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Snacktivity™ intervention to promote physical activity during pregnancy

Submission date
25/04/2023

Recruitment status
No longer recruiting

Registration date
31/05/2023

Overall study status
Completed

Last Edited
21/07/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many studies show that pregnant women do not achieve 150 minutes of moderate-intensity physical activity per week, which is the recommended guideline. To date, there is a large amount of research describing the benefits and barriers of physical activity during pregnancy, but very few studies have looked at how to best support pregnant women and their ability to reach and maintain their physical activity levels. Through participation in physical activity during pregnancy, women have decreased risk of complications such as high blood pressure, excessive protein in their urine, too much weight gain and gestational diabetes, as well as reduced anxiety and feelings of depression. To try and help women reduce their chances of pregnancy-related complications, we plan to conduct the SUNNY study which aims to test the feasibility and acceptability of an approach we have called Snacktivity™ during pregnancy. Snacktivity™ is based on the idea that small, frequent doses of physical activity throughout the day, called 'physical activity snacks', can help people accumulate at least 150 minutes of moderate-intensity physical activity per week.

Who can participate?
90 eligible pregnant women in the UK

What does the study involve?
Participants will be randomly allocated to receive either the Snacktivity™ intervention programme or a standard antenatal care programme. Participation in this study will take place from when women are around 10-16 weeks pregnant until they are 36 weeks pregnant. In addition to receiving standard antenatal care, participants in the Snacktivity™ intervention group will receive access to a mobile phone application called the SnackApp and a physical activity tracker (Fitbit watch), which will measure their physical activity snacks throughout the week.

What are the possible benefits and risks of participating?
It is hoped that the Snacktivity™ intervention will encourage pregnant women to be more physically active, which may help reduce pregnancy-related complications. The researchers do not expect any risks from taking part in this study.

Where is the study run from?
Loughborough University (UK)

When is the study starting and how long is it expected to run for?
June 2022 to June 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) via a Research Professorship to Professor Amanda Daley and Loughborough University (UK)

Who is the main contact?
Kayleigh Sharp, k.j.sharp@lboro.ac.uk (UK)

Contact information

Type(s)
Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319236

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55513, IRAS 319236

Study information

Scientific Title
A randomised controlled trial to investigate the feasibility and acceptability of Snacktivity™ in pregnant women

Acronym
SUNNY

Study objectives
The aim of the SUNNY study is to undertake a randomised feasibility trial, with nested qualitative interviews, to assess the feasibility and acceptability of the Snacktivity™ intervention during pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/07/2023, South Central - Hampshire B REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; 020 7104 8289 hampshireb.rec@hra.nhs.uk), ref: 23/SC/0159

Study design
Randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Reproductive health and childbirth

Interventions
Participants will be randomised to receive either standard physical activity advice during pregnancy or encouragement to achieve the recommended physical activity levels for pregnancy via Snacktivity™. For the intervention group, Snacktivity™ will be promoted with a physical activity tracker (Fitbit watch) and access to the SnackApp. Both resources will help participants monitor their physical activity, activity snacks, and steps each day. The researchers will measure physical activity at the start of the study and at 36 weeks gestation for both the intervention and control group; however, steps, light-to-vigorous physical activity, moderate-to-vigorous physical activity, and activity snacks will be monitored for the intervention group throughout the 24-week intervention period.

Snacktivity™ is based on the idea that small, frequent doses of physical activity throughout the day, called 'physical activity snacks', can help people accumulate at least 150 minutes of moderate-intensity physical activity per week. These physical activity snacks should last between 2-5 minutes and can include activities such as rushing for a bus, getting off the bus a stop earlier and walking to the destination, walking over to a colleague instead of sending an email when at work, taking the stairs instead of the lift, and calf raises whilst brushing their teeth. The Snacktivity™ approach also aims to reduce the time people spend sitting as a result of moving more frequently throughout the day, which can also have important benefits for health, particularly during pregnancy.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of a subsequent phase III randomised controlled trial (RCT) according to pre-specified progression criteria will be assessed at the final follow-up. The researchers are primarily interested in whether:
1. The trial is appealing measured using the number/percentage of people randomised against the recruitment target of 90 participants
2. The Snacktivity™ intervention is acceptable through assessing Snacktivity™ adherence measured using a physical activity tracker (Fitbit watch) and SnackApp data
3. Participant attrition measured using loss to follow-up in [the study notes]

The feasibility and acceptability will also be assessed with participant interviews (intervention group only) and healthcare practitioner interviews on the indicators after the final follow-up:
1. Intervention delivery
2. Participant satisfaction, enjoyment, and intervention acceptability
3. Intervention sustainability

Secondary outcome measures
1. Total physical activity (light-to-vigorous activity and steps per day) measured using a research-grade wrist-worn accelerometer at baseline and 36 weeks gestation
2. Moderate-to-vigorous physical activity measured using a research-grade wrist-worn accelerometer at baseline and 36 weeks gestation
3. Sedentary time measured using a research-grade wrist-worn accelerometer at baseline and 36 weeks gestation
4. Gestational weight gain measured at baseline and 36 weeks gestation
5. Depression measured using the Edinburgh Postnatal Depression Scale at baseline, 26- and 36 weeks gestation
6. Fatigue measured using the Multidimensional Assessment of Fatigue at baseline, 26- and 36 weeks gestation

Overall study start date
06/06/2022

Completion date
25/06/2024

Eligibility

Key inclusion criteria
1. Pregnant women > = 18 years between 10 and 16+0 weeks gestation
2. Singleton pregnancy confirmed at early foetal scan
3. Able to speak and read standard English
4. Able to provide informed written consent
5. Access to an email address
6. Access to a smartphone with Bluetooth capable of hosting mobile applications (Apple iOS 10.0 + and Android OS 4.0+)
7. Complete < = 150 minutes of physical activity per week pre-pregnancy (as measured by the Exercise vital signs (EVS))

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. Post-natal or non-pregnant women
2. Pregnant women past 16 weeks gestation

3. Severe sickness (hyperemesis gravidarum)
4. Currently taking part in a different research study that involves physical activity or other lifestyle behaviours
5. BMI >50 kg/m2
6. Inability or unwillingness to provide consent
7. Women whose GPs feel it is inappropriate for them to take part
8. Cannot speak and read standard English
9. No access to an email address
10. No access to a smartphone with Bluetooth capability for hosting mobile applications (Apple iOS 10.0+ and Android OS 4.0+)
11. Complete > 150 minutes of physical activity per week pre-pregnancy (as measured by the EVS)

Date of first enrolment
21/07/2023

Date of final enrolment
21/01/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

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Sponsor type

Hospital/treatment centre

Website
http://www.lboro.ac.uk/

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The anonymised data/results collected will be used in Kayleigh Sharp's Doctoral Thesis. The anonymised data/results collected may also be published in a high-impact peer-reviewed journal, conference papers, and the media promoting the results of the study.

Intention to publish date
25/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Loughborough University repository (https://repository.lboro.ac.uk/).

IPD sharing plan summary

Stored in non-publicly available repository