Metro North Health Service District

Enquiries to: Teresa Brown
Phone: 07 3646 7995
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Participant Information and Consent Form
Version4, Dated 22 June 2012

EARLY TUBE FEEDING IN H&N CANCER

Principal Researcher(s): Teresa Brown, Dept Nutrition & Dietetics, A/Prof Judith Bauer, University of Queensland, Dr Merrilyn Banks, Dept Nutrition & Dietetics, Dr Brett Hughes, Cancer Care Services

Associate Researcher: Dr Liz Kenny, Cancer Care Services, Dr Charles Lin, Cancer Care Services

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You are invited to take part in this research project.

Please read this information carefully. Feel free to ask questions. You may wish to discuss the project with a relative or friend. If you agree to participate, you will be asked to sign a Consent Form and you will be given a copy of this Participant Information and the Consent Form to keep as a record.

What is the study about?

The study is being carried out as part of a PhD research study at the University of Queensland. The study is to investigate the best time to start providing extra nutrition to patients receiving treatment for head and neck cancer. During treatment, many patients have difficulty eating enough food. The side effects of the radiotherapy or chemotherapy often reduce appetite or make it hard to chew and swallow food. A feeding tube is often used to provide enough nutrition whilst you are not eating well.

Currently we identify patients who may need a feeding tube during their treatment using hospital guidelines. This tube is usually placed a week or so before treatment starts. Once patients start to have difficulty eating, we advise they start using the feeding tube. While this approach has reduced complications during treatment and prevented unexpected hospital admissions, many patients still can lose a large amount of weight.

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The aim of this study is to see whether starting tube feeding earlier will improve patients' nutrition and weight. Improved nutrition is likely to have other positive benefits on quality of life with better energy levels and strength for everyday activities. We are also looking at whether it will improve your outcome to treatment.

What will it involve for me?

You are invited to take part in the study because you have been identified as needing a feeding tube (PEG tube) before your treatment for head and neck cancer. We are aiming to include 100 people like you. Participation will involve collecting information about your medical diagnosis and treatment, your weight and your nutrition intake from the PEG tube, both before, during and after treatment

You will need to attend an extra appointment with a research dietitian before you start treatment and 3 months after you finish treatment. At the appointment the dietitian will do an assessment/interview, check your weight on special scales that measure weight and body fat, and you will be asked to complete a survey to assess your quality of life. Each appointment will take approximately 30 minutes.

You will see the hospital dietitian as part of usual care when you come for your PEG tube to be placed. They will teach you how to care for your PEG tube. You will have an equal chance of being allocated to the standard care group or the intervention group.

- If you are in the standard care group, you are required to care for your PEG tube and flush water through it twice each day.
- If you are in the intervention group - you will also be asked to take two extra nutrition supplement drinks each day through your PEG tube in addition to the food you usually eat. Each supplement drink is about 200ml (less than 1 cup).

Both groups see their hospital dietitian throughout treatment as part of usual care. The hospital dietitian provides support and advises you on your diet and foods to eat. They will let you know if you need to start or have more tube feeds as treatment progresses. Once treatment finishes you are referred to your local dietitian for ongoing care.

After treatment, the research dietitian will contact you monthly by phone for a period of 6 months to check how you are eating and drinking and if still using the PEG. When you return to the hospital for your PET scans at 3 months, you will be seen by the research dietitian again to re-measure your weight, body fat, nutrition and quality of life survey.

If you have a family member or carer who you would like to be with you during these appointments, they are welcome to attend.

Your medical records will be reviewed for progress at 1 and 5 years post treatment.

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How will this study help me?

The study will not change the level of care you are currently receiving. You will have an equal chance of being allocated to either standard care or the intervention.

It is hoped that the extra nutrition in the intervention group will reduce any weight loss during treatment and maintain your nutrition. This should help your energy levels and strength during treatment. It may also assist you being well enough to receive optimal treatment from the chemotherapy and radiotherapy, and prevent emergency admissions to the hospital for complications.

Whilst we have good evidence from other research studies that nutrition advice during treatment is beneficial (our standard care), there is very little evidence for giving nutrition before treatment. This study will give us information we need to plan improvements to our service to other patients with head and neck cancer in the future and whether pre treatment nutrition is beneficial.

Is there any harm to me taking part?

The placement of a gastrostomy tube is associated with risks which your doctor will have explained to you to obtain your consent for the procedure. This risk applies to all patients receiving this procedure as part of standard care and so is the same for each group in this research project.

There may be inconveniences which include;

- having an extra appointment with the research dietitian pre treatment (after you see the medical oncologist) and then at 3 months post treatment (when you attend for your medical PET scans)
- keeping a simple diary record of how many PEG feeds you take each day and any symptoms
- experiencing some feelings of fullness with the extra nutrition

Your participation is voluntary, and your medical care will not be affected by whether you decide to participate or not. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

How can I find out more?

If you require further information or have any problems concerning this project, please contact the principle investigator, Teresa Brown on 3646 7995 (Dept Nutrition & Dietetics 3646 7997).

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If you would like to know the results of the project, please let the research dietitian know. They will record your name and address, and we will send a summary of the project results when they are available.

The Ethical Conduct of this Research

This study has been reviewed and approved by the Royal Brisbane & Women's Hospital Human Research Ethics Committee. Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the 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.

Privacy Statement

The conduct of this research involves the collection, access and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data will be used for purpose of publishing research results. Your anonymity and confidentiality will at all times be safeguarded.

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I have read, or have had read to me, and I understand the Participant Information version …….. dated……...

I freely agree to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed) ……

Signature Date

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

Research assistant's name (printed) ……

Signature Date

If participant is not able to consent for themselves, impartial witness is then required.

Witness name (printed) ……

Signature Date

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