



EMPOWER Interview sub study information leaflet
for pregnant women suffering from nausea and vomiting
(EMesis in Pregnancy, Ondansetron With metoclopramide)

We would like to invite you to take part in this research study

This interview study is an extra piece of research that we are doing alongside the main trial research, to help us to understand women's experiences of deciding to take part or not.

Joining this extra bit of research is entirely up to you, so before you decide we want you to understand why the research is happening and what it would involve for you. One of the research team and possibly a consultant obstetrician will already have discussed the EMPOWER trial with you, and you have decided to take part in the main trial. After this decision, one of the research team will have discussed taking part in an interview study in a few weeks' time. They will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take no more than 5-10 minutes, but you are welcome to talk to others about the study if you wish.

The aim of the EMPOWER trial is to find out which is the best treatment between 2 drugs, metoclopramide and ondansetron in pregnant women suffering from severe nausea, (feeling sick) and vomiting, (actually being sick) and Hyperemesis Gravidarum (NVP and HG). This interview sub-study is investigating why some women choose to take part in EMPOWER whilst others do not.

The standard of medical care you receive from your doctor and midwives will be the same whether you choose to take part in the study or not

Why have I been invited?

You are being invited to take part because you were eligible to take part in the EMPOWER trial.

Do I have to take part?

No. You can decide whether to take part in this extra interview study. We will describe the study in this leaflet and provide any further information you need. If you agree to take part we will then ask you to consent to an interview. This can be done by phone or by email. You can withdraw at any time, without giving a reason. If you do not wish to take part your care will not be affected in any way.

What will happen to me if I take part?

If you agree to take part you will be contacted by Dr Mabel Lie in about two weeks from now. Dr Lie will arrange a date and time to telephone you and carry out the interview. The interview would focus on your opinions about taking part in the main EMPOWER trial.

To ensure information is collected accurately, Dr Lie will ask your permission to record the interview. The length of the interview varies but most last between 10 and 15 minutes.



Dr Mabel Lie
Interview Researcher
What will happen to me if I take

part? If you feel that a telephone interview would be difficult for you, we can offer an email interview instead. You can discuss this further with Dr Lie if you would like to know more.

What are the possible disadvantages and benefits of taking part?

You will need to give up some of your time for the interview. There are no direct benefits for you, but the answers you provide will contribute valuable information to the results of this study. They will help to plan future research into women's experiences of healthcare in pregnancy.

Will my taking part in the study be kept confidential?

Yes. The interview will be recorded onto a digital audio recorder. This will be transferred to a password protected computer at Newcastle University. A research secretary will type up a transcript (a word for word account of what was said). The recording will only be accessible to the researcher who did the interview, one other social researcher, and the research secretary. We keep the written transcript for analysis, and delete the audio file.

The social researchers will anonymise the interview transcript (remove any names that were used during the interview) so that other researchers on the team do not know which women are taking part in the interviews and given their opinions.

Rules about research mean that we will need to keep a copy of the transcript for 15 years. It will be kept in a secure location and will only be accessible by the research team. We may share anonymous data with others who are involved in similar research to support the planning of future studies. We will also keep a copy of the consent form that you signed if you agree to take part.

What will happen if I don't want to carry on with the interview research study?

You can change your mind about taking part at any time up until we publish the results. You don't have to give a reason. Any information already collected from you can be destroyed if you wish. This will not affect the care you receive in any way.

Expenses and Payments

The interview study should not create any expense for you. If it does, we will reimburse you..

What will happen to the results of the interview research study?

The results will be published in academic or health services journals so that other researchers and clinicians can learn from the information we collect. You would not be identified in any results we present or publish. The results from the main EMPOWER trial will help to plan future research and healthcare for women suffering from nausea and vomiting in pregnancy. The results from this interview study will also help to plan future research and healthcare for women suffering from nausea and vomiting in pregnancy.

If you would like to have further information about the results of the study sent to you then the research team can arrange for this to happen.

Who is organising and funding this study?

The study is the responsibility of Newcastle upon Tyne NHS Foundation Trust. It is being run by the Clinical Trial Unit (CTU) at Newcastle University. It is funded by the National Institute of Health Research (NIHR) Health Technology Assessment Program (HTA) (ref: 16/15/03). None of the researchers receive payments for taking part in the study.

Who has reviewed the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been approved by the Newcastle and North Tyneside 1 committee. This means they are satisfied that your rights will be respected; that any risks have been reduced to a

minimum and balanced against possible benefits; that you have been given sufficient information on which to make an informed decision to take part or not; and that they believe the study is fair.

How have patients and the public been involved in this study?

Women who have previously suffered from severe nausea and vomiting in pregnancy have helped in the design of this study. They gave us feedback about this information leaflet.

What if there is a problem?

If at any stage you have any concerns about this interview study you could talk to the doctor or midwife who is leading the study in your hospital, or the lead social scientist on the project team, Dr Ruth Graham. If you prefer, you can talk to the Patient Advice and Liaison Service (PALS) in your hospital (their contact details are on the back page of this leaflet).

If you remain unhappy and wish to complain formally, you may use the normal NHS complaints procedure. Details of this procedure can be obtained from the following website:

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx>

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Local contacts

Principal Investigator:

Dr

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Tel:

Local Research Midwife:

Name

Address

Tel

Patient Advice and liaison services (PALS):

LOCAL address, tel no and email

EMPOWER Study Team

Email address:



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Patient Interview Study – reply sheet

If you would be happy for a member of the EMPOWER research team to contact you about the interview study, please complete this page and give it to a member of the research team.

I am willing to be contacted to discuss the interview study

☐ Yes

☐ No

If yes, please write your name and preferred contact details along with the best time to contact you:

Name: _____

Contact details:

Phone: _____

Email: _____

Date participation in EMPOWER study discussed: _____

Best days and times to contact you:
