

PIMMS-WL

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

*Nurses Training
Manual*

Introduction

This manual has been devised to help you understand more about the PIMMS-WL study and it provides details about what we would like you to do. You have received this booklet because your practice has been randomised to deliver the intervention for this study.



Summary of the PIMMS-WL Study

Why is this study needed and what is it about?

After the birth of their baby, many women find it hard to lose the weight they have gained during pregnancy. At 1 year after giving birth 25% of women retain more than 4kg of their 'baby' weight. This excess weight increases the risk of developing diseases in later life. Many women would welcome support to lose weight at this time. Most studies involving overweight/obese mothers during the postnatal period have tested intensive weight loss interventions; these types of intensive interventions cannot be offered by the NHS to all of the 530,000 overweight/obese women who give birth in the UK every year. It would be too expensive to do this and many women find it hard to find the time to attend additional visits to health care professionals at a time when they are focused on their baby. Instead, low cost interventions that are incorporated within existing health programmes or contacts can be offered to all women after having a baby.

We plan to embed a simple brief intervention alongside the national child immunisation programme. The first step is to test how acceptable our approach is to mothers and how practical it is for nurses to deliver the intervention during child immunisation appointments. The booklet will explain in more detail how we would like to do this.

What does the study involve?

About 10 practices (clusters) have been randomised to either deliver the intervention or offer no intervention (usual care). Your practice has been randomised to deliver the intervention for this study so **all** mothers taking part at your practice will receive brief additional advice and support to lose weight and be weighed by you at the baby's immunisation visit. We plan to recruit 80 postnatal mothers in total, so there will be about 8-10 at your practice.

Intervention summary

The main goal of the intervention is to encourage women to self-manage their own weight by weighing themselves weekly and recording this on a card in their baby's red book (see example at end of this manual). Women will be advised to aim for between 0.5 to 1kg weight loss a week in line with NICE guidance for adult weight management. To provide accountability ("big brother effect") women will be told that they will be weighed by the nurse at each child immunisation appointment to assess their progress. An individual who is regularly weighed (either by themselves or someone else) is more likely to stay focussed on changes in their weight and this is also likely to act as a source of motivation to adhere to their weight loss goals. We want women to reflect on their weight loss, what they have been eating and their physical activity levels each week.

We **do not** want nurses to provide any lifestyle counselling; your role is simply to provide regular external accountability for weight loss and to signpost women to using the POWeR for PIMMS-WL online weight loss programme for weight loss support. This is an interactive online programme that will encourage women to weigh themselves weekly and record this. It will also send automated email messages encouraging women to continue with their weight loss efforts. The programme includes a food diary, physical activity diaries and a weight tracker tool. Based on our previous work with community midwives we expect the intervention will take you about 1-2 minutes per immunisation appointment.

Intervention components

Women will be:

- Provided with a set of electronic scales and asked to weigh themselves each week and to record their weight on the yellow weight record card attached to their baby's red book and/or on the POWeR website.
- Weighed by the practice nurse at each child immunisation visit and given brief encouragement to stick to their weight loss goals.

- Signposted to use the POWeR online weight management programme for support and advice about weight loss.
- Given a healthy lifestyle advice leaflet.

NOTE: A PIMMS-WL sticker will be placed on the front of the red baby book so you know which mothers are taking part in the study.

What is the study looking at?

This study is investigating how practical and feasible it is for nurses to deliver a brief weight management intervention to mothers during baby's immunisation appointments. We also want to investigate how mothers feel about receiving this support at their baby immunisation visits. All the women have consented to take part in this study.

How long will the study take?

In total the study will run for about 12 months. We expect each practice will deliver the intervention to between 8-10 women over about six months so the time commitment is very small. If there are eight women taking part from your practice, then we expect this intervention will take about one hour of your time in total (2 mins for the intervention x 8 women x 3 immunisation appointments = 48 minutes).

How are mothers recruited in to the study?

Although you will not be involved in the recruitment process, it may be useful to know how the mothers have been recruited. Every two weeks Birmingham Women's Hospital will send a study invitation letter to women who have given birth in the previous 4 weeks at your practice. Birmingham Women's Hospital will do this for about six months, or until we are able to recruit 80 women in total. Women who are interested in taking part will be visited at home by the research team who will explain the study in more detail, take written informed consent, weigh women and ask them to complete some questionnaires about their health. At this visit women will also be told whether they will receive the intervention or usual care. The research team will also write to your practice and inform you which mothers have agreed to take part.

Who is eligible to take part?

Inclusion Criteria

- Aged 18 years or more
- Given birth at least four weeks previously and have not yet attended the first child immunisation appointment
- Planning to have their child immunised within the national immunisation appointment.
- BMI 25kg/m² or more (calculated by the research team at the time of recruitment)
- Patient able and willing to provide written informed consent

Exclusion Criteria

- Mothers whose babies have died or have been removed from their care at birth
- Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
- Unwilling to give consent to notify their GP
- Women who have been diagnosed with a serious mental health difficulty requiring hospitalisation in the past two years or been diagnosed with anorexia and/or bulimia in the past two years

How much weight are women supposed to try and lose?

In line with current NICE guidance women will be advised to aim for 0.5-1 kg weight loss per week until they are back to their pre-pregnancy weight or BMI.

What happens before the first immunisation visit?

Before the mother brings her baby to their first immunisation appointment, the PIMMS-WL research team at the University of Birmingham will ensure that the following take place with each mother:

- Screened for eligibility
- Asked to provide written informed consent
- Weighed and asked to complete a questionnaire
- Notified of group/practice allocation

MOTHERS IN INTERVENTION GROUP ONLY

- PIMMS-WL sticker placed on front of baby's red record book
- Weight record card attached to red book in front of immunisation record pages
- Given a PIMMS-WL POWeR start up card and instructions with the website address and encouraged to access the website
- Given a set of electronic weighing scales
- Asked to start weekly weighing and recording this on their weight record card and/or the POWeR website.

What happens at the baby immunisation appointments?

The intervention should be delivered at the first three immunisation appointments (when the baby is 2, 3 and 4 months old). When handed the baby's immunisation record book, **please check** for the PIMMS-WL sticker on the front of the book. We think it is best to deliver the intervention before you do the immunisation but it is up to you and the mother to decide this together. We will provide the practice with a set of electronic scales for you to use in the PIMMS-WL study (they will have a PIMMS-WL sticker on them).

i. Introducing the study to the mother

- If there is a PIMMS-WL sticker on the front of the red book, the mother will be expecting you to weigh her and record this in the red book.

"I see you're taking part in the PIMMS-WL study? In that case, I'll need to weigh you today".

ii. Weighing and recording the mother's weight



- Turn towards the immunisations section of the red book, there will be a bright yellow weight record card.
- Enter the date of the immunisation appointment in the immunisation table attached to the red book (see end of manual for an example).
- It is up to you and the mother to decide whether you weigh her before or after immunising her baby. Check the relevant box on the record card to indicate when this was done.
- Ask the mother to remove her shoes as well as any items of bulky clothing.
- Using the PIMMS-WL scales provided to the practice, take the mother's weight in kilograms.

- Record this weight on the weight record card in the red book.
- Strongly encourage mothers to weigh themselves and record this on their weight record cards at least once per week (women have been given home weighing scales that we would like them to use for this study).
- If the mother attends the appointment, but does not want to be weighed, please circle “declined” on the weight record card.
- If someone other than the mother (for example, a grandparent) attends the immunisation appointment please circle “did not attend” on the weight record card.

iii. Signposting mothers to the POWeR online weight loss programme website

- Gauge the mother’s reaction to the weight you have just recorded and use this as an opportunity to steer the conversation towards the POWeR website.
- At the first immunisation appointment (2months) give a brief summary of what the POWeR for PIMMS-WL website offers and how it could be helpful for them.
- At all the immunisation appointments remind mother to use the POWeR for PIMMS-WL website <https://powerpimms.lifeguidehealth.org> and record that you have done this on the record card at the back of the red book.

“Have a look at the POWeR website - it has lots of really helpful stuff on how to lose weight and lead a healthy lifestyle.”

- Reinforce the effort she has made by offering some positive feedback regarding the steps she has taken towards managing her weight, even if there is no weight loss.
- If there has been no weight loss emphasise the important role of regular self-weighing and use of the online website.

Why don’t you try to use the POWeR website more regularly?

Don’t worry your weight can fluctuate on a daily basis, but if you weigh yourself regularly, you’ll be more in tune with your body and how your weight changes day to day.

POWeR has great food and activity diaries that you can print out or complete online. They have links to supportive websites and information as well.

Many women find that weighing themselves regularly really helps.

POWeR has links to some great ideas for healthy meals and recipes.

Weighing yourself regularly will help you keep an eye on your progress towards your weight loss goals

Weigh yourself at the same time of day as your weight naturally changes throughout the day

The best way to track your progress is to weigh yourself regularly

POWeR can help you set your own goals and achieve them.

iv. Self-weighing

- Have a look at their weekly weighing records on the weight record card – have they already started weighing themselves weekly and recording this?
- If the mother has been recording her weight weekly, circle the Yes box on the record card. If she has not, circle No.
- Encourage/reinforce weekly self-weighing and recording of weight on the record card.
- Explain that weekly self-weighing and reflecting on weight loss will help towards achieving weight loss goals.

CHECKLIST

By the end of **EACH** immunisation appointment please ensure that you have completed the following:

- **Weighed and recorded mother's weight on weight record card**
- **Checked that she has been weighing herself on a weekly basis**
- **Asked if she has accessed the POWeR website**
- **Signposted mother to POWeR website**
- **Completed immunisation appointment section on weight record card**

What happens after the last immunisation appointment?

All women will be visited at home again and will be weighed by the study team. We will also ask women to complete some questionnaires about their health. Some women will also be asked for their feedback about their involvement in the study. At the end of the study we will ask nurses for feedback on this study.

What to do if you need help?

If the PIMMS-WL scales stop working please contact the PIMMS-WL research team who will come and replace them. If the mothers ask you for detailed lifestyle advice, or initiate a discussion, simply direct them to the PWeR for PIMMS-WL website for more information. If you need any further help with this study, please contact the research team (details below).

PIMMS-WL Research team contact information

If at any time something happens and you are unsure of what to do, please get in touch with a member of the research team who will gladly help. Their contact information is as follows

Mrs Alex Vince, Senior Trial Coordinator

PIMMS-WL Trial Office,

Birmingham Clinical Trials Unit (BCTU),

University of Birmingham,

Edgbaston, Birmingham, B15 2TT

Tel: 0121 415 9123

Email: PIMMS-WL@trials.bham.ac.uk

Website: www.birmingham.ac.uk/pimmswl



PIMMS-WL Trial Weight Record Card

PIMMS-WL

Trial No:

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2 Month Immunisation Appointment (please circle responses)

Date	Weighed before or after immunisation			Weight (kg)	Reminded about POWeR		Weekly self-weighing																
	Before	After	Declined		Yes	No	Yes	No															
<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y	Did not attend			<table border="1"> <tr> <td></td><td></td><td></td><td>.</td><td></td><td>kg</td> </tr> </table>				.		kg	Yes	No	Yes	No
D	D	M	M	M	Y	Y	Y	Y															
			.		kg																		

3 Month Immunisation Appointment (please circle responses)

Date	Weighed before or after immunisation			Weight (kg)	Reminded about POWeR		Weekly self-weighing																
	Before	After	Declined		Yes	No	Yes	No															
<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y	Did not attend			<table border="1"> <tr> <td></td><td></td><td></td><td>.</td><td></td><td>kg</td> </tr> </table>				.		kg	Yes	No	Yes	No
D	D	M	M	M	Y	Y	Y	Y															
			.		kg																		

4 Month Immunisation Appointment (please circle responses)

Date	Weighed before or after immunisation			Weight (kg)	Reminded about POWeR		Weekly self-weighing																
	Before	After	Declined		Yes	No	Yes	No															
<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y	Did not attend			<table border="1"> <tr> <td></td><td></td><td></td><td>.</td><td></td><td>kg</td> </tr> </table>				.		kg	Yes	No	Yes	No
D	D	M	M	M	Y	Y	Y	Y															
			.		kg																		

Weighing Record Card

Week	Weight (kg)	I feel..... (see faces below & enter relevant number)
Week 1		
Week 2		
Week 3		
Week 4		
Week 5		
Week 6		
Week 7		
Week 8		

Week	Weight (kg)	I feel (see faces below & enter relevant number)
Week 9		
Week 10		
Week 11		
Week 12		
Week 13		
Week 14		
Week 15		
Week 16		

				
1. Delighted	2. Happy	3. Alright	4. Disappointed	5. Upset