

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

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| <b>Submission date</b><br>31/07/2014   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>31/07/2014 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>25/06/2020       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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 child's 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).

## Contact information

### Type(s)

Scientific

### Contact name

Miss Dilisha Patel

### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Primary study design**

Interventional

## **Study design**

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

## **Study type(s)**

Prevention

## **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(s)**

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

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

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)

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Key exclusion criteria**

Specific dietary requirements that may conflict 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**

United Kingdom

England

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

## Sponsor information

**Organisation**  
University College London (UK)

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Government

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

## Results and Publications

### 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? |
|--------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |               |              | 28/06/2023 | No             | No              |
| <a href="#">Study website</a>        | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |