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Health promotion intervention among women with recent gestational diabetes mellitus: penetration, participation, and baseline findings from the Face-it randomized controlled trial

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ABSTRACT

Introduction Face-it is a randomized controlled trial for women with recent gestational diabetes mellitus (GDM) and their families designed to evaluate the effect of a health promotion intervention on type 2 diabetes mellitus (T2DM) risk and quality of life. This study examined (1) the penetration and participation rates for the Face-it trial, (2) the characteristics of the participating women and the potential differences in characteristics according to partner participation status, and (3) representativity of the women at baseline.

Research design and methods We identified women with GDM during pregnancy and invited them and their partners to a baseline examination 10–14 weeks after delivery. Representativity was assessed by comparing the baseline participants with non-participating women, the general population of women with GDM delivering in Denmark, and populations from other intervention trials.

Results The penetration rate was 38.0% (867/2279) and the participation rate was 32.9% (285/867). The 285 women who attended baseline had a mean age of 32.7 (±4.8) years and body mass index (BMI) of 28.1 (±5.4) kg/m^2, and 69.8% had a partner who participated. The women participating with a partner were more often primiparous, born in Denmark (82.8% vs 68.2%), were younger, and more often had a BMI ≤24.9 kg/m^2 (35.7% vs 21.2%) compared with women without a partner. Compared with the general population of women with GDM in Denmark, these women broadly had similar degree of heterogeneity, but had higher rates of primiparity and singleton deliveries, and lower rates of preterm delivery and prepregnancy obesity.

Conclusions The penetration and participation rates were acceptable. We found a high rate of partner participation. Overall, women participating with a partner were comparable with those participating without a partner. Participating women were broadly similar to the general national GDM population, however with prepregnancy obesity, multiparity, preterm delivery, and multiple pregnancy being less represented.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ High reach and good representativity of participants in intervention trials are critical to achieving the impact of interventions at the population level.

⇒ Partner participation may be of interest, as increased risk of type 2 diabetes mellitus (T2DM) has been identified in partners as well as women with recent gestational diabetes mellitus (GDM).

WHAT THIS STUDY ADDS

⇒ The Face-it trial evaluating a health promotion intervention had acceptable penetration and participation rates (38.0% and 32.9%), and 69.8% of the women participated with a partner.

⇒ The recruited women with recent GDM were heterogeneous in most sociodemographic, obstetric, clinical, and anthropometric characteristics.

⇒ Compared with other populations of women with GDM, the participating women were characterized by being, to a greater extent, primiparous and having prepregnancy obesity as well as a singleton delivery at term.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The reach and representativity of women participating in the Face-it trial are promising for achieving future population impact of the intervention, if proven effective.

⇒ The high proportion of partner participation is promising for the evaluation of the intervention on the shared risk of T2DM in the family.

Trial registration number NCT03997773.

INTRODUCTION

Gestational diabetes mellitus (GDM) affects approximately 14% of all deliveries globally, but the prevalence varies across countries among others due to variations in screening practices and diagnostic criteria.[1 2] Approximately 6% of all women delivering in Denmark are diagnosed with GDM.[3] Women diagnosed with GDM have a nearly 10-fold higher risk of developing type 2 diabetes mellitus (T2DM) than women without GDM.[4] The Diabetes Prevention Programme (DPP) demonstrated that it is possible to prevent T2DM with health behavior changes in women with prior GDM.[5] Song *et al*[6] have shown that the relative risk of diabetes is highest in the first 3–6 years after a pregnancy affected by GDM, suggesting that early prevention is urgently needed. T2DM prevention trials have been conducted in these critical years shortly after delivery.[7] However, most of the studies have faced problems with recruitment of women with recent GDM and showed modest effect sizes.[8]

Successful recruitment is decisive for achieving high reach of the intended target population.[9 10] Reach is defined as the proportion and risk characteristics of participants who are affected by an intervention trial.[10] Pronk[11] emphasized that the population impact of health promotion interventions depends on how well the intervention reaches its intended participants. Thus, if an intervention trial fails to achieve high reach, it is difficult to justify its scalability potential.[12] Therefore, it is critical to examine the target population invited to participate in trials, that is, the penetration rate, and the proportion enrolled, that is, the participation rate.[11] Dasgupta *et al* found in their systematic review that around half of the intervention trials in women with prior GDM reported insufficient data to estimate penetration and participation rates.[13] Furthermore, an evaluation of representativity, that is, comparison of characteristics with non-participants and the target population, in intervention trials among women with recent GDM has rarely been undertaken.[10]

Interestingly, partners of women with GDM are also at increased risk of subsequent diabetes.[14] Maternal, paternal, and offspring body weights are often correlated, suggesting susceptibility to T2DM at the family level.[14 15] Additionally, support from partners may be a facilitator to mobilize time and energy for women with recent GDM to engage in health behavior changes.[16] McManus *et al*[15] also showed that having a partner involved in the trial was associated with successful maternal study completion. In a recent review, we highlighted the importance of focusing on both parents to promote healthy behaviors in the period of life with a small child.[17] Therefore, both women with recent GDM and their partners were invited to the Face-it randomized controlled trial (RCT) running from 2019 to 2023 and designed to evaluate the effect of a 9-month health-promoting intervention in the first year after delivery on T2DM risk and quality of life.[18] The present study examined (1) the penetration and participation rates for the Face-it trial, (2) the characteristics of the participating women and the potential differences in characteristics according to partner participation status, and (3) representativity of the women at baseline.

METHODS

The Face-it trial has been described in detail elsewhere[18] (ClinicalTrials.gov: NCT03997773). The health-promoting intervention was coproduced and involved health visitor-led home visits, health technology, and cross-sectoral communication in the Danish healthcare system.[18 19] Detailed description of the intervention has previously been published.[20]

Pregnant women with GDM were recruited from three university hospitals in Copenhagen, Odense, and Aarhus, Denmark. Eligible candidates for participation were identified using a list of patients treated at the hospital sites. The candidates were approached in person during routine care by midwives or nurses. The recruitment strategy was based on the findings from a review by Dasgupta *et al*[13] showing that recruitment for postdelivery interventions was more successful during pregnancy than during the postpartum period.

Participants

We invited 867 pregnant women with GDM in the Face-it trial from May 2019 to June 2022. The partners of the enrolled women were encouraged to participate; however, their participation was not mandatory for the women to be enrolled. In Denmark, diagnosis of GDM involves a selective screening procedure.[20 21] A 75 g oral glucose tolerance test (OGTT) is performed between the 24th and 28th gestational week if the woman has family history of diabetes, maternal prepregnancy body mass index (BMI) ≥27 kg/m^2, diagnosis of polycystic ovarian syndrome, twin pregnancy, or previous delivery of a baby with a birth weight ≥4500 kg. Additionally, if a woman has more than one of these risk factors or holds a history of GDM, OGTT is also performed between the 10th and 20th gestational week.[20 21] Following OGTT, GDM is diagnosed if the 2-hour plasma glucose level is ≥9.0 mmol/L.[20 21] Women with GDM were eligible if they (1) attended prenatal care, (2) were expected to deliver at the recruiting hospitals, (3) were living in the surrounding project municipalities, and (4) were able to understand and provide written informed consent in Danish. Those who agreed to participate were invited to attend a baseline examination 10–14 weeks after delivery. The participants fasted (overnight >8 hours) before the examinations.

Data

Data from the Danish Medical Birth Registry (DMBR)[22] were used to estimate the penetration and participation rates.

In terms of baseline characteristics, we collected obstetric data from the women's medical birth records (MBR). Furthermore, the data collection at

baseline consisted of a self-reported questionnaire, clinical measurements, and blood tests.

Sociodemographic characteristics

Self-reported information about country of birth, educational level, and employment status was collected from the questionnaires. We defined the region of birth based on the country of birth. Age was reported at the date of baseline and at delivery. Employment status was reported as the status before a potential current maternity leave. Partner participation status was based on the partner's consent to participate and their attendance at baseline.

Clinical and anthropometric characteristics

Clinical and anthropometric data were collected by trained professionals. BMI (kg/m^2) was calculated using height and body weight. Height and weight were measured without shoes and in light clothes. Waist circumference was measured halfway between the lowest point of the costal margin and the highest point of the iliac crest, whereas hip circumference was measured at the level of the greater femoral trochanter. Body fat was measured using bioimpedance and reported as the percentage of total body weight.[18] Fasting venous plasma samples were used to measure lipids (triglycerides, total cholesterol, low-density lipoprotein, and high-density lipoprotein [HDL]), hemoglobin A1c (HbA1c), plasma glucose, and insulin. The 75 g OGTT provided venous samples for 2-hour plasma glucose and insulin. Dysglycemia and overt diabetes were defined according to the WHO guidelines.[23 24] Dysglycemia included impaired fasting glucose (fasting plasma glucose 6.1–6.9 mmol/L and 2-hour plasma glucose <7.8 mmol/L), impaired glucose tolerance (fasting plasma glucose <7.0 mmol/L and 2-hour plasma glucose ≥7.8 mmol/L and <11.1 mmol/L), and HbA1c 42–47 mmol/mol. Overt diabetes was defined as fasting plasma glucose ≥7.0 mmol/L or 2-hour plasma glucose ≥11.1 mmol/L or HbA1c ≥48 mmol/mol. The homeostasis model assessment was used to calculate insulin resistance and beta-cell function.[25] For cardiometabolic risk factors, we adhered to the International Diabetes Federation[26]: central obesity (waist circumference ≥80 cm), raised triglycerides ≥1.7 mmol/L, reduced HDL-cholesterol <1.29 mmol/L, and raised blood pressure (systolic ≥130 mm Hg, diastolic ≥85 mm Hg). Blood pressure was measured in sitting position and calculated as an average of three measurements with 2 min intervals. Use of glucose-lowering drugs and family history of diabetes were self-reported.

Psychosocial characteristics

Quality of life, psychological well-being, and stress were self-reported. Quality of life was measured using one item from the 12-item Short Form Health Survey (SF-12): "In general, how would you say your health is?"[27] Physical and mental component scores were also calculated using the SF-12.[27] Psychological well-being was measured using the WHO-5 Well-Being Index, with a score of ≤50 indicating risk of depression or stress.[28] The Perceived Stress Scale was used to assess levels of stress: 0–13=low, 14–26=moderate, and 27–40=high stress.[29]

Obstetric characteristics

We obtained data on prepregnancy BMI, singleton or twin pregnancy, parity, last HbA1c measurement during pregnancy, insulin treatment during pregnancy, diagnosis of pre-eclampsia or gestational hypertension, preterm delivery, and mode of delivery from the MBR. Mode of delivery was categorized into vaginal delivery, planned, or emergency cesarean section. Preterm delivery was defined as delivery <37 completed weeks of gestation. Parity was dichotomized into primiparous or multiparous.

Behavioral characteristics

Physical activity, dietary behaviors, breast feeding, and smoking were self-reported. Physical activity was measured using the International Physical Activity Questionnaire - Short Form.[30] Dietary behaviors were measured using the Dietary Quality Scale (DQS).[31] The DQS was developed to make a rough classification of diet by using eight items from an international 48-item Food Frequency Questionnaire (FFQ) and validated using the 198-item FFQ.[31] DQS concerns the intake of fruit, vegetables, fish, and fats. The total DQS score was grouped into high, average, and low dietary quality. Women whose baby was fed with only breast milk in the last 7 days were categorized as exclusive breast feeding, those who fed with breast milk supplemented with formula once or more were categorized as partial breast feeding, and those who fed with only formula were categorized as not breast feeding. Smoking was assessed by a question with a five-item scale from "daily smoking" to "no, I have never been smoking." Current smoking was defined by grouping the answers "daily smoking," "smoking a few times a week," and "smoking once a week."

Data on a selection of the non-participating women, that is, those who declined to participate in the Face-it trial or withdrew consent to participate and gave consent to access data from their MBR (50% of all non-participating women), were derived from the MBR and included obstetric characteristics, age at delivery, and insulin treatment during pregnancy.

Representativity

To examine representativity, we included data on three populations: (1) non-participating women in the Face-it trial, (2) the general population of women with GDM delivering in Denmark, and (3) populations from other intervention trials. For population 2, we included data from two sources: (1) women with GDM delivering in Denmark in the period from 2004 to 2015 based on the results from a Danish nationwide study of singleton deliveries[32] (n=18 795) and (2) women with GDM delivering in Denmark in the period from 2019 to 2021 based on data from the DMBR[22] (n=10 725). The 2004–2015 study[32] included information on the region of birth and

diagnosis of pre-eclampsia and gestational hypertension, which was not available in the DMBR data from 2019 to 2021. The two Danish populations were therefore reported separately. For population 3, we included data on populations from other intervention trials among women with recent GDM. These trials were identified in a literature search conducted in PubMed in February 2023 (online supplemental appendices 1 and 2) using the keywords "Gestational diabetes," "GDM," "Type 2 Diabetes Prevention," "Diabetes Prevention," and "Intervention." We restricted the search to clinical trials, RCTs, and English language. Pilot or feasibility studies were excluded. There were no limitations in terms of publication date. Search results were reviewed by NHJ and discussed with KKN, IKD-P, and HTM. The following criteria were applied: (1) studies based on the DPP and (2) studies including behavioral interventions initiated ≤3 years after delivery.

Analysis

Recruitment

We were not able to obtain data on the number of women with GDM at the recruiting hospital sites in the recruitment period. Thus, we used data from the DMBR[22] on the yearly average number of women with GDM at the recruitment hospitals from 2016 to 2018 (n=706). To account for an expected increase in the prevalence of GDM in the timespan from 2016 to 2018 and the Face-it recruitment period (2019–2022), we added an annual increase in the number of women with GDM at the recruiting sites from 2016 to 2018. This annual increase was estimated to be 6.0% based on data from 2013 to 2018 from the DMBR, meaning the estimated number of women who delivered at the recruiting sites from 2019 to 2022 was 2248. This number was used to extrapolate the target population by multiplying across the recruitment period (36.5 months).

We calculated the penetration rate as n invited/N target population and the participation rate as n attending baseline/N invited to participate.

Baseline characteristics

We analyzed the characteristics using descriptive statistics and reported data as mean (±SD), median (IQR), and/or proportion (%). The characteristics by partner participation status were compared using risk differences (RD), t-test, Mann-Whitney median test, and χ^2 test as appropriate.

Representativity

We compared the Face-it population with, first, the non-participating women in the Face-it trial; second, the two general populations of women with GDM delivering in Denmark; and third, populations from the other intervention trials. Analyses of representativity were performed using RD, χ^2 test, and t-test. A two-sided p value of <0.05 was considered statistically significant. The data were managed using REDCap electronic data tools hosted by the Capital Region of Denmark.[33 34] Analyses were performed in STATA V.17.0 and Excel.

RESULTS

Recruitment

As shown in figure 1, an estimated 2279 women with GDM delivered at the three hospitals during the recruitment period. Of these, 867 were invited to participate, resulting in a penetration rate of 38.0%. A total of 330 women agreed to participate, corresponding to an initial participation rate of 38.1%. However, 45 (13.6%) women withdrew consent between the time of recruitment and baseline, and the final participation rate was therefore 32.9% (285/867).

Characteristics

Table 1 presents the sociodemographic, psychosocial, and behavioral characteristics of the women. The examinations were conducted on average 12.1 (±2.4) weeks after delivery. In total, 61 (21.6%) women were born outside of Denmark, 54 (19.1%) had a low educational level, and 41 (14.5%) were unemployed, on sick leave, or outside the labor market. Excellent/very good self-rated health was reported by 153 (53.9%) women, and 156 (55.1%) perceived a low level of stress. The women spent a median (IQR) of 45.0 (12.9–128.6) min/day on moderate-intensity physical activity, 31 (10.9%) reported healthy dietary behaviors, and 179 (63.0%) were breast feeding exclusively.

Table 2 presents the obstetric, clinical, and anthropometric characteristics. The mean BMI at baseline was 28.1 (±5.4) kg/m^2. For cardiometabolic risk factors, 235 (83.0%) women had central obesity, 34 (12.0%) with triglycerides ≥1.7 mmol/L, 54 (19.0%) with HDL-cholesterol <1.29 mmol/L, 28 (9.8%) with systolic blood pressure ≥130 mm Hg, and 41 (14.4%) with diastolic blood pressure ≥85 mm Hg (online supplemental appendix 1). Furthermore, 54 (19.2%) women had dysglycemia, and additionally 7 (2.5%) women had overt diabetes (table 2). In total, 199 (69.8.%) had a partner who participated (tables 1 and 2). Women having a partner who participated were on average younger, more likely to be born in Denmark and to be primiparous, and fewer had overweight/obesity compared with women without a partner who participated.

Representativity

In total, 314 women allowed us access to their MBR; this population included 269 of the non-participating women, and 45 women who had initially agreed to participate in the trial withdrew but allowed access to their MBR (figure 1). The non-participants were more heterogeneous in terms of prepregnancy BMI, that is, more women had a prepregnancy BMI ≥30 kg/m^2 and had a lower frequency of primiparity and singleton pregnancies (table 3).

Compared with the general populations of women with GDM delivering in Denmark, the Face-it participants

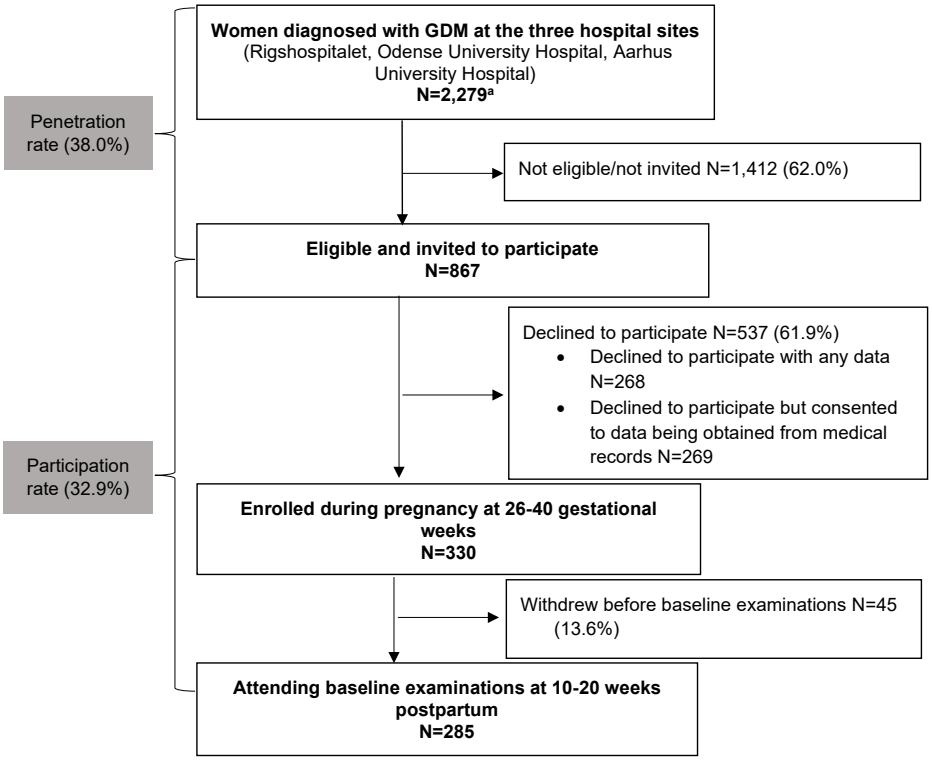

Figure 1 Flow chart of the recruitment process for the Face-it randomized controlled trial. GDM, gestational diabetes mellitus. [a]Extrapolated target population based on data from the Danish Medical Birth Registry.[24]

had less often prepregnancy obesity and lower rates of preterm delivery. The Face-it participants had a higher rate of singleton delivery than the general population of women with GDM in the 2019–2021 period (table 3).

Table 4 summarizes the reach and characteristics of the Face-it population and populations from nine other intervention trials identified from the literature search (online supplemental appendices 2 and 3). Only one trial provided sufficient data to estimate penetration rate. The Face-it trial demonstrated a remarkably higher participation rate than trials from Ireland and Australia,[35–37] but a rate which was lower than trials from India, Sri Lanka, Bangladesh, China, Spain, and the USA.[38–41] In the Face-it population, lower mean BMI and waist circumference were found compared with three trials from the USA, Australia, and Ireland.[35 36 40 42] Also, the Face-it population had a higher rate of dysglycemia compared with participants in a trial from Australia, but a lower rate compared with trials from the USA, India, Sri Lanka, and Bangladesh.[39 40]

DISCUSSION

The Face-it trial demonstrated a penetration rate of 38.0% and a participation rate of 32.9%. The recruited women were heterogeneous in most sociodemographic, obstetric, clinical, and anthropometric characteristics. Women participating with a partner had similar characteristics compared with women participating without, with region of birth, age, parity, and BMI as exceptions. However, compared with the general population of women with GDM in Denmark, women with prepregnancy obesity, multiparity, preterm delivery, and multiple pregnancy were less represented in the Face-it trial.

Aziz *et al*[12] conducted a systematic review of diabetes preventive intervention trials and categorized penetration and participation rates into ≤33%=low, 34%–66%=medium, and ≥67%=high. Based on these categories, the Face-it trial demonstrated a medium penetration rate and a low, yet close to medium, participation rate. In their review, Dasgupta *et al*[13] used other criteria than our literature search and found penetration rates ranging from 31% to 100% and many studies achieved participation rates ≤15%. Thus, the participation rate in the Face-it trial was higher than many other intervention trials included in the systematic review.[13]

Other studies have found that integration of recruitment in routine care improves reach in trials.[13 43] Therefore, we suggest that the achievement of acceptable penetration and participation rates in the Face-it trial may be a result of the personalized contact established during recruitment through routine care set-up in pregnancy.

Table 1 Sociodemographics, psychosocial, and behavioral characteristics of the women attending the baseline examination in the Face-it trial

	Women participating with a partner	Women participating without a partner	P value	All women
n (%)	199 (69.8)	86 (30.2)		285 (100.0)
Time from delivery to baseline (weeks), mean (±SD)	12.2 (±2.3)	12.0 (±2.7)	0.652	12.1 (±2.4)
Sociodemographics				
Age (years at baseline), mean (±SD)	32.2 (±4.5)	33.7 (±5.4)	0.025	32.7 (±4.8)
Region of birth*, n (%)			0.005	
Denmark	164 (82.8)	58 (68.2)		222 (78.4)
Europe	12 (6.1)	8 (9.4)		20 (7.1)
East and Southeast Asia	14 (7.1)	5 (5.9)		19 (6.7)
South Asia	2 (1.0)	5 (5.9)		7 (2.5)
Other	6 (3.0)	9 (10.6)		15 (5.3)
Educational level*, n (%)			0.063	
High (master's degree or higher)	71 (35.9)	23 (27.1)		94 (33.2)
Medium (bachelor's degree or equivalent)	96 (48.5)	39 (45.9)		135 (47.7)
Low (primary school, upper secondary, and short tertiary)	31 (15.7)	23 (27.1)		54 (19.1)
Employment status*, n (%)			0.376	
Employed	144 (72.7)	61 (71.8)		205 (72.4)
Student	27 (13.6)	9 (10.6)		36 (12.7)
Unemployed/long-term sick leave/outside the labor market	27 (13.6)	14 (16.5)		41 (14.5)
Other		1 (1.2)		1 (0.4)
Currently on maternity leave*, n (%)	195 (98.5)	85 (100.0)	0.081	280 (98.9)
Psychosocial characteristics				
Self-rated health†, n (%)			0.424	
Excellent/very good	111 (56.1)	42 (48.8)		153 (53.9)
Good	69 (34.8)	37 (43.0)		106 (37.3)
Fair/poor	18 (9.1)	7 (8.1)		25 (8.8)
Quality of life†, median (IQR)				
Mental component score	50.6 (44.4–54.7)	49.4 (42.8–54.8)	0.554	50.0 (44.3–54.7)
Physical component score	54.7 (50.4–57.2)	53.5 (48.3–57.2)	0.159	54.5 (49.8–57.2)
Psychological well-being*, n (%)				
Risk of depression or stress	39 (19.7)	23 (27.1)	0.188	62 (21.9)
Perceived level of stress*, n (%)			0.264	
Low perceived stress	113 (57.1)	43 (50.6)		156 (55.1)
Moderate perceived stress	84 (42.4)	40 (47.1)		124 (43.8)
High perceived stress	1 (0.5)	2 (2.4)		3 (1.1)
Behavioral characteristics				
Physical activity (min/day), median (IQR)				
Walk	60.0 (30.0–90.0)	60.0 (30.0–95.0)	0.954	60.0 (30.0–95.0)
Moderate intensity	42.9 (12.9–121.4)	59.0 (12.9–150.0)	0.641	45.0 (12.9–128.6)
Vigorous intensity	0.0 (0.0–8.6)	0.0 (0.0–13.7)	0.297	0.0 (0.0–8.6)
Missing range‡	1–5	1		2–6
Dietary quality†, n (%)			0.294	
Healthy dietary behaviors	25 (12.6)	6 (7.0)		31 (10.9)
Average dietary behaviors	134 (67.7)	65 (75.6)		199 (70.1)
Unhealthy dietary behaviors	39 (19.7)	15 (17.4)		54 (19.0)
Breast feeding, n (%)			0.914	

Continued

Table 1 Continued

	Women participating with a partner	Women participating without a partner	P value	All women
Exclusive	127 (63.8)	52 (61.2)		179 (63.0)
Partial	39 (19.6)	18 (21.2)		57 (20.1)
No breast feeding	33 (16.6)	15 (17.6)		48 (16.9)
Missing		1		1
Current smoking†, n (%)	9 (4.5)	2 (2.3)	0.313	11 (3.9)

IQR: 25th and 75th percentile.
*Missing values: women participating with a partner=1; women participating without a partner=1; all women=2.
†Missing values: women participating with a partner=1; all women=1.
‡Missing values: women participating with a partner: walk=5, moderate intensity=2, vigorous intensity=1; all women: walk=6, moderate intensity=3, vigorous intensity=2.

The Face-it intervention was developed in a coproduction process and sought to address barriers for women with recent GDM to engage in health promotion.[19] Involvement of the target group during intervention development seems to ease its acceptability[44 45] and may therefore also have been appealing to participants in the recruitment phase. The Face-it intervention was not designed as a high-intensity intervention, but rather as an intervention tailored to the resources of couples with a small child.[19] Aziz *et al*[12] showed that even low-intensity interventions with modest effectiveness can lead to high impact at the population level if the interventions achieve good coverage and participants display willingness to participate. With the identified reach, we believe this is promising for the potential of the Face-it intervention in terms of population impact, if the intervention is proven effective.

Representativity is also important in assessing the usefulness of findings from intervention trials as it influences the generalizability.[10] In the Face-it trial, we for practical reasons had an inclusion criteria of Danish language skills, which might have negatively influenced representativity. Yet this study shows that more than one-fifth of the population were born outside of Denmark, which is very close to the proportion reported for the general population of women with GDM delivering in Denmark.[32] Thus, it would appear that the Face-it trial was able to recruit a population representative of the target population in terms of ethnicity, something other trials have reported difficulties with.[13] We found that obesity, defined as waist circumference, was more common than obesity based on BMI at baseline. This could indicate high fat percentage among the normal-weight women in the Face-it population. However, baseline was performed shortly after delivery and the women's anthropometrics were likely still affected by this circumstance. When comparing the characteristics of the Face-it participants with the general population of women with GDM delivering in Denmark, we found lower prepregnancy BMI. The finding of lower prepregnancy BMI may be linked to an overall higher socioeconomic status in the Face-it participants, as BMI and socioeconomic status have been found to associate negatively.[46] Thus, the Face-it trial may have recruited women with more resources in terms of a higher socioeconomic status, and attention toward recruitment of groups with less resources may be needed. Another explanation for the finding of lower prepregnancy BMI could be related to stigma. Women with GDM may experience stigma associated with the GDM diagnosis and/or weight.[47] Additionally, the finding that women with multiparity, preterm delivery, and multiple delivery were less represented may be explained by higher level of strain, thus less surplus of energy to prioritize participation.

An overall aim of the Face-it intervention was to increase quality of life among the participants.[18] A study by Ferrari *et al*[48] found that more than three-quarters of women with recent GDM reported a moderate/high level of stress. This rate was significantly higher than the rate of women reporting a moderate/high stress level in the Face-it population. In terms of self-rated health, a lower proportion of the Face-it population reported fair/low self-rated health compared with the general population of Danish women aged 25–34 years (8.8% vs 12.4%).[49] These combined results may indicate better self-rated and mental health status in the Face-it participants compared with the general Danish population and the study by Ferrari *et al*.[48]

Finally, in the Face-it trial, we invited the partners of women with recent GDM to participate. Around 70% of the women had a partner who participated in the Face-it trial. This rate was higher than the findings in the trial by McManus *et al*,[15] who reported that only 37.1% of the women with prior GDM participated with a partner. The high rate of partner participation in the Face-it trial is promising for reducing T2DM risk at the family level. The group of women participating without a partner includes both women who did not have a partner at the time of recruitment and women whose partner declined participation. Future studies could benefit from investigations into the reasons for partners' declination to participate.

Table 2 Obstetric, clinical, and anthropometric characteristics of the women attending the baseline examination in the Face-it trial

	Women participating with a partner	Women participating without a partner	P value	All women
n (%)	199 (69.8)	86 (30.2)		285 (100.0)
Obstetric characteristics				
Primiparous, n (%)	121 (60.8)	38 (44.2)	0.009	159 (55.8)
Prepregnancy BMI (kg/m^2), mean (±SD)	27.3 (±5.7)	27.7 (±5.0)	0.592	27.4 (±5.5)
Missing	2	1		3
Clinical and anthropometric characteristics				
BMI at baseline* (kg/m^2), mean (±SD)	27.9 (±5.6)	28.7 (±4.8)	0.286	28.1 (±5.4)
BMI at baseline* (kg/m^2), n (%)			0.022	
≤24.9	71 (35.7)	18 (21.2)		89 (31.3)
25–29.9	69 (34.7)	37 (43.5)		106 (37.3)
30–34.9	31 (15.6)	22 (25.9)		53 (18.7)
≥35.0	28 (14.1)	8 (9.4)		36 (12.7)
Body fat percent*, mean (±SD)	37.7 (±7.9)	39.2 (±6.6)	0.114	38.1 (±7.5)
Blood pressure (mmHg), mean (±SD)				
Systolic	115.9 (±11.2)	115.4 (±10.5)	0.709	115.8 (±11.0)
Diastolic	76.7 (±8.3)	77.0 (±7.5)	0.791	76.8 (±8.0)
Lipids (mmol/L), median (IQR)				
Cholesterol total	4.9 (4.3–5.4)	4.9 (4.3–5.5)	0.956	4.9 (4.3–5.5)
Cholesterol HDL	1.5 (1.3–1.8)	1.5 (1.3–1.8)	0.296	1.5 (1.3–1.8)
Cholesterol LDL	2.9 (2.4–3.4)	2.9 (2.5–3.2)	0.857	2.9 (2.4–3.4)
Triglyceride	0.9 (0.7–1.2)	1.1 (0.8–1.3)	0.021	1.0 (0.7–1.3)
Missing range†	0–1	1		1–2
OGTT (mmol/L), median (IQR)				
Fasting plasma glucose	5.1 (4.8–5.4)	5.2 (4.9–5.6)	0.102	5.1 (4.8–5.5)
2-hour plasma glucose	6.1 (5.1–7.2)	6.4 (5.5–7.2)	0.234	6.2 (5.2–7.2)
Missing range‡	1	1–3		2–4
Insulin (pmol/L), median (IQR)				
Fasting insulin	53.0 (35.0–82.2)	61.0 (44.0–86.0)	0.077	56.0 (37.0–85.0)
2-hour insulin	262.0 (159.0–399.0)	289.0 (204.0–371.0)	0.366	268.0 (170.0–384.5)
Missing range§	2–3	3		5–6
Hemoglobin A1c (mmol/mol), mean (±SD)	34.8 (±3.8)	35.1 (±3.7)	0.588	34.9 (±3.8)
HOMA, median (IQR)¶				
Insulin resistance	1.7 (1.1–2.9)	2.0 (1.3–3.2)	0.055	1.9 (1.2–2.9)
Beta-cell function	100.8 (62.4–135.7)	103.3 (76.1–144.0)	0.301	100.8 (67.2–138.2)
Missing	5	3		8
Dysglycemic and overt diabetes, n (%)				
IFG	12 (6.1)	11 (12.9)	0.087	23 (8.1)
IGT	24 (12.1)	13 (15.7)	0.443	37 (13.2)
HbA1c 42–47 mmol/mol	6 (3.0)	7 (8.2)	0.105	13 (4.6)
Dysglycemia total**	32 (16.2)	22 (26.5)	0.060	54 (19.2)
Overt diabetes**	6 (3.0)	1 (1.2)	0.285	7 (2.5)
Missing range††	0–1	1–3		1–4

Continued

Table 2 Continued

	Women participating with a partner	Women participating without a partner	P value	All women
Use of glucose-lowering medication, n (%)	1 (0.5)	–	0.316	1 (0.4)
Missing	1	1		2
Family history of diabetes, n (%)	137 (69.2)	58 (68.2)	0.874	195 (68.9)
Missing	1	1		2

IQR: 25th and 75th percentile.
*Missing values: women participating without a partner=1.
†Missing values: women participating with a partner: triglyceride=1, all other=0; all women: triglyceride=2, all other=1.
‡Missing values: women participating without a partner: fasting plasma glucose=1, 2-hour plasma glucose=3; all women: fasting plasma glucose=2, 2-hour plasma glucose=4.
§Missing values: women participating with a partner: fasting insulin=3, 2-hour insulin=2; all women: fasting insulin=6, 2-hour insulin=5.
¶Insulin resistance was calculated as fasting plasma insulin (pmol/L)×fasting plasma glucose (mmol/L)/22.5×0.144, and beta-cell function was calculated as fasting plasma insulin (pmol/L)×0.144x20/(fasting plasma glucose (mmol/L)–3.5).[23]
**Individuals with at least one measurement of fasting plasma glucose or 75 g OGTT or HbA1c were included in the analysis.
††Missing values: women participating with a partner: HbA1c 42–47 mmol/mol=0, all other=1; women participating without a partner: impaired fasting glucose=1 and HbA1c 42–47 mmol/mol=1, all other=3.
BMI, body mass index; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; HOMA, homeostasis model assessment; HOMA-IR, homeostasis model assessment of insulin resistance; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; LDL, low-density lipoprotein; OGTT, oral glucose tolerance test.

Strengths and limitations

The main strength of this study was the detailed data on the recruitment process and the availability of data on a broad range of characteristics in both participants and non-participants. This enabled a comprehensive understanding of reach and representativity of importance for future implementation of the Face-it intervention or similar interventions targeting women with recent GDM. Recruitment for the trial took place during times with COVID-19 restrictions. These restrictions may have influenced reach negatively. The use of DMBR was a strength as the register includes data on around 99% of all deliveries in Denmark.[22]

Our study also has limitations. We had no access to data on the socioeconomic characteristics from the general population of women with GDM delivering in Denmark and could therefore not assess the representativity in terms of socioeconomic status. We also had to extrapolate the denominator in the penetration rate by using historical registry data instead of data on the exact number of women at the recruiting sites in the recruitment period. Whereas we used patient lists to identify participants eligible for inclusion, we were not allowed to save the lists for further inventory due togeneral data protection regulation rules. Therefore, our estimate of the penetration rate is an estimate with uncertainties attached, which may have hampered the validity of our penetration rate result. We used DMBR data from 2019 to 2021 to estimate representativity; however, recruitment of women for the Face-it trial took place from 2019 to 2022. Thus, some of the Face-it participants are included in the 2019–2021 period. This may lead to lack of independency between the Face-it participants and the general population of women with GDM and the analysis of representativity may thus be biased. Yet the Face-it participants constitute a small proportion of this group and we therefore do not expect this to have influenced the analysis substantially.

CONCLUSIONS

The Face-it trial achieved a penetration rate of 38.0% and a participation rate of 32.9%, suggesting that the intervention may be an initiative with potential for population impact, if proven effective in reducing T2DM risk. The finding of acceptable penetration and participation rates may be linked to the personalized recruitment strategy embedded in routine care and the tailored content of the coproduced intervention. Women participating with a partner had similar characteristics compared with women participating without, with region of birth, parity, age, and BMI as exceptions. Also, with 69.8% of the women having a partner that participated, the intervention seems to be appealing to partners of women with recent GDM and therefore promising for reducing T2DM risk among families where the mother had GDM. Women with prepregnancy obesity, multiparity, preterm delivery, and multiple pregnancy were less represented, which should be considered when designing future interventions.

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Table 3 Characteristics of women participating in the baseline examinations of the Face-it trial compared with non-participants of the Face-it trial and the general populations of women with GDM delivering in Denmark

	Women attending baseline examinations in the Face-it trial	Women who declined to participate or withdrew before baseline in the Face-it trial		Women with GDM delivering in Denmark: 2019–2021*		Women with GDM delivering in Denmark: 2004–2015†	
	n=285	n=314	P value	n=10 725	P value	n=18 795	P value
Born outside of Denmark, n (%)	61 (21.6)	–		–		4328 (23.0)	0.550
Missing	2						
Age (years at delivery), n (%)							
<30	89 (31.4)	95 (31.5)	0.788	3490 (32.5)	0.793	–	
30–34	103 (37.3)	116 (38.4)		4015 (37.4)			
35–39	69 (22.5)	63 (20.9)		2440 (22.8)			
40+	24 (8.9)	28 (9.3)		780 (7.3)			
Missing		12					
Age (years at delivery), mean (±SD)	32.4 (±4.8)	32.2 (±4.8)	0.479	–		32.0 (±5.1)	0.164
Missing		12					
Prepregnancy BMI (kg/m^2), n (%)							
≤24.9	105 (37.2)	105 (35.0)	0.017	3325 (32.6)	0.005	5306 (30.4)	<0.001
25–29.9	102 (36.2)	84 (28.0)		3195 (31.4)		5336 (30.5)	
≥30	75 (26.6)	111 (37.0)		3670 (36.0)		6839 (39.1)	
Missing	3	14		535		1314	
Primiparous women, n (%)	159 (55.8)	124 (41.1)	<0.001	4735 (44.2)	<0.001	7518 (40.6)	<0.001
Missing		12				268	
Diagnosis during pregnancy, n (%)							
Pre-eclampsia	14 (4.9)	16 (5.1)	0.918	–		939 (5.0)	0.841
Gestational hypertension	15 (5.3)	14 (4.5)	0.648			–	
Singleton delivery, n (%)	282 (98.9)	289 (95.7)	0.013	10 150 (94.6)	<0.001	–	
Missing		12					
Preterm delivery, n (%)	11 (3.9)	16 (5.3)	0.403	990 (9.2)	<0.001	1413 (7.5)	0.002
Missing		12		15			
Mode of delivery, n (%)							
Vaginal delivery	211 (74.0)	224 (74.2)	0.734	7595 (70.9)	0.412	13 027 (69.5)	0.231
Planned cesarean section	36 (12.6)	33 (10.9)		1385 (12.9)		2624 (14.0)	
Emergency cesarean section	38 (13.3)	45 (14.9)		1730 (16.2)		3095 (16.5)	
Missing		12		15		49	
Gestational weeks at GDM diagnosis (weeks), mean (±SD)	27.4 (±5.4)	26.9 (±5.1)	0.243	–		–	
Missing	5	12					
Latest measured HbA1c during pregnancy (mmol/mol), mean (±SD)	35.5 (±4.5)	35.7 (±5.3)	0.621	–		–	
Missing	2	16					
Insulin treatment during pregnancy, n (%)	66 (23.2)	75 (24.8)	0.634	–		–	
Missing		12					

Data not available are marked with "–". Risk differences, Student's t-test, and χ^2 test were used to compare the characteristics of the Face-it population with the remaining study populations, respectively.
*Danish Medical Birth Registry.[22]
†Kragelund Nielsen *et al*.[32]
BMI, body mass index; GDM, gestational diabetes mellitus; HbA1c, hemoglobin A1c.

Table 4 Characteristics of reach and women with recent GDM at study entry in the Face-it trial and other intervention trials

	Study country of origin	Penetration rate†	Participation rate‡	Study entry (time since delivery)	Age at baseline (years)	BMI at baseline (kg/m^2)	Primiparous	Family history of diabetes	Waist circumference	Body fat (%)	Dysglycemia
		(%)	(%)		Mean (±SD)	Mean (±SD)	n (%)	n (%)	Mean (±SD)	Mean (±SD)	n (%)
Face-it trial	Denmark	38.0	32.9	12.1 weeks	32.7 (±4.8)	28.1 (±5.4)	159 (55.8)	195 (68.4)	90.6 (±12.5)	38.1 (±7.5)	54 (19.2)
O'Reilly *et al*[37]	Australia	NAC	7.1	8.0 months	33.8 (±5.2)*	28.8 (±6.8)	253 (44.5)*	–	91.2 (±14.5)	–	57 (10.0)¶
Tandon *et al*[39]	India, Sri Lanka, and Bangladesh	NAC	47.6	6.9 months	30.9 (±4.9)¶	26.6 (±4.7)¶	–	775 (48.4)¶	89.6 (±11.6)	–	600 (37.5)¶
Nicklas *et al*[40]	USA	NAC	48.1	7.2 weeks	33.5 (±5.3)	31.4 (±5.7)¶	33 (44.0)	–	–	–	29 (38.7)¶
Liu *et al*[38]	China	62.6	40.6	27.2 months	32.4 (±3.5)	23.9 (±3.8)¶	–	402 (34.1)¶	80.1 (±9.2)¶	32.8 (±5.7)¶	–
Ratner *et al*[42]	USA	NAC	NAC	12 years	43.0 (±7.6)¶	34.2 (±6.2)¶	–	–	–	–	§
O'Dea *et al*[35]	Ireland	NAC	12.2	1–3 years	–	35.5 (±6.6)¶	–	–	113.7 (±16.6)¶	–	§
Peacock *et al*[36]	Australia	NAC	9.7	6 months–2 years		30.3 (±8.2)	6 (19.4)¶	–	100.7 (±11.8)¶	37.4(±7.1)	–
Pérez-Ferre *et al*[41]	Spain	NAC	86.7	7–12 weeks	–	–	79 (33.3)¶	–	–	–	–
Shyam *et al*[50]	Malaysia	NAC	41.2	5.5 months	31.2 (±4.4)	26.4 (±4.6)	–	–	83.0 (±9.1)¶	–	–

Data not available are marked with "–". Risk differences, Student's t-test and χ^2 test were used to compare the characteristics of the Face-it baseline population with the nine study populations, respectively.
*P≤0.05
†Calculated as (n invited/N target population).
‡Calculated as (n enrolled in the study/N invited to participate).
§All participants had dysglycemia at study entry.
¶P≤0.001.
BMI, body mass index; GDM, gestational diabetes mellitus; NAC, not able to calculate.

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