

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

<b>Submission date</b> 23/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/11/2012	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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

**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

**Study type(s)****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 clinics received the usual care.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

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, adverse events.

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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)

**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)**

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

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

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2007		Yes	No
<a href="#">Results article</a>	results	11/08/2008		Yes	No
<a href="#">Results article</a>	results	08/10/2010		Yes	No
<a href="#">Results article</a>	results	03/02/2012		Yes	No
<a href="#">Results article</a>	results	08/05/2012		Yes	No
	Study website				

[Study website](#)

11/11/2025

11/11/2025

No

Yes