Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

STUDY INFORMATION FOR WOMEN (INTERVENTION SITE)

The REDUCE Study

Study Information for women

INTRODUCTORY EMAIL/LETTER TO WOMEN (INTERVENTION GROUP)

Dear Madam

Women and healthcare professionals across the world are worried about rising caesarean section rates, which now vary from 15% to 38% across European countries. It is possible that individual clinician's approaches to clinical decision-making, and women's and partners' views, may influence the variation in CS rates.

This study aims to develop and test an intervention that is designed to reduce overall CS rates safely, in two hospital sites, and to see if it is possible to then do a larger study. Your hospital has been randomly chosen to conduct the intervention, and you have received this letter because you are pregnant and attending the hospital.

We are now asking women if they would like to join in the education part of the study. Taking part will involve attending 2 or 3 education sessions, designed to help prepare you for birth, and completing a survey while you are pregnant and again at three and six months after birth.

Your participation in this study is very valuable and we very much hope that you will choose to participate. All participants will be acknowledged in the final study report and will be forwarded with a copy of the final report.

If you would like to be part of this process please read the enclosed information leaflet and then reply to this email/letter with your name and contact details.

With best wishes,

(Name of researcher will be inserted here)

On behalf of the REDUCE project team

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The REDUCE Trial

Study Information for Women

We would like to tell you about an important research study that we are doing in this, and one other, hospital in Ireland. This study may help to improve birth outcomes, by reducing caesarean section rates safely, and increasing rates of vaginal birth after previous caesarean (VBAC). The study is known as the REDUCE study. Women who are healthy and have no compelling medical reason to have a caesarean section will be able to join the study.

Please read this information to see if you can, and would like to, join the REDUCE study.

Introduction

You are being invited to take part in a research study. However, before you decide whether or not to take part, it is important that you fully understand what the research is about and what you will be asked to do. It is important that you read the following information in order to make an informed decision and if you have any questions about any aspects of the study that are not clear to you, do not hesitate to ask me. Please make sure that you are satisfied before you decide to take part or not. Thank you for your time and consideration of this invitation.

What is the REDUCE study?

The REDUCE study is testing a new way of providing information to women to support them in making decisions around their birth. This type of study is known as a randomised trial and, for this study we are just testing the education materials and ways of doing the study to see will they work and are they possible to use. If everything appears satisfactory then we will be able to run the full study over a large number of hospitals.

Two hospitals have agreed to take part and will be allocated by chance to have either the intervention (the new way of providing information to women), or to be the control where information is unchanged. Your hospital has agreed to join the study and has been randomised to be the intervention hospital, which means that your hospital will test the new information package. The educational materials developed during this study will continue to be made available once the research has finished.

What does taking part involve?

If you agree to take part in this pilot study, it means you will be:

- Giving consent to the research team to access information from your, and your baby's, hospital notes such as: type of birth, medicines used during labour, any complicating factors such as pain, infection or bleeding, for example.
- Completing two surveys during your pregnancy (these take about 15 minutes each) and at 3 and 6 months after your baby is born (these take about 30 minutes each). These surveys are designed to help us assess your (and your baby's) health and wellbeing.
- Keeping a diary of any healthcare expenses (e.g., such as any payments for treatment, medicines or visits to your doctor) you incur during your pregnancy and during the first 3 months after your baby is born (we will provide the diary)
- Attending two or three specifically designed two-hour antenatal classes (if you wish) when you are between 24-31 weeks (class 1) and 31-35 weeks (class 2) of pregnancy. Accessing online information and support (if you wish, and have access to the internet).
- Giving consent that a researcher may be present at the education classes during the study to observe the way the classes are given, in order to check that the intervention is being implemented correctly.

Why is this hospital taking part in the study?

At the moment we know that caesarean section rates, and vaginal birth after a previous caesarean section (VBAC) rates, vary widely across health care settings and countries. We understand that reducing caesarean section rates and increasing VBAC is not only better for women, their babies and their families but it is also more cost effective for the health service. This hospital is taking part in testing this new information package in order to establish if offering it to women and their partners can improve care for women in Ireland.

Can I take part?

If you can answer YES to each of the following questions you can take part:

- Are you 18 years of age or older?

- Are you expecting to have a vaginal birth?; that is, you do not have any medical reason that means you would have to have a caesarean section

Do I have to take part in this study?

No, taking part is voluntary and it will not affect your care if you choose not to participate. However, even if you do not want to take part in the full study (i.e., attend classes, and/or complete the surveys and diaries) we should be really grateful if you would agree to allow the research team to access information from your, and your baby's, hospital notes. This is important to allow us to find out if the intervention has had an effect on the overall caesarean section rates at the hospital level, and not just in the groups of women who attend the classes.

Are there risks or benefits to taking part?

There are no known risks to taking part in this study. As your hospital has been allocated to test the new education programme, it is possible that you may find the information beneficial. However, the main benefit to taking part is that you will have helped us to answer whether this information package is effective or not in reducing caesarean section rates and improving VBAC rates.

Can I leave the study after I have joined?

Yes, you can leave the study any time you wish. If you decide to leave the study please tell the midwife on duty or contact the research team (the details are at the end of this booklet). If you leave the study, the relevant data about you will be removed from the database. This process cannot be reversed.

Is my personal information kept private?

All study information is kept private and secured in keeping with the law. Your information will be stored using a code so that any personal information will not be linked to your name. All study information will be kept for five years, and all

traces of your identity will be destroyed once the study is finished. Data that cannot be traced back to your identity will be stored for comparison with future studies. However, if the findings of REDUCE show that further research is required we would like permission to contact you for continued participation. If you agree, then your data will continue to be stored for the duration of the new study. The results of the study will be published. However, neither your name nor any personal details about you will appear in any publications. Your confidentiality will be maintained at all times.

Who is leading this study?

Professor Cecily Begley, Professor of Midwifery from Trinity College Dublin is leading this project. Other researchers involved are:

Xxx, Master of the xxx Hospital INSERT RELEVANT HOSPITAL NAME HERE

Professor Declan Devane, Professor of Midwifery in NUI Galway

Professor Valerie Smith, Assistant Professor in Midwifery in Trinity College Dublin

Professor Michael Turner, Professor of Obstetrics and Gynaecology, UCD and National Lead for the Health Services Executive Clinical Programme in Obstetrics and Gynaecology

Dr John Newell, Senior Lecturer in Biostatistics, NUIGalway.

Professor Eugene Dempsey, Professor of Neonatology, University College Hospital, Cork

Who is funding this study?

The Health Research Board is funding the study.

Has this study received ethical approval?

The study has received ethical approval from the INSERT RELEVANT HOSPITAL COMMITTEE NAME HERE and from the Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin. This study is covered by

standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

What do I do now if I wish to be in the study?

To join the study we ask you please to:

1. Sign the consent form, which you will find in the study pack, indicating that you agree to take part, and that you understand what taking part involves.
2. Complete the "REDUCE Trial Antenatal Health and Wellbeing Survey" which is also in the study pack.
3. Please then return the consent form and the survey to the research centre in the stamped addressed envelope, which you will also find in the study pack.
4. Once your consent form is returned to the research centre, you will receive an email giving you a password that will enable you to use the online information and support section of the REDUCE Website.
5. Also, once your consent form is returned, a midwife from the hospital will send you a diary for recording any healthcare expenses that occur for you during your pregnancy as well as information about the special antenatal information and education classes you can attend. You will also be sent a second survey later in your pregnancy.
6. After your baby is born we will ask you to complete a postnatal Health and Wellbeing Survey at 3 and 6 months, and a diary for recording any postnatal healthcare expenses.
7. We will send you two text reminders for the surveys at 3 and 6 months postnatal, and these will be in two different formats. If you agree to be part of the REDUCE study, you will be randomly assigned to one of these formats, so that we can see which one works best.

Where can I get more information or ask questions about the study?

The REDUCE midwife, INSERT NAME, will be happy to provide you with more information. You can contact INSERT NAME by emailing INSERT EMAIL or by telephoning INSERT TELEPHONE NUMBER. You will receive your access password for the online information and support section of the REDUCE Website once your consent form is returned.

THANK YOU FOR YOUR TIME AND FOR CONSIDERING TAKING PART IN THIS IMPORTANT RESEARCH STUDY