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Improving cardiometabolic and mental health in women with gestational diabetes mellitus and their offspring: study protocol for *MySweetHeart Trial*, a randomised controlled trial

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ABSTRACT

Introduction Gestational diabetes mellitus (GDM) carries prenatal and perinatal risk for the mother and her offspring as well as longer-term risks for both the mother (obesity, diabetes, cardiovascular disease) and her child (obesity, type 2 diabetes). Compared with women without GDM, women with GDM are twice as likely to develop perinatal or postpartum depression. Lifestyle interventions for GDM are generally limited to physical activity and/or nutrition, often focus separately on the mother or the child and take place either during or after pregnancy, while their results are inconsistent. To increase efficacy of intervention, the multifactorial origins of GDM and the tight link between mental and metabolic as well as maternal and child health need to be heeded. This calls for an interdisciplinary transgenerational approach starting in, but continuing beyond pregnancy.

Methods and analysis This randomised controlled trial will assess the effect of a multidimensional interdisciplinary lifestyle and psychosocial intervention aimed at improving the metabolic and mental health of 200 women with GDM and their offspring. Women with GDM at 24–32 weeks gestational age who understand French or English, and their offspring and partners can participate. The intervention components will be delivered on top of usual care during pregnancy and the first year postpartum. Metabolic and mental health outcomes will be measured at 24–32 weeks of pregnancy, shortly after birth and at 6–8 weeks and 1 year after childbirth. Data will be analysed using intention-to-treat analyses. The *MySweetHeart Trial* is linked to the *MySweetHeart Cohort* (clinicaltrials.gov/ct2/show/NCT02872974).

Ethics and dissemination We will disseminate the findings through regional, national and international conferences and through peer-reviewed journals.

Trial registration number NCT02890693; Pre-results.

INTRODUCTION
Definition and prevalence of gestational diabetes mellitus (GDM)
GDM is characterised by glucose intolerance diagnosed during pregnancy not fulfilling the criteria for diabetes.[1 2] It often resolves after

Strengths and limitations of this study

► The study will test the effects of a novel multidimensional interdisciplinary lifestyle and psychosocial intervention for women with gestational diabetes mellitus.
► The intervention focuses on both metabolic and mental health, of the mother and her offspring, which starts during pregnancy and continues beyond birth.
► The intervention draws on theories of health behaviour change through motivational and systemic approaches.
► Methodological rigour, including concealment of random allocation, blinded outcome assessors, regular monitoring and prospective trial registration and publication, should limit risk of bias.
► Unblinded participants and clinicians for some of the secondary outcomes may increase the risk of bias.

childbirth,[1 2] although up to 40% of women have prediabetes in the early postpartum period.[3] In Switzerland, the prevalence of GDM is 10.8%.[4]

Morbidity of GDM and related conditions
GDM carries prenatal and perinatal risk for the mother and her child and is also linked to postnatal risks. Long-term maternal risks include a 30%–70% GDM recurrence, a 7-fold higher 5–10 year risk of type 2 diabetes and an increased risk of metabolic syndrome and cardiovascular disease.[5–8] Compared with women without GDM, women with GDM are twice to four times[9] as likely to develop antenatal or postpartum depression and approximately one-third of women with recent GDM develop postpartum depression.[10] Postpartum depression leads to an increase in comfort eating and a decrease in physical

activity,[11] thus putting the women at higher risk of weight gain and future diabetes.[10]

Regarding the child, the importance of the intrauterine and early postnatal environments for metabolic programming and modifications of the epigenome is increasingly recognised,[12–14] particularly for metabolic diseases such as obesity and diabetes.[15] Thus, GDM is related to macrosomia at birth (>4 kg), to excess body fat and (central) obesity and to insulin secretion in infants and children, the obesity being in part mediated by maternal body mass index (BMI) or birth weight.[16–23] Intrauterine exposure to GDM also doubles the risk for subsequent type 2 diabetes in offspring compared with offspring of mothers with a high genetic predisposition for type 2 diabetes, but with normal glucose tolerance during the index pregnancy.[24] Maternal prepregnancy overweight and excessive gestational weight gain also predict high birth weight and adiposity during infancy.[12 25] This is highly relevant, as up to 60%–70% of women with GDM are overweight or obese before pregnancy.[26] Finally, maternal lifestyle behaviour such as a high fat diet or lack of physical activity during pregnancy can influence offspring adiposity independent of maternal obesity.[12 27]

The higher risk for maternal postpartum depression is also associated with reduced parenting skills, which may have negative consequences for the development of the child.[28–30] Parents of obese children may lack effective parenting skills providing both a consistent structured frame and emotional support.[31] In women with GDM, psychosocial vulnerability including low levels of social and family networks is associated with more adverse neonatal outcomes, especially increased birth weight.[32] Thus, there is a tight interaction between maternal lifestyle, weight status, mental health, social support as well as between maternal and child's overall health. In view of the high worldwide prevalence of (childhood) obesity and associated metabolic problems, this close link between maternal and child metabolic health and the resulting vicious cycle are very relevant.[33 34] Because of the deleterious impact of GDM and lifestyle during pregnancy on the health of the mother and her offspring, it is crucial to intervene during the prenatal, perinatal and postnatal period.

Modifiable risk factors of GDM

Risk factors for GDM that are modifiable during pregnancy include excessive weight gain which is a very frequent phenomenon that is observed in a majority of pregnant women (in up to 75% of pregnancies).[35 36] Further modifiable risk factors include lifestyle behaviours such as low levels of physical activity, high fat and animal protein consumption, high intake of added sugar and low intake of vegetable and fruit fiber.[37] Regular food intake and avoidance of snacking can have beneficial effects on weight and glucose tolerance, but this has mostly been tested outside of pregnancy.[38–42] Another key factor is mental health. Higher stress exposure and perceived stress during pregnancy have been linked to GDM and/or

higher glucose levels in women.[43–45] Psychological stress and negative life events can be associated with higher salivary cortisol levels during pregnancy, which might relate to higher glucose levels.[46] Higher depression scores early in pregnancy also increase the risk for GDM.[9 47] On the other hand, social support has been shown to be protective regarding mental health and depression in particular.[9 48 49]

Physical activity, nutrition and depression are interlinked. Physical activity can reduce symptoms of depression,[50] and there is a two-directional relationship between unhealthy eating and the incidence of symptoms of depression.[51] Mindfulness and mindful eating can have a beneficial impact on weight loss and food cravings.[52–54]

Prior studies having evaluated lifestyle interventions in GDM

Most interventions in GDM focus either on dietary or on physical activity changes and only last during pregnancy.

Dietary advice is recommended for all women with GDM to improve glycaemic control and to provide adequate nutrition.[1] Of the few existing trials, the majority focused on either low carbohydrate or low glycaemic index foods. Results were not consistent and effect sizes were small, but low glycaemic diets, sometimes in combination of higher fibre intake, were found to have a favourable impact on insulin requirements, birth weight and/or maternal weight gain.[55–57] A recent Cochrane review found that more evidence is needed to assess the effects of different types of dietary advice to give to women with GDM.[58] As fat, especially saturated fat, is a risk factor for both GDM and type 2 diabetes, decreasing animal fat intake represents an interesting novel approach.[59–62] Indeed, a high-complex carbohydrate/low-fat diet improved glycaemic values and insulin resistance in women with GDM as well as infant adiposity in a pilot study of women with GDM.[63] Regarding eating behaviour, a recent intervention focusing on mindfulness-based eating awareness that aimed at increasing awareness of inner cues, such as hunger and satiety, at identification of emotional eating and eating triggers, had a beneficial impact on glycaemic control.[64 65]

Although recommended for GDM treatment, guidelines do not specify the type of *physical activity* or its timing in regards to meal intake.[66 67] Aerobic and resistance exercise can be accomplished during pregnancy in the absence of contraindications,[68] but motivation, compliance, perceived health and lack of time appear to be major limiting factors.[48 69] A recent review concluded that physical activity, both aerobic and resistance exercise, may improve glycaemic control and/or limit insulin use in women with GDM.[70] Regular physical activity can also limit pregnancy weight gain, stabilise maternal mood and reduce fetal fat mass (FM) and physiological stress responses in the offspring.[27 69 71]

To our knowledge, there are no evidence-based *psychological interventions* for women with GDM and no international guidelines for psychosocial management exist,[72] although evidence shows that inclusion of partners can be helpful.[73 74]

Postpartum follow-up and interventions

Due to the increased risk of development or persistence of prediabetes and diabetes, management of women with GDM in the postpartum period is essential. The American Diabetes Association, the American College of Obstetricians and Gynaecologists and the National Diabetes Education Program recommend testing within 4–12 weeks postpartum with a 2 hour 75 g oral glucose tolerance test (oGTT).[2 75 76]

Weightloss is an important predictor to prevent diabetes in this high-risk population. Thus, in the Diabetes Prevention Program, weight loss after GDM reduced future diabetes incidence by 16% for every kilogram lost.[77] The Nurses Health Study found that healthy *diet* patterns such as a Mediterranean diet, a Dietary approaches to stop hypertension (DASH) pattern diet or an Alternative Healthy Eating diet reduced diabetes incidence by 40%–57% in women who had GDM 14 years before.[78] Evidence of the Gestational Diabetes' Effects on Moms study shows that a lifestyle intervention that starts during pregnancy and continues postpartum is feasible and may prevent pregnancy weight retention and help overweight women lose weight.[79 80]

In the postpartum period after GDM, low *social support* was related to low adherence to a healthy lifestyle, thus contributing to an increased risk of type 2 diabetes.[81] In another study, social support was a key factor for the adoption of physical activity among women after GDM.[82] Finally, integrating partners into the intervention helped to maximise participation in an intervention that aimed to prevent type 2 diabetes after GDM.[74]

Prevention strategies for the child

Offspring of women with GDM are at higher risk for childhood obesity[83] and intervening in the early postpartum period is therefore essential. Several modifiable risk or protective factors have been identified, such as infant feeding mode (bottle vs breastfeeding), parental responsiveness to infant feeding cues and infant distress, the age of bottle weaning, timing of the introduction of solid food, sweetened beverage consumption and lack of physical activity.[84–88] Inactivity can delay motor development and further increases the risk for early childhood obesity.[85 89–91]

Parenting skills interventions that focus on these factors provide anticipatory guidance and teach parents how to identify and respond appropriately to infant cues and distress to positively influence self-regulatory capacities, well-being and the developing control of the infant's food intake in order to avoid eating in the absence of hunger have shown beneficial results.[84 85 92 93]

Theoretical framework for behaviour change interventions

The chosen theoretical framework for the behaviour change interventions is the Health Action Process Approach (HAPA).[94]

The HAPA distinguishes between a motivational and a volitional phase of behavioural change. In the motivational phase, the process of forming an intention to engage in a health behaviour takes place. Being aware of a personal risk due to the unhealthy behaviour, perceiving more benefits than disadvantages of changing the behaviour (outcome expectancies) and believing in one's own abilities to change the behaviour (self-efficacy) are the factors that the HAPA specifies to increase the likelihood of a behavioural intention to change the behaviour. After an intention has been set, the individual enters the volitional phase. Here, action control, action planning, coping planning and again self-efficacy are assumed to be crucial for translating the intention into behaviour. Action control and its components (ie, the awareness of one's own standards for the new behaviour, self-monitoring and regulatory effort in case of a discrepancy between the intended and the actual behaviour) have been demonstrated in several populations and across several behaviours, among them physical activity and diet, to be effective in promoting behavioural change.[95] Moreover, action planning and coping planning are crucial postintentional variables in the HAPA. Action planning, which is also known as implementation intentions,[96 97] refers to if-then plans regarding the exact planning of when, where and how a behaviour will be implemented. Implementation intentions have been demonstrated to be an effective tool of behavioural change in numerous settings and behaviours, displaying medium to strong effect sizes.[98–100] Coping plans refer to plans that specify a critical barrier to the intended/planned behaviour and a specific strategy on how to cope with this barrier.[101] A recent systematic review attests that the combination of action planning and coping planning seems to be most effective for behavioural change.[102] Self-efficacy has also been shown to be a crucial factor in health behaviour change across different behaviours and different populations.

Development of a complex multidimensional interdisciplinary lifestyle intervention

Given that single risk factor interventions have shown limited efficacy, and considering the multifactorial origins of GDM, complex interdisciplinary approaches that start in pregnancy and continue postpartum, targeting both the mother and the child could be more efficient. This is especially important with regard to the intergenerational transmission of risk.[103] Some authors specifically called for the need to integrate psychological support in a lifestyle intervention.[104] Typical characteristics of *complex interventions* are that they contain several interacting components, their high number of outcomes and that a high degree of flexibility or tailoring of the intervention is permitted.[105] Furthermore, complex interventions work best if tailored to local circumstances rather than completely standardised.[105]

Aims

This study aims to test the effect of an evidence-based, complex interdisciplinary lifestyle and psychosocial continuous prepartum and postpartum intervention in women with GDM on maternal and offspring metabolic
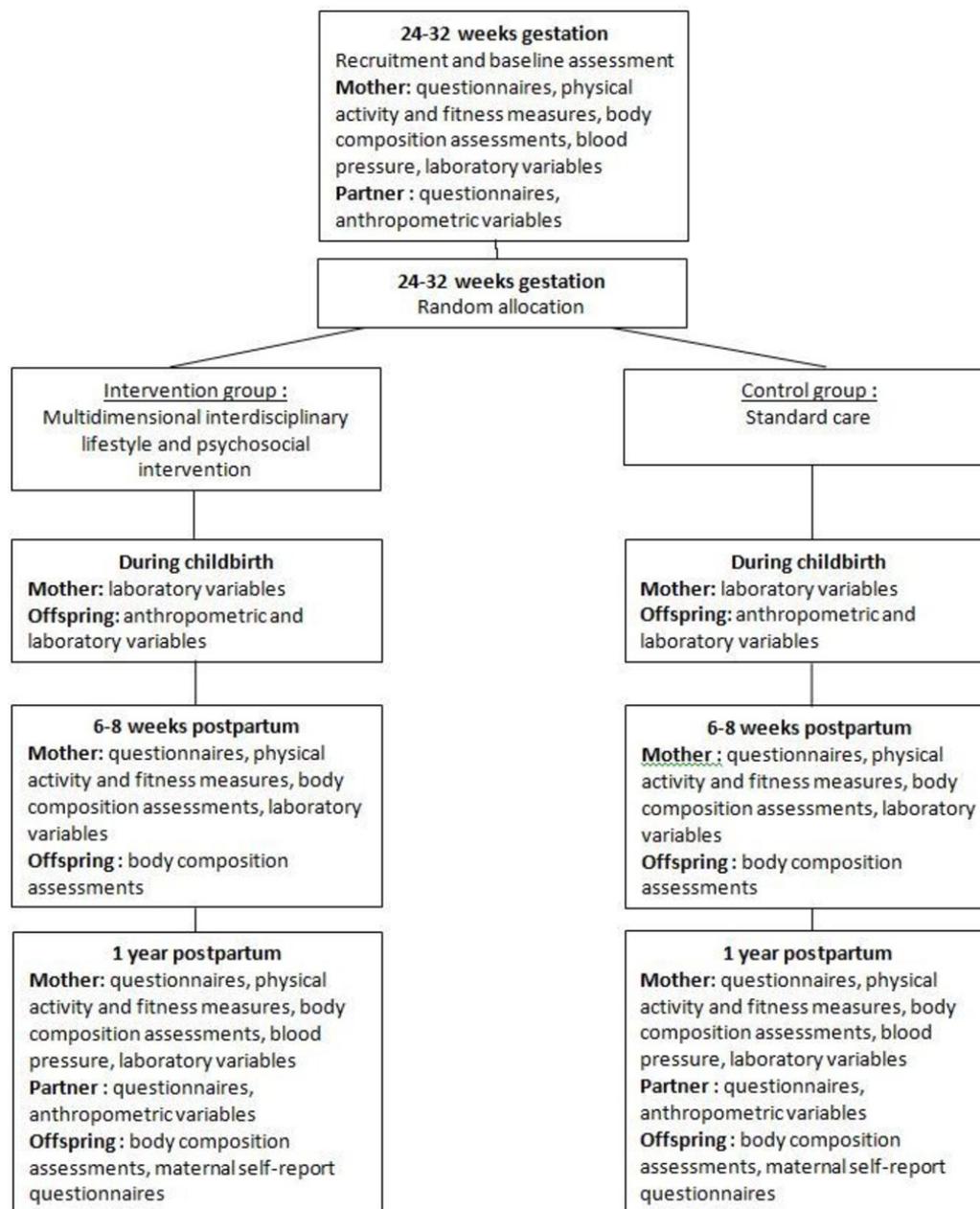
Figure 1 Trial flowchart.

and mental health outcomes up to 1 year postpartum. It also aims to investigate longitudinal associations, thus increasing the understanding of the development of maternal and child obesity, glucose intolerance and mental health problems.

METHODS
Study design
We will conduct a monocentric superiority open Randomised Controlled Trial (RCT) with minimal risk aiming to test the effect of a multidimensional interdisciplinary lifestyle and psychosocial intervention for pregnant women with GDM and their offspring, compared with treatment-as-usual (figure 1).

Study population, recruitment, group allocation and blinding
Women diagnosed with GDM according to IADPSG criteria[106 107] will be recruited (1) in our diabetes and pregnancy clinic, where patients both from the University Hospital Vaud (CHUV) antenatal care clinic and from obstetricians in private practice are referred to or (2) referred to our clinic for the study from diabetologists in private practice and from regional hospitals in the canton Vaud. Following their first clinical appointment, the study coordinator will explain the study and give the information sheet to the patient. Participating women will receive for their time, effort as well as the fees for their frequent travels CHF 250 at the 6–8 week postpartum visit and then CHF 200 at the 1 year visit.

The inclusion criteria are as follows: pregnant women aged ≥18 years, with GDM at 24–32 weeks of gestation and understanding French or English. Women on strict bed-rest, with pre-existing DM or current episode of severe mental disorder will be excluded.

The allocation ratio of randomisation is 1:1, using the block randomisation method (blocks of 4) after stratification for the place of the usual care (at the CHUV or the respective private diabetologist/regional hospital). Thus, each referral centre represents its own control. However, all intervention components and all the evaluations take place at the CHUV hospital. For allocation of the participants, a computer-generated list of random blocks is used (https://www.sealedenvelope.com/simple-randomiser). The allocation sequence will be concealed from the research staff assessing the primary outcomes in sequentially numbered, opaque, sealed envelopes. Envelopes will be opened only after the enrolled participants gave signed consent and completed all baseline assessments. Assessors of primary outcomes and the statistician will be blind to group allocation.

Control group
The control group will receive treatment-as-usual, which is based on the current guidelines of the American Diabetes Association[2] and of the Endocrine Society.[1] Patients are first seen at 24–32 weeks of gestation by a physician and/ or a specialised nurse practitioner who will then provide follow-up until childbirth. During the first visit, patients learn about GDM and how to perform self-control of blood glucose 4 times a day (fasting and 2 hours postprandially).[1 108]

Regarding the weight, lifestyle and mental health goals, details are provided in tables 1A and B. Standard advice about gestational weight gain according to the Institute of Medicine recommendations[109 110] will be given. Patients have one appointment with a registered dietician in order to receive individualised dietary advice, with a focus on how to distribute carbohydrate intake over several meals and snacks, limit the intake of free sugars to less than 10%, and increase fibre intake to up to 30g per day. Patients are encouraged to increase physical activity according to the Endocrine Society Guidelines.[1] If despite lifestyle measures, glucose values remain above targets,[1 2] twice or more during a 2-week period,[108] metformin or insulin treatment is installed depending on glucose values (eg, insulin in case of relatively high glycaemic values) and patient preference.[111]

In the postpartum period, patients then undergo a 75g oGTT at 6–8 weeks postpartum and are seen afterwards by the physician and a dietician jointly to discuss results and further management and provide general advice on lifestyle measures.[1 2] Patients then resume usual care by their healthcare provider outside of the clinic.

The frequency of blood glucose self-control, the thresholds for initiating treatment, the choice of the medical treatment and the first visit with the dietician will be the same in the control and in the intervention group.

Intervention group
The complex, multidimensional, interdisciplinary lifestyle and psychosocial intervention will be offered on top of usual care. Details for the goals of the intervention group are provided in tables 1A and B. All goals will be individually tailored and set by the respective experts (dietician and physiotherapist) during the face-to-face prepartum consultations, based on the patients' context and capacities[112] and transmitted to the coach (see below). The goals will also be discussed during bimonthly interdisciplinary meetings in the postpartum period and exchanges regarding further adaptations.[83–86 89–93 113–124]

Counselling about gestational weight gain according to the Institute of Medicine recommendations and about weight retention will be given.[109 110] In addition to the dietary goals set in the control group, the intervention aims to reduce intake of total lipid intake,[125] saturated fat,[126] to prioritise higher quality fats such as monounsaturated fat present in the Mediterranean,[127 128] DASH and plant-based diets and to reduce red or processed meat intake.[127] It also aims to encourage mindful eating[129–131] and regular, structured eating.[1] The intervention also includes the promotion of continuous breastfeeding for at least 6 months. The intervention encourages aerobic and resistance physical activity[66 68 132 133] and aims to reduce sedentary behaviour.[134]

Regarding the psychosocial part,[135] patients will be screened for depression at study beginning, at 6–8 weeks, at 7 months postpartum and at 1 year postpartum. According to a stepped care approach (based on the patient's Edinburgh Postnatal Depression Scale (EPDS) score), facilitated self-help with the coach or individual cognitive behavioural therapy sessions with the clinical psychologist will be offered.[135] Common elements are: (1) challenge most unhelpful negative cognitions, (2) schedule at least one pleasurable activity per day, (3) increase social contacts, (4) improve sleep routine, (5) identify most stressful situations and apply cognitive behavioural strategies to improve their management.[135 136] Patients who require a psychiatric evaluation will be referred to a psychiatry liaison service. Treatment goals for the offspring focus on diet, breastfeeding, nutrition, physical activity[137] and emotional regulation, all of which will be addressed via psychoeducation and parenting training (see tables 1A and B).

The intervention will take place during pregnancy and during the first year postpartum and will be delivered in individual sessions during the prepartum period with members of the multidisciplinary team, in 3–4 monthly individual interdisciplinary sessions in the postpartum period covering both the mother and the child or during group workshops. Throughout the pregnancy and up to 1 year postpartum, patients will be accompanied and supported by a lifestyle coach (with regular supervision by a clinical psychologist) who will monitor adherence to the intervention, provide booster messages, identify barriers and facilitators, discuss action plans, provide support and teach strategies to work towards the individual goals. The

Table 1A Goals (for the mother)

Domains	Intervention group	Control group
Weight goals	**Prepartum** Attain gestational weight gain according to the Institute of Medicine and National Research Council[110] **Postpartum** Weight retention: return to pregravid weight (or 5% less if BMI≥25 kg) at 1 year postpartum[79 180]	**Prepartum** Standard advice to attain gestational weight gain according to the Institute of Medicine and National Research Council[110]
Diet	**Prepartum and postpartum** *Carbohydrates* Distribute carbohydrates over several meals and snacks.[1] Limit the intake of free sugar to less than 10% of total energy intake avoiding added sugars and sugar naturally present in honey, syrups, fruit juices.[181] Increase fibre intake to up to 30 g per day[182 183] *Lipids* Limit total fat to less than 30%[125] and saturated fat to less than 10% of total energy intake,[126] Prioritise higher quality fats such as monounsaturated fat[127] Reduce red or processed meat[127 128] *Mindful eating* Improve eating regulation in developing an awareness of physical hunger and satiety cues, slowing down pace of eating and reduce emotional eating[129–131] *Regular eating* Structure eating into 2–3 small- to moderate-sized meals and structured snacks if necessary; avoid snacking[1]	**Prepartum** *Carbohydrates* Distribute carbohydrates over several meals and snacks.[1] Limit the intake of free sugar to less than 10% of total energy intake avoiding added sugars and sugars naturally present in honey, syrups, fruit juices.[181] Increase fibre intake to up to 30 g per day[182 183] **Postpartum** Provide general clinical advice on lifestyle measures[1]
Physical activity	**Prepartum**[66 68 132]: ▶ Type: combined aerobic and resistance physical activity. ▶ Frequency: 2 times per day; 7 days per week. ▶ Duration: at least 20 min per session. ▶ Intensity: moderate intensity (RPE=12–14 on Borg's scale). ▶ Timing: 1 hour to 1 hour 30 min postprandial (to target postprandial glycaemia). **Postpartum**[133]: ▶ Type: combined aerobic and resistance physical activity without specific timing. ▶ Frequency and duration: 150 min per week of aerobic physical activity and at least 2x/week of resistance physical activity. ▶ Intensity: moderate intensity. Sedentary behaviour: break sedentary time with physical activity every hour[134]	**Prepartum** Provide usual recommendations of 30 min per day of moderate physical activity as recommended by the Endocrine Society Guidelines[1] **Postpartum** Provide general clinical advice on lifestyle measures[1]

Continued

Table 1A Continued

Domains	Intervention group	Control group
Mental health	**Prepartum and postpartum** *Depression symptoms: Screening and treatment of moderate depressive symptoms* EPDS at first antenatal visit, 6–8 weeks postpartum and 1 year postpartum. Based on the EPDS score a stepped care approach[135] will be offered. The focus is on prevention and early intervention of depression symptoms, with facilitated self-help offered in case of mild symptoms, and individual sessions with a clinical psychologist integrated in the team in case of moderate to severe symptoms (EPDS=10+) *General prevention and treatment elements for all*[136] Common elements are: (1) challenge most unhelpful negative cognitions, (2) schedule at least one pleasurable activity per day, (3) increase social contacts, (4) improve sleep routine, (5) identify most stressful situations and apply cognitive behavioural strategies to their management	**Prepartum** *Depression symptoms: Screening and referral for moderate to severe depressive symptoms* EPDS at first antenatal visit and 1 year postpartum. If EPDS=13+, referral to Psychiatry Liaison Service as for usual clinical practice[135]
Social support	**Prepartum and postpartum**[139–141]: *Attain satisfactory social support on three levels* Healthcare providers: ensure that all adequate perinatal support services have been proposed Peers: offer support by group sessions to initiate exchange and contact Partner: integrate the partner in the consultations, groups sessions and the personal established goals	No specific intervention

Table 1B Goals for the infant up to 1 year (targeted through parent education)

Domains	Intervention group	Control group
Diet	Breastfeeding: encourage continuation for at least 6 months[184] Soothing: propose alternative methods than feeding[85 92 121] Hunger and satiety: recognise the respective cues[92 120] Food: introduce solid food after at least 4–6 months of age[185]	Provide general recommendation for breastfeeding[184]
Physical activity	Physical activity: encourage physical activity during waking hours, reaching 180 min/day at 1 year of age[137] Sedentary behaviour: no screen time[137]	No specific intervention
Mental health	Parental regulation of infant distress and self regulation capacity: increased through parent education during prenatal and postnatal workshops and postpartum interdisciplinary sessions and reinforced by coach[85 92]	No specific intervention

BMI, body mass index; EPDS, Edinburgh Postnatal Depression Scale; RPE, rate of perceived exertion.

coach will offer different behaviour change techniques[138] targeting the HAPA[90] constructs relevant for the respective phase participants are in. Depending on the needs and the progress of participants, the content of the theory-based interventions will be tailored to the individuals. Self-monitoring by the patient will help to clarify the situation and adjust the goals. During pregnancy, the coach will have approximately 15 min of biweekly contact (by phone, videophone and/or face to face after clinical visits). During the first year postpartum, the coach will have phone/videophone contact with the mother every 3 weeks until 6 months and then monthly. Patients will receive a folder with written materials and resources and worksheets or text messages (according to preferences) to monitor their personalised tailored goals and action plans in the different domains throughout the study period. Close collaboration with paediatricians, obstetricians and existing healthcare networks that form part of the patients' usual clinical care will be ensured.

Social support will be encouraged on three levels.[139–141] First, partners will be invited to attend individual and group sessions during both the prepartum and postpartum period. If partners are unable to attend those sessions, a phone/videophone contact at the end of the sessions will be offered. Second, small peer support groups will be formed during the prepartum and postpartum workshops. Third, the coach will also transmit information about other local support offers and will refer the patient to a lactation consultant, if desired by the patient. There are no specific other intervention parts

for the partners except their integration in the maternal and offspring goals, which include a family approach.

Primary outcomes

The primary outcomes are differences between the intervention and the control groups in (1) the decrease in maternal weight (calibrated Seca scale) between 24–32 weeks gestational age (GA) and 1 year postpartum and (2) attenuation in maternal symptoms of depression (EPDS) during the same time period.

Secondary outcomes

Maternal outcomes

The following *lifestyle behaviours* will be measured: carbohydrate and fat intake (Food Frequency Questionnaire (FFQ), see below), eating behaviour (French Intuitive Eating Scale (IES), see below), breastfeeding (self-report), physical activity (accelerometer GENE-Activ), sleep (Pittsburgh Sleep Quality Index (PSQI), see below). *Aerobic fitness* will be estimated using the Chester step test (see below) and *muscular fitness* will be assessed with the hand grip strength using a Jamar dynamometer (see below). *Body composition* measures include bioelectrical impedance analysis (BIA), the sum of four skinfolds (Harpenden callipers) as well as Dual-Energy-X-ray absorptiometry (iDXA device, GEHC-Lunar, Madison, Wisconsin, USA). *Cardiometabolic laboratory variables* and miRNA will be measured (for more details, see Di Bernardo *et al*[142]).

Additional mental health indicators include anxiety (Anxiety subscale of the Hospital Anxiety and Depression Scale (HADS), see below), depression (EPDS and Whooley questions, see below), well-being (WHO Well-Being Index, see below), social support (Medical Outcomes Study Social Support Survey-short form (mMOS-SS), see below) and parenting stress (Parenting Stress Scale-short form (PSI-SF), see below).

Offspring outcomes

Cardiometabolic laboratory variables and miRNA will be measured in the cord blood (for more details, see Di Bernardo *et al*[142]).

Body composition measures include height, weight (standardised tools for infants), BIA and the sum of four skinfolds (Harpenden callipers).

Mental health indicators include self-regulation (Difficult Child subscale of the Parenting Stress Index-Short form, see below) and sleep (Brief Infant Sleep Questionnaire (BISQ), see below).

Data collection and visits

The study started in September 2016. The participation in the study is voluntary and involves a sequence of events and measurements as summarised in table 2.

At 24–32 weeks GA, baseline assessments are carried out (visit 1), including the validated questionnaires, physical activity and fitness measures, body composition assessments and laboratory variables. If the women agree, their partners are also informed about the study and invited

to participate using a separate information sheet and consent form. Once they have signed a separate consent form, research staff will measure the partner's weight and height and ask him to complete validated self-report questionnaires (table 2).

During childbirth (visit 2), maternal blood will be drawn at the entry into the delivery room. After childbirth, blood will be drawn from the cord following clamping and birth weight will be recorded. Offspring birth weight and height will be collected from the hospital birth record.

At 6–8 weeks postpartum (visit 3), while attending a clinical appointment, women will be asked to complete a series of validated self-report questionnaires online, and physical activity and fitness measures, body composition assessments and laboratory variables will be measured. They will undergo a 75 g oGTT with blood sampling. Body composition assessments of their offspring will be assessed.

At 1 year postpartum (final visit, visit 4), participants will be asked to complete a series of validated self-report questionnaires online, and physical activity, aerobic and muscular fitness, body composition and laboratory variables will be measured. Women, who sign an additional consent, will also undergo Bone Densitometry (DEXA) measures for more detailed body composition. They will undergo a 75 g oGTT with blood sampling and blood pressure (three measures) will be measured. Body composition measures of their offspring will again be assessed.

Partners

Partners of participating women who also agree to participate will be asked to complete validated questionnaires and body composition assessments at study entry and study end (when the women are at 24–32 weeks GA and at 1 year postpartum, respectively).

Measures

All measures and their timings are listed in detail in table 2.

Self-report questionnaires: mother and partner

Symptoms of *depression* in the preceding 7 days are assessed with EPDS,[143] which has been validated for pregnant women.[144] Each item is scored on a 4-point scale, the minimum and maximum total scores being 0 and 30, respectively. The EPDS has been validated in a French sample and good psychometric properties have been reported.[145] The original authors suggested a cut-off score of 12.5 as an indication of clinically significant depression but others reported that a score of 10 was the most useful cut-off in a French sample of postnatal women.[145]

Exposure to life events is measured with the Life Events Questionnaire (see below), in which participants are given a list of three negative pregnancy-related major events (suspected growth retardation, vaginal bleeding, premature contractions) as well as 10 negative pregnancy-unrelated major life events (death of someone they were close to, serious illness, exposure to abuse, exposure to violence,

Table 2 Overview of assessment variables, measures and time points

Domain	Variables	Measures	Visit 1 24–32 GA	Visit 2 Birth	Visit 3 6–8 weeks pp	Visit 4 1 year pp
Mother						
Physical examination	Weight, height, BMI (pregravid weight will be obtained from medical charts and gestational weight gain and weight retention will be calculated)	Calibrated scale (Seca), standard stadiometer	X		X	X
	Total fat mass	Bioimpedance, skinfolds (callipers)	X		X	X
	Total and regional fat mass	Dual-Energy X-ray absorptiometry (Lunar)—optional				X
	Blood pressure	Oscillometric Sphygmomanometer	X		X	X
Sociodemographic background	Sociodemographic variables, exposure to life events	Sociodemographic questionnaire, Life Events Questionnaire [146 147]	X			X
Lifestyle behaviours	Carbohydrate and fat intake	Food Frequency Questionnaire [148]	X			X
	Eating behaviour	French Intuitive Eating Scale [150 151]	X			X
	Breastfeeding	Self-report (duration and exclusiveness)			X	X
	Food to soothe	Food to Soothe Questionnaire [87]				X
	Hunger/satiety clues	Infant Feeding Style Questionnaire: Satiety subscale [165]				X
	Physical activity	Accelerometer (GeneActiv): Total counts/min and time spent in different intensities	X			X
Fitness	Aerobic fitness	Chester step test with VO_{2max} estimation [170]	X			X
	Grip strength	Jamar dynamometer [172]	X			X
	miRNA (in plasma)	Plasma; various miRNA	X	X		
Laboratory biomarkers	Overall metabolic control	HbA1c	X		X	X
	Glucose tolerance	75 g oGTT			X	X
	Other cardiometabolic laboratory biomarkers	Glucose, insulin, HbA1c, lipid profile, indices of insulin resistance (during oGTT) [186] and other metabolic laboratory biomarkers	X		X	X
Mental Health	Depression	Edinburgh Postnatal Depression Scale [143]	X		X	X
	Anxiety	Anxiety subscale of Hospital Anxiety and Depression Scale [153]	X			X
	Well-being	WHO Well-Being Index [156]	X		X	
	Parenting stress	Parenting Stress Scale-short form [187]	X			X
	Sleep duration and quality	Pittsburgh sleep quality index [160]	X			X
Social support	Social support	Medical Outcomes Study Social Support Survey-short form [162]	X			X
Partner						

Continued

Table 2 Continued

Domain	Variables	Measures	Timing			
			Visit 1 24–32 GA	Visit 2 Birth	Visit 3 6–8 weeks pp	Visit 4 1 year pp
Physical examination	Weight, height, BMI	Calibrated scale (Seca), standard stadiometer	X			X
Sociodemographic background	Sociodemographic variables, exposure to life events	Sociodemographic questionnaire, Life Events Questionnaire[146 147]	X			X
Lifestyle behaviours	Eating behaviour	French Intuitive Eating Scale[150 151]	X			X
Mental Health	Depression	Edinburgh Postnatal Depression Scale[143]	X			X
	Anxiety	Anxiety subscale of Hospital Anxiety and Depression Scale[153]	X			X
	Well-being	WHO Well-Being Index[156]	X			X
	Parenting stress	Parenting Stress Scale-short form[187]	X			X
Social support	Social support	Medical Outcomes Study Social Support Survey-short form[162]	X			X
Offspring						
Physical examination	Weight, height, BMI	Calibrated baby scale (Seca), portable length board		X	X	X
	Total fat mass	Bioimpedance		X		X
		Skinfolds (callipers)			X	X
Laboratory biomarkers	miRNA	Cord blood; various miRNA		X		
	Other cardiometabolic laboratory biomarkers	Cord blood		X		
Mental health	Self-regulation	Difficult Child' subscale of Parenting Stress Index-short form[188]	X			X
	Sleep duration and quality	Brief infant sleep questionnaire[167]				X

BMI, body mass index; GA, gestational age; HbA1c, glycated haemoglobin; oGTT, oral glucose tolerance test; Pp, postpartum.

serious accident, unemployment, disability, alcohol/drug abuse, divorce, moving house) and have to indicate whether they have been exposed to any of these events in the last 12 months.[146 147]

Carbohydrate and fat intake is assessed with the FFQ.[148 149] The FFQ comprises 97 items listing different types of food and drinks (tea, butter, tomatoes, chicken and so on) and six available spaces which allow the person to write any additional food or drinks she/he might have taken over a 4-week period. Each item is rated for frequency of use on a 6-point Likert scale ranging from 1 '*never in the past 4 weeks*' to 6 '*twice a day*'. The items are also rated on a quantity scale which allows the person to compare the portion they took in comparison with a reference portion (ie, 150 g, one piece and so on) with three response choices: '*less*', '*same*' or '*more*'.

Eating behaviour is measured with the French IES,[150 151] assessing an individuals' tendency to follow their physical hunger and satiety cues when determining when, what and how much to eat.[152] In the current study, the IES was modified by taking out the unconditional permission to eat scale, as women with GDM are given strict diet counselling. Women respond using a 5-point Likert scale ranging from 1 '*strongly disagree*' to 5 '*strongly agree*'. To calculate the scale scores, negative items are reversed, so that high scores on the total measure and subscales indicate greater intuitive eating. The individual scores of items under each subscale are then summed to obtain subscale scores ranging from 1 to 5. The French version of the IES-2 demonstrated good psychometric properties.[151]

Anxiety symptoms are assessed with the HADS,[153–155] which has seven items measuring state-anxiety in the last 7 days. Each item is scored from 0 to 3, with higher scores indicating greater anxiety. Scores from 8 to 10 indicate possible clinical disorder and scores between 11 and 21 indicate probable clinical disorder. Furthermore, it may be used as a measure of symptom severity from normal (0–7), mild (8–10), moderate (11–14), to severe (15–21). The HADS has good psychometric properties.[154]

Well-being is measured with the WHO Well-Being Index (WHO-5),[156] which consists of 5 questions assessing the subjective well-being of the respondents. The items are measured on a 5-point Likert scale ranging from 0 '*at no time*' to 5 '*all of the time*'. The scale has adequate validity both as a screening tool for depression and as an outcome measure in clinical trials and has been applied successfully across a wide range of study fields. The scale has been used most extensively in endocrinology[156] and has good psychometric properties in French.[157]

Parenting stress is assessed with the PSI-SF.[158] It has 36 items and consists of three subscales that assess parental distress, dysfunctional parent–child interactions and child difficulties. Items are rated using a 5-point Likert scale from 1 '*totally agree*' to 5 '*totally disagree*'. The PSI has good psychometric properties.[159]

Sleep duration and quality are measured with the PSQI,[160] which has 19 items and measures retrospective sleep quality and disturbances over a 1-month period. It discriminates between good and poor sleepers and provides a brief, clinically useful assessment of multiple sleep disturbances. The 19 items are grouped into seven equally weighted component scores: Subjective Sleep Quality, Sleep Latency, Sleep Duration, Habitual Sleep Efficiency, Sleep Disturbances, Use of Sleeping Medication and Daytime Dysfunction. Items 1–4 are free entry of: usual bed and wake times, minutes of total sleep time and sleep latency (minutes). Items 5–18 are rated on a 4-point Likert scale responses pertaining to problem frequency: ranging from 0 '*not during the past month*' to 3 '*three or more times a week*'. Item 19 is rated on a 4-point Likert scale rating of overall sleep quality ranging from 0 '*very good*' to 3 '*very bad.*' All component scores range from 0 to 3. The Global Score ranges from 0 to 21, with a higher score indicating poorer sleep quality and a cut-off score of >5 distinguishing poor sleepers from good sleepers. The questionnaire is validated in French.[160] The English questionnaire was retrieved directly from the author.[161]

Social support is measured with the mMOS-SS,[162] which has two subscales assessing emotional and instrumental social support composed of four items to identify potentially modifiable social support deficits. It has good psychometric properties[162] and was translated into French.[163]

Food to soothe is assessed with the Food to Soothe Questionnaire,[87] the first subscale of the Baby's Basic Needs Questionnaire.[87] It measures parents' likeliness to use food to soothe their child by 33 items with a Likert scale ranging from 1 to 5. Twenty-six items present scenarios in which parents might use food to soothe. Seven items measure the use of food to encourage/discourage child behaviour. Five items are specified as 'other' so that the parents can fill in specific scenarios that might not be addressed in the questionnaire. There are also two more questions inviting parents to share more information about the use of food to soothe and the use of food to encourage or discourage behaviours.[87] The scales were retrieved by personal communication with the author[164] and translated into French using standard techniques.[163]

Parental response to *hunger/satiety clues* is assessed with the Infant Feeding Style Questionnaire: Satiety subscale,[165] designed to assess parental feeding practices. This parent-report measure consists of five subscales that tap parental control practices and attitudes in child feeding.[87] In this study, we use the satiety subscale. Two of the items probe beliefs and are coded on a 5-point Likert scale ranging from 1 '*disagree*' to 5 '*agree*'. The five other items probe behaviours and are coded on a 5-point Likert scale ranging from 1 '*never*' to 5 '*always*'. The scales were obtained directly from the author[166] and translated into French using standard techniques.[163]

Self-report questionnaires: offspring

Offspring *sleep duration and quality* are measured with the BISQ.[167] The role of the responder is asked as well as the age, gender and birth order of the child. The parent rates their child's nocturnal sleep duration, daytime sleep duration, number of night waking,

duration of wakefulness during the night hours, nocturnal sleep-onset time, settling time, method of falling asleep, location of sleep and preferred body position during the past week. It has 14 items, which all have specific scoring measures related to the type of question. BISQ scores correlate significantly with sleep measures derived from actigraphy and sleep diaries.[167] The scales were obtained directly from the author[168] and translated into French using standard techniques.[163]

Offspring *self-regulation* is assessed with the PSI-SF[158] (see above).

Physical activity and fitness measures

Physical activity (total physical activity and its intensity) is assessed using an accelerometer (GeneActiv) that is worn on the right wrist during 10 consecutive days.[169]

The Chester Step Test, a multistage submaximal exercise test, is performed to estimate *aerobic fitness* (maximal oxygen uptake ($V'O_{2max}$)).[170] Before starting the test, patients are instructed and experience a 30 s familiarisation. During the test, the step rate (assessed by an audiotape) starts at 15 step/min and increases of 5 step/min every 2 min. Patients are asked to step up and down for a maximum of 10 min. Step height (15, 20 or 25 cm) can be adapted depending on the physical characteristics and/or activity level of the patients. Heart rate (HR) and rate of perceived exertion (RPE) on Borg's scale are monitored at the end of each 2 min stage. The test is stopped when patients reach 80% of the estimated HR_{max} (220-age), when RPE≥15 or when the patient shows signs of distress during the test. The VO_{2max} is then estimated using a standardised equation. The Chester step-test was validated against indirect calorimetry and demonstrated reasonable validity.[171]

Muscular fitness is assessed with a hand grip strength dynamometer (Jamar dynamometer) following standard procedure.[172] Before starting the test, patients are instructed on the correct use of the dynamometer (hand and wrist position during squeezing). Then, patients are seated in a chair and are asked to squeeze the dynamometer as tightly as possible. A verbal encouragement is given during the test. Three measures are taken for each hand and the highest value is considered for analysis.

Physical examination: body composition assessments

Weight is measured in mothers, fathers as well as their babies to the closest 100 g. For the mothers and fathers, a calibrated scale (Seca model 220) is used. Participants are asked to remove their shoes as well as any heavy clothing (jeans, jacket, scarf and so on). For babies, a calibrated scale (model Seca 336) is used and they are weighed without any clothes or nappy.

Height is measured in mothers, fathers as well as length in babies to the closest mm. For the mothers and fathers, a calibrated scale (Seca model 220) is used and they are

asked to remove their shoes. For babies, a calibrated scale (Seca model 336) is used. The infant's head is placed against the head positioner (Seca model 419), then the experimenter lightly presses on the infant's knees and measures the infant's length with the measuring rod (Seca model 232).

Total fat mass of the mother and her offspring are measured with BIA and skinfolds. BIA measures the reactance and the resistance of the patient.[173] Any metallic objects such as watches, bracelets or others are removed before starting the BIA. The participant needs to lie down, arms and legs spread away from each other, so that there is no contact between the limbs. Four electrodes are positioned; two on the right hand and two on the right foot, at a distance of 3–4 cm from each other (BIA 101, Akern, Italy). Obese women with an altered body composition can be identified and monitored using vector BIA.[174] A relaxation phase of 10 min is respected before measurements are taken. Skinfolds are measured with a Harpenden skinfold calliper (HSK-BI, British Indicators, UK) on the biceps, the triceps, the subscapular and the iliac crest. Muscle tissues are not included in the skinfolds. Measures for the mothers are taken on the right side of the body while standing up. Measurements are taken twice, and a third time if the difference between the two first measures is over 1 mm. A mean between the two or three values is calculated.[175 176] For the babies, the measures are taken once on the left hand side while their mothers are holding them.[177]

Total and regional fat mass measured by Dual-Energy X-ray absorptiometry (mother). Participants are asked to remove all metal items before densitometry and are examined while wearing only their underwear and a cloth gown. The subjects are placed in a supine position with their arms at their sides but held slightly separated from their trunk and correctly centred on the scanning field. Regions of interest are defined by the analytical programme, and include different corporeal districts: total body, trunk, head, pelvic, upper limbs, lower limbs, android and gynoid region. For each region, DXA scans bone mineral content, bone areal size and weight (in grams) of total mass, FM and non-bone lean mass. For the android and gynoid regions, the ratio between android and gynoid fat distribution is also assessed. Also calculated are a FM index (kg/m^2), computed as the ratio of total body FM over height squared and a skeletal muscle mass index (kg/m^2), computed as the ratio of appendicular skeletal muscle mass over height squared. Finally, the intravisceral fat index is assessed using a special algorithm provided by the manufacturer.

Blood pressure in mothers and their partners is measured by obtaining three readings at 2 min intervals with a clinically validated oscillometric sphygmomanometer (OMRON HEM-907, Japan).

Laboratory variables
Mother
Cardiometabolic laboratory variables such as HbA1c, lipid levels, gamma-GT, B12 vitamin, ferritin will be measured at study beginning, at 6–8 weeks and at 1 year postpartum and miRNA will be additionally also measured at birth. At 6–8 weeks and at 1 year postpartum, a 75 g oGTT with blood sampling at 30 min intervals for 2 hour will be performed to assess glucose tolerance and indices of insulin secretion and sensitivity.

Offspring
Cord blood sample will be obtained at the time of birth to measure lipid levels, glucose, HbA1c and other cardiometabolic laboratory parameters as well as miRNA (for more details, see Di Bernardo et al[142]). A sample of the respective blood draw will be kept for future potential analyses.

Sample size calculation
Sample size was computed based on the expected difference in primary outcomes between the control and the intervention group. The weight assumptions are based on our pilot data and goals for weight retention. Regarding maternal weight, we assumed a weight reduction of 8.4 kg (SD: 5.5) between study enrolment at 24–32 GA, after GDM diagnosis and 1 year postpartum in women allocated to the control group compared with a weight reduction of 10.9 kg (SD: 5.5) in women allocated to the intervention group. The required sample size is 76 women in each study group to have a statistical significant difference with a power of 80% and an alpha-level set at 0.05 (two-sided).

This sample size is also sufficient to observe statistical significant differences in the reduction in the Edinburgh Postnatal Depression symptoms score, if we assume that the reduction in depression symptoms score between the above-mentioned two time points is 0.2 (SD: 4.3) in women allocated to the control group and 2.2 (SD: 4.4) in women allocated to the intervention group. Assuming a maximum attrition rate of 30%, we will include 100 women in the control and 100 in the intervention groups to provide adequate power.

STATISTICAL ANALYSIS
For the primary aim, differences in the changes in maternal weight and the EPDS symptoms score between enrolment after GDM diagnosis and 1 year postpartum at the end of the study between the intervention and the control group will be analysed using linear regression analysis. For the secondary aims, the analyses will be performed both for differences in changes between the intervention and the control group and for differences between groups at different time points (baseline at inclusion, childbirth, 6–8 weeks and 1 year postpartum)

in maternal metabolic health outcomes, maternal mental health outcomes and offspring metabolic and mental health outcomes. This will be tested using linear regression analysis. We will compare the proportion of patients meeting guidelines for gestational weight gain and for weight retention at 1 year postpartum between the two groups using logistic regression analyses. Associations between outcomes will be tested using linear regression analyses.

Differences between groups will be adjusted for the respective baseline values in case they differ. Variables will be transformed if residuals are not normally distributed. We will include potential confounding variables, if necessary. These include maternal age, sex of the children, the presence of prenatal, perinatal and early postnatal conditions/complications, BMI, EPDS symptoms score and socioeconomic status where applicable. Subgroup analyses will be performed according to weight status, mental health status (EPDS score <10 vs ≥10), prediabetes status at the initial postpartum evaluation (6–8 weeks postpartum) as well as sex (for the children). Analyses will be conducted with STATA V.14.0. For confirmatory analyses, a Bonferroni correction for multiple analyses will be applied. For initial exploratory analyses, no such correction will be used.[178] For the partners, we will evaluate changes between groups and differences between groups at different time points (baseline at inclusion, 1 year postpartum) in weight and paternal eating behaviour and mental health outcomes.

Finally, a process evaluation nested inside the trial will be conducted in order to assess fidelity and quality of implementation, to clarify causal mechanisms and to identify contextual factors associated with variation in outcomes.[179]

ADVERSE EVENTS
All expected and unexpected adverse events will be recorded during the entire study period. A recognised potential risk is the occurrence of early contractions due to intense physical activity. In order to monitor and mitigate this potential risk, patients will be closely supervised by a physician and a physiotherapist. In case of early contractions, participants will be requested to reduce or stop their physical activity.

DATA MANAGEMENT
All study data will be entered by research staff (PhD students and study co-ordinator). All data will be precoded and stored in a secured database (Secutrial), which will be regularly updated by the IT Service of the Lausanne University Hospital. Double data entry will be done for the primary outcomes. For the rest of the data, a random 5% will be double-checked.

MONITORING

Monitoring will be performed by a qualified person independent of the study group and will be organised in two parts: the initial visit took place before the start of recruitment and the second visit after approximately 10% of the study population have been recruited.

ETHICS AND DISSEMINATION

The trial poses little to no risk to participants and their offspring. Signed informed consent is obtained from all participating women. Participation in the study does not interfere with the typical care patients receive during pregnancy and after childbirth. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals. The *MySweetHeart Trial* is a registered trial (clinicaltrials.gov/ct2/show/NCT02890693) and linked to the *MySweetHeart Cohort* (clinicaltrials.gov/ct2/show/NCT02872974).

SIGNIFICANCE AND OUTLOOK

This project will provide relevant findings regarding understanding of GDM, potential pathways and its link to lifestyle, mental health and the development and trajectories of obesity and diabetes in the mothers and obesity in their offspring. It will also provide relevant findings regarding treatment of GDM and its impact on complications such as diabetes and obesity and may thus help to elucidate potential solutions, thus leading to significant changes in clinical practice and guidelines.

Due to its interdisciplinary nature, this research is of interest for clinicians, educators and researchers in the field of diabetes, obstetrics, paediatrics and development, psychology, sport and nutrition sciences and public health.

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