

## **iPLAN- Impact of a Personalised Lifestyle coaching phone Application in modifying peri-conceptual behaviours: a randomised control trial**

### **Introduction**

Women trying to conceive are advised to optimise their lifestyle to improve fertility and the health of their baby. You are being invited to take part in a study comparing different methods of delivering lifestyle advice in women who may be planning a pregnancy. We would like to trial the use of a personalised lifestyle smartphone coaching application, and compare it to the standard lifestyle advice delivered through an information leaflet and online resources. We seek to understand whether one method of delivering advice is more effective in increasing healthy behaviours and lifestyle choices.

Before you decide whether you wish to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with anyone you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **What is the purpose of the study?**

We seek to understand whether a smartphone lifestyle coaching application is a more effective method of delivering pre-conceptual lifestyle advice compared with the standard lifestyle advice delivered through an information leaflet and online resources. This will help us identify the best methods of delivering advice aimed at optimising a women's diet and lifestyle.

### **Why might I be approached?**

As you are attending the fertility and miscarriage clinic, with a wish to conceive, we hope you will be interested in participating in this study.

### **Am I eligible to take part?**

You are eligible to take part if:

- You are female and aged >18 and <45 years
- You are suffering from subfertility or recurrent miscarriages
- You are fluent in the use and understanding of English
- You are in possession of a smartphone capable of running a web based online platform
- You are actively trying to conceive

### **Do I have to take part?**

You decide whether or not to take part. If you do take part you are still free to withdraw at any time and without giving a reason. This will not affect the treatment or standard of care you receive. You will be required to sign a consent form if you wish to take part.

### **What will happen to me if I decide to take part?**

On the day of your outpatient appointment, a member of the clinical care team will approach you about the study. If you are interested in participating, one of our research nurses will speak to you about the study and if you are willing to participate, you will be allocated by a lottery system ('randomised') to one of two groups. You will be given a registration code and you can register online for the application 'Smarter Pregnancy' at [www.smarterpregnancy.co.uk](http://www.smarterpregnancy.co.uk). You will be randomised to either a web based online lifestyle coaching application accessed via your smartphone or standard information leaflets and online resources

All women will be asked to complete a baseline lifestyle questionnaire, which involves reporting of parameters including smoking habits, alcohol consumption, nutrition and diet, exercise and weight. The questionnaires will also be sent out at 6, 12, 18 and 24 weeks after the randomisation into the study. You may also receive a phone call at these times by a member of our research team, to see how you are getting on and for you to have a chance to ask any questions about the advice given or the study.

### **What are the possible disadvantages and risks in taking part?**

There are not thought to be any disadvantages to taking part in the study. There are no anticipated adverse effects from the mobile phone lifestyle coaching application or the standard information leaflets and online resources that we intend to use. The advice that we give will be in line with current national guidelines.

### **What are the possible benefits of taking part?**

You may receive a personalised lifestyle coaching application free of charge if you are randomised to that arm. There are no other advantages from taking part in this study.

### **Will my taking part in this study be kept confidential?**

All information collected about you will be kept strictly confidential. With your consent, your GP and obstetric team will be informed of your participation.

### **What will happen to the results of the research?**

The findings will be presented at scientific meetings, nationally and internationally, published in medical journals, and possibly in the local and national press. You will not be identified in these reports or publications in any way.

### **What if there is a problem?**

If you have a concern about any aspect of this study, please ask to speak to Dr Bonnie Ng, who will do her best to answer any questions you have ([bonnie.ng@soton.ac.uk](mailto:bonnie.ng@soton.ac.uk)).

You can also speak to Susan Wellstead, Research Nurse, who will also be involved in the study ([Susan.Wellstead@uhs.nhs.uk](mailto:Susan.Wellstead@uhs.nhs.uk)).

### **What if I want to complain?**

If you wish to complain formally, you can do this through the NHS Complaints Procedure (via Southampton General Hospital).

### **Who has reviewed the study?**

This study has been reviewed and approved by South Central - Berkshire Ethics Committee (Ethics No.: to be confirmed). It has also been peer reviewed by Dr Nisreen Alwan, Associate Professor in Public Health, University of Southampton.

### **Who is organising and funding the research?**

This study is primarily funded by the NIHR Southampton BRC Nutrition. The Smarter Pregnancy website and app is hosted by an external server through Erasmus University, however they are playing no part in funding the research. The study is being led by Professor Nick Macklon from the University of Southampton.

### **Contact for further information.**

For further information please contact Dr Bonnie Ng at the University of Southampton, email:  
bonnie.ng@soton.ac.uk