PARTICIPANT INFORMATION SHEET

A Trial of Optimal Personalised Care After Treatment – Gynaecological cancer (TOPCAT-G)

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the study is being undertaken and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact us using the details below.

What is the TOPCAT-G study about?

The TOPCAT-G study aims to develop and pilot test a new follow-up care intervention for patients who have undergone treatment for gynaecological cancer and are disease-free at the present moment. This is a study that compares this new follow-up care with the existing practice of follow-up care after cancer treatment. We are interested in gathering information on the usefulness and practicability of using this new follow-up care intervention as an alternative approach, hearing your views and opinions regarding its acceptability, and setting up a larger trial based on the outcomes of this pilot study.

Why have I been chosen to take part?

You have been asked to take part because you have recently undergone treatment for gynaecological cancer from a North Wales Hospital, and are disease-free at the present moment.

Do I have to take part?

No, participation in this study is completely voluntary. You have been given this information sheet to keep and, if you decide to take part, you will be asked to sign a consent form and be given a copy of the form. A specimen copy of the consent form is enclosed. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

What will I be asked to do if I decide to take part?

If you decide to take part you will be invited to meet the consultant, or research nurse, and/or the cancer nurse specialist (CNS) who will explain to you the details about the study and will answer any questions that you might have. After you have

fully understood what the study is about and decide to participate, you will be asked to provide written consent at your three-month routine follow-up appointment. You will be asked to sign two copies of the accompanying consent form. One copy of the consent form and this information sheet will be for you to keep. The second copy of the consent form will be retained by the research team. After you have signed the consent forms, you will be randomly allocated to one of two groups:

Group 1: You will receive follow-up care as part of the new intervention. At the end of your three-month routine follow-up appointment, the research nurse will introduce you to the CNS who will deliver the intervention. You will be given an information booklet which will be explained to you by the CNS. The CNS will arrange a date and time for a telephone call appointment with you, which will take place within the following four weeks. You will be given a set of needs assessment questionnaires to take home and you will be asked to complete the questionnaires one week before your scheduled telephone call. Your CNS will contact you again at 9 months post-treatment and you will receive a letter confirming the date and time of your telephone call appointment by post. You will also receive further needs assessment questionnaires by post and will be asked to complete them one week before your scheduled telephone call. During the course of the study, you are encouraged to make contact with the CNS if you think you have a problem that needs urgent attention.

Group 2: You will receive standard follow-up care. You will continue to have usual hospital-based doctor-led medical reviews at 6, and 9 months post-treatment.

We will be asking all patients (irrespective of which group you are in) to complete a set of questionnaires at three time points. The questionnaires will ask you about your quality of life, current status of health and wellbeing, and service use history and will take you approximately 20-30 minutes to complete. The first set of questionnaires will be completed at your three-month routine follow-up appointment with assistance from the research nurse. The same set of questionnaires will then be posted to you at the end of 6 and 9 months following completion of treatment and you will be asked to return them in a self-addressed pre-stamped envelope. Patients who have not returned the questionnaires within 2 weeks will receive a telephone call reminder. Your GP will be notified about your participation in the research study and will be regularly informed about your progress with the study.

Will my taking part in this study be kept confidential?

All information collected in this study will be kept strictly confidential. You will not be personally identifiable from any data collected from you. Only the researchers associated with the study are authorised access to the data. All the data will be transferred to secure, password protected computers at Bangor University.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you taking part in the study.

What are the possible benefits of taking part?

Although there are no direct benefits to you of taking part in this study, the information you give us will be used to help develop an improved follow-up care for people who had undergone treatment for gynaecological cancer.

What happens if something goes wrong?

We do not foresee any circumstance where you will come to harm by participating in this study. If you are harmed by taking part in study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

What will happen to the results of the study?

The results will be written up for publication in a medical journal. The details will be submitted for presentation at local, national and international gynaecologic cancer meetings so that the findings can inform better follow-up care in the future.

Who is organising and funding the research?

We have obtained a grant from the *Betsi Cadwaladr* University Health Board (BCUHB). The Chief Investigator is Mr Simon Leeson from Ysbyty Gwynedd and his team includes doctors and nurses from BCUHB and researchers from Bangor University.

Who has reviewed the study?

The study has been reviewed and approved by the Research Ethics Committee for North Wales.

Who can I contact for further information?

For more information about this research, please contact:

Caryl Butterworth, Research Nurse
Betsi Cadwaladr University Health Board
Research Office, Clinical School, Ysbyty Gwynedd
Bangor
LL57 2PW
Telephone: 01248 384423
E-mail: caryl.butterworth@wales.nhs.uk

What should I do if I have any concerns about the study?

If you have any concerns about the study, please contact the Chief Investigator in the first instance:

Mr Simon Leeson, Consultant Gynecologist
Chief Investigator, TOPCAT-G
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Bangor
LL57 2PW
Telephone: 01248 384954
E-mail: Simon.Leeson@wales.nhs.uk

If you continue to have concerns you can contact the Concerns Team at Betsi Cadwaladr University Health Board:

Concerns Team
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Bangor
LL57 2PW
Telephone: 01248 384384
E-mail: ConcernsTeam.bcu@wales.nhs.uk

What do I do now?

If you would like further information regarding the study, please contact the research nurse by phone or email (see details above). After agreeing to take part in the study, you will give written consent at your three-month routine follow-up appointment. We very much appreciate the time that you have taken in reading through the details of the study.