

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

Submission date 12/02/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/02/2021	Condition category 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)

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Study website

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

Contact information

Type(s)

Public

Contact name

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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) 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?
Participant information sheet	version V3	17/03/2016	22/02/2018	No	Yes
Protocol article	protocol	04/12/2018		Yes	No
HRA research summary			28/06/2023	No	No