PIMMS-Weight Loss Study
(Post Natal Weight Loss Study)

Participant Information Sheet

Version 5.0 1st February 2018

Invitation and brief summary

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please feel free to talk to others about the study if you wish. This Participant Information Sheet (PIS) tells you the purpose of the study, what will happen to you if you take part and details information about the conduct of the study. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

What is the purpose of the study?

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. This can significantly increase the risk of obesity and other serious chronic illnesses including type 2 diabetes, heart disease and cancer. It is therefore important to find ways to help new mothers lose weight gained during pregnancy. Currently women do not receive any advice or support about weight management after giving birth. We are investigating two different approaches to giving women information and support on managing their weight after giving birth. This study is investigating which of these approaches women prefer and we will then use this information to develop a bigger study to determine which method is most effective in helping women lose weight over the longer term.

Why have I been chosen?

You have received this leaflet because you have recently given birth and are over 18 years old. You will only be asked if you want to take part in the study if your body mass index (BMI) is 25kg/m² or more. We will check these points with you when we come to visit you in your baseline home visit, to make sure you are able to participate.

What would taking part involve?

This study has been designed so that you don't have any additional visits to your nurse, GP or hospital. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. You will be visited at home once at the start of the study and once at end of the study 3-months after you entered by a female member of our research team when we will measure your height and weight, give you some healthy life-style information and ask you to complete some questionnaires about your health and how you have been feeling. We will post the questionnaire to you before your baseline home visit so you can complete it prior to the visit in your own time. It will take about 10 minutes to complete the questionnaires. When booking the first home visit, we will ask for your consent to store your name and contact details. All data you provide will be stored securely at the University of Birmingham Clinical Trials Unit (BCTU).

Your involvement in the study will last about 3 months, and will take place in your home and when you visit your GP practice to have your child immunised.

Your GP practice (and therefore you) will be randomly allocated (like tossing a coin) to one of two groups. All women will be given written information, but some will also receive brief support from their nurse at their baby's immunisation appointments at 2, 3 and 4 months. Whichever group you are allocated to, both you and your baby will receive all of the care you would normally receive from your practice and health visitor. Your GP will be informed that you are taking part in this study.

Your practice nurse, with your permission, may also ask you if we could voice record this part of your baby's immunisation appointment. You may also be asked to take part in an interview about your experiences of taking part in this study. This will take about 30 minutes, by telephone or at your home, at the end of the study.

What are the possible benefits of taking part?

There may be no benefit in taking part in this study, however we hope that it may help you lose weight. The main benefit will be that the information gained from this study will help inform the design of a future larger study which may help us to provide better support for

women to lose weight after having a baby in the future. We will give you a £20 High Street voucher to thank you for participating in the study.

What are the possible disadvantages and risks of taking part?

We do not expect any risks or disadvantages from taking part in this study. If you have any concerns during your participation in the study, please contact the PIMMS-WL team.

Who is organising and funding the research?

The **PIMMS-WL** study was developed by the University of Birmingham in partnership with the Universities of Oxford and Southampton. The study is coordinated by the **PIMMS-WL** trial office at University of Birmingham Clinical Trials Unit (BCTU) and is sponsored by the University of Birmingham. The research is being funded by the Department of Health.

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 a favourable opinion by Black Country Research Ethics Committee. The study reference number is 17/WM/0399.

Will my taking part in this study be kept confidential?

If you decide to take part in this study, all information collected about you and your new born baby for the study will be securely transferred and stored at the University of Birmingham Clinical Trials Unit (BCTU). Information that can identify you, including your name, address and telephone number, will be collected to arrange follow-up visits with you, to send you a follow-up questionnaire and to inform you of the results of the research at the end of the study. All information collected will be kept strictly confidential in the same way as all of your other medical records. It will be securely handled and stored in accordance with your consent and the provisions of the Data Protection Act. At the end of the study, once we have sent you a copy of the study results, all the information collected 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 consent, your data up to the date of withdrawal may be used, unless you specify differently.

If you are in the group that receives the brief support, some of your data will be collected at the University of Southampton. This data will be securely transferred and stored at the University of Birmingham. If you take part in the interview part of the study, the 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 the audio recording will be destroyed. It will be analysed for the purposes of this research only.
With your permission, and where relevant to your involvement in the study, your medical records may be looked at by authorised individuals from the University of Birmingham Clinical Trials Unit (BCTU), the NHS Trust, the trial Sponsor (University of Birmingham) or the regulatory authorities who may wish 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 normal National Health Service complaints mechanisms, this is usually the Patient Advisory and Liaison Service (PALS).

NHS PALS Service at Birmingham Women's Hospital - Tel: XXXXXXXXX

What if I do not want to take part?
It is up to you to decide if you want to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason and this will not affect the standard of care you or your baby receives from your healthcare team.

What will happen to the results of the research study?
Once the study has finished we may publish the findings in a medical journal. No individual patients will be identified in any publications. A copy of the study findings will be sent to all women who have participated in the study within 12 months after the end of the trial, we will retain your personal details until this is carried out.

Do you have any further questions?
The UK Clinical Research Collaboration has produced a guide entitled, 'Understanding Clinical Trials'. This leaflet can be downloaded from their website: www.ukcrn.org.uk and could be useful if you are interested in learning more general information about clinical research.

Contact Information

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

XXXXXXXX, Senior Trial Coordinator

PIMMS-WL Trial Office,

Birmingham Clinical Trials Unit (BCTU),

University of Birmingham,

Edgbaston, Birmingham, B15 2TT

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Email: xxxxxxxxx

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