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ORIGINAL ARTICLE

The STORK Groruddalen research programme: A population-based cohort study of gestational diabetes, physical activity, and obesity in pregnancy in a multiethnic population. Rationale, methods, study population, and participation rates

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Abstract

Background: Gestational diabetes mellitus (GDM) and obesity may cause adverse pregnancy outcomes for mothers and offspring. We have set up a research programme to identify predictors for GDM and fetal growth in a multiethnic population in Oslo to improve the identification of high risk pregnancies and reduce adverse short and long-term outcomes for mothers and offspring. *Aims:* To present the rationale, methods, study population and participation rates. *Methods:* Population-based cohort study of pregnant women attending the Child Health Clinics (CHC) in Groruddalen, Oslo, and their offspring. Questionnaire data, blood pressure, anthropometric measurements, and fasting blood and urine samples are collected (gestational weeks 8–20 and 28, and 12 weeks postpartum) and an oral glucose tolerance test (28 weeks). Physical activity is measured, three ultrasound measurements are performed and paternal questionnaire data collected. Routine hospital data are available for all mothers and offspring. Umbilical venous blood and placentas are collected, sampled, and stored and neonatal anthropometric measurements performed. Ethnicity is self-reported country of birth. *Results:* 823 women were included, 59% of non-Western origin. The participation rate was 74% (64–83% in main ethnic groups), mean age 29.8 years (95% CI 29.5–30.1) and median parity 1 (inter-quartile range 1). The cohort is representative for women attending the CHC with respect to ethnicity and age. A slight selection towards lower parity (South Asians) and age (Africans) was found. Few were lost to follow-up. ***Conclusions:*** **Unique information is collected from a representative group of multiethnic women to address important public health problems and mechanisms of disease. Participation rates are high in all ethnic groups.**

Key Words: *Adiposity, birth weight, diet, ethnicity, fetal growth, gestational diabetes mellitus, physical activity, placenta, pregnancy outcomes, umbilical venous blood*

Abbreviations: GDM, Gestational diabetes mellitus; T2DM, type 2 diabetes; LBW, Low birth weight; CHC, Child Health Clinic; OGTT, oral glucose tolerance test

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Background

Low socio-economic status is associated with adverse pregnancy outcomes for mother and offspring [1,2]. Low birth weight and adult body height may serve as markers of adverse environmental influences hampering growth and increase the risk of later cardiovascular disease and type 2 diabetes (T2DM) [3]. Mean birth weight varies between countries around the world and between ethnics groups within Europe [1,2,4]. Early catch up growth, long viewed as an essential recovery from the deleterious effects of poor growth on development and health, is now recognised as a risk factor for obesity and T2DM [5].

Along with the increase in obesity and T2DM in women in reproductive age, an increase in gestational diabetes mellitus (GDM) is observed [6]. GDM constitutes a risk for adverse pregnancy outcomes and for later development of T2DM [7]. Pregestational physical inactivity [8], obesity, T2DM, and GDM are associated with neonatal macrosomia and adiposity, conditions increasing future T2DM risk in the offspring [6,9,10]. Hence "diabetes begets diabetes". However, short-term pregnancy outcomes in women with GDM may be improved and their risk of later T2DM reduced by lifestyle intervention [11,12].

The fetal nutritional environment, mediated through the diet and metabolic and endocrine status of the mother and by the placenta [13], may imply long-term effects on phenotypic characteristics of the offspring by epigenetic regulation [14]. The graded relation between glucose levels and pregnancy complications, including macrosomia, may have large effects in societies where the whole population is drifting in the direction of overweight and glucose intolerance [9]. Ethnic differences in susceptibility for abdominal adiposity, T2DM and GDM are found, which for South Asians may be tracked to fetal life, with low birth weight and relative preservation of subcutaneous fat [15].

During the last decades, immigration to Norway from non-Western countries has increased rapidly, reaching 21.8% of the whole population in Oslo (January 1st 2009), but >40% in some Eastern districts of the city (Groruddalen). An alarmingly high prevalence of diabetes, especially in South Asian women (27.5% versus 2.9% in Norwegians), was found in this area [16] and the majority of middle-aged non-Western women were physically inactive and obese. Perinatal mortality is doubled in offspring of non-Western women compared to Norwegians [17].

The STORK Groruddalen research programme is targeting pregnant women and their offspring. It was set up to increase the knowledge about GDM in a multiethnic population and establish better methods for identification of high-risk pregnancies, with the ultimate goal to reduce complications and long-term health risks for the mother and the offspring. The name of the study refers to the bird's symbolic function as well as the residential area of study participants to avoid confusion with the STORK study at Oslo University Hospital, Rikshospitalet, covering ethnic Norwegian women [8].

The aim of this paper is to present the rationale for the research programme, the methods applied, the study population, and the participation rates.

Methods

The main research questions are related to both maternal and offspring data. For the women, the questions were: What is the proportion of women with GDM in ethnic minority groups from Asia and Africa compared to Europeans? What are the most important predictors for GDM, adverse pregnancy outcomes, and postpartum dysglycemia? For the offspring, the questions were: What is the prevalence of adverse fetal outcomes in the major ethnic groups? How does birth weight differ between and within ethnic groups? What are the most important predictors for fetal growth, birth weight, neonatal body composition, and adverse neonatal outcomes?

Design, setting and study population

This is a population-based cohort study of 823 pregnant women attending the Child Health Clinics (CHC) in Groruddalen, Oslo (Stovner, Grorud, and Bjerke administrative city districts) for antenatal care and their offspring born at Akershus University Hospital and Oslo University Hospital, Ullevål. These districts cover a population of 82,500 with a proportion of non-Western origin inhabitants of 40.9% in Stovner, 37.8% in Grorud, and 33.1% in Bjerke (January 2009). The proportion of newborn in 2008 with ethnic Norwegian background in Stovner was 25%, in Grorud 39%, and in Bjerke 62%. The study is led by The Oslo Diabetes Research Centre, Oslo University Hospital, Aker, in close collaboration with partners from the maternity, paediatric, and pathological unit at the study hospitals, other research institutions, and the administrative districts.

Data collection procedures

Information about the study has been widely distributed in the participating city districts.

General practitioners were asked to remit pregnant women to the CHC early in pregnancy. Information material and questionnaires were translated to eight languages: Arabic, English, Sorani, Somali, Tamile, Turkish, Urdu, and Vietnamese, covering the largest ethnic groups. The translations were quality checked by bilingual health professionals.

The women were given oral and written information when attending the CHC for antenatal care and invited to participate. They were eligible if they were: (1) living in one of the districts, (2) would give birth at the study hospitals, (3) were in gestational week $\leq$20, (4) not suffering from diseases necessitating intensive hospital follow-up during pregnancy, (5) not already included with a pregnancy lasting $\geq$22 weeks, (6) could communicate in Norwegian or any of the other eight languages, and (7) were able to give informed consent. Table I presents a chart of the data collection that started in May 2008 and is estimated to end in February 2011. At the CHC, data from questionnaires, measurements, and fasting blood and urine samples are collected during three visits (V1–3), and a standard oral glucose tolerance test (OGTT) is performed at V2 (and at V3 if GDM was diagnosed). In addition, three ultrasound measurements (U1–3) are performed. Paternal questionnaire data are collected. From the maternity units, routine measurements are available for all offspring.

Table I. Main data collection in relation to gestational weeks/postpartum period.

	Gestational weeks					
	8–20	21–29	30–34	35–42	0–28 days after birth	10–14 weeks postpartum
Mother	V1	V2				V3
Questionnaire data						
Demographic factors, family, medical and obstetric history	8–20	28 ± 2				12 ± 2
Physical activity and related psychosocial factors	8–20	28 ± 2				12 ± 2
Diet		28 ± 2				12 ± 2
Pregnancy complications	8–20	28 ± 2				12 ± 2
Delivery complications						12 ± 2
Measurements						
Blood pressure	8–20	28 ± 2				12 ± 2
Anthropometry	8–20	28 ± 2				12 ± 2
Physical activity, intensity, duration objectively measured[a]	8–20	28 ± 2				12 ± 2
Blood and urine samples						
Fasting EDTA blood, serum/plasma[b]	8–20	28 ± 2				12 ± 2
Oral glucose tolerance test[c]		28 ± 2				12 ± 2
Urine[b]	8–20	28 ± 2				12 ± 2
Electronic medical records						
Pregnancy and delivery complications					Pregnancy + 0–28	
Father						
Questionnaire data						
Demographic factors, family, and medical history		28 ± 2				
Fetus/offspring						
Fetal ultrasound visits	UR	U1	U2	U3		
Fetal weight, cardiovascular, and haemodynamic system	17–19	22–24	30–32	36–38		
Offspring measurements						
Body weight, HC, and length					0	12 ± 2
Anthropometry, skin folds					0–3	
Offspring blood samples						
Umbilical cord venous plasma (EDTA)[c]					0	
Placenta						
Macro- + microscopic examination[c]					0	
Electronic medical records						
Neonatal adverse outcomes					0–28	12 ± 2
Questionnaire data						
Breastfeeding, nutrition, and health						12 ± 2

[a]Sensewear Armband [27].
[b]Bio-banked and stored at −80°C.
[c]Oral glucose tolerance test performed in all women at V2 and at V3 only in women with gestational diabetes mellitus.
HC, head circumference; UR, routine ultrasound at maternity unit; U1–3, ultrasound visits at the child health clinics; V1–3, mothers' visits at the child health clinics.

Maternal and offspring routine data will be obtained from hospital records. Umbilical venous blood and placentas are collected, sampled, and stored, and neonatal anthropometric measurements are performed. The study staff members at CHC and hospitals are certified after extensive education, training courses, and on-site supervision. To ensure accuracy and reliability of anthropometric measures, intra- and inter-rater variability are assessed every sixth month.

Age, parity, and ethnic origin of all women attending the CHC and of study participants based on routinely recorded data at the CHC will be presented in this paper. Ethnic origin is defined by own country of birth, or mother's if she is born outside Europe or North-America, and is categorised as follows: Europe (including North America), Asia (mainly South Asia), Middle East (including North Africa/ Central Asia), Africa (except North Africa, mainly Somalia), and South America (including Central America). The non-Western category includes ethnic origin from Eastern Europe, Asia, Middle East, Africa, and South America.

Questionnaires

The questionnaires cover information regarding socioeconomic factors, several aspects of ethnicity, medical history, actual pregnancy, and modifiable factors such as physical activity and food intake (Table II). Validated or frequently used questions from other Norwegian or international surveys are used when available, some adapted to the actual context. A detailed interview guide was developed as part of the study protocol. The questionnaires were pilot tested for clarity and feasibility.

Physical activity is characterised by type and intensity, frequency, and duration, allowing estimation of pre-pregnancy and last week energy expenditure at visits V1–3, and by the five stages of change in physical activity construct [18]. Psychosocial variables potentially related to physical activity: social support [19], self-efficacy [20], perceived control [21], identity [22], awareness [23], perceived social [24], and physical environment [25] are also collected.

A new food frequency questionnaire was developed to reflect the variation in the diet of ethnic minority groups. It includes 20 questions about frequency of consumption the last two weeks; 13 questions about 65 food items, two questions about use of fat for food preparation and on bread, two questions about meal pattern, two questions about changes in food habits the last 14 days and during pregnancy, and one question about special food habits. The food items included were beverages rich in sugar or fat, fruit and vegetables, beans and lentils, meat (low and high fat), fish (low and high fat), bread and cereals, sweets, and cakes and snacks. Pictures of different food items were used to facilitate categorisation. We also assess intake of dietary supplements (V1–3), lactation and offspring feeding practices at 3 months of age (V3).

Measurements

Blood pressure and pulse are measured three times on the dominant arm sitting after 5 minutes rest with Omron HEM-7000-E M6 Comfort (Omron HealthCare, Kyoto, Japan) electronic devices.

Height is measured to the nearest 0.1 cm using a fixed stadiometer (checked against a standard meter before study start and twice yearly). Body weight and composition are measured by a body fat analyser in light clothing without shoes with Tanita-weight BC 418 MA (Tanita, Tokyo, Japan), a simpler version validated in pregnant women [26]. Skin fold thicknesses (triceps at midpoint between top of humerus and elbow, subscapular and at iliac crest) are measured twice with a calliper (Holtain T/W Skinfold Caliper, UK).

Physical activity is objectively assessed by a SenseWear Armband (BodyMedia Inc, Pittsburg, PA, USA), placed on the triceps at the mid-humerus of the right upper arm at V1–3, and carried for 4–7 days, removed only for bathing/water activity. The device (software version: 6.1) measures total energy expenditure, validated against doubly labeled water [27], steps, and intensity, duration, and frequency of activity and rest [28].

From maternity units measurements of offspring weight, length, and head circumference within 2 hours after birth are available for all. These and additional neonatal measurements; thighs, mid upper arm, and abdominal circumference and skin folds (triceps, subscapular, waist, thighs) with calliper (Holtain T/W Skinfold Caliper, UK), are measured by study staff within 72 hours. Offspring weight, length, and head circumference are also measured at V3.

To indicate growth, fetal weight is estimated by ultrasound (Volusone 730 Pro; GE Healthcare, Kretz, Austria) measuring head and abdominal circumference and femur length at U1–3. Additionally, to investigate the fetal cardiovascular and haemodynamic system, blood flow velocity waveforms are

Table II. Main variables collected from maternal and paternal questionnaires.

	Mother		Father
	Visit	Reference	Reference
Demographic factors			
Date of birth	V1–3	–	V2
Childhood socioeconomic position			
Social class (type of work) of parents	V1	ISCO 88[a]	
Material standards of household/place of residence	V1	MCCS[b,c]	
Adult socioeconomic position			
Marital status	V1–3	MCCS[b]	
Education	V1	MCCS[b]	MCCS[b]
Social class (type of work) and work participation	V1	ISCO 88[a]	ISCO 88[a]
Material standards of household/place of residence	V1	MCCS[b,c]	
Ethnicity			
Country of birth (own and parents), nationality	V1	[c]	[c]
Religion	V1	[c]	[c]
Mother tongue	V1	[c]	
Length of stay in Norway (if not born in Norway)	V1	OIHS[b]	OIHS[b]
Reason for immigration (if not born in Norway)	V1	OIHS[b]	OIHS[b]
Acculturation/experience of discrimination (if not born in Norway)	V1	OIHS[b]	
Medical history			
Family history			
CVD/diabetes mother/father/other first-degree relatives	V2	RIMS[b,c]	RIMS[b,c]
Consanguinity, hereditary diseases	V1	MCCS[b]	
Childhood exposures			
Own birth weight/born prematurely	V1	[c]	[c]
Mother's age at birth of study participant	V1	[c]	
Exposed to smoking during fetal life	V1	MCCS[b]	
Breastfed in infancy	V1	[c]	
Obstetric history			
Parity, year of birth, delivery method, offspring sex, birth weight	V1	MCCS[b,c]	
Weight gain during earlier pregnancies	V1	MCCS[b]	
GDM and other adverse outcomes	V1	MCCS[b,c]	
Duration of lactation	V1	MCCS[b]	
Actual pregnancy (prepregnancy/postpartum when relevant)			
Subjective health (prepregnancy/pregnancy/postpartum)	V1–3	OIHS[b]	
Body weight (age 18, 25, and prepregnancy)	V1	OIHS[b,c]	
Actual body height/weight			MCCS[b,c]
CVD/diabetes	V1–3	MCCS[b,c]	MCCS[b,c]
Other diseases/pregnancy complications	V1–3	MCCS[b,c]	
Pregnancy-related pelvic joint pain (pregnancy/postpartum)	V2–3	PRPJP[d]	
Binge-eating disorders (ever/pregnancy/postpartum)	V2–3	MCCS[b,c]	
Depression (ever/pregnancy/postpartum)	V2–3	EPNDS[e]	
Negative life events last 6 months	V1–3	OIHS[b,c]	
Urinary incontinence	V2–3	ICIQ[c,f]	
Medication (prepregnancy/pregnancy/postpartum)	V1–3	MCCS[b,c]	
Smoking (prepregnancy/pregnancy/postpartum)	V1–3	MCCS[b,c]	MCCS[b,c]
Alcohol (prepregnancy/pregnancy/postpartum)	V1–3	MCCS[b,c]	
Lactation	V3	SPEDKOST[g]	
Physical activity			
Activity level (prepregnancy/actual), psychosocial variables	V1–3	See Methods	
Diet			
Food frequency questionnaire	V2–3	[c]See Methods	
Dietary supplements (prepregnancy/pregnancy/postpartum)	V1–3	MCCS[b,c]	

[a]ISCO 88: International Standard Classification of Occupations (www.ssb.no).
[b]Three surveys performed by The Norwegian Institute of Public Health: www.fhi.no: MCCS: Mother & Child Cohort Study, RIMS: Romsås in Motion Study, OIHS: Oslo Immigrant Health Study.
[c]Developed or modified for The STORK Groruddalen Study.
[d]PRPJP: Pregnancy-Related Pelvic Joint Pain [34].
[e]EPNDS: Edinburgh Postnatal Depression Scale [35].
[f]ICIQ: International Consultation on Incontinence [36].
[g]SPEDKOST: Norwegian Directorate of Health (www.helsedirektoratet.no).

obtained from arteria umbilicalis, arteria cerebri media, and arteriae uterinae.

Blood and urine samples

Venous blood samples are drawn after an overnight fast, transferred to Matrix tubes after proper handling and frozen on site, or sent for routine analyses or further handling before freezing at the Akershus University Hospital and Hormone Laboratory, Oslo University Hospital, Aker. Glucose is analysed on site in venous EDTA blood samples (HemoCue, Angelholm, Sweden), with the three instruments externally validated and calibrated for plasma and with the same batch number for cuvettes and controls (run weekly). Women with fasting glucose $\geq$7.0 mmol/l or 2-hour values $\geq$9 mmol/l are remitted to secondary care for follow-up. Women with 2-hour values 7.8–8.9 mmol/l are given lifestyle advice and remitted to their general practitioner for follow-up. Morning urine after an overnight fast is sampled and transferred to Nunc tubes and frozen on site. Biological materials frozen at the CHC are transported on ice and biobanked at -80°C.

Power calculations and statistics

The primary power calculations were performed to show differences in the prevalence of GDM between the major ethnic groups, anticipated to be approximately 5% in Western women, 20% in South Asian women, and 10% in the other minority groups. Based on 800 study participants and the ethnic origin of women attending the CHC in two of the districts in 2007, this gave about 100 cases of GDM.

In this paper, differences between the study cohort and those not included were tested by chi square tests for ethnic origin, by t-test for the normally distributed continuous variable age, and by Mann–Whitney's test for the non-parametric variable parity with SPSS version 18. A significance level of 0.05 was used and 95% confidence intervals (CI) or interquartile range (IQR) given as appropriate.

Ethics

Participation is based on written consent. The Regional Ethics committee and The Norwegian Data Inspectorate have approved the study protocol. The Norwegian Directorate of Health accepted the storage of biological material.

Results

During the inclusion period from 6 May 2008 to 15 May 2010, 1918 pregnant women (42 women with two pregnancies) attended the CHC for antenatal care, 1114 (58%) were invited to the study and 823 women (74% of the invited) were included (Figure 1). As 37% attended the CHC in the second half of pregnancy, this was the main reason (82%) for not being eligible. Among all CHC women 47% were from Europe, 27% from Asia, 16% from Middle East, 8.1% from Africa, and 1.4% from South America, with nearly identical figures for the study cohort (Table III). Of the invited, 82% of women from Europe, 71% from Asia, 65% from the Middle East, and 64% from Africa agreed to participate. 59% of participants were of non-Western origin. Mean age was 29.8 (95% CI 29.5–30.1) years for the study cohort compared to 30.0 (29.8–30.2) years for all CHC women. Median parity was 1 (IQR 1) in both groups (Table IV). However, ethnic differences in mean age and parity were found among all CHC women and reflected in the study cohort. The proportion of primiparous women among participants was lowest among South Asians (31% compared to 54% in Norwegian women). Ethnicity, age, and parity of those not eligible and those who refused participation are also given (Tables III and IV). For Asians/South Asians a slight selection towards lower parity for the study cohort compared to those not included was found and participants from Africa were slightly younger. Mean gestational age at the first visit to the CHC was 14.4 (14.0–14.8) weeks for the study cohort.

To date, 3.2% of women were lost to follow-up between V1 and V2 (abortion/stillbirths <28 weeks excluded). Of the 593 women giving birth to a living offspring so far, study specific neonatal anthropometric measurements were performed in 77%, placentas were collected from 77% and umbilical venous blood samples from 69%.

Discussion

This research programme with special relevance to public health explores potential health hazards of pregnant women from city districts with low socioeconomic status. The study cohort represents 65 different countries of birth and the majority (59%) are of non-Western origin. Some have a short stay in Norway, some are illiterate, and many are in need of translation services. Such groups are excluded in many research protocols. Participation rates of 64–71% for ethnic groups from Asia, Middle East, and Africa and low drop out rates, indicate that our

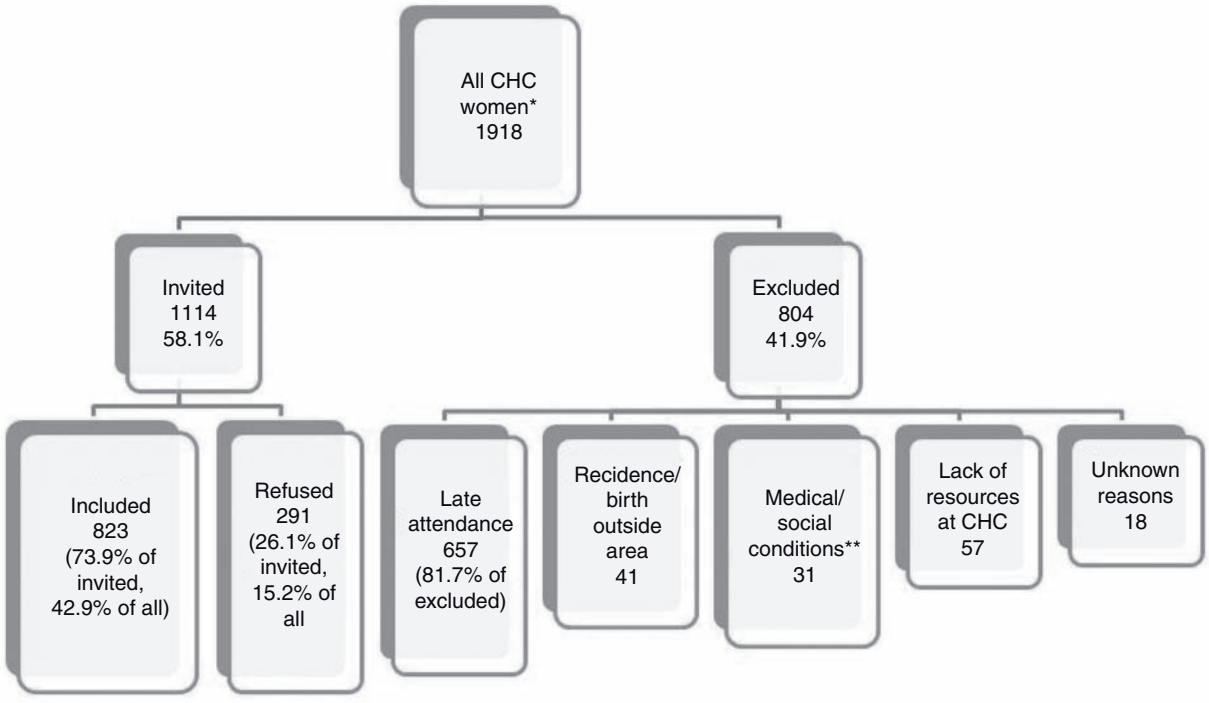

Figure 1. Attendance at the CHC from 6 May 2008 to 15 May 2010, those invited to the study, those who refused participation and those excluded categorised by reasons for not being invited. *represents number of pregnancies, of women attending the CHC in this period, 42 women represented with two pregnancies (1876 unique women). Approximately 50% of those with two pregnancies were included in their second pregnancy. **includes nine women excluded in one pregnancy as they were already included in the study.

Table III. Ethnic origin of all CHC women, those excluded (not invited), those invited but refused participation and study cohort.

Ethnic origin	All (%, *n*)	Excluded (%, *n*)	Refused participation (%, *n*)	Study cohort (%, *n*)[a]	Participation rates (%)	
					Of invited	Of all
All	(1918)	41.9 (804)	15.2 (291)	(823)	73.9	42.9
Europe	46.8 (897)	53.7 (432)	29.6 (86)	46.1 (379), $p=0.48$	81.5	42.2
Norway	39.3 (753)	46.5 (374)	22.7 (66)	38.2 (313), $p=0.36$	82.6	41.4
Asia	27.3 (523)	22.3 (179)	34.4 (100)	29.6 (244), $p=0.063$	70.9	46.7
South Asia	21.3 (408)	16.7 (134)	25.4 (74)	24.3 (200), $p=0.008$	73.0	49.0
Middle East	15.7 (302)	13.6 (109)	23.0 (67)	15.3 (126), $p=0.57$	65.3	41.7
Africa	8.1 (155)	7.2 (58)	12.0 (35)	7.5 (62), $p=0.40$	63.9	40.0
South America	1.4 (27)	1.5 (12)	1.0 (3)	1.5 (12), $p=0.74$	78.6	44.0

All CHC women: from 83 countries, study cohort: from 65 countries.
Ethnicity missing for $n=14$ (0.7%) of all CHC women; 42 women represented with two pregnancies during the study period (1876 unique women in total).
[a]*p*-values for difference in proportion of ethnic origin between study cohort and those not included (excluded + those who refused participation) by Pearson chi-squared test.

efforts to adapt the invitation and the data collection process to the specific needs of these women have worked fairly well.

The multiethnic context

Only 39% of the women who attended the CHC were ethnic Norwegians and 59% of the study cohort had non-Western origin, underlining the multiethnicity of this population. According to the National Clinical Guideline for Antenatal Care, women with a normal pregnancy should be cared for either by a midwife or a general practitioner, or by shared care. A basic programme of eight check-ups, including an ultrasound examination in gestational weeks 17–19, is recommended. Women with known pre-gestational

Table IV. Mean age with 95% CI, and median (mean) parity with IQR (for all CHC women, those excluded (not invited), those invited, but refused participation and study cohort).

	All ($n=1376$)		Excluded ($n=597$)		Refused ($n=217$)		Study cohort ($n=562$)[a]	
Ethnic origin	Age (mean, 95% CI)	Parity (median (mean), IQR)	Age (mean, 95% CI)	Parity (median, (mean), IQR)	Age (mean, 95% CI)	Parity (median, (mean), IQR)	Age (mean, 95% CI)	Parity (median, (mean), IQR)
All	30.0	1 (0.95)	30.2	1 (0.79)	29.9	1 (1.30)	$29.8^{0.14}$	$1^{0.60}$ (0.96)
	29.8–30.2	1	29.9–30.6	1	29.3–30.5	2	29.5–30.1	1
Europe	30.8	0 (0.63)	31.0	0 (0.56)	30.9	1 (0.84)	$30.6^{0.27}$	$0^{0.43}$ (0.64)
	30.5–31.2	1	30.5–31.5	1	29.7–32.0	1	30.2–31.1	1
Norway	31.0	0 (0.61)	31.2	0 (0.55)	30.9	1 (0.81)	$30.8^{0.42}$	$0^{0.30}$ (0.63)
	30.6–31.3	1	30.6–31.7	1	29.6–32.2	1	30.3–31.3	1
Asia	29.3	1 (1.24)	29.0	1 (1.12)	30.5	2 (1.80)	$29.1^{0.25}$	$1^{0.012}$ (1.12)
	28.9–29.7	2	28.3–29.8	2	29.6–31.4	2	28.5–29.7	2
South Asia	29.0	1 (1.34)	28.9	1 (1.26)	30.5	2 (1.98)	$28.6^{0.071}$	$1^{0.002}$ (1.17)
	28.6–29.5	2	28.0–29.7	2	29.4–31.6	2	28.0–29.2	2
Middle East	29.1	1 (1.15)	29.5	1 (1.15)	27.8	1 (0.97)	$29.4^{0.43}$	$1^{0.11}$ (1.25)
	28.5–29.7	2	28.5–30.6	2	26.5–29.1	2	28.4–30.4	2
Africa	29.3	1 (1.44)	30.2	1 (0.86)	29.9	1.5 (1.84)	$28.2^{0.025}$	$1^{0.34}$ (1.63)
	28.5–30.1	2	28.8–31.5	1	28.2–31.6	2	26.9–29.5	3
South America	31.5	1 (1.00)	30.9	0.5 (0.90)	–	–	$32.3^{0.63}$	$1^{0.51}$ (0.51)
	28.9–34.2	2	26.8–34.9	2	–	–	27.2–37.5	2

Parity missing for $n=204$ (11%, ranging from 8–13% in different ethnic groups) of all CHC women, mostly from 2008.
[a]Value in superscript: p-value for difference between study cohort and those not included (excluded + those who refused participation) by t-test (age) and Mann–Whitney-test (parity).

diabetes mellitus should be remitted to endocrinologists or maternity units prior to conception or early in pregnancy for intensive follow-up.

Most groups of ethnic minority women have lower education than women of Norwegian ethnicity [29]. Many among the first-generation immigrants rate their performance in the Norwegian language as poor. Adequate written information in their mother tongue is scarce. Although professional interpreter service is available, language and cultural gaps may not be overcome to secure equity in health service by following the standard antenatal programme [17]. Recently there is a growing recognition nationally of the need of a more structural approach for better adaptation of the health services in Norway to the multicultural context [30].

Representativeness

According to data monitoring the activity at the CHC, the majority (75–85%) of pregnant women in the study districts attend the CHC for antenatal care and nearly all children from birth until 5–6 years of age for preventive health services. The study districts have a large proportion of the non-Western population in Norway, so we suppose that women attending the CHC are representative for healthy women of childbearing age from these groups. The ethnicity of study participants was comparable to that of all CHC women, and the mean age of women in Norway giving birth in 2008 was 29.7 years, comparable to that of study participants.

A participation rate of 74% is substantially higher than in recent health surveys in Oslo (40–49%) [31,32] and in hospital-based studies of pregnant, mainly ethnic Norwegian, women (30–42%) [8,33]. In our study, attendance at the CHC too late in pregnancy was the main reason for not being invited. Several information barriers exist. Many had not heard of the study in time, partly because more women than anticipated used general practitioners outside the districts. Some did not speak any of the languages covered by the questionnaires. Long-term sick-leave among staff and delayed fusion of local CHC in two of the districts made the antenatal services periodically less available and affected the invitation and inclusion.

Reasons to refuse participation was mostly lack of time because of work obligations or care of small children. Participation implies: three visits in the fasting state, one extra visit during pregnancy, one 12 weeks post partum and three extra ultrasound measurements during pregnancy. These logistics also place limits on the number that could be included per week. Inclusion started gradually, first with Norwegians testing the logistics while waiting for the translated material. To facilitate inclusion of Pakistani and Somali women, 6 months after study start they were allowed to be included if gestational week <25.

Strengths

The study is collecting unique prospective information from early pregnancy from a representative and large group of multiethnic women living in Scandinavia to address both important public health problems and mechanisms of disease. Despite several challenges, the inclusion rate is high and the study cohort seems fairly representative. These issues will be analysed in detail when data collection is finished. Furthermore, studies of associations between exposures and outcomes are less prone to bias. For the first time in Norway we will quantify glucose intolerance in a population-based sample of pregnant women. The multiethnic setting in particular may add to the general knowledge of pregnancy physiology and pathology. This is fundamental for understanding developmental origins of health and disease and the short and long-term consequences observed in disease patterns [14]. This necessarily involves prospective collection of data covering a range of factors: societal, cultural, behavioural, psychosocial, physical, and factors reflecting pathophysiological processes. The use of trained midwifes and translators trained and familiar with the questionnaires implies reduced barriers for inclusion of illiterate women and standardisation of data collection to ensure high data quality.

The research programme furthermore aims to develop evidence-based culturally sensitive health promotion strategies for pregnant and postpartum women, focusing on physical activity and a healthy diet, in close collaboration with the CHC staff. Group-based programmes will use the knowledge from the new data and lessons learnt from a successful combined high-risk and population-based intervention in the area [31]. Physical activity is extensively assessed both by questionnaires and objectively by a user-friendly device which also may be used as an educational tool. The new culturally sensitive food frequency questionnaire looks into the "usual" diet which is specially relevant for overweight, GDM, and T2DM. The best compromise was sought between quantity and quality of information and use of time for data collection.

Few other studies of pregnant women collect serial ultrasonic measurements, placenta, and anthropometric and biological data of the offspring, with study specific neonatal measurements covering nearly 80% of the offspring. Some newborns are not measured when remitted to the intensive care units; others leave the hospital within 24 hours after birth. So far dropouts are few which fit well with our impression that included women generally seem to evaluate the study positively. Furthermore, in the future we plan long-term follow-up of both the mothers and offspring in close collaboration with national and international partners.

Limitations

The broad data collection is resource intensive which limits the duration of the inclusion period. Although we have included 823 women, the numbers in several ethnic minority groups are relatively small. Women with known pre-gestational diabetes mellitus and other medical conditions necessitating intensive specialist follow-up are unlikely to attend the CHC. Paternal biological material is not collected. Due to resource limitations we were not able to back-translate the new questions and formally test their cross-cultural validity. Although the data collection is closely monitored, we have not analysed data yet and unknown methodological problems may be discovered later.

Conclusion

The research programme explores potential health hazards of women from districts with low socioeconomic status, the majority of non-Western origin, as there is a great need to know more about societal and individual health determinants in these groups. Participation rates are high and dropouts few.

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Conflict of interest

None declared.

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