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CARER INFORMATION SHEET

'Malignant mesothelioma- Can we improve quality of life?'

We would like to invite you to take part in a research study. Before you decide whether to participate, we would like you to understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you if you wish.

Take your time and please ask questions. Talk to others about this if you wish.

PART 1 - INTRODUCTION

What is the purpose of this study?

Palliative care doctors and nurses are experts in treating symptoms from an illness. Palliative care is not just for the late stages of terminal illness any more. We would like to know if involving palliative care specialists for symptom control treatment earlier in the treatment of mesothelioma can improve the quality of life and wellbeing of patients throughout the course of their illness. We are also interested in how this specialist treatment may improve the wellbeing of family or friends, closest to the patient.

Why have I been invited?

Someone you know has recently been diagnosed with a cancer of the lining of the chest called mesothelioma. After discussion of their case with a number of different cancer specialists we have identified that you may be suitable to take part in this study.

Do I have to take part?

It is completely up to you whether you take part. If you decide not to, the patient will still receive all the necessary and appropriate treatment that they need.

We will go through what the study entails for both of you. If you are willing to take part, we will ask you and the patient to sign a consent form. Either of you can withdraw from the study at any time if you wish to do so. This will not affect any further treatment the patient would normally receive. If you do not wish to participate the patient may still take part in the study. You are also welcome to accompany him/ her to their study visits if you are both in agreement.

If you are still interested, please continue to Part 2.

PART 2 – WHAT DOES THE STUDY INVOLVE?

We cannot be sure that taking part in this study will make things better for you or the person you are caring for. However, we hope that the findings from this study will improve care and support for patients with mesothelioma and their carer's in the future.

What will happen to me if I consent to take part?

Patients will receive all usual treatments and support for their illness. In addition, some patients will be randomly selected, to receive extra treatment and support from the palliative care specialists. This specialist care will be from within a few weeks of the patient being diagnosed with mesothelioma.

If the patient is offered this early additional treatment and support, both of you will have an initial appointment with a Specialist Nurse in palliative care medicine which will last approximately 1 hour. This will be followed by appointments every 4 weeks which will last approximately 30 minutes for the duration of the study. This support is for both of you. The patient will also be offered all the other usual treatments.

If the patient is not selected for the early additional specialist symptom control treatment, they will still receive all the treatments and support that are usually offered. No treatment will be withheld from them at any time and if a referral to the palliative care team is felt to be of help to them, this will happen straight away.

I am the carer- What do I have to do?

As the main carer you will be asked to complete a set of questionnaires similar to those completed by the patient at the start of the study, at 12 weeks and at 24 weeks. This is because we are very keen to learn how this additional support will help you as a carer. All of these will help us to find out about both you and the patients quality of life during their illness.

The loss of the person you are caring for is always a difficult time for you as their carer. We would therefore like to see if the additional palliative care treatment and support helps the main caregiver cope. With your agreement, this would involve completing a final questionnaire over the telephone 24 weeks after bereavement.

We realise that these extra visits may not always be convenient for you. In recognition of this and in gratitude for your help we hope to lighten the burden of the commute to these visits by providing free transport.

What happens if the patient is selected for early symptom control treatment?

If the patient is selected to receive the early symptom control treatment and support we ask that you accompany them for an extra appointment with our palliative care specialists. This will be within 3 weeks of receiving the diagnosis and then every month. There are no extra blood tests to have or study medicines to take – all the treatment offered will be the same as any other patient in the NHS.

But isn't Palliative Care just about helping the dying?

Palliative Care provides support for physical symptoms, emotions such as stress and, worry, and spiritual needs (but not religious) for patients and families at any time during an illness. We would like to know if input from these specialists at a much earlier stage can improve the care both patients and carers receive.

What happens if the patient is not selected for early symptom control treatment? Will they miss out?

They will get the same treatment as everybody else who is not in this study. Most patients are referred to the palliative care team at some point in their illness. If needed, the patient will get all the extra treatment and support they need.

Everyone in the study will be asked to answer the same questionnaires, so that we can compare the responses between the two groups.

What are the possible benefits of taking part?

If you are in the early specialist symptom control treatment and support group it is possible that the person you are caring for may receive earlier support and attention for their symptoms and mood, but we do not know this for sure. By being cared for by the palliative care team earlier, both of you will have additional specialist nurses to ask for help should you need it.

What are the disadvantages of taking part?

As we are not testing any new medicine or device, there is no risk of extra pain, discomfort or side effects. The main thing we ask of you is a small amount of your time.

If you are not selected for the extra symptom control treatment group, the only thing we ask of you is to fill in questionnaires as already mentioned. If you are in the extra symptom control treatment group you will be asked to accompany the patient for an appointment with the palliative care specialists every 4 weeks.

PART 3 – FURTHER INFORMATION

Who has reviewed this study? Is it safe?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. They are there to protect you. This study has been given a favourable opinion by London – Hampstead Research Ethics Committee, reference 12/LO/0078. This means they have read about the study, interviewed the lead researcher and have no concerns with this project.

Why randomly select patients for this extra treatment?

Sometimes we don't know which treatments are best. To find out, we need to compare different treatments. We put people into different groups and give each group different treatment. The results

are then compared to see which one is better. To try to make sure the groups are the same at the start, each patient is put into a group by chance (randomly).

In this study there is a 50% chance of either being in the early specialist symptom control treatment and support group, or standard treatment. This is the same as tossing a coin.

Expenses and payments

We will pay for your travel and any other reasonable costs you have for coming to the extra appointments. There is no additional payment for taking part in this study.

What happens when the research study stops?

Once we have enough patients taking part in the study, we will stop inviting more to join. Those already taking part will continue to get all the additional treatment and support as they were getting before.

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

You can stop taking part in this study at any time. You do not have to give a reason to the research team. Your loved one's normal NHS treatment will not be affected in any way.

If you withdraw from the study, we will ensure that any personal information is either destroyed or kept with your medical notes. We may still like to use what information we have learnt from you taking part.

What happens if new medical information becomes available during the study?

Should new research appear, we may have to change what treatment and support we are giving. We will consider this carefully and contact both of you to discuss the options. The study might have to be stopped, or changed in some way. We will always do what is best for the patient.

Will my taking part in this study be kept confidential?

Any information given to the research team will be treated the same way as the patient's medical notes. Whilst not in use, any personal information will be kept locked up, usually within the research team offices.

Once your data is entered onto a computer we will stop using anything that may identify you (such as your name or date of birth). A unique study number will be used instead (a bit like a hospital number). This confidential anonymous data will only be used on password protected NHS or University computers in files that can only be used by authorised persons in the research team. After the study has finished it may take up to a year to calculate all the results. This study is only taking place in NHS hospitals in the UK.

What will happen to the results of the study?

Studies of this sort normally publish results in a medical journal. You or your family will not be identifiable in any way in the report. We will inform you of the results once the study has been completed if you wish.

Who is organising and funding this study?

The money to run this study is from a charity called the British Lung Foundation. Several NHS hospitals around the country including this one are taking part. The lead centre for this study is Portsmouth

Hospitals NHS Trust at Queen Alexandra Hospital. The doctors and nurses running this study will not receive any additional payments. No one involved in the study has any links to companies that may benefit financially from this research.

What if there is a problem?

If you have any complaints about how you are treated during the study you should contact the research staff (LOCAL NUMBER XXXXXX) who will try address any concerns or problems.

If you remain unhappy and wish to complain formally, you can do this by contacting your hospital's Patient Advice and Liaison Service (PALS). PALS can be contacted by phone (XXXXX XXXXXXX) or email (xxxx@xxxxxx).

In the event that something goes wrong and you are harmed during the research study due to someone's negligence then you may have grounds for legal action for compensation against the study sponsor (Portsmouth Hospitals NHS Trust) or the NHS Trust or NHS Board where you received your care. However, you may have to pay for your legal fees. The normal NHS complaints mechanisms will still be available to you.

Please take your time to think about this study. Talk to friends and family and let us know what you think.

PART 4 - FURTHER INFORMATION AND CONTACT DETAILS

We will try to answer all your questions. If you still would like to know more the following information might be useful:

Specific information about this research project

RESPECT-Meso website www.respect-meso.org

Please contact;

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- General information on research in the UK

Department of Health www.dh.gov.uk

The British Lung Foundation http://www.lunguk.org/

The National Council for Palliative Care http://www.ncpc.org.uk/

Mesothelioma UK www.mesothelioma.uk.com