ISRCTN03259732 https://doi.org/10.1186/ISRCTN03259732

Start At The Beginning: a nutrition and lifestyle digital intervention for women planning a pregnancy

Submission date
31/07/2014

Recruitment status
No longer recruiting

Registration date
31/07/2014

Overall study status
Completed

Last Edited
25/06/2020

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
The period before conception is increasingly regarded as important for the health of future generations. Many of the major threats to reproductive health are the same as those affecting public health more generally, including obesity, smoking, alcohol, diabetes and high blood pressure. In this study we aim to test how well an online education tool works in improving nutritional and lifestyle behaviours in women planning a pregnancy, through motivational coaching.

Who can participate?
Women who are planning a pregnancy within the next 12 months will be recruited through Health Visiting teams at their childs developmental review. These take place at 8-12 months and at 2.5 years after childbirth where we expect 1 in 5 women to be planning another pregnancy. We aim to recruit 300 women over 6 months.

What does the study involve?
Women who consent to enter the trial will be invited to complete a baseline questionnaire on a portable electronic device. On completing the baseline questionnaire, participants will be randomly put into either the intervention or the control group of the trial. Participants will have access to the online education tool (app) to input their dietary and lifestyle behaviours. Their answers will generate a risk score and a personal profile for each person. They will be reminded to input their information on the application every 6 weeks (intervention group) or every 12 weeks (control group) for 6 months. At each time point a risk score is generated so that we can see any changes over time. Coaching tips and messages are sent directly to each woman through email and SMS. Those in the intervention group will receive three recipes per week, whereas those in the control group will only receive one recipe a week to help motivate them. They will also receive a paper leaflet with information on planning a pregnancy that has been designed by the Family Planning Association. We will compare the changes in risk score between the two groups. After the 6-month follow up survey, a subgroup of consenting women will take part in an interview to discuss their thoughts and opinions on the app and the study as a whole.

What are the possible benefits and risks of participating?
All women will be given vouchers in appreciation of their participation worth £20 on completion of the final 6-month questionnaire. We do not anticipate the participants to experience any side effects from participation in this study.

Where is the study run from?
This study will take place at two NHS Trust sites, Homerton University Foundation Trust and Bart s Health NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The trial is funded for 15 months from January 2014 to March 2015.

Who is funding the study?
The study is funded from Health Education England (UK).

Who is the main contact?
The principal investigator for this trial is Professor Judith Stephenson and the main contact is Dilisha Patel (dilisha.patel@ucl.ac.uk).

Study website
http://www.prepregnancy.org.uk/

Contact information

Type(s)
Scientific

Contact name
Miss Dilisha Patel

Contact details
Institute for Women's Health
University College London
74 Huntley Street
London
United Kingdom
WC1E 6AU
-
dilisha.patel@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16827

Study information

Scientific Title
Efficacy of a nutrition and lifestyle digital intervention for women planning a pregnancy: a pilot randomised controlled trial in primary care

Acronym
SATB

Study objectives
The trial hypothesis is that women receiving the web-based intervention, in addition to an information leaflet, will achieve a greater improvement in their preconception risk score than women receiving a lighter version of the app, with less frequent follow-up and the leaflet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North West- Liverpool Central, 09/05/2014, ref: 14/NW/0316

Study design
Randomised; Interventional and Observational; Design type: Prevention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
Participants will be randomized into either the intervention or the control group. All participants will have access to the online education tool (app) to input their dietary and lifestyle behaviours. They will be reminded to input their information on the application every 6 weeks (intervention group) or every 12 weeks (control group) for 6 months. Coaching tips and messages are sent directly to each woman through email and SMS. Those in the intervention group will receive three recipes per week, whereas those in the control group will only receive one recipe a week

to help motivate them. They will also receive a paper leaflet with information on 'planning a pregnancy' that has been designed by the Family Planning Association. After the 6-month follow-up survey, a subgroup of consenting women will take part in a single qualitative interview to discuss their thoughts and opinions on the app and trial as a whole.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
A composite risk score is calculated at 6 months post randomisation from self-reported data on smoking, consumption of fruit, vegetables and supplementation with folic acid in both groups

Secondary outcome measures
1. Recruitment rate: the proportion of women planning a pregnancy at recruitment visits; the proportion eligible for the trial; proportion entering (randomised into) the trial
2. The number and rate (per participant) of queries and requests for help in using the web-based intervention
3. Follow-up rates by group at 3 and 6 months after randomisation
4. Participant experience of using both interventions will be assessed through qualitative interviews
5. Pregnancy: all women who become pregnant during the pilot trial will be asked to complete a short 6-item validated questionnaire, the London Measure of Unplanned Pregnancy (LMUP.com)

Overall study start date
01/09/2014

Completion date
30/03/2015

Eligibility

Key inclusion criteria
1. Women aged between 18 and 45 who are planning a pregnancy within the following 12 months
2. Willingness to be randomised to either the control or intervention group
3. Ability to access the internet, via a desktop PC, laptop, smartphone, tablet, or any other device whereby the participant can access SmarterPregnancy
4. Enough understanding of English to be able to follow the online application and the leaflet
5. Willingness to participate in the trial, which includes following the protocol for 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
Specific dietary requirements that may conflicts with the online application advice, i.e. strict vegetarians and vegans

Date of first enrolment
01/09/2014

Date of final enrolment
30/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Women's Health
London
United Kingdom
WC1E 6AU

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Education England (UK); Grant Codes: 2003201401

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2015 report in https://s31836.pcdn.co/wp-content/uploads/FULL-Outline-Satb-Report.docx.30.9.2015.pdf (added 25/06/2020)

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?
HRA research summary			28/06/2023	No	No