

A randomised controlled trial comparing group to individual prenatal care

Submission date 27/07/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 03/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2007	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Quality of life

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 women's 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration