CANAssess 2: Cancer Patients' Needs Assessment in Primary Care – A Cluster Randomised Controlled Trial

CARER INFORMATION SHEET

We would like to invite you to take part in a research study called CANAssess

A person to whom you provide support has agreed to take part in a research study called CANAssess. This study is taking place at their GP Surgery

This study is testing a way to better identify and manage the symptoms and concerns of people living with cancer.

Before you decide if you would like to take part, we would like you to understand what this involves.

Please read this information carefully and take time to decide whether you would like to take part. You can also discuss it with your relatives or friends if you wish.

You are free to decide whether or not to take part. If you choose not to it will not affect you or the person you provide support to in any way. The person to whom you provide support is still able to take part even if you do not wish to.

Thank you for reading this information sheet

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1. Why are we doing this study?

Sometimes, people living with cancer have physical and/or emotional symptoms and concerns that they would like help with.

The CANAssess study is looking at how to identify and manage the symptoms and concerns of people living with cancer.

To do this, we have developed a way to help the participant's GP or practice nurse identify what people living with cancer may need.

We will work with half of the GP surgeries that are taking part to use this new approach for some of their patients. These GP surgeries will be in the "**intervention**" group. The other half of GP surgeries that are taking part in the study will continue to deliver care in the same way as usual. These general practices will be in the "**usual care**" group.

Which GP surgeries will be in the intervention group has been decided by chance randomly (as if by the roll of a dice). This means that neither the GP surgery, nor the researchers who run the study have influenced the groups. In this way, we can compare the two groups at the end of the study.

2. Why am I being invited to take part?

We are inviting you to take part as you have been identified as a carer for a person that has also been invited to take part in CANAssess. By carer, we mean a person who you are close to and provide support to, but you may or may not be providing hands on personal care. You could be a relative, friend or neighbour.

3. What will happen if I take part?

Do I have to take part?

No, your participation is voluntary and you may withdraw your consent to take part at any time, without giving us a reason.

If you decide not to take part, your family member/friend's treatment and care will not be affected in any way, or their participation in CANAssess.

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

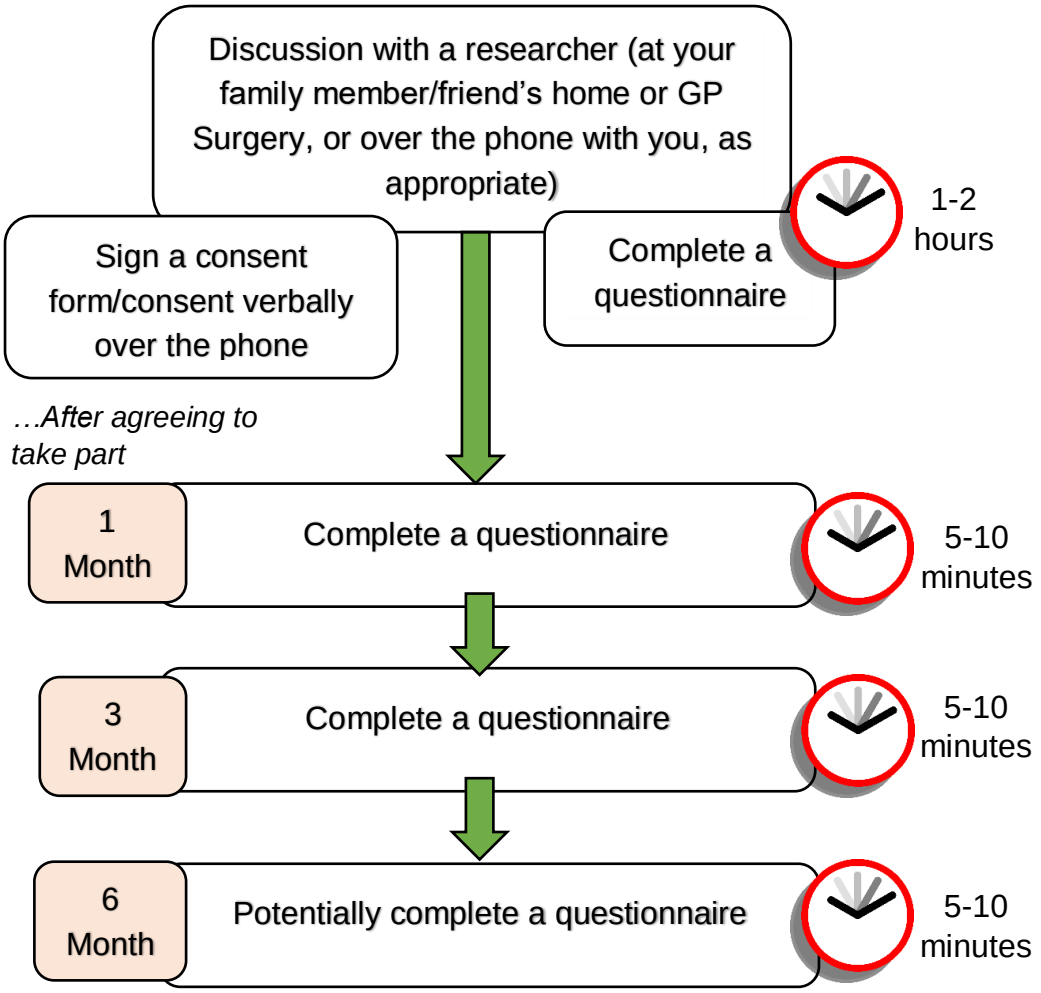
A researcher will discuss the study with you in more detail during the visit with the CANAssess participant or over the phone. We will ask you to sign a consent form to document your willingness to share information with us, or ask you to consent verbally over the phone. Phone conversations will not be recorded.

If you are willing to take part, the researcher will also:

- Ask you a few questions to ensure you are eligible to take part;
- Collect some information about you, for example, address, age, relationship to CANAssess participant;

- Ask you to complete a questionnaire about your general quality of life. This will take around 5-10 minutes to complete. You could complete this in person, over the phone, or online.

We will then contact you at 1 month, 3 months and potentially 6 months after you agree to take part to complete questionnaires again. This is so we can see any changes. These questionnaires may be completed by post or online.



4. What are the advantages and risks of taking part?

We hope that this study could help to identify the symptoms and concerns of people living with cancer, so that they can be best managed by the appropriate professional. However, we cannot say that every participant will experience an improvement.

Agreeing to take part in this study will mean giving up some of your time to complete questionnaires.

We do not expect any direct risks or disadvantages to taking part in this study.

5. Your personal information

What information will you ask me for?

The researcher will ask you to provide some general information about yourself and your relationship to the CANAssess participant.

We will also ask you some questions about your quality of life in the questionnaires.

How will my information be used?

We will need to use information from you for this research project. This information will include your:

- Name
- Contact details

People will use this information to do the research or to make sure that the research is being done properly.

The information needed for study purposes will be collected on paper forms and sent (usually using standard Royal Mail post, but in some cases by fax or secure email), or will be completed by you online and stored at the Clinical Trials Research Unit (CTRU) at the University of Leeds. Paper forms are sent from the researcher to the CTRU.

Your full name will be sent to the CTRU on your signed consent form so that we can check that you have definitely agreed to take part in the study.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. This code number will be used alongside the CANAssess participant's initials and date of birth.

Your name, address, phone number and email (if you have one) are collected on a contact details form for us to send questionnaires to your home address, send you a link to questionnaires by email or text, or collect questionnaire data from you over the phone, as appropriate. This form is sent to CTRU by post, fax or secure email. If you choose to complete questionnaires by post, we may send your questionnaire together with the CANAssess participant's questionnaire in a letter addressed to them.

We will keep all information about you safe and secure. Your data will be entered onto a secure database held at the CTRU. All access to data and databases will be restricted just to the staff who require access to process and analyse the data.

Can I see the data you have about me?

All information we have about you will be given to us by you. By taking part in this study, you agree to share this information with us.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Who is managing my information?

Under UK Data Protection laws the University of Hull and the University of Leeds will act as joint data controllers for this study. We will be using information from

you in order to undertake this study. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for at least 5 years after the study has finished.

If you withdraw from the study, or if you are no longer able to make your own decisions, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. We will not collect any further data.

You can find out more about how we use your information at https://ctru.leeds.ac.uk/privacy/.

As universities we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Who will see my information?

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. This includes information you have already provided if you stop taking part in the study. However, information will only be shared for worthwhile research projects with appropriate ethical approvals, only in such a way that no individual person can be identified, and only when we are sure the other researchers will manage your data correctly and securely. Sharing of clinical trial data is an important way to make the most of the time and effort required to carry out trials.

Will my taking part be kept confidential?

If you decide to participate in this study, the information collected about you will be handled confidentially and strictly in accordance with relevant data protection laws, including the Data Protection Act 2018.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

How long will you keep my information for?

Once we have finished the study, we will keep some of the data so we can check the results. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

6. Further details about the study

Who has organised, reviewed and funded the research and who will be supervising it?

This research is led by Professor Miriam Johnson based at the University of Hull. The sponsor is the University of Hull and the study is organised by the University of Leeds CTRU on their behalf.

All research is looked at by an independent committee of people called a Research Ethics Committee to protect your interests. This study has been reviewed and approved by the London-Surrey REC.

This study is funded by Yorkshire Cancer Research.

7. Frequently Asked Questions

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

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We would like to know the reason if you are willing to say. If you decide you would like to withdraw, you would need to tell us by contacting the research nurse listed on the front page of this information sheet. We would then stop asking you for information.

What if there is a problem?

If anything about your care, treatment or health worries you, you should speak to your GP. If you have a concern about any aspect of this study, you should ask to speak to your GP or practice manager at your GP surgery who can advise on local NHS complaints procedures or contact the customer contact centre/patient feedback service at your local Clinical Commissioning Group (CCG). Details can be found on the NHS Choices website. You can also contact the study team (contact details on first page) who will do their best to answer your questions. There are no special compensation arrangements in place for this study.

What will happen with the results of the study?

When the study is complete the results will be published in a medical journal and all GP surgeries will be sent a summary of the results. We will write our reports in a way that no-one can work out that you took part in the study. If you would like to obtain a copy of the published results, please ask your researcher.

Thank you for taking the time to read this information sheet.