# Primary prevention of gestational diabetes among women at risk: a cluster-randomized controlled trial

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
12/09/2007	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/10/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/03/2013	Pregnancy and Childbirth			

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

#### Study objectives

Women at risk (overweight, age 40 years or older, earlier macrosomic child, diabetic first stage relatives) will receive intensified diet and physical activity counselling, which prevents their gestational diabetes.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethical Committee of Pirkanmaa Hospital District. Approved on 24/02/2007. Amendments approved on 11/09/2007 (ref: R02630)

#### Study design

A cluster-randomized controlled trial.

#### Primary study design

Interventional

#### Study type(s)

Prevention

#### Health condition(s) or problem(s) studied

Gestational diabetes

#### **Interventions**

14 counties are participating in the trial. They are randomised to the intervention and control groups (7 counties each).

Intervention group: Intensified, tailored diet and physical activity counselling during five scheduled visits to a public health nurse in maternity health care. Visits take place at 8-9, 16-18, 22-24, 32-34 and 36-37 pregnancy weeks. In addition to physical activity counselling, participants have monthly meetings with peers guided by a physiotherapist.

Participants in the maternity health care in control counties receive usual care only.

(See ISRCTN21512277 for pilot study)

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Prevention of gestational diabetes, assessed by:

- 1. Oral glucose tolerance test during pregnancy weeks 26-28
- 2. Weight of the newborn

#### Key secondary outcome(s))

- 1. Maternal weight development. Maternal weight will be measured 5 times during pregnancy, on pregnancy weeks 8-9, 16-18, 22-24, 32-34 and 36-37, and 6-8 weeks after delivery.
- 2. Child weight development, followed one year after delivery.
- 3. Need of insulin treatment during pregnancy. This will be determined at time of possible GDM diagnosis (earliest 26-28th week of pregnancy based on Oral Glucose Tolerance Test [OGTT]).

#### Completion date

31/12/2008

# Eligibility

#### Key inclusion criteria

Pregnant women in their 8-12th pregnancy week and with at least one of the following criteria:

- 1. Body mass index at least 25 kg/m2
- 2. Age at least 40 years
- 3. History of gestational diabetes or macrosomic child
- 4. Type 1 or 2 diabetes in any of the first stage relatives

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### Key exclusion criteria

- 1. Age < 18 years
- 2. Type 1 or 2 diabetes before pregnancy
- 3. Twin pregnancy or otherwise problematic pregnancy based on physician's opinion
- 4. Physical disability preventing from exercising
- 5. Substance abuse or history of severe mental illness

#### Date of first enrolment

15/09/2007

#### Date of final enrolment

31/12/2008

## Locations

#### Countries of recruitment

Finland

# Study participating centre UKK Institute

Tampere Finland 33501

# Sponsor information

#### Organisation

The Urho Kaleva Kekkonen (UKK) Institute for Health Promotion Research (Finland)

#### **ROR**

https://ror.org/05ydecq02

# Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institutes of Health (USA)

#### Alternative Name(s)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United States of America

#### **Funder Name**

Ministries of Education and Social Affairs and Health (Finland)

#### **Funder Name**

Diabetes Research Fund (Finland)

#### Funder Name

Pirkanmaa Hospital District (EVO) (Finland)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2010		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	05/09/2012		Yes	No
Other publications	cost-effectiveness	01/09/2013		Yes	No