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A randomised controlled trial comparing group to individual prenatal care

Submission date	Recruitment status	[X] Prospectively registered
27/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/10/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/10/2007	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
It was hypothesised that group prenatal care would improve maternal mental health (depression and anxiety), psychosocial health (social support, stress, parenting morale, parenting self-efficacy) and infant birth outcomes (low birth weight, small for gestational age and preterm birth rates) compared to individual prenatal care among a community sample of women in Calgary, Alberta.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Conjoint Health Research Ethics Board, University of Calgary and Calgary Health Region on the 7th June 2007 (ref: E-20821).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Maternal mental health

Interventions
Pregnant women are randomised to:
1. Standard individual prenatal care
2. Group prenatal care

Control: Standard Prenatal Care
Women randomly assigned to individual prenatal care will receive a standard schedule of one-on-one prenatal visits with a physician. The timing and frequency of visits will be decided by each womens' physician, although it is anticipated that they will follow the clinical practice guidelines, Healthy Beginnings: Guidelines for Care during Pregnancy and Childbirth provided by the Society for Obstetrics and Gynaecologists of Canada (SOGC). Women with high medical risk pregnancies will be referred for obstetrical care.

Intervention: Group Prenatal Care
Women randomly assigned to group prenatal care will receive an initial individual prenatal visit with a physician to confirm their pregnancy and subsequently will be grouped with 8 - 12 other women who are at a similar stage in pregnancy. Each group will meet with a health care provider for nine group sessions including one-on-one time with the provider for a prenatal check-up, time to conduct self measurements of their weight and blood pressure and a group discussion covering a topic appropriate to their stage of pregnancy. The group discussion will be co-facilitated by the physician and a perinatal educator who will encourage group members to participate in discussing topics of interest related to pregnancy, childbirth, parenting, and personal growth. These group sessions will take place at approximately 16, 20, 24, 28, 32, 34, 36, 38 weeks gestation and 2 weeks postpartum. Women will also receive individual prenatal visits at 37 and 39 weeks gestation. Women with high medical risk pregnancies will be referred for obstetrical care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Maternal mental health: depression and anxiety - measured at study intake (prior to 20 weeks gestation), third trimester (32 - 36 weeks gestation) and 4 months postpartum
2. Maternal psycho-social health:
2.1. Social support and stress - measured at study intake (prior to 20 weeks gestation) and 4 months postpartum
2.2. Parenting morale and parenting self efficacy - measured at 4 months postpartum

Secondary outcome measures
1. Rates of infant birth outcomes (low birth weight, small for gestational age, preterm birth) - measured at birth
2. Rates of breast feeding, uptake of parenting classes/supports, attendance at well child visits, immunisation rates - measured at 4 months postpartum

Overall study start date
01/11/2007

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Pregnant woman living in Northeast Calgary
2. Less than 20 weeks gestation at study intake
3. Able to communicate in English, Punjabi, Mandarin, Hindi, Arabic, Urdu or Spanish

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1200

Key exclusion criteria
1. Pregnant woman living outside Northeast Calgary
2. Greater than 20 weeks gestation at study intake
3. Unable to communicate in English, Punjabi, Mandarin, Hindi, Arabic, Urdu or Spanish

Date of first enrolment
01/11/2007

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Canada

Study participating centre
Alberta Children's Hospital (ACH)
Calgary
Canada
T3B 6A8

Sponsor information

Organisation
Calgary Health Region (Canada) - Three Cheers for the Early Years

Sponsor details
5th Floor
1509 Centre Street South
Calgary
Canada
T2G 2E6

Sponsor type
Research organisation

Website
http://www.calgaryhealthregion.ca/3cheers/home.htm

ROR
https://ror.org/02nt5es71

Funder(s)

Funder type
Research organisation

Funder Name
Calgary Health Region (Canada) - Three Cheers for the Early Years

Funder Name
Alberta Heritage Foundation for Medical Research (Canada)

Alternative Name(s)
AHFMR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration