TreatWELL

TreatWELL – a feasibility study to assess the delivery of a lifestyle intervention for colorectal cancer patients undergoing potentially curative treatment

INFORMATION ABOUT THIS STUDY FOR PARTICIPANTS

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PART 1: BACKGROUND TO THE STUDY

Current evidence suggests that lifestyle improvements have considerable potential to improve outcome for patients with colorectal cancer. This study aims to assess the feasibility of delivering an intervention programme (TreatWELL) for colorectal cancer patients undergoing treatments. The lifestyle intervention (advice) programme involves smoking cessation, physical activity and dietary components and would start at diagnosis.

Why am I being invited to take part in this study?

With this study, we wish to look at the practicalities of providing a lifestyle advice programme for colorectal cancer patients from diagnosis right through treatment. We have successfully organised lifestyle programmes in other research studies but need your help with how best to do this within the colorectal cancer setting.

Why should I read this leaflet?

Before you decide whether or not you would like to take part in this study, it is important that you understand why we are doing it, and what it involves. Please read this leaflet carefully. If you have any questions, you should contact the study co-ordinator and research nurse Jacqui Sugden on 01382 383197. Jacqui will answer any questions that you have and give you any further information you may need. You may also want to discuss it with your family and friends. You do not have to make an immediate decision about taking part in the study.

Where is the study being carried out?

This study is being carried out in Tayside. The study is being led by the University of Dundee, together with the University of Stirling and NHS Tayside.

Who is the study funded by?

The study is funded by the Chief Scientist Office (CSO). The CSO is part of the Scottish Government that supports and promotes high quality research aimed at improving the quality and cost-effectiveness of services offered by NHS Scotland.

PART 2: WHAT WILL I HAVE TO DO?

This study takes place in three phases:

- Phase 1 starts within 3-10 days of diagnosis and continues until surgery takes place
- Phase 2 is in the weeks immediately after surgery
- Phase 3 continues for a minimum of 10 weeks post treatment and a maximum of 25 weeks (depending on the length of therapies received).

It is important to note that remaining in the study for all three phases is subject to clinical approval and the length of time of treatment plans.

Study measurement visits

There will be four 'measurement' visits. These will be at the start of the study (Visit 1), a few days prior to surgery (Visit 2), at the end of post-operative recovery (Visit 3) and after a minimum of 10 weeks post treatment (Visit 4).

They will be at Ninewells hospital and you will be seen by the research nurse. At these measurement visits the research nurse will:

- Take measurements of your height, weight, waist and skin fold thickness (thickness of skin relates to body fat).
- Ask you questions about diet, medications, side effects (including fatigue bowel function), activity levels (including a walking test*), alcohol consumption and views on your health. The sort of questions you will be asked include; "In general, how would you describe your health?", you'll be given a choice of answers.

* You'll be asked to walk along a 25 metre (82 feet) course as many times as you can in 6 minutes. You can rest as many times as you need to during test.

Lifestyle guidance and advice

You will have three face to face consultations with the lifestyle counsellor during the study. The lifestyle counsellor will call you after your first visit with the research nurse to make arrangements.
The lifestyle advice programme will be personalised to you and will work towards smoking cessation (if applicable), decreasing alcohol intake (if applicable), increasing physical activity to at least 150 minutes moderate activity per week and dietary advice as appropriate. Lifestyle advice will be tailored according to phase of treatment and will be supported by NHS physiotherapists and dieticians.
A minimum of 12 telephone consultations will support the face to face sessions with the lifestyle counsellor over a 31 week period.

Acceptability interviews

We are also interested in how you find taking part in this study. At the end of phases 2 and 3, we may ask you to take part in an

interview about your experiences. This will be with a separate member of the research team and can be done face-to-face or over the telephone. We would like to record this discussion for later analysis if you allow us. This recording will be typed up anonymously and the tape will be erased.

PART 3: YOUR SAFETY AND RIGHTS

Do I have to take part?

No, you do not have to take part in the study. Taking part in this study is completely voluntary, you can refuse to take part. If you do choose to take part, you can withdraw from the study at any time, and do not have to give us a reason. This will not affect your future medical care. If you do withdraw, all information we have that might identify you will be removed from our files, only your anonymised data will be kept.

Reimbursement of travel expenses

Reasonable travel expenses will be paid to and from the study visits.

What will happen to the information you collect about me?

All information we collect about you will be kept strictly confidential. At the start of the study you will be assigned an identity (ID) number to protect your anonymity. This will be used on all questionnaires, forms and databases.

Any information we report, such as quotes from interviews, will also be kept anonymous. Your name will not be shown to anyone who is not part of study team. With your permission, we will inform your GP that you are taking part in case there is any reason you are not suitable for the study.

Confidentiality

Personal (identifiable) information will be kept up to three months after the research is complete. Non-identifiable information (using only your ID number) will be kept for a minimum of 10 years on a University of Dundee secure (password protected) server. Any paper documentation will be kept in a locked filing cabinet.

Are there any risks to me taking part in this study?

There are no known risks for you taking part in this study.

Who has reviewed the study?

The East of Scotland Research Ethics Service which has responsibility for scrutinising proposals for medical research on humans, has examined the study and has raised no objections. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Dundee and NHS Tayside whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

What if something goes wrong?

In the unlikely event that something goes wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Dundee or NHS Tayside but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). If you have a complaint about your participation in the study you should first talk to a researcher involved in your care. You

can ask to speak to a senior member of the research team or the Complaints Officer for NHS Tayside.

Complaints and Claims Manager
Ninewells Hospital, level 7
Freephone: 0800 027 5507

Complaints and Advice Team
Dundee DD1 9SY
nhstaysidecomplaints@thb.scot.nhs.uk

PART 4: WHAT HAPPENS NOW?

After receiving this information from the specialist cancer nurse involved in your hospital care, please return the pre-paid reply slip indicating whether or not you would be interested in taking part in the study. If you are interested, the research nurse Jacqui Sugden will contact you. When she does, she will be able to answer any questions you may have and provide any further information you need. You will be given at least 24 hours to consider taking part in the study. If you are interested in taking part Jacqui will then make arrangements for your first study visit and will pass your contact details to the lifestyle counsellors. At your first study visit, you will be asked to sign a consent form and, with your permission your GP will be informed that you are taking part and will be given a copy of this leaflet.

Where can I find out more information?
If you would like any further information or would like to discuss any particular aspects of the study you can contact the study coordinator **Jacqui Sugden** at the University of Dundee on 01382 383197. You may also wish to contact your GP if you would like any further advice about participating in research in general.

If you need to talk to the study team during the study you should call Jacqui on 01382 383197 or email on j.a.sugden@dundee.ac.uk

THANK YOU FOR TAKING THE TIME TO READ THROUGH THIS INFORMATION LEAFLET.

After reading this leaflet you should understand that:

- Your participation is entirely voluntary (**you** decide whether or not you want to take part) and you can withdraw at any time and your care will not be affected.

- Participating in the study will involve extra visits to hospital: four visits with the research nurse and three visits with the lifestyle counsellor. There will be a minimum of 12 telephone consultations with the lifestyle counsellor during the study.

- The study will start at diagnosis of colorectal cancer and will continue throughout treatment and post-operative recovery, a maximum of 31 weeks in total.

- Remaining in the study for all three phases is subject to clinical approval and the length of time of treatment plans.

- The study involves participating in a lifestyle advice programme about smoking cessation, alcohol intake, physical activity and diet.

- The study is funded by the Chief Scientist Office and is being led by the University of Dundee, together with the University of Stirling and NHS Tayside.

- The East of Scotland Research Ethics Service (responsible for scrutinising proposals for medical research on humans) has examined the proposal and has raised no objections from the point of view of medical ethics.