Contents page Section 2: Background: Patient Information

University College London Hospitals NHS
NHS Foundation Trust

Department of Women's Cancer
Gynaecological Cancer Research Unit
University College London
1st Floor Maple House
149 Tottenham Court Road
London, W1T 7NF

Participant Information Sheet (Staff)

Title of Project: Developing a Stepped Approach to Improving Sexual Function after Gynaecological Cancer: A feasibility study. (SAFFRON)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. The information sheet is in two parts. PART A is a summary of the SAFFRON study. PART B gives more detailed information on the study and administration issues. Please read both sections before making your final decision. One of our team will go through the information sheet with you and answer any questions you have. Though you do not need to give written consent to take part it is important you are fully informed of the study. Please ask us if there is anything that is not clear in this information sheet or you have further questions.

What is the purpose of the study?

The study will answer important questions for women who have had treatment for gynaecological cancer. Gynaecological cancer and its treatments affect women in many ways, and quite often it is only after the first treatment is over that women can begin to think about how it has affected them and their relationships. In particular, women often tell us that their sexual life is affected and that their health care professional team often don't ask about it. Many women tell us that they aren't aware that anything can be done to make things better, although there are some treatments available.

We have been conducting a feasibility trial to find out what treatments are better for women who have had gynaecological cancer and who feel that they have not fully recovered in their sexual lives. Another important part of the study is to find out whether we can offer these treatments within the normal life of a busy NHS gynaecological cancer service; and if so what may be the best way of doing this.

Why have I been invited?

You are being invited because you have been involved in the feasibility study SAFFRON either directly providing the interventions used in the study or indirectly in your role within the NHS Trust.

What will happen to me if I take part?

If you agree to participate you will be asked to take part in a one-to-one interview with a researcher. The interview would take about 40 minutes and we would arrange it at a time and place convenient to you. We would audio-record the interview with your permission. During the interview you would be asked some general questions about your experience of the trial, what it was like to deliver the interventions or assist in the recruitment of patients, what you think is good about the treatments given to women and how the trial has been delivered, so that you have an opportunity to tell us what is and has been important for you.

Do I have to take part?

You do not have to take part. It is entirely up to you to decide whether or not to take part. If you decide to withdraw at any time, or decide not to take part now, this will not be communicated to your immediate colleagues or any member of the multi-disciplinary team.

What are the possible disadvantages and risks of taking part?

There are no physical risks to taking part in this study. This may be positive and raise awareness that could lead to you gaining further insight into this aspect of gynaecological oncology care.

What are the possible benefits of taking part?

There are no direct benefits to taking part in the study.

You may find participation in the study a positive experience personally as you will be contributing information to research that will help us decide about effective and acceptable treatments for women in the future.

At the end of the study when the results have been analysed we will provide a summary of the results of the study to you and the multidisciplinary team.

Who is organising and funding the research?

This research study is organised by the PRIMENT Clinical Trials Centre at University College London and is sponsored by University College London. Dr Sue Gessler, at University College London Hospitals (UCLH) NHS Foundation Trust is the Chief Investigator. The study is funded by the National Institute for Health Research and some funding has been provided by the UCLH Trustees. The researchers conducting the research are not paid for including you or any other participants in the study.

What happens when the research study stops?

Your involvement on the study would be for the one-to-one single interview only.

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

You can withdraw from the study at any time and we would ask you to notify a member of the research team. If you withdraw after the research study interview we will request to use the data you have provided. If you do not wish us to use this data it will be destroyed immediately.

In the event that you lost mental capacity during the study you would be withdrawn and we request to use data already collected from you.

What if there is a problem?

Every care will be taken in the course of the study. If you are concerned about any aspect of this study, please speak to the researcher to clarify any queries (See below for principal researcher's contact details). If you remain unhappy and wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your researcher if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your researcher, please make the claim in writing to the Dr Sue Gessler who is the Chief Investigator for the research and is based at University College Hospital, London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will there be expenses and payment?

You will not be paid for taking part in this study.

Will my taking part in the study be kept confidential?

We will follow ethical and legal procedures and all information we obtain from you will remain entirely confidential. Your name will be replaced with a study ID number. All information about you will remain completely confidential. We need to keep your name and professional role on file but will keep it separately from the interview data from you. The PRIMENT CTU at UCL is registered under the Data Protection Act to hold such information on a confidential basis. Any non-identifiable data will be stored in password protected computers and locked cabinets within the premises of University College London.

Interview data will be transcribed with your permission. Any identifiable information that you give us in audio-recorded form or transcripts, will be held in strictest confidence and will not be shared in any way that can lead to your identification. This data will be stored on a programme called IDHS Technical Service at University College London. This is designed to meet the requirements of confidential data storage according to the NHS Information Governance. On completion of the study audio-recorded information will be destroyed.

Only those members of the research team who are directly involved in analysing the information will have access to the data collected. All of the people who may see your

information have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

The results of the study will be published in peer reviewed articles. Confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications.

What will happen to the results of the study?

The results of the study will be published in peer reviewed papers and articles for the media which cater to clinical academics and to practitioners and users in health care settings. No personal identifying details will be used in any reports or publications. Voluntary sector organisations including Jo's Trust, Ovacome, The Eve Appeal, Macmillan Cancer Support and Target Ovarian Cancer will also be informed of the results.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study was reviewed and given a favourable opinion by the NRES Committee ……..on……2015. The study has also been reviewed by the National Institute for Health Research and the Department of Women's Cancer at UCL. The study is taking place at University College Hospital and University Hospitals Bristol Gynaecological Oncology Cancer Centre, St Michael's Hospital.

Everyone who enters the trail will contribute useful information towards research in the treatment of gynaecological cancers. An independent group of experts will be reviewing the data from this research throughout the trial. This is done to maintain safety and standards.

……..

Principal Investigator

Dr Sue Gessler
Consultant Clinical Psychologist/Hon Senior Lecturer
UCLH Gynaecological Cancer Centre
UCLH
250 Euston Road
London NW1 2PG

Telephone: 0203 447 8636
Email: sue.gessler@uclh.nhs.org

Further information and contact details

If you have any questions about the study or require further information please do not hesitate to contact the study Researcher Mr Phil McNamee by telephone: **020 7679 6143** or email: **p.mcnamee@ucl.ac.uk**

Thank you for taking the time to consider taking part in the SAFFRON study. Please keep this information sheet for reference.

University College London Hospitals NHS
NHS Foundation Trust

Department of Women's Cancer
Gynaecological Cancer Research Unit
University College London
1st Floor Maple House
149 Tottenham Court Road
London, W1T 7NF

Patient Information Sheet

Title of Project: Developing a Stepped Approach to Improving Sexual Function after Gynaecological Cancer: A feasibility pilot study. (SAFFRON)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. The information sheet is in two parts. PART A is a summary of the SAFFRON study. PART B gives more detailed information on the study and administration issues. Please read both sections before making your final decision. One of our team will go through the information sheet with you and answer any questions you have. This should take about 15 minutes. You may also like to talk about the study with friends, relatives and your doctor. Please ask us if there is anything that is not clear in this information sheet or you have further questions.

Part A

What is the purpose of the study?

The study will answer important questions for women like you who have had treatment for gynaecological cancer. Gynaecological cancer and its treatments affect women in many ways, and quite often it is only after the first treatment is over that women can begin to think about how it has affected them and their relationships. In particular, women often tell us that their sexual life is affected and that their health care professional team often don't ask about it. Many women tell us that they aren't aware that anything can be done to make things better, although there are some treatments available.

We would like your help to find out what treatments are better for women who have had gynaecological cancer and who feel that they have not fully recovered in their sexual lives. Another important part of the study is to find out whether we can offer these treatments within the normal life of a busy NHS gynaecological cancer service; and if so what may be the best way of doing this.

Why have I been invited?

You are being invited because you have recently had treatment for a gynaecological cancer and have told your doctor or nurse that you would like help to recover your sexual life more fully after this treatment.

What will happen to me if I take part?

If you give consent to take part you will first complete a study screening questionnaire. Depending on your score you will join the study and will follow one of the treatments described below. If your score does not allow entry to the study you will receive the same care as you would have received if the study had not been running. All women who agree to participate in SAFFRON will have a clinical assessment of their sexual difficulties. This may be helpful to you in any case as it may help you think about the problems and talk to your clinical team about them.

There are a range of treatments used for sexual difficulties following gynaecological cancer, for example, psycho-educational booklets and advice leaflets on psychosexual problems; being taught to use vaginal dilators, lubricants and topical creams. These treatments may be used alone or alongside one another. In addition the treatments may be used with various types of psychological therapies. SAFFRON will compare standard medicinal and practical treatments with a 'stepped care' model of treatment where women can progress as needed through 3 levels of psycho-educational and psychological 'talking' therapies.

We are not sure which way of treating patients is best so we need to make a comparison. An important part of making a fair comparison is "randomization". If you agree and are eligible to take part in the study you would be randomly allocated to either enhanced treatment as usual or the research treatment. The results are compared to see if one treatment is better. This process is essential to avoid bias: if the groups of women receiving each treatment are the same, any differences in the results can only be down to the treatments. Therefore, randomization means that the results are more reliable. The process of randomization will be carried out by a computer-based system. You have an equal chance of receiving either treatment.

If you agree to take part, you would be randomized to one of these two treatments:

- Enhanced treatment as usual
- Stepped care intervention

What does Enhanced treatment as usual involve?

This means you would receive the same treatment as you would have received were there no study. You will get help via your doctor, nurse or other sources such as the Macmillan Cancer Support information services. This may involve a psycho-educational booklet and advice leaflet on psychosexual problems from Macmillan; advice on the use of dilators, lubricants and topical creams and face to face or telephone advice and support from your clinical nurse specialist (CNS).

In addition, you will receive a specially prepared psycho-educational self-help booklet which has been prepared for the SAFFRON study. This was devised as a result of a world-wide search

for the best available self-help material and was decided on by the project team and our two patient advocates. This is not available in this form in any other way. We will give women in both groups this booklet and this is why we call it Enhanced treatment as usual, as we have added in something that you would not usually get and which we hope will be helpful.

What does stepped care involve?

Stepped care is a way of delivering a range of therapies at different levels of intensity depending on the patient's need. It involves a careful assessment and usually begins at the least intense level and then other therapies are offered if the first is not effective. The therapies you will be offered are adapted from existing therapies that have been shown to be helpful.

The clinical team who would look after you normally will deliver the treatments. You will receive special self-help books and counselling sessions given by a specially prepared clinical nurse specialist (CNS) or possibly a psychologist depending on our assessment of what is happening for you. If randomized to stepped care, you will have regular clinical assessments so that you receive the appropriate 'step' or level of care to match your particular needs in terms of the range and regularity of treatments. For example you may receive up to five 20-30 minute counselling sessions either face-to-face or over the telephone with your CNS, or if you have more severe difficulties, or your CNS sessions have not helped, you may see a clinical psychologist for around 16 therapy sessions of 50 minutes. If the assessments show there is little improvement in your sexual recovery you would be 'stepped up' to receive other treatments. You may see both a CNS and psychologist, or only one of these.

What else would happen to me if I took part?

In either group we will ask you to fill in some questionnaires, with the help of our research assistant, at the beginning, 6 weeks after you have begun, and then 3, 6 and 12 months later. They will provide information about how you are feeling. The questionnaires will take between 15-20 minutes to complete.

In addition and in either group you may be asked to take part in a one-to-one interview with a researcher. The interview would take about an hour and we would arrange it at a time and place convenient to you. We would audio-record the interview with your permission. During the interview you would be asked some general questions about your experience of your care and time on the research study, what you think is good about the treatments you receive and what might be improved, so that you have an opportunity to tell us what is and has been important for you.

If at any stage, you mention medical problems that have arisen which give your clinician (nurse or psychologist) cause for concern, they will contact your key worker to let your medical team know. As all your treating therapists are part of your clinical team, this is the normal way in which we would act clinically even outside the trial.

Confidentiality of what you discuss: what you say within the sessions will remain confidential, except if your treating nurse or psychologist has concerns for your safety or the safety of

others. This is unlikely to occur, but if it does, we would discuss it with you, your medical team, and if we were further concerned, we would let your GP know of our concern.

Do I have to take part?

You do not have to take part. It is entirely up to you to decide whether or not to take part. We will describe the study and go through this information sheet, which we will then give to you. If you do decide to take part you will be asked to sign a consent form to show you have agreed to take part. It is important that you know you are still free to withdraw at any time and without giving any reason. If you decide to withdraw at any time, or decide not to take part now, this will not affect in any way the standard of care or treatment you receive from the doctors and nurses here.

What are the possible disadvantages and risks of taking part?

There are no physical risks to taking part in this study. You may feel uncomfortable discussing personal issues such as your sexual activity and it may be that participation in the study introduces new thoughts about your cancer. This may be positive and raise awareness that could lead to you gaining appropriate help for difficulties you may be experiencing. The research team will be supportive and sensitive to any discomfort you may feel and if needed, and with your permission, will refer you to an appropriate member of the care team for help. If during the course of the study you inform the research team of any general symptoms that are disturbing to you and for which you do not receive treatment, following your verbal consent, we will speak to your consultant who can discuss the matter with you. The assessments, intervention sessions, questionnaires and possibly an interview involve your time. Where your participation involves an additional journey to the hospital or child care costs we will reimburse your travel expenses.

If you are visited in your home for an interview after the study is completed, to give your views on how it has gone (if you agree to such an interview), you and the visiting researcher would be bound by our safeguarding procedures (both UCLH and UCL have policies that we will abide by).

What are the possible benefits of taking part?

There are direct benefits to taking part in the study because you will be offered information or treatments or both of these, which are not currently offered as part of treatment as usual.

In addition you may find participation in the study a positive experience personally as you will be contributing information to research that will help us decide about effective and acceptable treatments for women in the future.

At the end of the study when the results have been analysed we will provide a summary of the results of the study to you and your family if you should wish.

This is the end of **Part A**. If you have any questions about anything you have read, please ask the researcher or your doctor.

Part B has more specific questions about the study. Please make sure you read Part B too, before deciding if you want to take part in the study.

……

PART B

Who is organising and funding the research?

This research study is organised by the PRIMENT Clinical Trials Centre at University College London and is sponsored by University College London. Dr Sue Gessler, at University College London Hospitals (UCLH) NHS Foundation Trust is the Chief Investigator. The study is funded by the National Institute for Health Research and some funding has been provided by the UCLH Trustees. The researchers conducting the research are not paid for including you or any other participants in the study.

What happens when the research study stops?

Your involvement on the trial would be for one year. Once the study treatment has finished, you will be assessed and treated according to standard practice at your hospital for women with sexual difficulties after gynaecological cancer treatment.

If for any reason the research study stops or the treatment programme needs to be changed, the reasons will be explained. Arrangements will be made for you to continue treatment according to best available information at the time.

What if relevant new information becomes available?

Sometimes during the course of a research study new information becomes available about the treatments that are being studied. If this happens, a researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to leave the study, your hospital doctor will ensure your treatment continues according to best available information at the time.

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

You can withdraw from treatment and the study at any time. If you decide to withdraw your consent for the study once it has started, we would ask you notify a member of the research team before you withdraw. If you withdraw your consent, the effective date of notification will be the date on which your withdrawal is received by the study team. Information about you that we have collected prior to that date will continue to be used and form part of the study. On withdrawal we request permission to access your medical records for collection of follow-up information for research and analysis; this is important information for the study. In the event that you lost mental capacity during the study you would be withdrawn and we request to use data already collected from you.

What if there is a problem?

Every care will be taken in the course of the trial. If you are concerned about any aspect of this study, please speak to the researcher to clarify any queries (See below for principal researcher's contact details). If you remain unhappy and wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your researcher if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your researcher, please make the claim in writing to the Dr Sue Gessler who is the Chief Investigator for the research and is based at University College Hospital, London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will there be expenses and payment?

You will not be paid for taking part in this study. Travel expenses will be reimbursed for any additional hospital visits or child care costs required by your participation in the study. Every effort will be made to keep additional hospital visits to a minimum and where possible face-to-face contacts will be arranged to coincide with routine care visits to the hospital.

Will my taking part in the study be kept confidential?

If you decide to take part in the SAFFRON study information about you will be passed to the PRIMENT Clinical Trials Unit (CTU) at UCL who are coordinating the study. Occasionally staff from the CTU or regulatory authorities will need to visit the hospital to review your notes to check that the information being provided is correct.

We will follow ethical and legal procedures and all information we obtain about you will remain entirely confidential and will not be included in your hospital files. Your name will be replaced with a study ID number.

Your GP, and your hospital consultant and clinical care team will be kept fully informed, but otherwise all information about you and your treatment will remain completely confidential. We need to keep your name, postcode and NHS number on file but will keep it separately from other data about you. The PRIMENT CTU at UCL is registered under the Data Protection Act to hold such information on a confidential basis. Any non-identifiable data will be stored in password protected computers and locked cabinets within the premises of University College London.

Interview data will be transcribed with your permission. Any identifiable information that you give us in audio-recorded form or transcripts, will be held in strictest confidence and will not be shared in any way that can lead to your identification. This data will be stored on a

programme called IDHS Technical Service at University College London. This is designed to meet the requirements of confidential data storage according to the NHS Information Governance. On completion of the study audio-recorded information will be destroyed.

Only those members of the research team who are directly involved in analysing the information will have access to the data collected. All of the people who may see your information have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

The results of the study will be published in peer reviewed articles. Confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications.

Will my doctor be informed?

We will send a letter to the health care professional in charge of your care at UCLH and to your GP informing them of your participation in the study. A copy of your signed consent form will be kept in your hospital notes.

What will happen to the results of the study?

The results of the study will be published in peer reviewed papers and articles for the media which cater to clinical academics and to practitioners and users in health care settings. No personal identifying details will be used in any reports or publications. Voluntary sector organisations including Jo's Trust, Ovacome, The Eve Appeal, Macmillan Cancer Support and Target Ovarian Cancer will also be informed of the results.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study was reviewed and given a favourable opinion by the Queen Square NRES Committee on 12th March 2015. The study has also been reviewed by the National Institute for Health Research and the Department of Women's Cancer at UCL. The study is taking place at University College Hospital and University Hospitals Bristol Gynaecological Oncology Cancer Centre, St Michael's Hospital.

Everyone who enters the trial will contribute useful information towards research in the treatment of gynaecological cancers. An independent group of experts will be reviewing the data from this research throughout the trial. This is done to maintain safety and standards.

.....

This is the end of **Part B**. If you agree to take part you will be given a copy of the information sheet and a signed consent form to keep.

Principal Investigator

Dr Sue Gessler
Consultant Clinical Psychologist/Hon Senior Lecturer
UCLH Gynaecological Cancer Centre
UCLH
250 Euston Road
London NW1 2PG

Telephone: 0203 447 8636

Email: sue.gessler@uclh.nhs.org

Patient Advice and Liaison Service (PALS)

Ground Floor Atrium
University College Hospital 235 Euston Road
London NW1 2BU

Further information and contact details
If you have any questions about the study or require further information please do not hesitate to contact the acting study Researcher Dr Gessler by telephone: 020 3447 8636 or email: sue.gessler@uclh.nhs.uk

Thank you for taking the time to consider taking part in the SAFFRON study. Please keep this information sheet for reference.

2.3 SAFFRON Randomisation letter - ETAU

Developing a Stepped Approach to improving sexual Function aFteR treatment fOr gyNaecological cancer

Dear [Name],

Thank you very much for agreeing to take part in *Saffron*, a study that invites women to take part who have been treated for gynaecological cancer and would like help in addressing difficulties they have experienced in their sexual life as a result of their illness and the treatment for it.

As we discussed on the phone, the process of randomisation to the study has been carried out by our computer-based system and you have been allocated to the 'Enhanced Treatment as Usual group'.

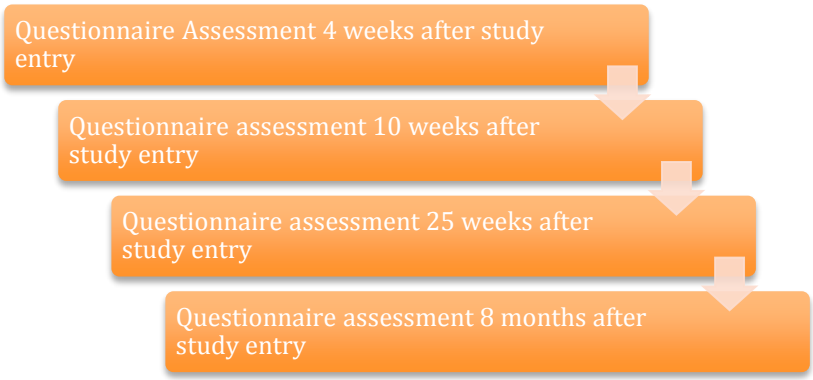
This means that you will receive our *Saffron* self-help booklet which is not available elsewhere. This is in addition to your normal care. You can access your CNS and doctor in the usual way for any help and treatment that they would normally give.

With this letter you have received the *Saffron* self-help booklet. It was compiled after a search of international documents which address the effects of gynaecological cancer specifically, and has been specially prepared for this study. We hope that this booklet will help you by giving you information and tips about your sexuality. You don't have to read this booklet front-to-back, you can go straight to the parts that apply to you, and dip in and out of it as you feel you need. You can also use the booklet as a means to start conversations about your concerns with your partner, doctor or nurse. You may find that this booklet gives you all of the help you need but if not, please feel free to discuss with your CNS or doctor who can offer further help.

We appreciate that not receiving the level 2 and 3 treatments within *Saffron* may well be disappointing to you. We want to assure you that you are contributing to our understanding of whether the *Saffron* treatments really are helpful and worthwhile to offer to women more widely within the NHS. This can only be done through this type of study, so all your experience and responses during the whole length

of the study are very important to us. Please do let us know whether you would like to discuss your thoughts and feelings with us on this. We are available to you throughout the study. Please see our contact details at the end of the letter.

We will be asking you some questions about how you have been feeling at several points during your time on the study. These are shown in the diagram below. We will contact you at 4 more points over the next 8 months. Please find below an overview of the steps that will follow in the study. We will be in contact shortly to arrange the next assessment with you.



Thank you very much again for your contribution to this project. We are immensely grateful for your time and effort. With your participation in the study we will be able to inform clinical practice and improve the care women with gynaecological cancer receive.

For any questions, concerns, or feedback please contact the team by phone on 020 7679 6143 or email ifwh.saffron@ucl.ac.uk.

With best wishes,

Sue Gessler (Chief Investigator, Consultant Clinical Psychologist)

Philip McNamee (Research Associate)

Becky Anderson (Research Assistant)

2.4 Randomisation letter- Intervention

Developing a Stepped Approach to improving sexual Function aFteR treatment fOr gyNaecological cancer

Dear [Name],

Once again, thank you very much once again for agreeing to take part in *Saffron*. Saffron is a study for women who have been treated for gynaecological cancer and would like help in addressing difficulties they have experienced in their sexual life as a result of their illness or its treatment.

As we discussed on the phone, the process of randomisation to the study has been carried out by our computer based system and you have been allocated to the 'intervention group'.

With this letter you have received the *Saffron* study self-help booklet which is the first level of help available. It was compiled after a search of international documents which specifically address the effects of gynaecological cancer, and has been specially prepared for this study. We hope that this booklet will help you by giving you information and tips about your sexuality. You don't have to read this booklet front-to-back, you can go straight to the parts that apply to you, and dip in and out of it as you feel you need. You can also use the booklet as a means to start conversations about your concerns with your partner, doctor or nurse. You may find that this booklet gives you all of the help you need, but depending on your symptoms and how much help you may need or wish to have, other treatments may follow. This will depend on questionnaire assessments which we will complete with you after each stage of the treatment. In addition to this, we will be asking you some questions about how you have been feeling at several points during your time on the study. These are shown in the diagram on the next page. To remind you, you may not wish to go through all the different levels of the *Saffron* interventions but we will ask you to complete all the assessments regardless.

We will be in contact in around 3 weeks to arrange the next assessment with you.

Thank you very much again for your contribution to this project. We are immensely grateful for your time and effort. With your participation in the study we hope to improve the help available in future for women who have sexual difficulties after treatment for gynaecological cancer.

For any questions, concerns, or feedback please contact the team by phone on 020 7679 6143 or email ifwh.saffron@ucl.ac.uk.

With best wishes,

Sue Gessler (Chief Investigator, Consultant Clinical Psychologist)

Philip McNamee (Research Associate)

Becky Anderson (Research Assistant)

University College London Hospitals NHS
NHS Foundation Trust

2.5 SAFFRON Study Advert - UCLH

Are you experiencing sexual difficulties after your treatment for gynaecological cancer?

At UCLH we are conducting a research study developing a stepped approach to improving sexual function after gynaecological cancer.

The trial is called **SAFFRON**

If you answer 'yes' to all 3 questions below you may be interested to take part:

3 Questions

Are you having any sexual difficulties/problems in your intimate relationships?	Is this a problem for you?	Would you like some help with this

If you answer 'yes' to the questions and you:

- have had treatment for a cancer of the ovary, womb, cervix or vulva more than 3 months ago
- have good spoken English
- and are over 18 years of age

you may wish to find out more about the study so that you can decide if you would like to be screened to take part.

For further information, please contact xxxxxxx, a trained psychologist and member of the SAFFRON Research Team.

Email: **Free phone:**

uclh University College Hospital | National Hospital for Neurology and Neurosurgery | Eastman Dental Hospital | Royal National Throat, Nose and Ear Hospital | Heart Hospital | Royal London Hospital for Integrated Medicine

University Hospitals Bristol NHS
NHS Foundation Trust

2.6 SAFFRON Study Advert - Bristol

Department of Women's Cancer

Are you experiencing sexual difficulties after your treatment for gynaecological cancer?

At UCLH we are conducting a research study developing a stepped approach to improving sexual function after gynaecological cancer.

The trial is called **SAFFRON**

If you answer 'yes' to all 3 questions below you may be interested to take part:

3 Questions

Are you having any sexual difficulties/problems in your intimate relationships?	Is this a problem for you?	Would you like some help with this

If you answer 'yes' to the questions and you:

- have had treatment for a cancer of the ovary, womb, cervix or vulva more than 3 months ago
- have good spoken English
- and are over 18 years of age

you may wish to find out more about the study so that you can decide if you would like to be screened to take part.

For further information, please contact xxxxxxx, a trained psychologist and member of the SAFFRON Research Team.

University College London Hospitals NHS Foundation Trust

Email: **Free phone:**

uclh

University College Hospital | National Hospital for Neurology and Neurosurgery | Eastman Dental Hospital | Royal National Throat, Nose and Ear Hospital | Heart Hospital | Royal London Hospital for Integrated Medicine