# Physical activity and dietary counseling and supervised group exercise for first-time pregnant women - a feasibility study of a controlled trial

Submission date 23/02/2007	Recruitment status No longer recruiting	Prospectively registered	
Registration date	Overall study status	<ul><li>Protocol</li><li>Statistical analysis plan</li></ul>	
06/03/2007	Completed	[X] Results	
<b>Last Edited</b> 07/11/2012	Condition category Pregnancy and Childbirth	Individual participant data	

#### Plain English summary of protocol

Not provided at time of registration

#### Study website

http://www.ukkinstituutti.fi/upload/jy2xgvvr.doc

## Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

N/A

# Study information

#### Scientific Title

#### Acronym

NELLI (Lifestyle and counseling in maternity and child health care [Neuvonta, Elintavat ja Liikunta neuvolassa, in Finnish])

#### **Study objectives**

The primary aim of this pilot study is to test the feasibility of the trial. The secondary aims are to test whether individual counseling on physical activity and diet and supervised group exercise sessions have an effect on leisure time physical activity, dietary habits, gestational weight gain and postpartum weight retention.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The Ethics Committee of the Pirkanmaa Hospital District, approved on 24 August 2004. Ref: R04047

#### Study design

Non-randomized controlled trial, clinics are allocated to intervention and control clinics (not individuals)

#### Primary study design

Interventional

#### Secondary study design

Non randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

**Not Specified** 

#### Participant information sheet

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

Excessive gestational weight gain and postpartum weight retention

#### Interventions

40 pregnant and 40 postpartum women in the intervention and control clinics participated in the study (total 160 women).

The intervention included individual counselling on diet and physical activity during five routine visits to a public health nurse in primary health care. These visits were at 8-9, 16-18, 22-24, 32-34 and 36-37 weeks' gestation or at 2, 3, 5, 6 and 10 months postpartum. The counseling focused on promoting healthy dietary and physical activity habits. The participants in the intervention clinics had also an option to participate in group exercise sessions once a week (60 min). The participants of the control clinicss received the usual care.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The feasibility of the study protocol, e.g. participation rate, drop-out-rate, success of data collection, realization of the counseling sessions, participation rate in the group exercise sessions, advers events.

#### Secondary outcome measures

- 1. Dietary habits (proportion of women having breakfast and at least one hot meal per day; intake of vegetables, fruit and berries; proportion of high-fiber bread of total weekly amount of bread; intake of high-sugar snacks)
- 2. Leisure time physical activity (days and mins of at least moderate intensity physical activity, total weekly metabolic equivalent minutes [METmins])
- 3. Proportion of pregnant women exceeding the recommendations for gestational weight gain (Institute of Medicine 1990)
- 4. Proportion of women returning to their pre-pregnancy weight by 10 months postpartum Maternal wellbeing
- 5. Levels of selected breast cancer risk markers (hormones, growth factors) in blood and nipple aspirate fluid (only in postpartum women)

Institute of Medicine. Nutrition during pregnancy, weight gain and nutrient supplements. Report of the Subcommittee on Nutritional Status and Weight Gain during Pregnancy, Subcommittee on Dietary Intake and Nutrient Supplements during Pregnancy, Committee on Nutritional Status during Pregnancy and Lactation, Food and Nutrition Board. Washington, DC: National Academy Press, 1990:1-233.

#### Overall study start date

11/08/2004

#### Completion date

30/09/2005

# Eligibility

#### Key inclusion criteria

Pregnant (at 8-9 weeks' gestation) and postpartum (2 months postpartum) women with no earlier deliveries

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Female

#### Target number of participants

80 pregnant and 80 postpartum women, 160 in total

#### Key exclusion criteria

- 1. Age < 18 years
- 2. Type 1 or 2 diabetes mellitus
- 3. Twin pregnancy
- 4. Physical disability that prevents from exercising
- 5. Otherwise problematic pregnancy (based on physician estimation)
- 6. Substance abuse
- 7. Treatment or clinical history for any psychiatric illness and women who are going to change residence within three months

#### Date of first enrolment

11/08/2004

#### Date of final enrolment

30/09/2005

## Locations

#### Countries of recruitment

Finland

# Study participating centre The UKK Institute for Health Promotion Research

Tampere Finland 33501

# Sponsor information

#### Organisation

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

#### Sponsor details

PO Box 30 Tampere Finland 33501 mikael.fogelholm@uta.fi

#### Sponsor type

Research organisation

#### Website

http://www.ukkinstituutti.fi/en/

#### **ROR**

https://ror.org/05ydecq02

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Doctoral Programs in Public Health (DPPH) (Finland)

#### **Funder Name**

National Institutes of Health (USA)

#### Alternative Name(s)

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

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United States of America

#### Funder Name

Ministry of Education (Finland)

#### Alternative Name(s)

Ministry of Education of the Republic of Korea, , MOE

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

Korea, South

#### Funder Name

Ministry of Social Affairs and Health (Finland)

# **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

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2007		Yes	No
Results article	results	11/08/2008		Yes	No
Results article	results	08/10/2010		Yes	No
Results article	results	03/02/2012		Yes	No
Results article	results	08/05/2012		Yes	No