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Effect of the New Nordic Diet compared with usual care on glucose control in gestational diabetes mellitus: Study protocol for the randomized controlled trial intervention with new Nordic DIet in women with GestatiOnal diabetes mellitus (iNDIGO)

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a pregnancy complication associated with short- and long-term health consequences for mother and child. First line treatment is diet and exercise but there is a recognized knowledge gap as to what diet treatment is optimal. A healthy Nordic diet has been associated with improved health but no studies in women with GDM exist. The New Nordic Diet (NND) is an initiative with the purpose to develop a healthy Nordic diet including foods with the potential to grow in Nordic countries; including fruit, berries, vegetables, whole-grain cereal products, nuts, fish, and rapeseed oil. The purpose of the intervention with new Nordic DIet in women with GestatiOnal diabetes mellitus (iNDIGO) is to test if the NND compared with usual care improves glucose control in women with GDM.

Methods: The iNDIGO study is a randomized parallel controlled trial where 50 women with GDM will be randomized to either an NND or usual care for 14 days (30–32 weeks of gestation). Participants in the NND group will receive menus and food bags containing foods to be consumed. Primary outcome is glycemic control (time in target) measured using continuous glucose monitoring. Compliance to the dietary intervention will be tested using dietary biomarkers and adherence questionnaires.

Conclusion: Diet treatment represents first line treatment in GDM but it remains unclear what type of diets are effective. iNDIGO is an efficacy study and will provide evidence as to whether a healthy Nordic diet can improve glucose control in women with GDM.

Trial registration: ClinicalTrials.gov registration Number: NCT04169243. Registered 19 November 2019, https://clinicaltrials.gov/ct2/show/NCT04169243.

1. Background

Gestational diabetes mellitus (GDM) is a significant complication during pregnancy. GDM is defined as any degree of glucose intolerance during pregnancy that is not clearly preexisting type 1 (T1DM) or type 2 diabetes mellitus (T2DM) [1]. Developing GDM is associated with an increased risk of pre-eclampsia and pregnancy-induced hypertension as well as large for gestational age (LGA), preterm delivery, neonatal hypoglycemia, caesarean section and shoulder displacement [2,3]. Long-term, offspring of mothers developing GDM are more likely to suffer

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from obesity, T2DM and the metabolic syndrome [4,5]. Insulin resistance and insulin secretion defects in relation to GDM [6] seem to be chronic and women who developed GDM have increased risk of not only T2DM but also of hypertension and ischemic heart disease later in life [7]. During the past decades, prevalence of GDM has increased in parallel with increased prevalence of overweight, obesity and T2DM. Globally, prevalence of GDM varies between 1.8 and 25.1%, reflecting population characteristics as well as different screening methods and diagnostic criteria [8].

Self-monitoring of blood glucose is standard method for glucose control in GDM. However, continuous glucose monitoring (CGM), i.e., measuring glucose in interstitial fluid continuously, can detect a more detailed glycemic profile and assess various aspects of glycemic control. Recently, an international consensus panel identified time in range (TIR; % of readings spent in range 3.9–10.0 mmol/l) as the CGM metric with best clinical relevance and suggested this as end point in clinical trials [9]. The specific needs of glucose control during pregnancy are addressed by applying time in target (TIT; % of readings spent in target range 3.5–7.8 mmol/l). Only two dietary intervention studies have evaluated CGM metrics in GDM and both were short term (only 3–4 days) [10,11], even though recommended number of days to use CGM is 14 days [9,12].

A diet that shows robust scientific evidence of improving health is the Mediterranean Diet (MedDiet) [13–15]. Further, there is increasing interest for whether regionally based diets could have the same positive outcomes as the MedDiet, yet being more environmentally sustainable and culturally relevant. The New Nordic Diet (NND) is an initiative to investigate whether a diet based on foods grown in the Nordic climate also may have the same beneficial health effects as MedDiet [16]. In randomized controlled trials in non-pregnant individuals, a healthy Nordic diet has improved blood lipid profile, insulin sensitivity and blood pressure [17,18]. No trial has yet evaluated its effect in women with GDM. However, higher adherence an NND score constructed among pregnant women in the Norwegian Mother and Child Cohort Study was associated with higher nutrient density, healthier macronutrient distribution, lower risk for excessive pregnancy weight gain and lower risk for pre-eclampsia [19,20].

Improved glucose control during GDM is important to achieve and subsequent less adverse health outcomes will benefit both individual and society. Diet treatment represents first line treatment in GDM and some dietary interventions have been shown to improve glycemic control [21]. However, it remains unclear what type of diets are effective, and it is urgent that the knowledge gap of identifying dietary treatment options for women with GDM is filled. The NND seems promising but has never been tested in women with GDM. The aim of the iNDIGO study is to investigate if a diet intervention during pregnancy according to NND, compared to routine care, will improve blood glucose control in the third trimester among pregnant women with GDM. We hypothesize that pregnant women with GDM receiving NND will have an improved glucose control, with TIT as primary outcome, compared to those treated in routine care.

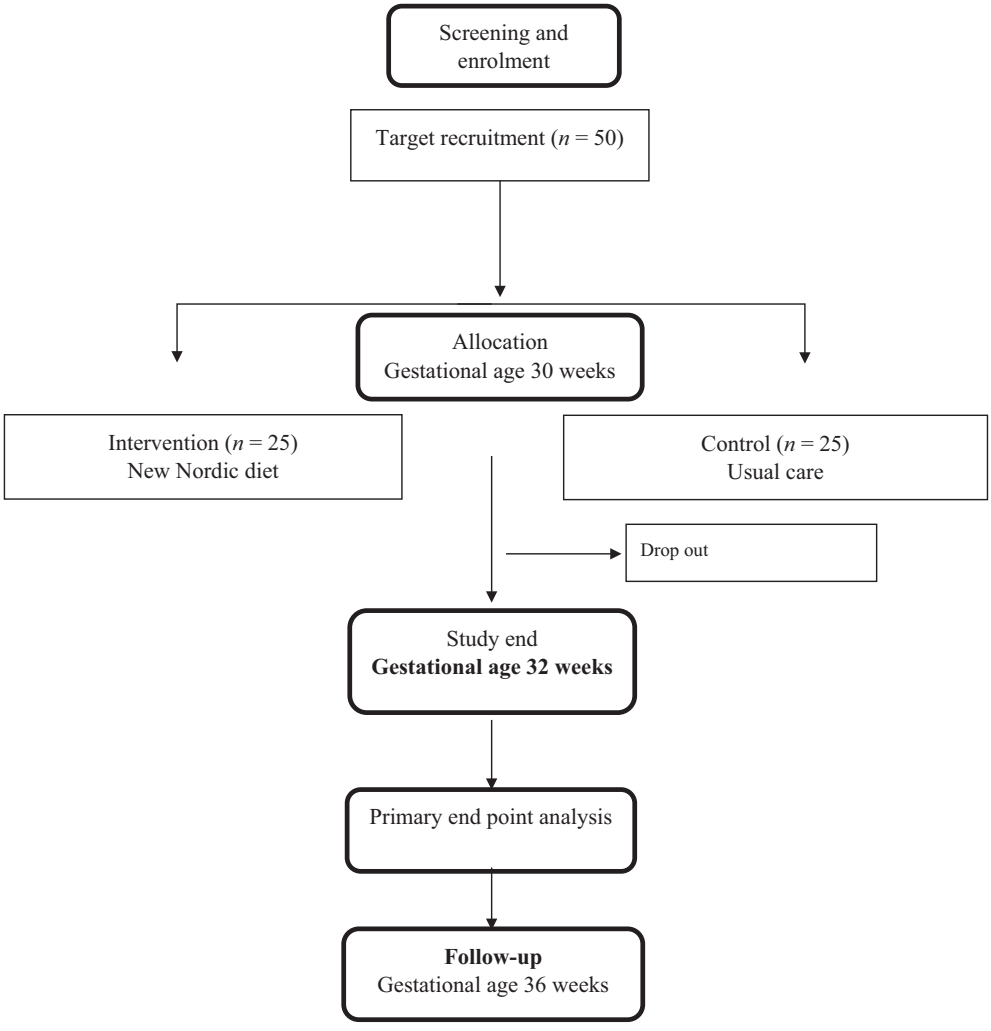

Fig. 1. Flow diagram of study.

2. Methods/design

The intervention with new Nordic DIet in women with GestatiOnal diabetes mellitus (iNDIGO) study is a single center randomized controlled trial. It involves recruiting 50 pregnant women diagnosed with GDM from antenatal care clinics in the Gothenburg area of Sweden. The study is presented in Fig. 1, and the schedule of enrolment, intervention and measurements according to Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) requirements is shown in Fig. 2. The SPIRIT Checklist is available as Online Supplemental material (Additional file 1).

2.1. Population and recruitment

Pregnant women diagnosed with GDM will be recruited via antenatal care clinics, which principally all pregnant women in Sweden attend. Pregnant women from antenatal care clinics in the Gothenburg area, Region Västra Götaland in the Western part of Sweden will be invited to participate in the study. Inclusion criterion is GDM diagnosed in gestational age 24–30 weeks not needing insulin or oral diabetes medication. Currently, diagnostic criteria for GDM used in Region Västra Götaland is either a random non-fasting plasma glucose ≥12.2 mmol/l or a fasting plasma glucose ≥7.0 mmol/l, or a plasma glucose ≥10 mmol/l 2 h after an oral glucose tolerance test (OGTT). Exclusion criteria for iNDIGO are manifest diabetes (diabetes mellitus prior to or diagnosed during pregnancy), not able to read or speak Swedish, unwillingness to follow dietary intervention and multiple pregnancy.

After GDM diagnosis, pregnant women will receive written and oral information of the study by their midwife. Responders will be contacted via telephone by iNDIGO study personnel and evaluated for inclusion in the study. If included, baseline visit will be booked in gestational age 30 weeks. Informed consent will be collected by study personnel before any study measurement is started.

2.2. Randomization and blinding

Enrolled participants will be randomized 1:1 to the two study arms New Nordic Diet (NND) and usual care (control). The randomization list will be computer generated by a colleague not involved in the study. The random assignment will be concealed until the baseline examination. Blinding of the study participants and study staff meeting the women is not possible due to the design of the dietary intervention. Main outcome and the majority of study outcomes are objectively measured.

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		
TIME POINT	**$-t_1$**	**Day 0**	***Day 0*** ***Gestational age 30 weeks***	***Day 14*** ***Gestational age 32 weeks***	***Gestational age 36 weeks***
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTION:					
New Nordic Diet			◆—	—◆	
Usual care			◆—	—◆	
ASSESSMENTS:					
Dietary assessment			X	X	X
Anthropometry			X	X	
Blood			X	X	
Continuous glucose monitoring			◆—	—◆	
Questionnaires			X	X	

Fig. 2. Content for the schedule of enrollment, interventions and assessments.

2.3. Diet intervention

The NND is an initiative with the purpose to develop a diet under the principles: (i) health; (ii) gastronomic potential and Nordic identity, and (iii) sustainability [16]. The diet in iNDIGO is based on foods that have the potential to grow in the Nordic countries and considered healthy. A healthy Nordic diet includes intake of fruit and berries (apples, pears, blueberry, raspberry, strawberry), vegetables (primarily cabbages, kale and root vegetables), whole-grain cereal products (rye bread, barley and oatberry, whole-grain pasta), nuts and seeds (hazel nuts, almonds, sunflower seeds and flaxseed), fish and shellfish, low-fat dairy products, rapeseed oil (for cooking and dressing) and low-fat margarine based on vegetable oils (on bread). Also, reduced intake of red and processed meat is encouraged and with a focus to include game in the diet. Dietary goals of the NND intervention: fish and shellfish intake $\geq$3 times/w (fatty fish at least once per week), $\geq$ 500 g fruit, berries, vegetables and legumes daily, legumes as main protein source at least twice per week, whole-grain cereal products, rapeseed oil for cooking/dressing and three table spoons of nuts and seeds per day (Additional file 2). The intervention diet is provided ad libitum with some portion size specifications (e.g. ½ plate of vegetables at main meals and three table spoons daily of nuts and/or seeds). In Sweden, there are some food restrictions in pregnancy that have been accounted for (e.g., unpasteurized dairy products, freshwater fish and game not securely handled for lead residues). A two-week menu including all daily meals has been created, see Additional file 2 for example menu. There will be some differences in the menus between participants due to seasonal variation and food availability in grocery stores Participants will prepare their own food but are provided with simple recipes and food bags containing all the foods to be consumed during the two-week intervention. In addition to emphasis on Nordic foods, consideration to meal and carbohydrate distribution, dietary factors slowing glucose increases and caution with some foods that are generally considered healthy Nordic foods but generally impose fast rises in glucose (eg. porridge and crisp bread). At the baseline visit, participants randomized to intervention will meet for a 1.5 h face-to-face visit with the study dietitian. At gestational age 32 weeks, women again meet with the study dietitian and will be encouraged to continue with the NND diet throughout pregnancy on their own.

2.4. Control

Participants randomized to the control group will continue with standard care at their ordinary antenatal care clinic where they receive dietary advice. Therefore, the diet may vary considerably depending on where and who provides it. The Swedish Food Agency publish advice about healthy food in pregnancy aimed at antenatal care [22]. This includes general advice on the plate model, 500 g fruit and vegetables daily, whole-grain cereals, low-fat dairy, fish and shellfish 2–3 times/week, keyhole-products (national labeling for foods with healthier fat, less sugar and salt and more fibre). Also, women with GDM currently have the opportunity to see a film on dietary treatment during GDM recorded by a dietitian produced by the Sahlgrenska University hospital in Gothenburg. The dietary advice in this film include information mainly on meal pattern, carbohydrate distribution and dietary factors for slow blood sugar increases. Women with GDM have the option to book a meeting with dietitian. Participants in the control group will receive a gift certificate that can be used in grocery stores on-line.

2.5. Dietary compliance assessment

Adherence to the intervention diet will be evaluated using an adherence questionnaire during the two-week intervention and through diet biomarkers in blood at baseline and follow-up in gestational age 32 weeks. The women in the intervention group will fill in the adherence questionnaire (study diary) daily. Diet biomarkers include fatty acid profile in plasma, alcylresorcinols as biomarker of whole-grain intake, and folate as well as carotenoids as biomarkers of fruit and vegetable intake.

2.6. Dietary intake

Dietary intake will be assessed for all participants using a web-based method developed by the Swedish National Food Agency (Livsmedelsverket) [23]. Two 24-h recalls will be registered on non-consecutive days; both weekdays and weekend days will be represented. Participants will be asked to recall and register all foods and beverages consumed from midnight to midnight the preceding day. The first 24-h recall will be registered at the baseline visit, and the second 24-recall will be registered within 3–4 days. The set of two 24-h recalls will be repeated at gestational age weeks 32 and 36. The main purpose of the dietary assessment at gestational age week 36 is to explore if any dietary changes related to the intervention are sustained short-term. Dietary data are calculated within the program through linkage to the Swedish national food composition database and data from food manufacturers. Dietary data include micro- and macronutrients, energy intake, foods, food groups and dietary patterns.

2.7. Clinical measurements

At baseline and gestational age 32 weeks, blood pressure and anthropometric measurements will be assessed. Weight will be measured without shoes and in light clothing to the nearest 0.1 kg using an electronic scale. Height will be measured to the nearest 0.5 cm using a wall-mounted stadiometer. Body mass index (BMI) will be calculated through body weight (kg)/height^2 (m). Systolic and diastolic blood pressure will be measured three times in the supine position after a 5 min rest.

2.8. Continuous glucose monitoring

Interstitial blood glucose will be measured continuously with a CGM (FreeStyle Libre Pro Flash Glucose Monitoring System, Abbott) which measures the interstitial glucose level every 15 min producing 96 reads/24 h. At baseline, the glucose sensor will be applied onto the back of the participant's upper arm. The sensor will be worn during the 14-day intervention and participants will have the sensor removed at their last study visit. The glucose measurements will be masked for the participants. The event of applying the sensor is much like pricking the tip of the finger for a blood sample, a small flexible needle penetrating the skin with a light stinging sensation. Wearing the sensor may in same cases cause light skin irritation but no other discomfort is expected. In case of reported discomfort, the sensor will be adjusted or removed. The sensor is waterproof (up to 1 m) and not sensitive to temperature, which means no restrictions to sanitation or recreational activities. In addition, all pregnant women receive glucose meters within usual care for self-monitoring of blood glucose. Preprocessing of CGM data includes data format transformation, removing patterns with physiologically implausible data and imputation of missing data using methods for time series imputation.

2.9. Laboratory measurements

Venous fasting (at least 8 h) blood samples will be collected at baseline (gestational age 30 weeks) and in gestational age 32 weeks by trained personnel. Blood will be analyzed for diet biomarkers (alkylresorcinols, carotenoids, folate, fatty acid composition), inflammatory markers (C-reactive protein, white cell count), vitamin- and mineral status (hemoglobin, ferritin, iron) and glucose metabolism (fasting glucose, insulin, HbA1c). Blood samples will be sent to accredited commercial laboratories for immediate analysis or centrifuged with serum/plasma aliquots subsequently stored at −80 °C for future analysis.

2.10. Questionnaires

A questionnaire on lifestyle including family history of diabetes, medical history, education, smoking, breast-feeding, country of birth and dietary supplements will be distributed at baseline, gestational age 32 weeks. Health related quality of life will be evaluated using RAND36 (www.rand.org) at baseline, gestational age 32 weeks. The RAND36 has been used in pregnant populations to assess health related quality of life however; no reliability studies in the current population have been identified. The RAND36 has been evaluated in a Swedish general population showing good internal consistency reliability (Cronbach's alpha >0.80) [24].

2.11. Physical activity

Physical activity will be measured for all participants using a step counter with 30-d memory (Yamax EX-510 Power-Walker pedometer). This will be worn for 14 days, from baseline through gestational age 32 weeks. Participants will be instructed to wear the pedometer in a pocket or hanging from the neck using a key chain cord, from wake-up until bedtime and not to divert from their usual physical activity. Data will be reported as average step counts and physical activity level. Extremely low or high step counts will be considered implausible and excluded.

2.12. Outcome measures

The primary outcome is average TIT between gestational age 30 and 32 weeks. Secondary outcome measures include additional measurements from CGM [mean glucose, CV, SD, % time with values >7.8 mmol/l, % time with values <3.5 mmol/l [9], mean amplitude of glycemic excursion (MAGE) [25], glucose in different time periods, and area under the curve (AUC) using the trapezoid method [26]], excessive pregnancy weight gain, pregnancy-induced hypertension and preeclampsia, insulin or oral diabetes medication, nutritional status (vitamin- and mineral status) and dietary quality, caesarean section, gestational age, preterm delivery, health-related quality of life, birth weight, small for gestational age, large for gestational age, macrosomia, shoulder dystocia, clavicle fracture, brachial plexus injury and low Apgar scores.

2.13. Sample size calculation

A treatment difference of 5% in TIT between groups is presumably clinically relevant; this corresponds to just over one additional hour (72 min) per 24 h in range. For example, a 5–7% lower TIT has been related to higher risk of poor neonatal outcomes in women with T1DM [27]; unfortunately, no such data exist for women with GDM. Two previous dietary intervention studies in women with GDM have used CGM to evaluate clinical endpoint but only one reports TIT. In a cross-over study among 12 women with GDM (mean gestational age 33.5 weeks, four days of high-carbohydrate morning meal and low-carbohydrate evening meal were compared to low-carbohydrate morning meal and high-carbohydrate evening meal [10]. MAGE was significantly higher ($P = 0.004$) and TIT lower, although not statistically significant ($P = 0.08$), with the high-carbohydrate morning meal vs. low-carbohydrate morning. In this study by Rasmussen et al. [10], women with GDM achieved a 4.5% treatment difference (97.96% vs. 93.46% TIT, P = 0.08) during their 4 + 4 days cross-over diet intervention. Based on this study, we believe that our 14-day intervention can achieve a difference in TIT between groups of at least 4.5%. With 80% power, $\alpha = 0.05$ and a standard deviation of 5.0 [based on results in [10]], a treatment difference between groups as small as 4.5% requires 19 women per group to detect. With an estimated 20% dropout rate, iNDIGO will recruit 50 pregnant women.

2.14. Statistical analysis

Study outcomes will be analyzed according to completers. Missing data will be handled using multiple imputation. TIT will be compared between intervention and control group in linear random effects mixed models adjusted for potential confounding factors. Secondary outcomes will be analyzed identically for continuous variables and as relative risks for incidents. Potential confounders will be evaluated for primary and secondary analyses including maternal age, maternal BMI, gestational age, gestational weight gain, parity, education, reported energy intake, smoking and country of birth.

2.15. Ethical considerations

Ethical approval has been granted by the Swedish Ethical Review Authority (Dnr: 2019–03876 and 2021–02841). This study will be conducted in accordance with the Declaration of Helsinki.

3. Discussion

Developing GDM is associated with both short- and long-term health consequences, for both woman and child. A 2018 meta-analysis concluded that several different types of dietary interventions have been investigated in women with GDM and some dietary interventions have been shown to improve glycemic control *[21]*. However, more evidence is needed to assess the effects of different types of dietary advice for women with GDM. This protocol describes a randomized controlled trial in women with GDM aiming to explore effects of the New Nordic Diet compared with usual care on glucose control. iNDIGO is an efficacy study aiming at high internal validity.

The primary outcome measure in iNDIGO, TIT of desired blood glucose range, is recommended as desirable clinical endpoint in trials aiming to improve glucose control [28]. iNDIGO will use CGM which offers a more complete evaluation of the glucose profile than would use of self-monitoring blood glucose alone. Importantly, metrics not usually captured by self-monitoring of blood glucose such as nocturnal mean glucose have been associated with adverse outcomes, such as increased birth weight in infants of women with GDM [29,30]. CGM is currently not standard in clinical treatment of GDM in Sweden. All women will continue with self-monitoring of blood glucose as prescribed within their usual care program during the study. To avoid an independent effect in iNDIGO of improved glucose control by the use of CGM per se, the CGM will be masked for participants. Previous dietary studies have been short term (3–4 days), but iNDIGO will apply the recommended time of CGM use of 14 days [9].

There are some challenges when choosing control diet. The Declaration of Helsinki states that a new intervention should be tested against the best current intervention [31]. Currently, there are no specific Swedish national dietary guidelines for GDM and usual care is therefore regarded as the best current intervention. An important challenge is that in Sweden usual care may vary considerably depending on where and who provides it. By recruiting pregnant women from the Gothenburg area only, iNDIGO may minimize some of the variation. In addition, using usual care as control diet, iNDIGO will be able to draw conclusions of beneficial effects of tested structured dietary intervention based on a Nordic diet pattern.

Potential limitations also include non-adherence to the dietary regimen. To increase adherence to the 2-week menu some actions have been taken. The menu of the NND intervention diet in iNDIGO, developed by a registered dietitian, is based on the change of commonly consumed dishes to instead include Nordic foods, which will to some extent maintain familiarity to diet. The meals are easy to prepare and ready meals of high nutritional quality are used for convenience. To further increase compliance, recipes and food bags including all the foods needed for the 2-week intervention is provided to all women in the intervention group. Still, achieving total adherence to diet regimen is

difficult under free-living conditions. In order to assess adherence, iNDIGO will include both self-reported adherence using a study diary and dietary assessment (24-h recall) as well as biomarkers in blood at baseline and study end. Furthermore, usual care is not eucaloric nor matched for macronutrient composition between patients and therefore intervention was chosen to be ad libitum. This may, in addition to dietary quality, have an influence on glucose parameters and need to be considered when interpreting the results.

Finally, the recruitment is currently limited to the Gothenburg area within region Västra Götaland and women not speaking Swedish are excluded. Hence, potential selection bias has to be evaluated and iNDIGO participants will be compared with socio-demographic data from population based Swedish registers of the general population and of pregnant women.

Strengths of iNDIGO include the use of CGM for optimal outcome measurement; blinding of assessors of outcome; the implementation of the New Nordic Diet which is similar to the Mediterranean Diet where evidence exist for a beneficial effect on blood glucose control but that also incorporates a sustainability perspective; and provision of food bags to the intervention group to increase adherence. Results from this randomized controlled trial will meet the demand for evidence to base dietary guidelines to pregnant women developing GDM.

Ethics approval and consent to participate

This study has been approved by the Swedish Ethical Review Authority (Dnr: 2019–03876 and 2021–02841). This study will be conducted in accordance with the Declaration of Helsinki. Each subject will sign an informed consent form.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Competing interests

The authors declare that they have no competing interests.

CRediT authorship contribution statement

T. Karlsson: Methodology, Writing – original draft. **H. Augustin:** Conceptualization, Methodology. **M. Lindqvist:** Conceptualization, Methodology. **J. Otten:** Methodology. **K. Petersson:** Conceptualization, Methodology. **E. Storck-Lindholm:** Conceptualization, Methodology. **I. Mogren:** Conceptualization, Methodology. **A. Winkvist:** Conceptualization, Methodology.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2022.106706.

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