UNIVERSITY OF BIRMINGHAM

PIMMS-WL Trial

Nurses Information Sheet

Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care: randomised controlled cluster feasibility trial with nested qualitative study.

Version 5.0 1st February 2018

Invitation and brief summary

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether you wish to take part.

What is the study about?

Pregnancy and the postnatal period are vulnerable life stages for gaining excess weight. Many women have reported that pregnancy is an important factor that has led to weight problems later on in life. It is therefore important to find ways to help new mothers lose weight gained during pregnancy and return to their pre-pregnancy weight. Currently women do not receive

any advice or support about weight management after giving birth. We are investigating two different approaches to helping women to manage their weight after giving birth.

What is the aim of the study?

The study aims to evaluate the feasibility and acceptability of a brief routine weight management intervention embedded within the national child immunisation programme on helping postnatal mothers to manage their weight. We are interested in the views of women who take part and also the views of practice nurses who delivered the intervention.

What will I have to do?

If you decide to take part, you will be asked to sign a consent form and you will be given a study identification number. You will be interviewed by a member of the **PIMMS-WL** research team to determine your thoughts and feelings about delivering the intervention for this study. We expect that this will last no more than 30 minutes. Your interview will be audio recorded. The audio recording and transcription will be securely transferred and stored at the University of Birmingham Clinical Trials Unit. The recording will be transcribed by an external company after which it will be destroyed. We may use quotes from your interview in study reports but you will not be identified on any of the study reports.

Do I have to take part?

It is up to you to decide if you want to take part. If you are interested in taking part, you will be given this information sheet to keep and you will be contacted with details of the time and place of the interview. You will have opportunity to ask further questions and you will be asked to sign a consent form, if you are happy to participate. If you decide to withdraw from the study, at any time, you may do so, without giving a reason.

Who is organising and funding the study?

The study is being coordinated by the **PIMMS-WL** trial office at the University of Birmingham Clinical Trials Unit and is sponsored by the University of Birmingham. The research is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme. The research has been approved and reviewed by all these organisations.

Will my taking part in the study be kept confidential?

If you decide to take part in **PIMMS-WL**, all information collected about you during the course of the trial will be kept strictly confidential; it will be securely transferred and stored at the University of Birmingham Clinical Trials Unit (BCTU) in accordance with your consent and the provisions of the Data Protection Act. At the end of the study, once we have sent you and the study participants a copy of the results, data collected that identifies you by name, including a copy of your signed consent form, will be anonymised (with your personal details removed) and securely archived at the University of Birmingham or in an approved secure facility for a minimum of 25 years after which it will be destroyed. If you withdraw your consent for your data to be used, it will be confidentially destroyed.

With your permission, data collected during the study may be inspected by authorised individuals from the University of Birmingham Clinical Trials Unit (BCTU). They may also be looked at by the NHS Trust, the trial Sponsor or the regulatory authorities to check that the study is being carried out correctly.

What happens if I have a complaint about the study?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting XXXXX at the NHS Birmingham Cross City Clinical Commissioning Group. Contact details are:

XXXXXX
NHS Birmingham Cross City Clinical Commissioning Group
Bartholomew House, 142 Hagley Road, Birmingham, B16 9PA
Tel: XXXXXXXX

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by Black Country Research Ethics Committee. The study reference number is 17/WM/0399. Permission from the relevant R&D departments has also been gained.

What will happen to the results of the research study?

Once PIMMS-WL has finished we will publish the results in a medical journal. We will also publicise the results on the study's website. No individual will be identified in any publications. A copy of the published results of the study will be sent to all patients and nurses who have participated in PIMMS-WL upon request.

Do you have any further questions?

Contact Information

If you would like to speak to someone about the study please contact:

<<Insert Name>>, PIMMS-WL Research Fellow

<<Telephone and/or E-mail>>