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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

Registration date
22/02/2018

Overall study status
Completed

Last Edited
16/02/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
34220

Study information

Scientific Title
iLAN: Impact of a Personalised Lifestyle coaching phone ApplicatioN in modifying peri-conceptional 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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

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

ROR
https://ror.org/0485axj58

Funder(s)

Funder type

Government

Funder Name
NIHR Southampton Respiratory Biomedical Research Unit

Results and Publications

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?
Protocol article	protocol	04/12/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	17/03/2016	22/02/2018	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes