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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

Registration date
06/03/2007

Overall study status
Completed

Last Edited
07/11/2012

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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
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33501

Sponsor information

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

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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