Participant Information Sheet

Views of women at high-risk of ovarian cancer towards removal of fallopian tubes for ovarian cancer prevention

Before you decide to take part in this survey, it is important for you to understand the purpose of this and what it will involve. Please take time to read the following information carefully. Do discuss it with your family, friends, healthcare professional or others if you wish. Please ask if there is anything you do not understand or if you would like more information.

Aim of this survey

This survey is meant for women who are at high-risk of developing ovarian cancer. Some women may carry a fault/alteration in their BRCA1 or BRCA2 gene, whilst others may have a strong family history that puts them at an increased risk of developing ovarian cancer. It aims to understand what they feel about having only their fallopian tubes removed, to prevent ovarian cancer.

If you wish to take part in this survey after reading this information, please complete the short eligibility questionnaire followed by consent form-1. You may then proceed to the online survey.

Background Information

Some women may have an alteration or fault in their DNA sequence or genetic code. Two such genes in which a fault may lie are known as the BRCA1 and BRCA2 genes. Pronounced '"brakka-1'" and '"brakka-2"'. Women with a strong family history of ovarian cancer or breast & ovarian cancer may also have a higher risk of developing ovarian cancer.

The currently advised practice is to offer removal of <u>both</u> tubes **and** ovaries to prevent ovarian cancer in such high-risk women. This is undertaken after a woman has completed her family. It is called **R**isk **R**educing **S**alpingo **O**ophorectomy or **RRSO**.

It involves undergoing an operation to remove the 'tubes **and** ovaries' (Figure 1a). This is usually done through keyhole surgery under a general anesthetic and is available on the NHS (National Health Service). It is usually undertaken after the age of 35-40 years. In women who have not had breast cancer, RRSO may halve their risk of developing this if carried out before the menopause.

Removal of the ovaries will mean the woman will go into early menopause. Early menopause in some women is associated with side effects like hot flushes, sweats, thinning of the bones, and a higher risk of heart disease. It may also reduce libido and sexual function. Taking hormone replacement therapy can minimise these side effects. A number of women choose to decline or delay this operation to avoid the potential symptoms/problems of early menopause.

The fallopian tube is the tube that is connected to the womb. It collects the egg from the ovary and transports it to the womb. Current research suggests that a number of cancers of the ovary actually start in the fallopian tube. It is important to understand that ovarian cancers may start outside of the tube too.

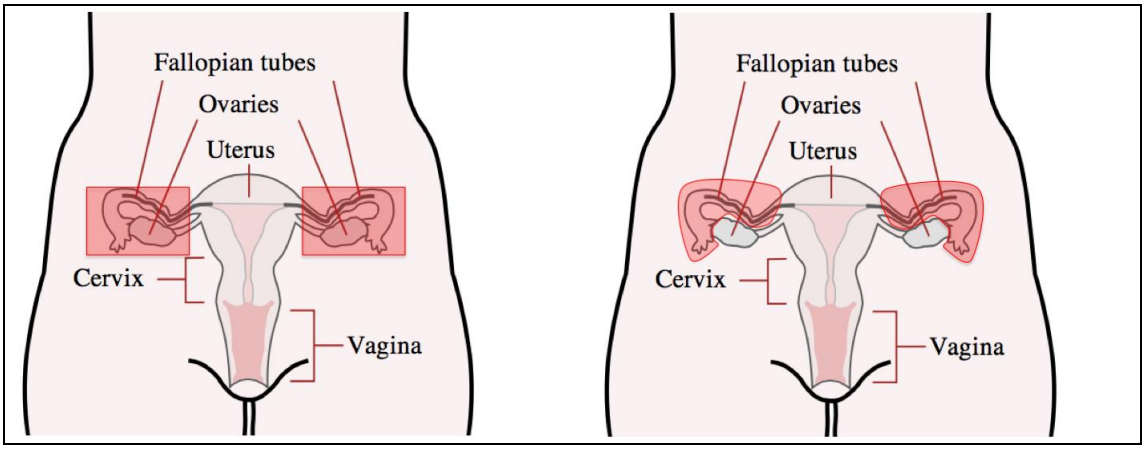

Figure 1a: Current procedure showing removal of tubes and ovaries (shaded in red).

Figure 1b: Proposed procedure showing removal of tubes alone (shaded in red)

A number of experts believe that removing the tubes alone would provide some protection from getting ovarian cancer (Figure 1b). This 'first stage' is called **R**isk **R**educing **E**arly **S**alpingectomy (RR**ES**). This may be particularly helpful for those women who wish to avoid or delay the removal of ovaries, for example, until after the menopause. Women who just have their fallopian tubes removed will need to have a *second* operation at a later date to remove their ovaries. This 'second stage' can be undertaken once they reach the menopause. This is called **D**elayed **O**ophorectomy (**DO**). This is essential to provide optimal protection against ovarian cancer. Both operations are usually carried out by keyhole surgery (laparoscopy) under general anesthesia. Each operation may involve an overnight stay in hospital and the recovery time is usually 1-2 weeks.

At present the precise level of benefit obtained from removing the tubes alone is not known. There are no research studies to show whether this 'two-stage procedure' is acceptable and effective for preventing ovarian cancer. Further research is needed to establish this.

This survey will help us understand your views on this 'two-stage' strategy to prevent ovarian cancer.

QUESTIONS & ANSWERS

Why have I been invited to take part in this survey?
You have been invited because you are a member of a support group made up of women at high risk of developing tubal/ovarian cancer. Or your healthcare team may have identified you as someone at high risk of developing tubal/ ovarian cancer. This is either because you carry an alteration/fault in a gene like BRCA1/BRCA2 or you have a strong family history that puts you at higher risk of developing ovarian cancer.

What do I have to do to take part in the survey?
Once you have reviewed the information sheet online, the website will guide you through a short eligibility questionnaire followed by consent form-1. You will be able to access the survey questionnaire once you have completed consent form-1.

What will I be asked to do if I take part and when will this happen?
If you have decided to take part, please complete a short eligibility questionnaire followed by consent form-1, ensuring that you follow the instructions and sign the relevant sections. You may then go on to complete the survey. This should take approximately 10 minutes to complete.

It is important for you to understand, that should you become mentally incapacitated or in the event of your death, during the course of this project, we will continue to retain/include your valuable information in this research study.

Do I have to take part?
You do not have to participate in this study if you do not wish to. Your participation in this survey in entirely voluntary. You are free to withdraw from responding at any time without giving a reason. It will not affect your current or future healthcare.

How confidential is this survey?
The survey is completely confidential. You will not be personally identified from any analysis or outcomes of the survey. All the information that you provide will be treated in the strictest confidence and will comply with UK Data Protection Laws.

How will I benefit from participating in this survey?
By taking part, you will help us understand how women like you feel towards this new approach of preventing ovarian cancer. It will help develop research studies for ovarian cancer prevention in high-risk women. Your participation in this survey will hopefully benefit the health of women at high risk of ovarian cancer in the future.

You will not personally benefit from taking part in this survey.

What will happen if I don't want to carry on with the survey?
You are free to withdraw from the survey at any time, through personal choice and without giving any reason for doing so. In addition should you change your

mind after completing the consent form, you can still opt out by not completing the survey.

If you have provided contact details and subsequently change your mind, your data can be withdrawn from any analysis in the study. If you have not provided your name or contact details then any submitted data will be anonymous. It cannot be linked to you or excluded from the analysis.

Do I need to provide my contact details?

No this is not essential.

What is the second consent form for?

The last section in the survey asks if you are happy to be contacted by the research team in the future. This is for other research studies (not linked to this survey). If you are happy to be contacted, you will need to fill in your name and contact details and sign a consent form. This is the second consent form, named **'CONSENT FORM-2'**

You are '**not**' obliged to provide this information. You do **not** need to provide this information for the purpose of this survey. Do not provide this information if you do not wish to be contacted by the research team.

If you do elect to provide this information, the research team may contact you in the future to enquire if you are interested in taking part in future research. Any future research you are informed about will be ethically approved by an independent Research Ethics Committee. You are **not** obliged to participate in any future research studies by signing this form.

Who are the researchers involved in this project?
The project will be run by health professionals under the leadership of Dr Ranjit Manchanda and co-ordinated by QMUL. It is the result of collaborative work of a number of individuals:

Dr Ranjit Manchanda	Consultant Gynaecological Oncologist, Royal London Hospital & Clinical Senior Lecturer, Queen Mary University of London
Professor Usha Menon	Professor of Gynaecological Oncology, University College London
Mr Ertan Saridogan	Consultant Gynaecologist, University College Hospital
Dr Faiza Gaba	Clinical Research Fellow Gynaecological Oncology, Queen Mary University of London
Professor Gareth Evans	Professor of Medical Genetics and Cancer Epidemiology, University of Manchester
Ms Vishaka Tripathi	Genetic Counsellor, Clinical Genetics, Guys Hospital

Who has reviewed the survey?
The survey has been reviewed by a number of experts and some lay people.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. The survey has been reviewed and given a favourable opinion by West Midlands – Edgbaston Research Ethics Committee. Research Ethics Committees are made up of healthcare professionals and members of the public who are not connected to the study.

What will happen to the results of the survey?
The results of this survey will be presented at conferences and published in a scientific journal. Your personal details will not be mentioned in any such publication. This will also be made available through supporting charity websites.

This survey will also contribute towards setting up a study. This future study will assess the two-step strategy to prevent ovarian cancer. This will involve removing fallopian tubes alone followed by removal of ovaries after the menopause.

If I need to contact someone about the research, whom should I contact?
If you have any questions, queries or concerns regarding the survey, please contact the study team using the contact details below.

Email: bci-rresdo@qmul.ac.uk

Write to:
RRESDO Team
Barts Cancer Institute, ECMC
Queen Mary University of London
Charterhouse Square
London EC1M 6BQ

What if you have any concerns or worries?
If you have any concerns or questions you should initially contact the RRESDO team who will do their best to answer your questions. The contact details are provided at the end of this information booklet. If there is something that you are unhappy with and you wish to complain formally, you can do this through the Research Governance Sponsor of this study by writing to:
Dr Sally Burtles
Director of Research Services & Business Development
Joint Research Management Office (JRMO)
Queen Mary University of London
QM Innovation Building
5 Walden Street
London, E1 2EF, UK

Please quote reference 012048 in all correspondence. All communication will be treated in strict confidence.

For further independent information or support please contact:

BRCA Umbrella
Website: www.brcaumbrella.ning.com

Eve Appeal
Email: office@eveappeal.org.uk
Website: www.eveappeal.org.uk

Ovacome
Email: support@ovacome.org.uk
Website: www.ovacome.org.uk