Statistical Analysis Plan (SAP) for the manuscript reporting the primary outcomes of the Face-it randomised controlled trial

Title: Effect of a co-produced, complex health promotion intervention for women with prior gestational diabetes and their families: Findings from the Face-it Randomised Trial 1-year follow-up.

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The statistical analysis plan is prepared in accordance with guidelines for Statistical analysis plans in clinical trials (1).This document is a supplement to the Face-it study protocol (2) and comprises a statistical analysis plan for the main paper reporting the primary outcomes and key secondary and tertiary outcomes in the Face-it study. The SAP does not cover the statistical analysis of data for outcomes to be included in secondary manuscripts.

Signature page:

Title: Effect of a co-produced, complex health promotion intervention for women with prior gestational diabetes and their families: Findings from the Face-it Randomised Trial 1-year follow-up

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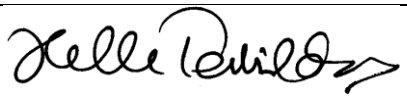
Helle Terkildsen Maindal [1,2]	MPH, PhD	Principal investigator, co-writer of the SAP		23.05.2023
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Contents

Section 1: Introduction

Background, rationale, and study aim

With a prevalence of approximately 6% in Denmark, Gestational diabetes mellitus (GDM) is one of the most common medical conditions during pregnancy. GDM predisposes women and their offspring to a range of short- and long-term morbidities, including early onset type 2 diabetes (T2D) and cardiovascular disease. Evidence from the US Diabetes Prevention Program (DPP) suggests that intensive lifestyle interventions can reduce the risk of T2D among women with prior GDM. However, more knowledge is needed about how to effectively reduce the risk of diabetes through sustained behavioural interventions after delivery. The Face-it intervention is a complex health promotion intervention embedded in multi-level supportive environments and addressing the individual, family, and health care system levels. This randomised controlled trial seeks to demonstrate whether the Face-it intervention is superior to usual care in reducing diabetes risk and improve quality of life for mothers in the first year following a GDM-affected pregnancy by promoting physical activity, healthy dietary behaviours and breastfeeding through a focus on social support, motivation, self-efficacy, risk perception and health literacy. The primary outcomes are body mass index (BMI) and quality of life (SF-12 mental component).

For a further description of the background and rationale for the Face-it trial, please refer to the Face-it study protocol (2) and the paper describing the development of the intervention (3).

Objectives and Hypotheses

The primary objectives

The primary objectives of this trial are to investigate the effect of the Face-it intervention compared to usual care on change in BMI and quality of life among women with prior GDM.

Hypotheses for the primary outcomes: We hypothesise that the Face-it intervention is superior to no intervention (the usual care group) in reducing BMI from baseline to follow-up (12 months after delivery). The null hypothesis is that women in the intervention group have the same change in BMI at follow-up examination as usual care. The alternative hypothesis is that there is a difference between the two groups. We further hypothesise that the Face-it intervention is superior to no intervention (the usual care group) in increasing quality of life measured with the SF-12 mental component score from baseline to follow-up (12 months after delivery). For this primary outcome, the null hypothesis is also that women in the intervention group have the same change in quality of life at follow-up examination as usual care.

Secondary objectives

Secondary objectives are to describe changes associated with the intervention for the secondary and tertiary outcomes listed below. Hypotheses for each outcome in terms of expected change in intervention group relative to the usual care group are indicated with +/-.

Clinical

Anthropometric measurements (e.g., body composition)

Waist circumference (cm)	-
Hip circumference (cm)	-
Body fat%	-
Weight loss%	+

Metabolic

Blood tests (venous samples), OGTT, blood pressure

Fasting glucose (mmol/L)	-
2-h Glucose (mmol/L)	-
HbA1c (mmol/mol)	-
Impaired Fasting Glucose	-
Impaired Glucose Tolerance	-
Fasting insulin (pmmol/L)	-
2-h insulin (pmmol/L),	-
HOMA-IR	-
HOMA-β	-
Systolic blood pressure (mmHg)	-
Diastolic blood pressure (mmHg)	-
Total cholesterol (mmol/L)	-
HDL cholesterol (mmol/L)	+
LDL cholesterol (mmol/L)	-
Triglycerides (mmol/L)	-

Behavioural

DQS-2017 score	+
IPAQ-SF Walk (min/day)	+
IPAQ-SF Moderate to Vigorous activity (min/day)	+
Breastfeeding duration, (months)	+

Quality of Life & Mental health

SF12 physical component score	+
Self-perceived health	+
Perceived stress scale score	-
WHO-5 percentage score	+
General Anxiety Disorder (GAD-7)	-

Psychosocial

Social support for diet Encouragement Family scale	+
Social support for exercise Participation Family scale	+
TSRQ Exercise self-regulation and motivation Autonomous scale score	+
General self-efficacy	+
RPS-DD Perceived risk of getting diabetes, % high risk	+
RPS-DD Made behaviour changes to change risk of diabetes, % Yes	+
HLQ Domain 3 Actively engage my health	+
HLQ Domain 6 Ability to actively engage with healthcare providers	+

Section 2: Study methods

Trial design

Multicentre, randomised, two-arm parallel controlled trial consisting of a health examination 10-14 weeks after delivery (baseline V1) and 12 months after delivery (follow-up V2). Randomisation to intervention or usual care group is performed at baseline examination.

Brief description of the intervention

For a further description of the intervention please refer to the Face-it study protocol and the paper describing the development of the Face-it intervention (2,3).

Randomisation

Women with prior GDM are the unit of randomisation. Randomisation was stratified on Centres: Odense, Aarhus, Copenhagen sites, i.e. for each centre, random allocation is performed in a 2:1 ratio to the intervention (2/3 of participants) or usual care (1/3 of participants). Randomisation was in random blocks of sizes 6/9/12/15, which ensures that allocation to intervention or usual care is unpredictable for recruiters and that the cumulative ratio of participants included to intervention vs. usual care is close to 2:1 throughout the inclusion period at each hospital. Randomisation will not be based on stratification for baseline variables. Details of the randomisation method are held securely within the files of the statistician. The randomisation procedure was generated by a statistician (Henrik Støvring) prior to the commencement of recruitment. The allocation sequence will be implemented using the REDCap (Research Electronic Data Capture) electronic system. The randomisation process is described in full within the clinical trial protocol (2).

Blinding

Randomisation to either the intervention or usual care group will occur immediately after baseline data collection. Thus, allocation will be concealed from both the participant and the investigators until participation has been accepted, eligibility confirmed, and baseline data collected. Neither participants nor the investigators will be blinded to the participants' allocation status after this point.

Sample size

Calculation of the projected sample size is based on individual changes in BMI among women with prior GDM after 12 months of follow-up. The mean changes are compared between the intervention and usual care group. We expect the mean change in the intervention group to differ by − 1.0 kg/m^2 relative to the usual care group. The standard deviation of individual changes after 12 months is expected to be 2.5 kg/m^2. Based on a 2:1 randomisation procedure, a power of at least 80% and type 1 error of 5% (two-sided), a sample size of 225 will be required to detect such a difference in BMI. Assuming 30% of participants will be lost between baseline (after randomisation) and follow-up, we will need to include 322 women at baseline in the study. Because of the relatively long period (10–30 weeks) between recruitment and baseline and the exclusion of women with overt diabetes at baseline (before randomisation), we also assume that 30% of those agreeing to participate will withdraw before baseline data collection or be excluded (see section 4) before randomisation. We therefore need to recruit 460 women. For full details of the sample size calculation, please refer to Face-it trial protocol (2).

Framework

Superiority trial. Please refer to section on objectives.

Statistical interim analyses

No statistical interim analyses will be performed and no guidelines for terminating the trial early has been made.

Timing of final analysis

The final analyses of the primary outcomes will be performed when the last participant has completed the follow-up examination 12 months after delivery. All analyses described in this document will take place after ended data collection, which will be after participants have finished their last health examination in all study centres (expected to be in June 2023).

Timing of outcome assessment

The primary outcomes are measured at baseline (V1) and at follow-up examination (V2).

Section 3: Statistical principles

Confidence intervals and p-values

All relevant statistical tests will be based on two-sided p-values using a 5% significance level. P-values will be reported for estimates related to the primary outcome and secondary outcomes. Wald-based 95% confidence intervals will be given for all reported estimates.

Primary outcomes: We will employ a hierarchical testing procedure with two separate hierarchies (one hierarchy for each of the two primary outcomes) to control the type 1 error rate for tests. Thus, if a test fails to confirm a given hypothesis, all subsequent tests within the specific hierarchy will be considered as tertiary outcomes. If the null hypothesis is rejected at the α level of 0.05 (two-sided), i.e., the p-value of the null hypothesis test is < 0.05, statistical significance will be claimed. In order for the results to be declared in accordance with the hypothesis, the size of the estimated mean effect of the primary outcome, its direction, and the 95% confidence intervals will be required to support the tested hypothesis.

Secondary outcomes: Secondary outcomes within the clinical, metabolic and behavioural domains will belong to the hierarchy for BMI. Secondary outcomes within the quality of life & mental health domain will be embedded in the Quality of Life (SF-12 mental component) hierarchy. We will control for multiplicity using the Holm-Bonferroni method.

Tertiary outcomes: These outcomes are considered descriptive/explorative meaning no definite inferences can be made. Therefore, we will not correct for multiplicity.

Adherence, protocol deviations and population sample

Compliance

Intervention compliance is defined in two degrees as:

1. Intended intervention activity dose compliance: 3 home visits and ≥9 contacts in the LIVA app.
2. Minimum intervention activity dose compliance: ≥2 home visits and ≥ 1 contacts in the LIVA app but <3 home visits and 9 contacts in the LIVA app.

Completers

Participants who have participated in the follow-up health examination (V2) and who are not pregnant at V2 will be considered completers in relation to the primary outcome on BMI.

Item non-responders/partial completers

Participants who have not participated in the follow-up health examination (V2) and are not pregnant at V2 but have contributed with questionnaire data on the primary outcome on quality of life and/or secondary/tertiary outcomes at V2, will be considered completers in relation to the secondary/tertiary outcomes.

Lost to follow-up
Participants who do not participate in the follow-up health examination (V2) nor provide questionnaire data at V2 will be considered lost to follow-up in relation to the primary outcomes. Participants who are pregnant at the follow-up visit will also be considered as lost to follow-up and excluded from analyses.

Per Protocol
Completers/partial completers in the intervention group are considered *per protocol* if they:

- Are not lost to follow-up
- Comply with the intended intervention activity dose defined a priori

Completers/partial completers in the intervention group are considered *partial per protocol* if they:

- Are not lost to follow-up
- Comply with the minimum intervention activity dose defined a priori

All completers/partial completers in the usual care group are considered per protocol.

Protocol deviators
All completers in the intervention group who are not considered as having fully or partially followed the protocol (i.e per protocol or partial per protocol).

Data related to measures of adherence will be presented for all completers, item non-responders and for per protocol completers and partial per protocol completers. The distribution of the outcome will be visually inspected using QQ-plots and histograms and if Gaussian distributed it will be presented as means and standard deviations; if not it will be presented as medians (25th and 75th percentiles).

Protocol deviations and changes of the intervention delivery and health examinations during the COVID-19 pandemic

During the COVID-19 pandemic and lock-down period in Denmark, the health examinations and the delivery of the intervention had to be adapted to national and local restrictions and reconsidered to minimise risk and concerns of the participants and the intervention deliverers.

During the first lock-down from March 2020 to June 2020 (4 months), the baseline and follow-up health examinations were conducted at the three sites. However, it was decided to implement a wider time span for attending the baseline examination (up to 21 weeks after delivery) and no time limit for participation in the follow-up-examination, in order to secure a medical and ethical treatment of participants by offering a health examination as planned. During the same period, the delivery of home visits by health visitors, as a part of the intervention activity, were postponed or converted to online visits. Therefore, a few participants did not receive three visits as expected; however, in line with the re-opening of society (late spring 2020), physical home visits were reimplemented (with protective adaptations).

During the second lock-down from December 2020 to March 2021 (4 months), the health examinations were conducted similar to the first lock-down. The delivery of the intervention was adapted due to local restrictions for health visitors in the municipalities. Overall, the guidance was to prioritise home-visits. Online visits were offered if the participants expressed any concerns or if the health visitor assessed it as preferable to minimise the risk of COVID-19.

From November 2021 to May 2022 (5 months), the COVID-19 pandemic resulted in temporary local restrictions for health visitors in the municipalities, however, with minor consequences for the trial and intervention delivery.

From June 2021 to August 2021 (2 months), a national strike among selected groups of nurses affected one of the intervention municipalities (Aarhus), which resulted in the postponement of a few home visits or that two visits were converted to one if time to health examination date was limited.

All adaptations were recorded in a log.

Due to challenges in the recruitment process, primarily due to a temporary stop for recruitment of women during the first lock-down from March to June 2020 and an unexpected high number of women giving birth at the trial hospitals with a residence in municipalities not included in the trial, we decided to expand the geographic recruitment area. This expansion was initiated on August 1, 2020, and included possibilities for recruitment from all municipalities within Funen and municipalities within 45 km from Aarhus municipality, in addition to recruitment of participants residing in Odense and Aarhus municipality. The aim was to speed up the recruitment process of women to the project. Consequently, a few of the second or third home visits were adapted to either online or being accomplished at the "Sundhedshuset" – a formal workplace for health visitors in Odense Municipality.

Section 4: Trial population

Eligibility, inclusion, and exclusion

Inclusion and exclusion criteria are defined in detail in the Face-it trial protocol.

Eligibility and inclusion criteria:

- Women with a GDM diagnosis when attending or giving birth at one of the three recruiting hospitals. According to Danish guidelines, GDM is diagnosed when, following a 75 g oral glucose tolerance test (OGTT), the 2 h value is ≥ 9.0 mmol/l (venous plasma or capillary blood)
- Live in either Aarhus, Copenhagen, or Odense municipalities
- Able to understand and provide written informed consent in Danish

Exclusion criteria:

- Concomitant participation in other postpartum intervention
- Overt diabetes at baseline

The flow chart of the trial will comply with the CONSORT guidelines and will include the number of individuals who a) were invited during pregnancy b) consented to participate in the trial, c) attended baseline examination, d) were randomised at baseline, e) were lost to follow-up and f) were analysed for follow-up.

Withdrawal/loss to follow-up

If a randomised participant withdraws from the intervention, she will be offered to participate in the final follow-up examination. Participants without body weight measurement at V2 will be regarded as lost-to-follow-up in regard to the primary outcome on BMI during the intervention period. Participants without completed SF-12 questionnaire at V2 will be regarded as lost-to-follow-up in regard to the primary outcome on Quality of Life. In addition, participants who are pregnant at follow-up (V2) will also be considered lost to follow-up in the outcome analyses. The number of participants lost-to-follow-up for each group will be reported in a CONSORT diagram. If possible, the reasons for participants not completing the trial will be given. Summary of baseline levels for variables reported in the baseline table will be provided for completers, item non-responders and non-completers.

Baseline characteristics

The distribution of all continuous outcomes and included baseline characteristics will be visually inspected using QQ-plots and histograms; those with a Gaussian distribution will be presented as means and standard deviations and those with a non-Gaussian distribution will be presented as medians plus 25th and 75th percentiles (IQR), number of observations will be presented for each outcome presented. Categorical data will be summarised by numbers and percentages. Tests of statistical significance will not be undertaken for baseline characteristics; rather the clinical importance of any imbalance will be noted.

The following outcomes will be included in the baseline participant characteristics table for all participants combined and stratified by randomisation group:

- Time from delivery to baseline (weeks)
- Age (years)
- Parity (n and % primiparous)
- Has a partner (n and %)
- Partner participating in the Face-it study (n and %)
- Study site
    - Copenhagen (n and %)
    - Aarhus (n and %)
    - Odense (n and %)
- Country/Region of birth
    - Denmark (n and %)
    - Europe
    - Asia
    - Other
- Education
    - Low education (n and %)
- Employed (n and %)
- On maternity leave at baseline (n and %)
- Current tobacco use (n and %)
- First degree family history of diabetes (n and %)
- Insulin use during last pregnancy (n and %)
- Use of glucose lowering medication at baseline (n and %)

- Pre-pregnancy BMI (kg/m^2)
- BMI at baseline (kg/m^2)
- Weight at baseline (kg)
- Waist circumference (cm)
- Hip circumference (cm)
- Body fat%

- Fasting glucose (mmol/L)
- 2h glucose (mmol/L)
- HbA1c (mmol/mol)
- Impaired Fasting Glucose (n and %)
- Impaired Glucose Tolerance (n and %)
- Fasting insulin (pmol/L)
- 2h insulin (pmol/L)
- HOMA-IR
- HOMA-β

- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)

- Total cholesterol (mmol/L)
- HDL cholesterol (mmol/L)
- LDL cholesterol (mmol/L)

- Triglycerides (mmol/L)

- SF12
    - Self-perceived health
        - Excellent/Very good (n and %)
    - Mental component score
    - Physical component score
- Perceived stress scale score
- WHO-5 percentage score
- General Anxiety Disorder (GAD-7) score

- Dietary Quality Scale (DQS)-2017 score
- IPAQ-SF
    - Walk (min/day)
    - Moderate to vigorous activity (min/day)
- Currently breastfeeding (n and %)

- Social support for Diet and Exercise
    - Encouragement Family scale
    - Participation Family scale
- TSRQ Exercise self-regulation and motivation
    - Autonomous scale score
- General self-efficacy

- RPS-DD Risk perception
    - Perceived risk of getting diabetes
        - Moderate/high (n and %)
    - Made behaviour changes to change risk of diabetes,
        - Yes (n and %)
- HLQ Health literacy
    - Domain 3 Actively engage my health
    - Domain 6 Ability to actively engage with healthcare providers

Section 5: Analyses

Outcome definitions

Primary outcomes
The primary outcomes, BMI and Quality of Life, are assessed at V1 and V2. BMI is calculated from measured height and weight (measured to the nearest 0.1 kg). Quality of life is measured with the SF-12 mental component score. The treatment effect will be given as the baseline corrected differences in kg/m^2 and SF-12 mental component score, respectively, between the groups at V2

Secondary outcomes
The treatment effect will be given as the baseline corrected difference between the groups at V2. The secondary outcomes are grouped into two hierarchies.

Secondary outcomes in hierarchy 1 (BMI):

- Fasting glucose (mmol/L)
- HDL cholesterol (mmol/L)
- Triglycerides (mmol/L)
- Dietary Quality Scale (DQS)-2017 score
- IPAQ-SF
    - Moderate to vigorous activity (min/day)

Secondary outcomes in hierarchy 2 (Quality of Life):

- SF12
    - Self-perceived health, Excellent/Very good (n and %)
- Perceived stress scale score
- WHO-5 percentage score
- General Anxiety Disorder (GAD-7) score

Tertiary outcomes

The treatment effect will be given as the baseline corrected difference between the groups at V2.

- Waist circumference (cm)
- Hip circumference (cm)
- Body fat%
- Weight change%

- 2h glucose (mmol/L)
- HbA1c (mmol/mol)
- Impaired Fasting Glucose (n and %)
- Impaired Glucose Tolerance (n and %)
- Fasting insulin (pmol/L)
- 2h insulin (pmol/L)
- HOMA-IR
- HOMA-β
- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)
- Total cholesterol (mmol/L)
- LDL cholesterol (mmol/L)

- SF12
    - Physical component score

- IPAQ-SF
    - Walk (min/day)
- Breastfeeding duration (months)

- Social support for Diet and Exercise
    - Encouragement Family scale (Diet)
    - Participation Family scale (Exercise)
    -
- TSRQ Exercise self-regulation and motivation
    - Autonomous scale score
- General self-efficacy
- RPS-DD Risk perception
    - Perceived risk of getting diabetes, Moderate/high (n and %)
    - Made behaviour changes to change risk of diabetes, Yes (n and %)

- HLQ Health literacy
    - Domain 3 Actively engage my health
    - Domain 6 Ability to actively engage with healthcare providers

Analysis methods

Analysis population

The primary analysis is an intention-to-treat analysis (ITT) including all participants who will be analysed as randomised.

Prior to further analyses and unblinding, all variables will be inspected to detect outliers to identify potential data entry errors.

Descriptive statistics will be summarised by randomisation group (see Section 4, Baseline characteristics).

The intervention effect for the primary outcomes will be estimated as the difference in BMI by randomisation group adjusted for BMI at baseline as well as the difference in SF-12 mental component score by randomisation group adjusted for SF.12 mental component score at baseline analysed in mixed models. Intervention effect for secondary and tertiary outcomes will likewise be estimated as difference in the outcome by randomisation group adjusted for the outcome at baseline. Continuous outcomes will be analysed in mixed models with a random effect for hospital, categorical outcomes will be analysed in generalized linear mixed models (family binomial, link logit) with a random effect for hospital, and duration of breastfeeding will be analysed using Cox proportional hazards regression with robust variance estimates for clustering due to hospital.

Due to randomisation, baseline values will not be statistically tested between groups. Mean differences between the study groups will be analysed using analysis of covariance, adjusted for baseline levels. Study site will be included as a random effect in the mixed models. Sample size of the study was based to prove a difference in BMI of – 1.0 kg/m^2 between the two randomisation groups (SD 2.5 kg/m^2, $\alpha = 0.05$, power 80%).

Between group differences will be null-hypothesis tested and presented with P-values. The following supplementary analyses are planned for the primary outcomes as well as the secondary and tertiary outcomes:

1. An analysis similar to the one described above but including the per-protocol analysis population only. We will carefully consider the findings from the ITT analysis when drawing conclusions based on the per-protocol analysis, including whether a potential statistically significant result of the per-protocol analysis may be due to selection or the intervention.

2. A sensitivity analysis, including the ITT analysis population, assessing the impact of missing data for the primary outcome. This analysis will only be performed in the case of a loss-to-follow-up rate > 10%, i.e., more than 10% of all participants are missing at V2.

3. A sensitivity analysis excluding participants reporting use of glucose lowering medication at baseline.

4. A subgroup analysis stratified according to baseline BMI i) <25kg/m^2 and ii) ≥25kg/m^2.

5. A subgroup analysis stratified according to i) partner participation (defined as having a partner participating in the baseline visit) and ii) no partner participation (defined as not having a partner participating in the baseline visit).

Missing data

Missing outcome data will be reported. We will not perform imputation of missing data but will examine if the level of missing is equally distributed between randomisation groups and perform sensitivity analyses (worst / best case scenarios) to assess the impact of missing data.

Harms

Information about adverse events is not systematically collected, however if noticed it will be registered and reported to the scientific ethical committee yearly.

Statistical software

The statistical analysis will be performed using the latest version of SAS and data management in SPSS and STATA.

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