋,⌊_ _⌋

APGAR-Score ⌊_ _⌋ *(1 min)* ⌊_ _⌋ *(5 min)* ⌊_ _⌋ *(10 min)*

Geburtsgewicht ⌊_ _ _ _⌋ g

Geburtsgröße ⌊_ _⌋,⌊_⌋ cm

Kopfumfang ⌊_ _⌋,⌊_⌋ cm

Geschlecht ○ männlich ○ weiblich

Besonderheiten beim Säugling ○ ja ○ nein

- ☐ Infektion
- ☐ Hypoxie / Atemstörungen
- ☐ Fehlbildung
- ☐ andere: _____

Blutdruck *(der Mutter im Wochenbett)* ⌊_ _ _⌋ *systol.* / ⌊_ _ _⌋ *diastol.* mmHg

Version 01 final 22.05.2013 11 von 14

GeliS | **Visite 4** [6. – 8. Woche postpartum] | **V4**

Praxis ID |_|_|-|_|_|_| Teilnehmer ID |_|_|-|_|_|_|_|

LEBENSSTILBERATUNG (Interventionsgruppe)

Datum |_|_|.|_|_|.|_|_| (T T M M J J)

Allgemeine Lebensstilberatung durchgeführt? ◯ ja ◯ nein

Wenn nein, bitte begründen: ◯ terminliche Probleme
◯ anderer Grund: _____

KÖRPERGEWICHT DER MUTTER

Gewicht |_|_|_|,|_| kg **Datum** |_|_|.|_|_|.|_|_| (T T M M J J)

FRAGEBOGENPAKET

Fragebogenpaket 2 vollständig eingesammelt? ◯ ja ◯ nein

Wenn ja:

Ausfülldatum des Fragebogenpakets |_|_|.|_|_|.|_|_| (T T M M J J)

Fehlender Fragebogen:
- ☐ Wohlbefinden
- ☐ Bewegung
- ☐ Ernährung
- ☐ Nahrungsergänzungsmittel

Fragebogenpaket 3 ausgegeben? ◯ ja ◯ nein

Fragebogenpaket 3 vollständig zurückerhalten? ◯ ja ◯ nein

Wenn ja:

Ausfülldatum des Fragebogenpakets |_|_|.|_|_|.|_|_| (T T M M J J)

Fehlender Fragebogen:
- ☐ Wohlbefinden
- ☐ Bewegung
- ☐ Ernährung
- ☐ Nahrungsergänzungsmittel
- ☐ Fragebogen zur Bewertung der Studie

SCHRITTZÄHLER-TAGEBUCH

Nur zutreffend, wenn Probandin in entsprechender Subgruppe ist.

Tagebuch zum Schrittzähler 2 eingesammelt? ◯ ja ◯ nein ◯ nicht zutreffend

Tagebuch zum Schrittzähler 3 ausgegeben? ◯ ja ◯ nein ◯ nicht zutreffend

Tagebuch zum Schrittzähler 3 zurückerhalten? ◯ ja ◯ nein ◯ nicht zutreffend

GeliS | **Studienende** | **SE**

Praxis ID ___-___ Teilnehmer ID ___-___

Hat die Teilnehmerin die Studie vorzeitig beendet? ○ ja ○ nein

Wenn ja:

Datum des Studienabbruchs: ___ ___ ___ ___ ___ ___
T T M M J J

Grund für den Studienabbruch

(bitte kreuzen Sie alle zutreffenden Punkte an)

- ☐ Ungenügende Compliance gemäß Studienprotokoll
- ☐ Wunsch der Teilnehmerin
- ☐ Wegzug
- ☐ Nicht mehr erreichbar
- ☐ Abort / Frühgeburt
- ☐ Schwangerschaftskomplikation, die die Einhaltung des Protokolls nicht ermöglicht
- ☐ Anderer Grund, *bitte angeben:* _____

GeliS

Unterschrift

U

Praxis ID [ ]-[ ]

Teilnehmer ID [ ]-[ ]

Ich bezeuge, dass alle Einträge in diesem Case Report Form sorgfältig geprüft wurden.

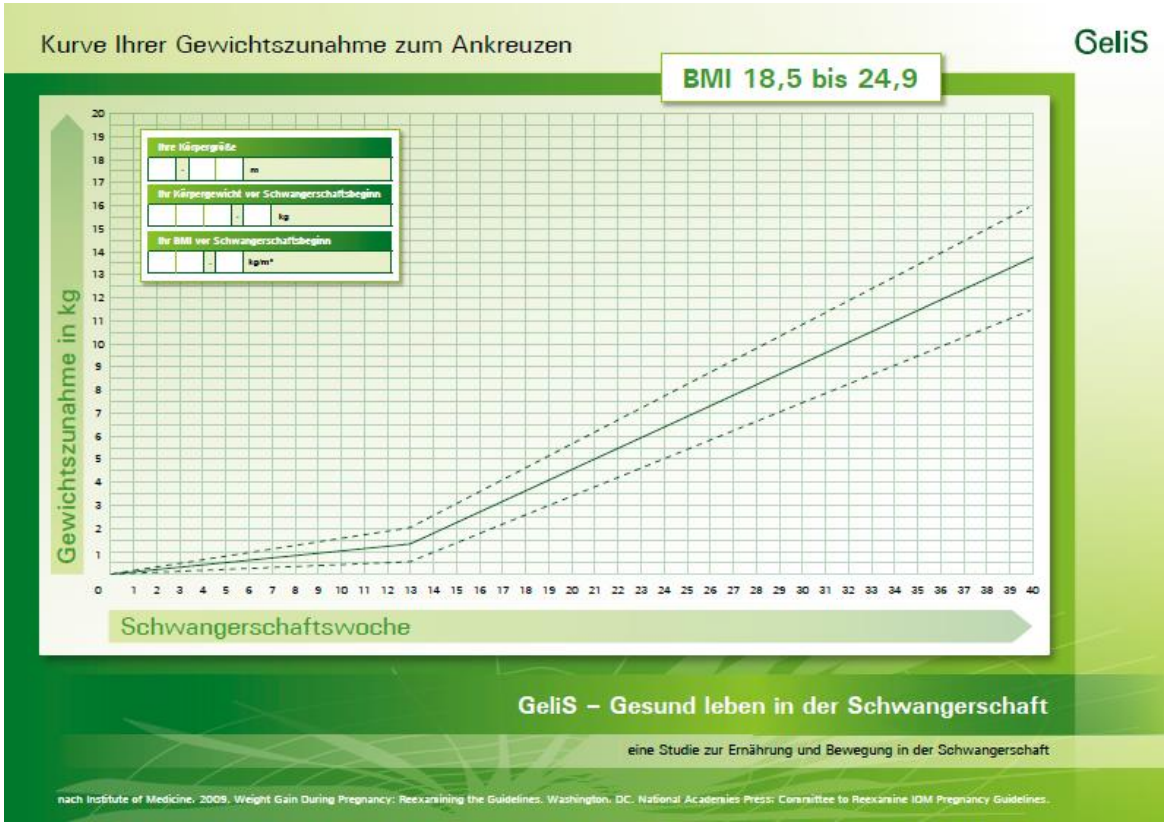
Nach bestem Wissen und Gewissen sind alle Einträge korrekt.

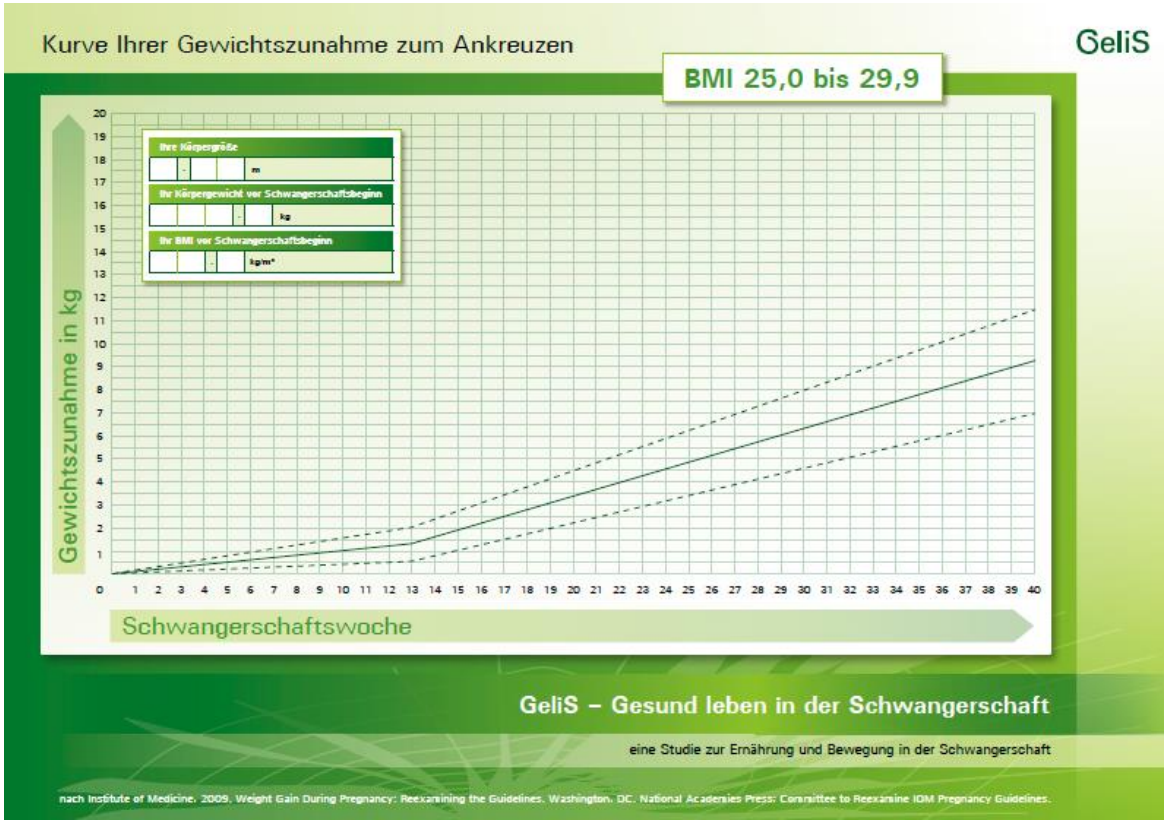
Datum	*Name des Projektkoordinators*	*Unterschrift des Projektkoordinators*

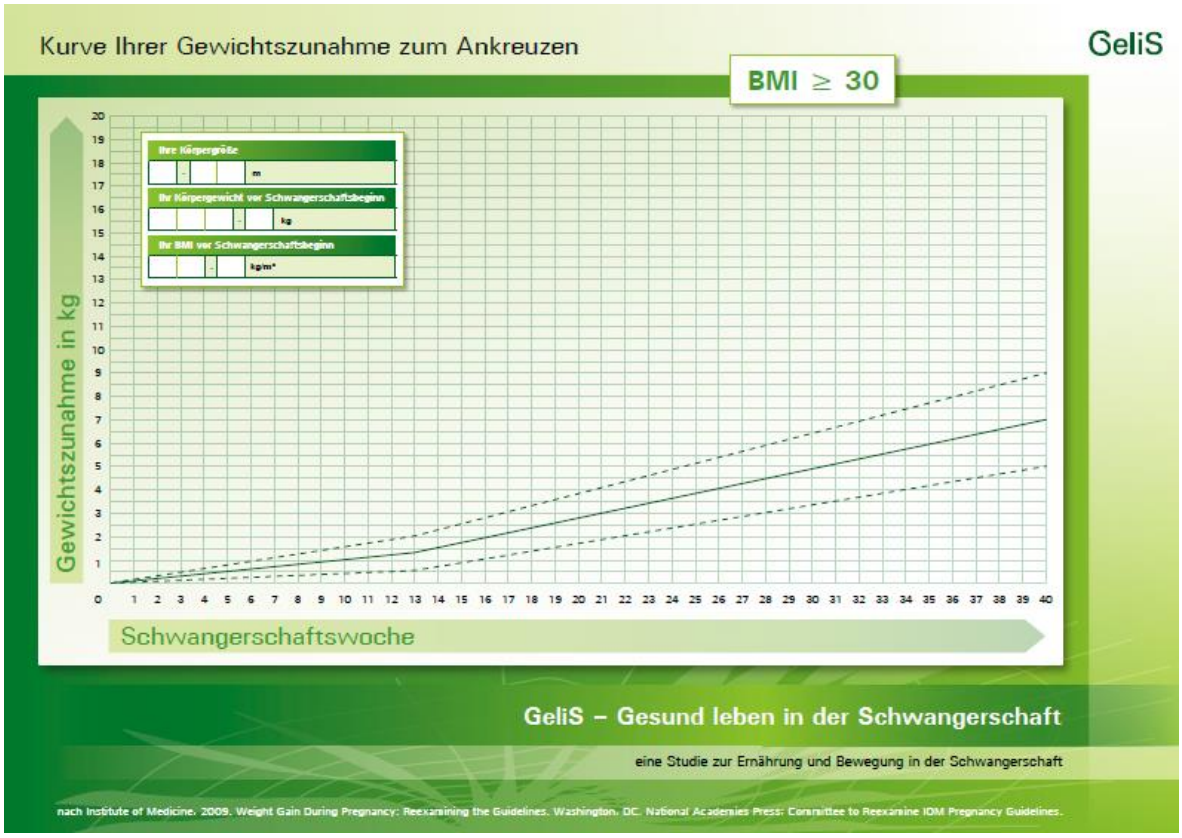
Bitte datieren und signieren Sie diese Seite erst, wenn das CRF vollständig ausgefüllt und monitoriert wurde.

Study document 5: Folder with presentation boards for parental counseling

Study document 6: Weight gain charts




Kurve Ihrer Gewichtszunahme zum Ankreuzen
GeliS
BMI 25,0 bis 29,9
Ihre Körpergröße
m
Ihr Körpergewicht vor Schwangerschaftsbeginn
kg
Ihr BMI vor Schwangerschaftsbeginn
kg/m²
Gewichtszunahme in kg
Schwangerschaftswoche
GeliS – Gesund leben in der Schwangerschaft
eine Studie zur Ernährung und Bewegung in der Schwangerschaft
nach Institute of Medicine. 2009. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington. DC. National Academies Press: Committee to Reexamine IOM Pregnancy Guidelines.


Kurve Ihrer Gewichtszunahme zum Ankreuzen
GeliS
BMI ≥ 30
Ihre Körpergröße
m
Ihr Körpergewicht vor Schwangerschaftsbeginn
kg
Ihr BMI vor Schwangerschaftsbeginn
kg/m²
Gewichtszunahme in kg
Schwangerschaftswoche
GeliS – Gesund leben in der Schwangerschaft
eine Studie zur Ernährung und Bewegung in der Schwangerschaft
nach Institute of Medicine. 2009. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington. DC. National Academies Press: Committee to Reexamine IOM Pregnancy Guidelines.

Study document 7: Instructions

GeliS	**Merkblatt Berater**	**B**

• Erhalt des Kurzfragebogens mit Teilnehmerdaten von Praxis
→ Kontaktaufnahme mit der Schwangeren und Terminvereinbarung

Folgende Inhalte sind in den Beratungsgesprächen zu besprechen (die Seitenzahlen beziehen sich auf die jeweiligen Präsentationstafeln des Tischaufstellers zur Beratung). Die genannten Tafeln sollten auf jeden Fall in den jeweiligen Gesprächen eingesetzt werden. Je nach Zeit und Bedarf können weitere Tafeln besprochen oder wiederholt werden.

1. Beratungsgespräch
- Präsentationstafeln **1-7** (gesunder Lebensstil, Energiebedarf, Folsäure/Jod, Gewichtszunahme, Bewegung)
- Individuelle Kurve zur Gewichtszunahme
- Präsentationstafeln **12, 13** (aid Pyramide, Portionsgrößen)
- Präsentationstafeln **19, 20** (Lebensmittelinfektionen, Alkohol & Rauchen)

Folgende Materialien sind im 1. Gespräch auszugeben:
- Flyer „Fit durch die Schwangerschaft“
- Broschüre „Das beste Essen in der Schwangerschaft“
- Bewegungsübungen
- Liste mit lokalen Angeboten

2. Beratungsgespräch
- Individuelle Kurve zur Gewichtszunahme
- Präsentationstafeln **7-10, 12-18** (detaillierte Informationen zu Ernährung und Bewegung)
- Integration individueller Probleme, welche anhand des Fragebogens erarbeitet wurden
- Präsentationstafel **24** (Schwangerschaftsdiabetes)

3. Beratungsgespräch
- Präsentationstafel **2** (Einstieg, Wiederholung)
- Individuelle Kurve zur Gewichtszunahme
- Präsentationstafel **11** (Ausblick Bewegung nach der Geburt)
- Präsentationstafeln **21-23** (Stillen, Allergieprävention)
- Wiederholung von Inhalten der ersten beiden Gespräche (individuell, je nach Bedarf)

Folgende Materialien sind im 3. Gespräch auszugeben:
- Flyer „Stillen – was sonst?“

4. Beratungsgespräch
- Präsentationstafeln **1-9 aus Ernährung von Säuglingen** (5-6 nur wenn Mutter nicht stillt)

Folgende Materialien sind im 4. Gespräch auszugeben:
- Aufkleber für das Kinder-Untersuchungsheft
- Fotobroschüren (Ernährung/Bewegung im 1. LJ)
- Liste mit lokalen Angeboten

• Fragebogenpakete entsprechend der Checkliste ausgeben und einsammeln

• Weiterleitung von ausgefüllten Fragebogenpaketen, Checklisten an Fachzentrum und Erhalt der Aufwandsentschädigung

Version 01 29.04.2013

GeliS	Merkblatt Fachzentrum	FZ

Rekrutierung der Frauenarztpraxen (ca. 8-10 Praxen pro Region)

- Anschreiben mit Rückantwortkarte verschicken
- Information der Praxis vor Ort
- Einverständniserklärung/Vertrag zur Studie unterschreiben lassen
- Einweisung des Praxispersonals in Studienunterlagen und Abläufe
- Studienmaterialien (Flyer, Plakate, Studienordner, Teilnehmermappen) ausgeben
- Praxis ID vergeben und Praxis in entsprechende Liste aufnehmen

Rekrutierung der Berater (Hebammen/Praxispersonal) (ca. 8-10 in Interventionsregion)

- Abklären, ob teilnehmende Praxis mit Hebamme zusammenarbeitet und diese Interesse an Studie hat oder Praxispersonal Beratungen übernehmen möchte
- alternativ: Hebammen im Umfeld der Praxis anschreiben und informieren
- Schulungstermin für Berater im Fachzentrum durchführen (Schulung zu Ernährung/Bewegung in der Schwangerschaft, Einweisung in Studienunterlagen und Abläufe, Ausgeben von Studienmaterialien)
- Einverständniserklärung/Vertrag zur Studie unterschreiben lassen
- Berater ID vergeben und Berater in entsprechende Liste aufnehmen

Arbeiten im Studienverlauf (ca. 250 Schwangere je Region)

- Prüfung der erhaltenen Dokumente auf Vollständigkeit/Plausibilität, evtl. Rückfragen an Praxen/Berater (siehe Datenfluss)
- Vergabe von Teilnehmer IDs und Codierung der Fragebögen (siehe Datenfluss)
- Aufnahmebestätigungen der Teilnehmerinnen an Praxis faxen
- Übertragung der Daten in den CRF

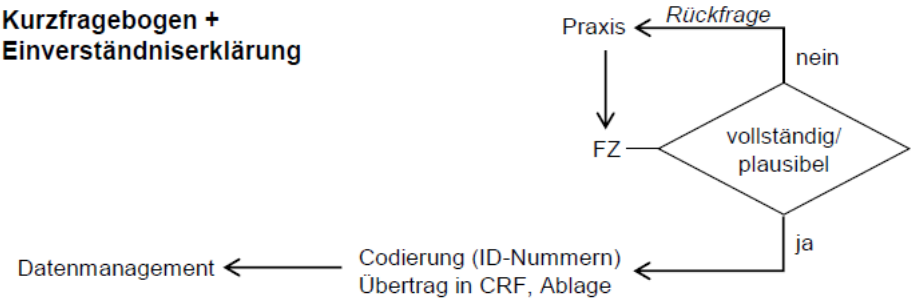
- Versorgung der Praxen/Berater mit Materialien

Version 01 29.04.2013

GeliS | **Merkblatt Fachzentrum (FZ)** | **FZ**

Datenfluss Studienverlauf

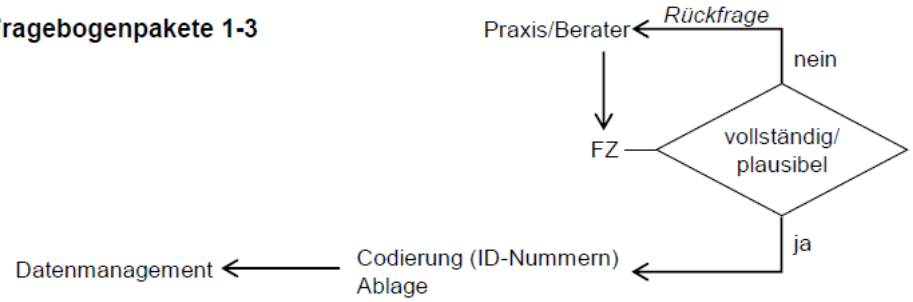
Kurzfragebogen + Einverständniserklärung



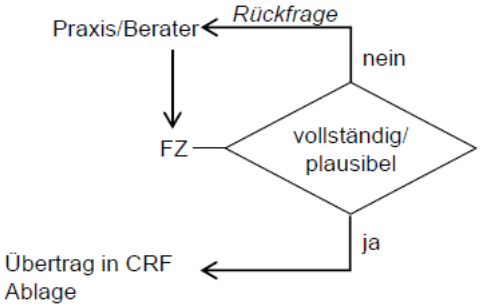
Registrierung der Teilnehmerin

Teilnehmer ID vergeben → Teilnehmeridentifikationsliste
Registrierung an Praxis per Fax bestätigen → Teilnehmerliste für Praxis

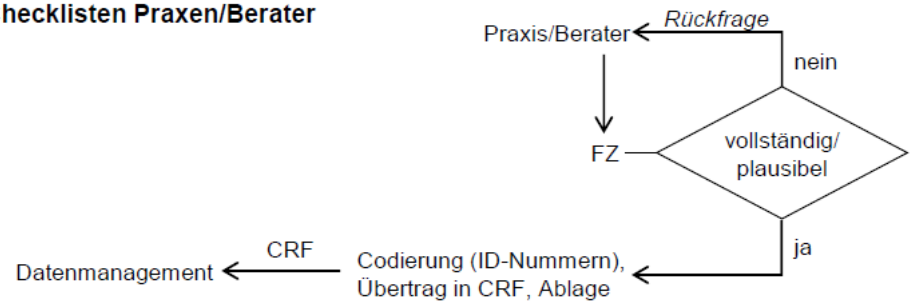
Fragebogenpakete 1-3



Kopien Geburtenprotokoll/ Mutterpass



Checklisten Praxen/Berater



Version 01 29.04.2013

GeliS	Merkblatt Interventionsregion	IN

- Bitte jeder Schwangeren ≤ 12. SSW Flyer mit Kurzfragebogen zur Studie aushändigen

- Schwangere möchte nicht teilnehmen
→ Kurzfragebogen anonym ausfüllen lassen und im Studienordner abheften

- Schwangere möchte teilnehmen
  → Ein- und Ausschlusskriterien anhand des Kurzfragebogens überprüfen
  (Sind ein oder mehrere Kriterien nicht erfüllt, kann die Schwangere nicht in die Studie eingeschlossen werden. Kriterien werden entsprechend angekreuzt, Schwangere informiert und Fragebogen im Studienordner abgeheftet.)
  → Ausführliche Teilnehmerinformation ausgeben und Einverständniserklärung unterschreiben lassen
  → Teilnehmermappe zur Studie ausgeben
  → Aufkleber zur Erinnerung an den jeweiligen Stellen im Mutterpass anbringen
  (Einband: Teilnehmerin der GeliS-Studie, S. 4: oGTT/HbA1c-Aufkleber, S. 16: Kopierhinweis)
  → Einverständniserklärung und Kurzfragebogen (im Original) an Fachzentrum weiterleiten (Kopie des Kurzfragebogens im Studienordner abheften)
  → Kurzfragebogen an Berater weiterleiten
  → Erhalt einer Einschlussbestätigung vom Fachzentrum

- Bei jeder Teilnehmerin 75g-oralen Glukosetoleranztest (**oGTT**) zwischen der 24.-28. SSW durchführen und **HbA1c** zwischen der 30.-34. SSW bestimmen

- Studienteilnehmerinnen bei **jeder** Vorsorgeuntersuchung sowie bei der **Nachuntersuchung** (6-8 Wochen nach Entbindung) wiegen:

  Waage auf einer festen, glatten Oberfläche positionieren
  Patientin ohne Schuhe und schwere Kleidung wiegen
  Dokumentation des Körpergewichts in Kilogramm (kg) auf 1 Dezimalstelle genau im Mutterpass
  Nichts für die Kleidung abziehen!

- Lesbare, sorgfältige Eintragungen von allen Messungen, Komplikationen (insb. Kontra-indikationen zur körperlichen Aktivität) während der Schwangerschaft und Geburt in den Mutterpass

- **Kopie der Seiten 4-9, 15, 16** (bei 2. Schwangerschaft: S.20-25, 31, 32) des Mutterpasses und Kopie des **Geburtenprotokolls** bei der Nachuntersuchung (6-8 Wochen nach Geburt)

- Weiterleitung von Kopien (Mutterpass, Geburtenprotokoll), Checklisten an Fachzentrum und Erhalt der Aufwandsentschädigung

Version 01 29.04.2013

GeliS	**Merkblatt Vergleichsregion**	**V**

- Bitte **jeder** Schwangeren ≤ 12. SSW Flyer mit Kurzfragebogen zur Studie aushändigen

- Schwangere möchte nicht teilnehmen
→ Kurzfragebogen anonym ausfüllen lassen und im Studienordner abheften

- Schwangere möchte teilnehmen
  →Ein- und Ausschlusskriterien anhand des Kurzfragebogens überprüfen
  (Sind ein oder mehrere Kriterien nicht erfüllt, kann die Schwangere nicht in die Studie eingeschlossen werden. Kriterien werden entsprechend angekreuzt Schwangere informiert und Fragebogen im Studienordner abgeheftet.)
  → Ausführliche Teilnehmerinformation ausgeben und Einverständniserklärung unterschreiben lassen
  → Teilnehmermappe zur Studie ausgeben
  → Aufkleber zur Erinnerung an den jeweiligen Stellen im Mutterpass anbringen
  (Einband: Teilnehmerin der GeliS-Studie, S. 4: oGTT/HbA1c-Aufkleber, S. 16: Kopierhinweis)
  → Einverständniserklärung und Kurzfragebogen (im Original) an Fachzentrum weiterleiten (Kopie des Kurzfragebogens im Studienordner abheften)
  → Erhalt einer Einschlussbestätigung vom Fachzentrum

- Bei jeder Teilnehmerin 75g-oralen Glukosetoleranztest (**oGTT**) zwischen der 24.-28. SSW durchführen und **HbA1c** zwischen der 30.-34. SSW bestimmen

- Fragebogenpakete entsprechend der Checkliste ausgeben, einsammeln und im Studienordner abheften

- Studienteilnehmerinnen bei **jeder** Vorsorgeuntersuchung sowie bei der **Nachuntersuchung** (6-8 Wochen nach Entbindung) wiegen:

  Waage auf einer festen, glatten Oberfläche positionieren
  Patientin ohne Schuhe und schwere Kleidung wiegen
  Dokumentation des Körpergewichts in Kilogramm (kg) auf 1 Dezimalstelle genau im Mutterpass
  Nichts für die Kleidung abziehen!

- Lesbare, sorgfältige Eintragungen von allen Messungen, Komplikationen (insb. Kontra-indikationen zur körperlichen Aktivität) während der Schwangerschaft und Geburt in den Mutterpass

- **Kopie der Seiten 4-9, 15, 16** (bei 2. Schwangerschaft: S. 20-25, 31, 32) des Mutterpasses und Kopie des **Geburtenprotokolls** bei der Nachuntersuchung (6-8 Wochen nach Geburt)

- Weiterleitung von Kopien (Mutterpass, Geburtenprotokoll), ausgefüllten Fragebogenpaketen, Checklisten an Fachzentrum und Erhalt der Aufwandsentschädigung

Version 01 29.04.2013

Study document 8: Checklists

GeliS | **Checkliste Berater** | **B**

Teilnehmerdaten

Nachname: _____

Vorname: _____

Adresse: _____

_____

Name des Beraters

_____

≤ 12. SSW (Einschluss)

Kurzfragebogen erhalten? ○ ja ● nein

↓

Von welcher Praxis: _____

Teilnehmerin kontaktiert und Termin zum 1. Beratungsgespräch vereinbart? ○ ja ● nein

↓

Gesprächstermin: T T M M J J

12. - 16. SSW (1. Beratung)

1. Beratungsgespräch hat stattgefunden? ○ ja ● nein

↓ Begründung:

_____

_____

Datum des 1. Gesprächs: T T M M J J

SSW: +

Dauer des 1. Gesprächs:

min

Das Gespräch hat stattgefunden:

_____

Unterschrift der Schwangeren

Infomaterialien und Gewichtskurve ausgegeben? ○ ja ● nein

Hinweis auf Schrittzähler? ○ ja ● nein

Fragebogenpaket 1 + Tagebuch Schrittzähler 1 liegen ausgefüllt vor? ○ ja ● nein

Termin zum 2. Beratungsgespräch vereinbart? ○ ja ● nein

↓

Gesprächstermin: T T M M J J

Version 01 29.04.2013

GeliS | **Checkliste Berater** | **B**

16. - 20. SSW (2. Beratung)

2. Beratungsgespräch hat stattgefunden? ○ ja ● nein

Datum des 2. Gesprächs: **SSW:** +

T T M M J J

Dauer des 2. Gesprächs:

min

Begründung:

Das Gespräch hat stattgefunden:

Unterschrift der Schwangeren

Hinweis auf oralen Glukosetoleranztest? ○ ja ● nein

Termin zum 3. Beratungsgespräch vereinbart? ○ ja ● nein

Gesprächstermin: T T M M J J

30. - 34. SSW (3. Beratung)

3. Beratungsgespräch hat stattgefunden? ○ ja ● nein

Datum des 3. Gesprächs: **SSW:** +

T T M M J J

Dauer des 3. Gesprächs:

min

Begründung:

Das Gespräch hat stattgefunden:

Unterschrift der Schwangeren

Fragebogenpaket 2 + Tagebuch Schrittzähler 2 ausgegeben? ○ ja ● nein

Flyer zum Stillen ausgegeben? ○ ja ● nein

Termin zum 4. Beratungsgespräch vereinbart? ○ ja ● nein

Gesprächstermin: T T M M J J

Version 01 29.04.2013

GeliS	Checkliste Berater	B

6. - 8. Woche nach Geburt (4. Beratung)

4. Beratungsgespräch hat stattgefunden? ○ ja ● nein

Datum des 4. Gesprächs: **SSW:** ← Begründung:

T T M M J J + ____

Dauer des 4. Gesprächs:

____ min

Das Gespräch hat stattgefunden: _____ Unterschrift der Schwangeren

Fragebogenpaket 2 + Tagebuch Schrittzähler 2 liegen ausgefüllt vor? ○ ja ● nein

Infomaterialien ausgegeben? ○ ja ● nein

Fragebogenpaket 3 + Tagebuch Schrittzähler 3 + Rückumschlag ausgegeben? ○ ja ● nein

Studienabbruch

Hat die Teilnehmerin die Studie vorzeitig beendet? ○ ja ● nein

Datum des Studienabbruchs: T T M M J J

Grund für den Studienabbruch: _____

Studienende

Fragebogenpaket 1/2 , Tagebuch zum Schrittzähler 1/2 und Checkliste an Fachzentrum übermittelt? ○ ja ● nein

Kontaktdaten Fachzentrum:
Amt für Ernährung, Landwirtschaft und Forsten
Fürstenfeldbruck
Fachzentrum L 3.10 Ernährung/Gemeinschaftsverpflegung
Bettina Dörr und Stefanie Schirle
Kaiser-Ludwig-Str. 8a
82256 Fürstenfeldbruck
Telefon: 08141/3223 -253 oder -300
E-Mail: Bettina.Doerr@aelf-ff.bayern.de
Stefanie.Schirle@aelf-ff.bayern.de

Kontaktdaten Studienleitung:
Kompetenzzentrum für Ernährung – KErn
Kathrin Rauh
Am Gereuth 4
85354 Freising
Tel. 08161/71 2788
Mobil 0152/226 37 381
GeliS@KErn.bayern.de

Version 01 29.04.2013

GeliS	Checkliste Praxis	IN

Teilnehmerdaten

Nachname: _____

Vorname: _____

Adresse: _____

_____

Name/Stempel der Praxis

_____

≤ 12. SSW (Einschluss)

Kurzfragebogen liegt ausgefüllt vor?	○ ja	● nein
Ein- und Ausschlusskriterien überprüft?	○ ja	● nein
Einverständniserklärung unterschrieben?	○ ja	● nein
Teilnehmermappe ausgegeben?	○ ja	● nein
Kurzfragebogen und Einverständniserklärung an Fachzentrum übermittelt?	○ ja	● nein
Bestätigung von Fachzentrum zur Aufnahme in die Studie erhalten?	○ ja	● nein
Kopie Kurzfragebogen an Berater übermittelt?	○ ja	● nein

↓

Name des Beraters: _____

24. - 28. SSW (oGTT)

75g-oGTT durchgeführt und Ergebnisse im Mutterpass dokumentiert?	○ ja	● nein

↓

Screening-Test (50g Glukoselösung) durchgeführt und Ergebnis im Mutterpass dokumentiert?	○ ja	● nein

30. - 34. SSW (HbA1c)

HbA1c bestimmt und Ergebnisse im Mutterpass dokumentiert?	○ ja	● nein

6. - 8. Woche nach Geburt (Nachuntersuchung)

Körpergewicht gemessen und im Mutterpass dokumentiert?	○ ja	● nein
Kopie Seite 4-9, 15 und 16 des Mutterpasses?	○ ja	● nein
Kopie Geburtenprotokoll?	○ ja	● nein

Version 01 29.04.2013

GeliS	Checkliste Praxis	IN

Studienabbruch

Hat die Teilnehmerin die Studie vorzeitig beendet? ◯ ja ◉ nein

Datum des Studienabbruchs: T T M M J J

Grund für den Studienabbruch: _____

_____

Studienende

Kopie Mutterpass, Kopie Geburtenprotokoll und Checkliste an Fachzentrum übermittelt ◯ ja ◉ nein

Kontaktdaten Fachzentrum:

Amt für Ernährung, Landwirtschaft und Forsten Fürstenfeldbruck
Fachzentrum L 3.10 Ernährung/Gemeinschaftsverpflegung
Bettina Dörr und Stefanie Schirle
Kaiser-Ludwig-Str. 8a
82256 Fürstenfeldbruck

Telefon: 08141/3223 -253 oder -300
E-Mail: Bettina.Doerr@aelf-ff.bayern.de
Stefanie.Schirle@aelf-ff.bayern.de

Kontaktdaten Studienleitung:

Kompetenzzentrum für Ernährung – KErn
Kathrin Rauh
Am Gereuth 4
85354 Freising

Tel. 08161/71-2788
Mobil 0152/226 37 381
GeliS@KErn.bayern.de

Version 01 29.04.2013

GeliS	Checkliste Praxis	V

Teilnehmerdaten

Nachname: _____

Vorname: _____

Adresse: _____

_____

Name/Stempel der Praxis

_____

≤ 12. SSW (Einschluss)

Kurzfragebogen liegt ausgefüllt vor?	◯ ja	◯ nein
Ein- und Ausschlusskriterien überprüft?	◯ ja	◯ nein
Einverständniserklärung unterschrieben?	◯ ja	◯ nein
Teilnehmermappe ausgegeben?	◯ ja	◯ nein
Kurzfragebogen und Einverständniserklärung an Fachzentrum übermittelt?	◯ ja	◯ nein
Bestätigung von Fachzentrum zur Aufnahme in die Studie erhalten?	◯ ja	◯ nein

24. - 28. SSW (oGTT)

Fragebogenpaket 1 + Tagebuch Schrittzähler 1 liegen ausgefüllt vor?	◯ ja	◯ nein
75g-oGTT durchgeführt und Ergebnisse im Mutterpass dokumentiert?	◯ ja	◯ nein

↓

Screening-Test (50g Glukoselösung) durchgeführt und Ergebnis im Mutterpass dokumentiert?	◯ ja	◯ nein

30. - 34. SSW (HbA1c)

HbA1c bestimmt und Ergebnisse im Mutterpass dokumentiert?	◯ ja	◯ nein
Fragebogenpaket 2 + Tagebuch Schrittzähler 2 ausgegeben?	◯ ja	◯ nein

6. - 8. Woche nach Geburt (Nachuntersuchung)

Fragebogenpaket 2 + Tagebuch Schrittzähler 2 liegen ausgefüllt vor?	◯ ja	◯ nein
Körpergewicht gemessen und im Mutterpass dokumentiert?	◯ ja	◯ nein
Kopie Seite 4-9, 15 und 16 des Mutterpasses?	◯ ja	◯ nein
Kopie Geburtenprotokoll?	◯ ja	◯ nein
Fragebogenpaket 3 + Tagebuch Schrittzähler 3 + Rückumschlag ausgegeben?	◯ ja	◯ nein

Version 01 29.04.2013

GeliS	Checkliste Praxis	V

Studienabbruch

Hat die Teilnehmerin die Studie vorzeitig beendet? ◯ ja ◉ nein

Datum des Studienabbruchs: T T M M J J

Grund für den Studienabbruch: _____

_____

Studienende

Fragebogenpaket 1/2, Tagebuch Schrittzähler 1/2, Kopie Mutterpass, Kopie Geburtenprotokoll und Checkliste an Fachzentrum übermittelt ◯ ja ◉ nein

Kontaktdaten Fachzentrum:

Amt für Ernährung, Landwirtschaft und Forsten Fürstenfeldbruck
Fachzentrum L 3.10 Ernährung/Gemeinschaftsverpflegung
Bettina Dörr und Stefanie Schirle
Kaiser-Ludwig-Str. 8a
82256 Fürstenfeldbruck

Telefon: 08141/3223 -253 oder -300
E-Mail: Bettina.Doerr@aelf-ff.bayern.de
Stefanie.Schirle@aelf-ff.bayern.de

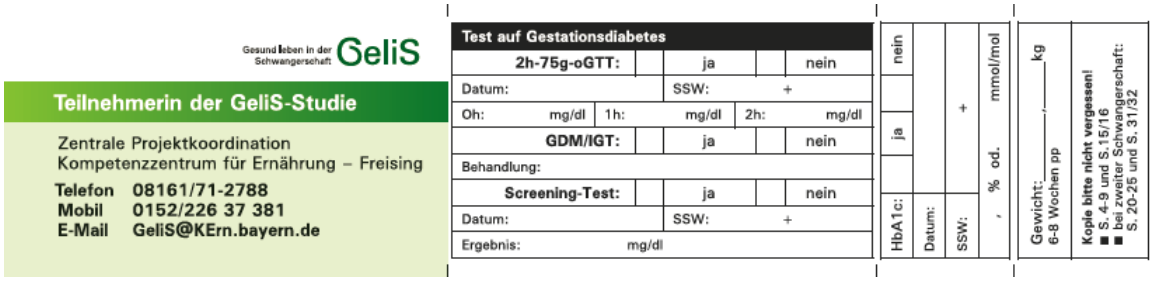
Kontaktdaten Studienleitung:

Kompetenzzentrum für Ernährung – KErn
Kathrin Rauh
Am Gereuth 4
85354 Freising

Telefon: 08161/71 2788
Mobil: 0152/226 37 381
E-Mail: GeliS@KErn.bayern.de

Version 01 29.04.2013

Study document 9: Sticker for maternity card



Gesund leben in der Schwangerschaft GeliS

Teilnehmerin der GeliS-Studie

Zentrale Projektkoordination
Kompetenzzentrum für Ernährung – Freising
Telefon 08161/71-2788
Mobil 0152/226 37 381
E-Mail GeliS@KErn.bayern.de

Test auf Gestationsdiabetes

2h-75g-oGTT:		ja		nein
Datum:		SSW:	+	
Oh: mg/dl	1h: mg/dl	2h: mg/dl		
GDM/IGT:		ja		nein
Behandlung:				
Screening-Test:		ja		nein
Datum:		SSW:	+	
Ergebnis: mg/dl				

nein / ja

HbA1c: Datum: SSW: + % od. mmol/mol

Gewicht: ,__ kg
6-8 Wochen pp

Kopie bitte nicht vergessen!
- S. 4-9 und S.15/16
- bei zweiter Schwangerschaft: S. 20-25 und S. 31/32

2. SUPPLEMENTAL TABLES

Table 28: GWG among study participants according the IOM recommendations.

	All Participants			Normal weight women		Overweight women		Obese women	
	Int (n=946)	Con (n=939)	Adjusted p value[1]	Int (n=608)	Con (n=624)	Int (n=230)	Con (n=200)	Int (n=108)	Con (n=115)
<IOM	202 (21.4)	187 (19.9)	**0.002**	156 (25.7)	147 (23.6)	26 (11.3)	19 (9.5)	20 (18.5)	21 (18.3)
=IOM	317 (33.5)	324 (34.5)	-	244 (40.1)	254 (40.7)	54 (23.5)	43 (21.5)	19 (17.6)	27 (23.5)
>IOM	427 (45.1)	429 (45.7)	0.79	208 (34.2)	224 (35.9)	150 (65.2)	138 (69.0)	69 (63.9)	67 (58.3)

Data are given as n (%)
Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit
[1]Generalized estimating equations (GEE) logistic regression model adjusted for pre-pregnancy BMI, age, parity and gestational age at 1st visit
IOM=Institute of Medicine; Int=Intervention; Con=Control

Table 29: Mean total GWG among all study participants.

Mean total GWG (n=1885)	14.1 ± 5.2
Normal weight	14.7 ± 4.5
Overweight	14.0 ± 5.8
Obese	11.0 ± 6.7

Data are given as mean ± standard deviation
Gestational weight gain=weight change between the weight measured at the first and the last prenatal visit

Table 30: Maternal blood pressure.

Maternal blood pressure (mmHg)	Intervention	Control
Visit 0		
Systolic	117.7 ± 12.4	115.5 ± 11.9
Diastolic	73.4 ± 9.2	70.7 ± 9.2
Visit 1		
Systolic	117.3 ± 12.4	114.0 ± 12.0
Diastolic	72.9 ± 9.3	69.4 ± 9.2
Visit 2		
Systolic	116.0 ± 12.3	114.0 ± 12.6
Diastolic	71.6 ± 8.7	68.5 ± 9.0
Visit 3		
Systolic	116.9 ± 12.4	114.3 ± 12.0
Diastolic	72.7 ± 9.2	69.3 ± 9.1
Visit G		
Systolic	120.9 ± 13.0	118.6 ± 13.1
Diastolic	76.2 ± 9.8	73.3 ± 9.9
Blood pressure after birth/ in puerperium		
Systolic	119.9 ± 13.2	118.6 ± 12.5
Diastolic	73.3 ± 10.1	75.4 ± 9.8

Data are given as mean ± standard deviation

Table 31: Qualitative evaluation of lifestyle counseling sessions.

Quality parameters	
Monitored counseling sessions (n)	53
Median duration of sessions (min)	35
Utilization of study documents (n)	46/53 (**86.8 %**)
Among study document users: completeness of counseling contents (n)	32/46 (**69.6 %**)
Weight monitoring with weight gain chart (n)	39/53 (**73.6 %**)
Individual counseling (n)	33/53 (**62.3 %**)

Table 32: Experiences of GeliS counselors with study procedures.

Data were recorded at the end of the trial using an evaluation questionnaire. The feedback was available from 63.5 % of counselors.

	Completely true	Rather true	Partly	Rather not true	Not true at all
Experiences with counseling sessions					
Pregnant women are willing to take part in the counseling program.	35 %	54 %	11 %	0 %	0 %
The number of counseling sessions was sufficient.	69 %	26 %	5 %	0 %	0 %
The duration of the counseling sessions was sufficient.	49 %	35 %	8 %	5 %	3 %
There were a few questions that I was unable to answer.	3 %	5 %	10 %	49 %	33 %
I would like to continue to inform women about a healthy lifestyle during pregnancy.	55 %	32 %	13 %	0 %	0 %
In future, the counseling should be offered as part of routine prenatal care.	82 %	11 %	5 %	3 %	0 %
In future, it would make sense if counseling sessions would be supported by nutrition and exercise specialists.	15 %	41 %	28 %	13 %	3 %
Compatibility of counseling sessions with routine practice					
Counseling sessions can be easily integrated into the daily routine of the practice in terms of time.	10 %	21 %	38 %	23 %	8 %
Counseling sessions can be easily integrated into the daily routine of the practice in terms of organization (rooms, coordination, etc.).	21 %	31 %	23 %	21 %	5 %
I was able to conduct most of the counseling sessions during normal office hours.	32 %	24 %	16 %	8 %	19 %
Satisfaction with qualifying seminars and materials					
The presentation folder was helpful during the counseling sessions.	51 %	31 %	13 %	5 %	0 %
The information material provided was helpful.	41 %	44 %	15 %	0 %	0 %
The weight curves provided were helpful.	21 %	34 %	32 %	13 %	0 %
The qualifying seminars made me feel well prepared for the counseling sessions.	45 %	39 %	12 %	3 %	0 %

ACKNOWLEDGEMENTS

Die wissenschaftliche Arbeit im Rahmen dieser Doktorarbeit wurde am Else Kröner-Fresenius-Zentrum für Ernährungsmedizin der Technischen Universität München durchgeführt. An erster Stelle danke ich Prof. Dr. Hauner, Leiter des Institutes, für die Möglichkeit dieses Thema zu bearbeiten, sowie für seine fortwährende Unterstützung während der Durchführung und Ausarbeitung dieser Arbeit. Seine wissenschaftliche Expertise war essentiell für diese Arbeit. Die Entfaltungsmöglichkeiten, die ich im GeliS Projekt genießen durfte, weiß ich wirklich sehr zu schätzen.

Besonders möchte ich mich beim gesamten GeliS Team für die großartige Zusammenarbeit bedanken. Das kontinuierliche Interesse am Fortschritt dieses Projektes, die Begeisterung für die Thematik sowie die herzliche Arbeitsatmosphäre und die fruchtbaren Diskussionen haben meine Arbeit vom ersten Tag bis zur Abgabe der Dissertation enorm bereichert. Dr. Kathrin Rauh möchte ich für die aufopferungsvolle und respektvolle Betreuung, die stets zielführenden Gespräche sowie die über die Arbeit hinaus fortwährende Unterstützung danken. Ein ganz besonderer Dank gilt auch Julia Günther. Ich hätte mir keine bessere Büropartnerin, Freundin und Begleiterin auf den Wegen dieser Arbeit vorstellen können. Danke für die produktive Zusammenarbeit an diversen Manuskripten, die lustigen Stunden auf den Autobahnen Bayerns und dein stets offenes Ohr. Außerdem möchte ich mich ausdrücklich bei Eva Rosenfeld und Luzia Kick für die mir entgegengebrachte Herzlichkeit und den geistreichen Austausch im Projekt GeliS bedanken. Allen Projektmanagerinnen der GeliS-Studie möchte ich für die hervorragende Kooperation sowie deren überdurchschnittlichen Einsatz im gesamten Verlauf des Projektes danken.

Auch den Kollegen und Kolleginnen des Lehrstuhls gilt mein besonderer Dank. Vor allem möchte ich meiner Kollegin und Freundin Dr. Britta Wessels sowie ihrem Ehemann Dr. Malte Wessels für die unvergessliche Zeit in Freising danken. Unvergessen werden mir neben den aufschlussreichen Fachgesprächen besonders die warmherzigen, ehrlichen und vor allem lustigen Stunden bleiben. Danke Britta, dass du mich so oft zu meinem Glück gezwungen hast. Für die bedingungslose und liebevolle Unterstützung in allen Belangen bin ich auch Sylvia Heinrich zutiefst dankbar. Weiterhin möchte ich Lynne Stecher für ihre ausführliche Hilfe bei den statischen Auswertungen und Analysen danken.

Schließlich möchte ich mich ausdrücklich bei meinen Eltern Birgit und Uwe Kunath sowie meiner Schwester Dr. Franziska Kunath bedanken. Danke, dass ihr mich in all meinen Wegen und

Entscheidungen bedingungslos unterstützt und mir das Gefühl gebt, nichts falsch machen zu können. Meinem Freund Dennis Dienst kann ich nicht genug danken. Das Vertrauen sowie die Liebe, die du mir schenkst, haben mir auch während der Promotionszeit geholfen, nicht aufzugeben. Danke, dass du mir alle Freiheiten gibst, ohne mich dabei loszulassen.

LIST OF PUBLICATIONS AND CONGRESS CONTRIBUTIONS

Publications

Rauh K[1], **Kunath J**[1], Rosenfeld E, Kick L, Ulm K, Hauner H. Healthy living in pregnancy: a cluster-randomized controlled trial to prevent excessive gestational weight gain - rationale and design of the GeliS study. BMC Pregnancy & Childbirth. 2014; 14:119.

Kunath J, Rauh K, Rosenfeld E, Kick L, Hauner H. GeliS: An evaluation of a lifestyle intervention programme on exercise and nutritional habits in pregnant women, families, and infants. Science & Sports. 2014; 29(1):44.

Rosenfeld E, Rauh K, Kick L, **Kunath J**, Günther J, Hauner H. Gesund leben in der Schwangerschaft (GeliS) – gesundheitsförderliche Ernährung von Schwangeren. Gesundheitswesen. 2015; 77:656.

Günther J, **Kunath J**, Wessels B, Rauh K, Hauner H. Fetale Prägung und frühkindliche Ernährung – ist eine Primärprävention von Adipositas möglich? Adipositas. 2015; 4.

Rauh K[1], Günther J[1], **Kunath J**, Stecher L, Hauner H. Lifestyle intervention to prevent excessive maternal weight gain: mother and infant follow-up at 12 months postpartum. BMC Pregnancy & Childbirth. 2015; 15:265.

Kunath J, Günther J, Kick L, Rauh K, Rosenfeld E, Hauner H. GeliS – Gesund leben in der Schwangerschaft. Eine Studie zur Ernährung und Bewegung in der Schwangerschaft. Die Hebamme. 2016; 29:354-360.

Kunath J[1] & Günther J[1], Rauh K, Hoffmann J, Stecher L, Rosenfeld E, Kick L, Ulm K, Hauner H. Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care – the cluster-randomised GeliS trial. In preparation.

[1] The first two authors contributed equally to this work.

Congress contributions

Talks

CIAPSE 2014 – 1st International Congress on Children's Physical Activity and Sport, 16.-18.10.2014, Liège. **Kunath J**, Rauh K. Rosenfeld E., Kick L. Hauner H. GeliS: An evaluation of a lifestyle intervention programme on exercise and nutritional habits in pregnant women, families, and infants.

11. Forum Hebammenarbeit, 18.-19.11.2016, Mainz. **Kunath J**, Günther J, Kick L, Rauh K, Rosenfeld E, Hauner H. GeliS (Gesund leben in der Schwangerschaft) - Eine Studie zur Ernährung und Bewegung in der Schwangerschaft.

33. Jahrestagung der DAG (Deutschen Adipositas-Gesellschaft e.V.), 28.-30.09.2017, Potsdam. **Kunath J**. Nutzen von Lebensstil-Interventionen in der Schwangerschaft.

8. Update Ernährungsmedizin, 13.-14.10.2017, Munich. **Kunath J**, Günther J, Rauh K, Kick L, Rosenfeld E, Hauner H. Übermäßige Gewichtszunahme in der Schwangerschaft – ein unterschätztes Problem!

Poster

Liesel Beckmann Symposium, 27.11.2015, Munich. **Kunath J**, Günther J, Rauh K, Rosenfeld E, Kick L, Hauner H. Healthy living in pregnancy: a cluster-randomized controlled trial to prevent excessive gestational weight gain - design and current status of the GeliS study.

The Power of Programming, 13.-15.10.2016, Munich. **Kunath J**, Günther J, Rauh K, Rosenfeld E, Kick L, Hauner H. GeliS - A lifestyle intervention trial to prevent excessive weight gain during pregnancy.

53. Wissenschaftlicher Kongress der DGE (Deutsche Gesellschaft für Ernährung e.V.), 02.-04.03.2018, Fulda. Rauh K, Hoffmann J, **Kunath J**, Günther J, Kick L, Rosenfeld E, Hauner H. Evaluation der Beratungsgespräche des Lebensstilinterventions-Programms „Gesund leben in der Schwangerschaft" (GeliS).

Tagungen

Fachtagung „Frühkindliche Prävention", 23.09.2015, Berlin

Tagung UNICEF Schweiz, „Gesunder Lebensstart – Gesundheitsförderung für Mutter und Kind", 10.11.2015, Basel

EIDESSTATTLICHE ERKLÄRUNG

Ich erkläre an Eides statt, dass ich die bei der promotionsführenden Einrichtung Wissenschaftszentrum Weihenstephan für Ernährung, Landnutzung und Umwelt der TUM zur Promotionsprüfung vorgelegte Arbeit mit dem Titel:

Lifestyle intervention for pregnant women to prevent excessive gestational weight gain: a cluster-randomized study in ten Bavarian regions.

am Lehrstuhl für Klinische Ernährungsmedizin unter der Anleitung und Betreuung durch Univ.-Prof. Dr. med. J. J. Hauner ohne sonstige Hilfe erstellt und bei der Abfassung nur die gemäß § 6 Abs. 6 und 7 Satz 2 angebotenen Hilfsmittel benutzt habe.

Ich habe keine Organisation eingeschaltet, die gegen Entgelt Betreuerinnen und Betreuer für die Anfertigung von Dissertationen sucht, oder die mir obliegenden Pflichten hinsichtlich der Prüfungsleistungen für mich ganz oder teilweise erledigt.

Ich habe die Dissertation in dieser oder ähnlicher Form in keinem anderen Prüfungsverfahren als Prüfungsleistung vorgelegt.

Die vollständige Dissertation wurde noch nicht veröffentlicht.

Ich habe den angestrebten Doktorgrad noch nicht erworben und bin nicht in einem früheren Promotionsverfahren für den angestrebten Doktorgrad endgültig gescheitert.

Die öffentlich zugängliche Promotionsordnung der TUM ist mir bekannt, insbesondere habe ich die Bedeutung von § 28 (Nichtigkeit der Promotion) und § 29 (Entzug des Doktorgrades) zur Kenntnis genommen. Ich bin mir der Konsequenzen einer falschen Eidesstattlichen Erklärung bewusst.

Mit der Aufnahme meiner personenbezogenen Daten in die Alumni-Datei bei der TUM bin ich einverstanden.

_____ _____

Ort, Datum Julia Kunath