

# Assessing the effectiveness of a personalised lifestyle coaching phone application in changing behaviours of women planning a pregnancy

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<b>Registration date</b> 22/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/02/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The impact of lifestyle, and in particular obesity and smoking on fertility has been well described, and advice regarding optimizing lifestyle behaviours around the time of conception is imperative in managing couples presenting with reproductive failures. Moreover, funded access to IVF treatment is in many areas dependent on meeting criteria relating to smoking and BMI. While there is a widespread recognition of the impact of a healthy lifestyle on fertility outcomes, there is lack of data demonstrating the efficacy of interventions designed to improve healthy lifestyle behaviours for women planning to conceive. Recently, a novel smartphone accessed lifestyle coaching application system has been developed, which may offer an effective, low burden and low cost alternative to passive information provided by NHS resources. The aim of this study is test the efficacy of this intervention in women suffering from infertility or recurrent miscarriages, attending the outpatients department.

### Who can participate?

Women aged 18 to 45 who are suffering from fertility problems or have had recurring miscarriages.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive lifestyle coaching delivered via their smartphone. The program is automatically generated based on 5 identified risk factors and pregnancy state. Coaching includes sending facts, advice and recipes by SMS or email. Participants are screened on a 6- weekly basis to tailor their coaching program to the identified risk factors and their pregnancy state. The results of their risk profile are shown on their personal home page. Those in the second group are given access to the standard lifestyle advice provided by NHS websites and publications through their smartphone. Lifestyle behaviours of the women are assessed using lifestyle questionnaire sent to them to complete at baseline, 12 and 24 weeks. The results are analysed to determine whether a smartphone lifestyle coaching application is more effective in improving lifestyle behaviours in women planning a pregnancy compared to standard advice

What are the possible benefits and risks of participating?

Woman participating in the study may benefit from a free lifestyle coaching smartphone application to use if they are randomised to the intervention arm. Due to the nature of the study, there are no direct risks for those taking part in the study. Patients will be informed of a telephone number for the research team should they wish to report any adverse events from the study. Patients reporting an adverse event from the study will be invited for follow up in the outpatient clinic one week after the reporting of the incident.

Where is the study run from?

1. Princess Anne Hospital (UK)
2. Salisbury District Hospital (UK)

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

October 2015 to August 2019

Who is funding the study?

NIHR Southampton Respiratory Biomedical Research Unit (UK)

Who is the main contact?

Dr Ka Ying Bonnie Ng (Public)

bonnie.ng@doctors.org.uk

#### **Study website**

<https://www.smarterpregnancy.co.uk/research/>

## **Contact information**

#### **Type(s)**

Public

#### **Contact name**

Dr Ka Ying Bonnie Ng

#### **ORCID ID**

<http://orcid.org/0000-0002-2770-6148>

#### **Contact details**

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## **Additional identifiers**

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

34220

## **Study information**

### **Scientific Title**

iLAN: Impact of a Personalised Lifestyle coaching phone Application in modifying periconceptional behaviours: a randomised controlled trial

### **Acronym**

iPLAN

### **Study objectives**

The hypothesis being tested in this study is that a smartphone based online lifestyle coaching application will be a more effective means of improving periconceptional lifestyle behaviours compared to conventional measures of periconceptional counselling through standard information provided by NHS websites and patient information leaflets.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Yorkshire and The Humber Research Ethics Committee (NRES), 23/05/2016, ref: 16/YH/0129

### **Study design**

Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Internet/virtual

### **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**

Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and Sexual Medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Other obstetric conditions, not elsewhere classified

## **Interventions**

This study is a two-centre randomised control trial of using an online smartphone application in providing lifestyle coaching and modifying lifestyle parameters in women suffering from infertility or recurrent miscarriages. Women from both intervention and control group will be asked to visit the 'Smarter Pregnancy' website ([www.smarterpregnancy.org.uk](http://www.smarterpregnancy.org.uk)) and will be asked to register and activate their account by a unique validation code. Women will be asked to complete a baseline lifestyle questionnaire which assesses parameters including smoking habits, alcohol consumption, diet, exercise and weight, and then will be randomised by the 'Smarter Pregnancy' computer programme to either intervention arm or control arm. Both intervention and control group login to 'Smarter Pregnancy' using their personalised credentials created at registration.

In the intervention arm, women will have access to a personalised smartphone lifestyle coaching program. Through baseline and follow up lifestyle questionnaires (at 6, 12, 18 and 24 weeks) sent out via email, tailored lifestyle advice is generated; emails with tips, facts and recipes are sent to the intervention arm participants to encourage them to change unhealthy habits and maintain healthy habits. Those randomised to the control arm will have access to standard periconceptional advice, including information from NHS websites.

## **Intervention Type**

Other

## **Primary outcome measure**

Composite dietary and lifestyle risk score is measured using a validated online lifestyle questionnaire sent to participants via the smarter pregnancy platform at 12 weeks after randomisation.

## **Secondary outcome measures**

1. Percentage of patients remaining compliant with system is measured using case report forms at 12, 18 and 24 weeks after randomisation
2. Proportion achieving spontaneous conception during study period. Participants can update their pregnancy status via the online Smarter Pregnancy platform
3. Composite dietary and lifestyle risk score is measured using a validated online lifestyle questionnaire sent to participants via the smarter pregnancy platform at 24 weeks

## **Overall study start date**

01/10/2015

## **Completion date**

31/08/2019

# **Eligibility**

## **Key inclusion criteria**

1. Age > 18 years and less than 45 years
2. Women suffering from subfertility or recurrent miscarriages attending the outpatient

department

3. Fluent in the use and understanding of English

4. In possession of a smartphone capable of running the application

5. Actively trying to conceive

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

Planned Sample Size: 440; UK Sample Size: 440

**Key exclusion criteria**

1. On a specific diet for medical reasons (including those on gluten free diet, specific carbohydrate diet or a healthy kidney diet)

2. Insulin dependent diabetes

3. Women who are undergoing any other means of lifestyle coaching, i.e. personal trainer or group lifestyle coaching (e.g. Slimming World)

4. Women undergoing oocyte donation treatment

**Date of first enrolment**

01/06/2016

**Date of final enrolment**

31/08/2018

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Princess Anne Hospital**

Coxford Road

Southampton

United Kingdom

SO16 5YA

**Study participating centre**  
**Salisbury District Hospital**  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

## **Sponsor information**

### **Organisation**

University Hospitals Southampton NHS Foundation Trust

### **Sponsor details**

R&D Department  
University Hospitals NHS Trust  
SGH - Level E, Laboratory & Pathology Block,  
SCBR - MP 138  
Southampton  
England  
United Kingdom  
SO16 6YD

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/0485axj58>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NIHR Southampton Respiratory Biomedical Research Unit

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in high impact peer reviewed journal.

## Intention to publish date

31/05/2021

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V3	17/03/2016	22/02/2018	No	Yes
<a href="#">Protocol article</a>	protocol	04/12/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No