ISRCTN61829137 https://doi.org/10.1186/ISRCTN61829137

Physical activity in pregnancy: the Active Pregnancy Profile (APP) trial

Submission date
23/09/2013

Recruitment status
No longer recruiting

Registration date
07/11/2013

Overall study status
Completed

Last Edited
22/12/2015

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to investigate if an individually tailored physical activity (PA) intervention can help women who are pregnant for the first time to achieve optimal levels of PA. PA in pregnancy has been linked to a number of psychological, biological and social benefits for mothers. Despite these benefits, PA in pregnancy is even lower than PA in the general population, with only between 3-15% of pregnant women meeting published PA guidelines. Furthermore, PA is seen to decline throughout the course of pregnancy. There is a lack of evidence regarding interventions based solely on promoting PA throughout pregnancy. Existing interventions often incorporate a range of lifestyle factors which make it difficult to measure determinants of PA in the short and long term. This study investigates whether an individually tailored intervention can help pregnant women become physically active or maintain physical activity throughout pregnancy.

Who can participate?
We aim to recruit 200 women who are pregnant for the first time.

What does the study involve?
Following a routine antenatal appointment, if the midwife deems the woman eligible to participate, they will give them a brief description of the study and ask if they are interested. If so, the researcher will be invited in to explain the research in more detail. If interested, the woman will be given an information sheet and consent form and asked to attend an information session. At this session, more information will be provided and participants who provide consent will be randomly allocated to either the intervention or the control group. Those in the intervention group will receive three individual consultations with the researcher and be invited to attend a weekly walking group. Those in the control group will receive usual care. All participants will be asked to wear an accelerometer (physical activity monitor) for one week in each trimester. They will also be asked to complete a questionnaire once in each trimester and once postpartum.

What are the possible benefits and risks of participating?
It is unknown whether the individually tailored intervention will produce any benefits for patients. There is a possibility that women who attend the meetings with the researcher and

attend the weekly walking meetings will feel better supported to engage in physical activity and engage in greater physical activity than those in the control group. There are no known risks when taking part in this study. All decisions made regarding physical activity will be made jointly between the researcher and participant.

Where is the study run from?
The study will be run in the Ulster Hospital Maternity Unit, South Eastern Health and Social Care Trust, Northern Ireland.

When is the study starting and how long is it expected to run for?
Recruitment started in September 2012 and will finish in July 2013. Participants will be enrolled for the length of their pregnancy. The intervention will continue until the last participant gives birth, around January 2014. Data collection will subsequently be completed by March 2014.

Who is funding the study?
Department of Education and Learning (DEL), Northern Ireland.

Who is the main contact?
Prof. Marlene Sinclair, Professor of Midwifery Research, M.Sinclair1@ulster.ac.uk
Dr Elaine Madden, Head of Midwifery & Gynaecology at South Eastern Health & Social Care Trust, elaine.madden@setrust.hscni.net
Miss Sinead Currie, Currie-S4@email.ulster.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
What effects does an individually tailored intervention have on the physical activity of primigravida pregnant women?

Acronym
APP

Study objectives
It is hypothesised that physical activity participation will be higher in the intervention group than control/usual care group. Women who receive the tailored physical activity intervention will self-report more positive psychological outcomes than controls.

The null hypothesis is that there will be no difference in physical activity or psychological outcomes between groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 14/05/2012, ref: 12/NI/0036

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information can be found at: http://www.doctoralmidwiferysociety.org/Portals/c8d3e3f8-9c01-4bf5-abd9-3fd6b4c510ae/Participant%20Information%20Sheet%20version%209%2019%20June%20no%20footer.docx

Health condition(s) or problem(s) studied
Physical activity in pregnancy

Interventions

1. The intervention group will receive three face-to-face individual consultations with the researcher, one per trimester. After they reach 20 weeks gestation, they will be invited to attend a weekly walking group held in the hospital.
2. The control group will receive usual care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical activity measured using an accelerometer and a self-report 7-day physical activity diary

Secondary outcome measures
1. Psychological wellbeing
2. Social support
3. Quality of life
4. Gestational weight gain
5. Mode of delivery
6. Gestational age

All of these were measured using a questionnaire.

Overall study start date
15/09/2012

Completion date
11/03/2014

Eligibility

Key inclusion criteria
1. Primigravida (pregnant with first child)
2. Viability scan confirming ongoing pregnancy between 8 and 18 weeks gestation
3. Singleton pregnancy
4. Speak and understand English
5. 18 years or over
6. Volunteers who are able to give full written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Women with medical or obstetric complications or risks such as hypertension requiring medication, heart conditions, history of more than two miscarriages, metabolic disorders, existing diabetes (decided by midwife)
2. Any existing conditions which may contraindicate regular PA (physical activity)
3. Multiple pregnancies: twins, triplets or any other multiple gestation
4. Under 18 years of age
5. Gestation over 18 weeks at recruitment

Date of first enrolment
15/09/2012

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
University of Ulster
Newtownabbey
United Kingdom
BT37 0QB

Sponsor information

Organisation
South Eastern Health and Social Care Trust (UK)

Sponsor details
c/o Mr Paul Carlin
Ulster Hospital
Upper Newtownards Road
Dundonald
Northern Ireland

United Kingdom
BT16 1RH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05w2bg876

Funder(s)

Funder type
Government

Funder Name
Department of Employment and Learning (DEL) (UK)

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	18/12/2015		Yes	No