**Participant Information Sheet/Consent Form**

**Health/Social Science Research** -*Adult providing own consent*

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| **Title** | Dietary counselling to increase soluble fibre in patients with gynaecological cancers undergoing pelvic radiotherapy: a feasibility study |
| **Protocol Number** | V4.0  |
| **Project Sponsor** | *The University of Queensland* |
| **Coordinating Principal Investigator/ Principal Investigator** | Miss Emilie Croisier, PhD candidate at the University of Queensland and Accredited Practicing Dietitian at the Royal Brisbane and Women’s Hospital (RBWH) (07) 3365 6313 | *emilie.croisier@uqconnect.edu.au* |
| **Associate Investigator(s)** | Dr Teresa Brown, PhD, AdvAPD; Nutrition & Dietetics, RBWHAssociate Professor Judy Bauer, PhD, AdvAPD; The University of QueenslandAlice Grigg, Radiation Therapist, Cancer Care Services, RBWHDr Philip Chan, Radiation Oncologist, Cancer Care Services, RBWHDr Jeffrey Goh, Medical Oncologist, Cancer Care Services, RBWH |
| **Location** | Royal Brisbane & Women’s Hospital |

**Part 1 What does my participation involve?**

**1. Introduction**

You are invited to take part in this PhD research project (supported by a University of Queensland scholarship), which aims to determine if increasing soluble fibre intake via dietary counselling is feasible in patients with gynaecological cancers undergoing pelvic radiotherapy.

Decision to participate in this study is voluntary. Should you choose to participate, this information sheet will tell you about the research project and explain the processes involved with taking part, to help you decide if you want to take part in the research.

**2. What is the purpose of this research?**

Patients with gynaecological cancers undergoing pelvic radiotherapy can result in short and long-term toxicity side effects such as diarrhoea, which can have a major impact on quality of life. Currently, the evidence around effective dietary management remains inconclusive and of low quality, however there has been recent studies showing an improvement in bowel symptoms with a high fibre diet. Therefore, we would like to further investigate the feasibility of increasing dietary fibre (particularly soluble fibre) via dietary counselling alone, in order to inform future dietary guidelines.

**3. What does participation in this research involve?**

Eligibility criteria includes anyone who has been diagnosed with a gynaecological malignancy and is undergoing definitive or adjuvant radiotherapy (as specified by your treating Radiation Oncologist). If you are eligible and are considering taking part in the research project, you will be provided an opportunity to inquire further at a follow-up phone call by the principal investigator/ research dietitian. Consent for participation will be required prior to commencement of this study, which will occur at least 3 days prior to the commencement of your radiation therapy treatment planning session.

A telehealth or face to face appointment at the hospital with the research dietitian will be scheduled at your convenience, in order to conduct your baseline assessments, provide nutrition education on fibre and determine your individualised diet plan. Baseline assessments will involve the completion of questionnaires relating to bowel symptoms, quality of life, nutrition status and weight, and dietary fibre intake. The first session is expected to take 45 – 60 minutes to first assess your usual fibre intake and to develop a recommended meal plan to increase your intake of soluble dietary fibre if necessary, with the goal of increasing your soluble fibre intake gradually throughout treatment. Your soluble dietary fibre goal will be personalised to your baseline intake and will be increased gradually each week if required throughout radiation treatment. A list of commonly eaten foods will be provided, with details of fibre content for you to use as a guide.

Throughout your radiation treatment, weekly appointments with the research dietitian (~30 minutes) will also be organised at your convenience (available via telehealth or face to face). A three-day food and symptom diary will be provided for you to record and monitor your fibre intake each week including symptoms relating to your bowels (e.g. diarrhoea, constipation etc) and the use of any medications. These diaries will be discussed with the dietitian at your weekly appointments. Data collection will occur over the duration of your radiation treatment and finish upon completion of your radiation treatment.

This study will be conducted over 10 to 12 months commencing early 2021. A consent form is available in Appendix A; by signing this form, you are consenting to the research team collecting de-identified (coded) information provided by yourself. This data will be stored in secure password protected servers at the University of Queensland and the Royal Brisbane and Women’s Hospital. If you would like to withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form (Appendix B). Unless specified to the researcher, the data collected up until this point will be used in the analysis of results.

 Your data will not be shared to third parties outside of the research team and all data will be de-identified prior to dissemination of findings. Data collected will pertain to:

 - Fibre intake via food diaries

- Use of anti-diarrhoea medications

- Weight and nutrition status

- Bowel symptoms

- Review of radiation treatment delivery plans

- Quality of life ratings

There are no costs associated with participating in this research project, other than your time spent in the weekly dietetic appointments, nor will you be paid. Once this trial intervention is completed, further access to the trial will not be permitted.

**4. Other relevant information about the research project**

This is a single-site study being conducted in the radiation oncology outpatient setting; ideally, 40 participants are planned for recruitment.

**5. Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to and there will be no implications to the standard of care you receive. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without explanation.

If you do decide to take part, you will be able to keep this Participant Information Sheet.

**6. What are the possible benefits of taking part?**

Possible benefits of the results of this research relate to improving nutritional care provided to future patients diagnosed with gynaecological cancers undergoing pelvic radiotherapy. The results of this study will also contribute information to update evidence-based guidelines and the development of a population specific model of care in the future. Previous studies have shown that increasing fibre may potentially help reduce side effects from treatment, such as diarrhoea, hence we are interested in further investigating the role of fibre and its possible benefits. However, there will be no guaranteed direct benefit to you from your participation in this research.

**7. What are the possible risks and disadvantages of taking part?**

Your time provided to undertake this dietary intervention will not be reimbursed. Please be aware that participation in this study will require your time to attend the weekly dietetic appointments and weekly completion of the three-day food diary throughout your radiation treatment.

If you do not wish to modify your diet during any particular point during your treatment, or you have difficulties following the diet plan for any reason, that is ok. This information can be recorded in your food diary and it will help the research team understand more about these difficulties you encounter during treatment in following in the diet plan and whether this is a feasible approach for future patients.

**8. What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, you may contact the research team to inform them of your decision and you will be required to fill out the withdrawal of participation form (Appendix B). You will also need to specify to the researchers if you do not want your data at any point to be used in the results of the study.

**Part 2 How is the research project being conducted?**

**9. What happens when the research project ends and what will happen to information about me?**

Once the results have been collected and analysed, this will be submitted for publication in a peer-reviewed journal and will be presented at conferences. Each participant will be randomly assigned a participant ID number to ensure their data remains private and confidential. Data will be remain unidentifiable and securely stored on password protected servers at the University of Queensland and/or the Royal Brisbane and Women’s Hospital. The data will be stored for 15 years and will remain on these secure servers and will not be accessed by individuals or third parties outside of the research team. Personal and/or identifiable details will not be accessible.

Upon completion of this study, a summary of results can be provided upon request by participants by contacting the principal researcher, Emilie Croisier (details provided below) by phone or email. You have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information. Any personal or sensitive information obtained for the purpose of this research project will be treated as confidential and securely stored as de-identified data. It will be disclosed only with your permission, or as required by law.

**10. Who has reviewed the research project**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of the University of Queensland and the Royal Brisbane and Women’s Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11. Further information and who to contact**

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, please do not hesitate to contact:

**Research contact person**

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| --- | --- |
| Name | *Emilie Croisier* |
| Position | *Co-ordinating Principal Investigator* |
| Telephone | 07 3365 6313 |
| Email | *emilie.croisier@uqconnect.edu.au* |

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| --- | --- |
| Name | *Dr Teresa Brown* |
| Position | *Associate Investigator* |
| Telephone | 07 3646 0543 |
| Email | *Teresa.Brown@health.qld.gov.au* |

 If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

* *Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women’s Hospital, Herston, Qld, 4029 or telephone (07) 3646 5490, email: RBWH-Ethics@health.qld.gov.au.*
* *Research Governance Officer, Research Governance Office, Royal Brisbane & Women’s Hospital, Herston, Qld, 4029 or telephone (07) 3646 8579, email RBWH-RGO@health.qld.gov.au.*

## Appendix A: Consent Form - Adult providing own consent

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| --- | --- |
| **Title** | Dietary counselling to increase soluble fibre in patients with gynaecological cancers undergoing pelvic radiotherapy: a feasibility study |
| **Protocol Number** | 4.0 |
| **Project Sponsor** | *The University of Queensland* |
| **Coordinating Principal Investigator/ Principal Investigator** | Miss Emilie Croisier, PhD candidate at the University of Queensland and Accredited Practicing Dietitian at the Royal Brisbane and Women’s Hospital (RBWH) (07) 3365 6313 | *emilie.croisier@uqconnect.edu.au* |
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| **Location** | Royal Brisbane & Women’s Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

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| --- |
|   |
|   | Name of Participant (please print) |   |   |   |   |
|   |
|   | Signature |   |  Date |   |   |
|   |
|  |  |  |  |  |  |  |  |

 **Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|   | Name of Researcher† (please print) |   |   |
|   |   |
|   | Signature |   |  Date |   |   |
|   |
|  |  |  |  |  |  |  |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

## 6.3 Appendix B: Form for Withdrawal of Participation –

*Adult providing own consent*

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| --- | --- |
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| **Location** | Royal Brisbane & Women’s Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationships with the researchers or the University of Queensland or the Royal Brisbane & Women’s Hospital.

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| --- |
|   |
|   | Name of Participant (please print) |   |   |   |   |
|   |
|   | Signature |   |  Date |   |   |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|   |
|   | Name of Researcher (please print) |   |   |
|   |   |
|   | Signature |   |  Date |   |   |
|   |
|  |  |  |  |  |  |  |

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.