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

PARTICIPANT INFORMATION SHEET

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

Your GP Surgery is taking part in a new study to test if there is a way to improve how to identify and manage the symptoms and concerns of people who have been diagnosed with cancer.

We believe that you may be able to help us by taking part in this study.

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

Please read this information carefully and take your time to decide whether or not you would like to take part. You can also discuss it with your relatives or friends if you wish.

We are also interested in learning about the experiences of a person who is close to you who provides you with support, but who may or may not be providing hands on personal care. This could be a family member, friend or neighbour.

You are free to decide whether or not to take part. If you choose not to it will not affect your care in any way.

You can keep this information sheet to remind you about the study.

If you have any questions please contact the study team using the details on this page or speak to somebody at your GP Surgery.

Thank you for reading this information sheet.

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Part 1 – Overview of CANAssess study

1. Why are we doing this study?

Sometimes, people living with a diagnosis of cancer have physical and/or other problems that they would like support with.

The CANAssess study is looking at how to identify and manage issues faced by people living with a diagnosis of cancer.

To do this, we have developed a way to help your GP or nurse identify any problems you may (or may not) be having for which you would like additional support.

The best way of finding out whether this approach is more effective than current usual care is in a randomised controlled study.

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 GP Surgeries 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 your 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 to see which is most helpful.

2. Why am I being invited to take part?

Your GP Surgery has agreed to take part in this research. Based on your records, you have been identified as someone who may be suitable to help us with this study.

We are asking whether you are willing to take part in order to find out whether the intervention improves the usual way of providing services.

We are hoping to involve around 1080 people in this study, from 54 GP Surgeries across Yorkshire and the North East.

3. What will happen if I take part?

Please also refer to section 5. 'What if we are socially distancing?'

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

If you decide to take part, a researcher will contact you to arrange a convenient time to visit you at your home or at your GP Surgery if you prefer.

At the visit, the researcher will check whether you are eligible to take part, discuss the study in more detail and answer any questions you may have. They will also ask you to sign a consent form to show you have understood and agree to what is involved in taking part.

During this visit, the researcher will also

- Ask you a few questions to ensure you are eligible to take part;
- Ask you to complete a questionnaire about your general health, quality of

life, and your use of care providers. You could complete this in person, over the phone, or online;
- Ask you a few questions about your physical ability; and
- Invite your carer to take part, if you have one you think might be interested in helping us with this study. By carer we mean any family member, friend or neighbour who supports you in a way that is important to you– they do not have to be providing "hands-on" personal care.

This first visit is likely to last 1 – 2 hours.

These questionnaires are likely to take between 30-45 minutes to complete.

We will also collect some information about you from your medical records at your GP Surgery.

We will then contact you 1 month, 3 months and potentially 6 months after you agree to take part to complete questionnaires again and to ask you verbal questions about your physical ability. This is so we can see whether there have been any changes in your care, concerns or physical ability.

If your GP Surgery is in the "intervention" group of the study, the Surgery will contact you to arrange an appointment with one of the doctors or nurses at the Surgery or arrange a home visit. If your GP Surgery is in the "usual care" group, you will not need to attend an appointment in addition to your usual contact with the Surgery.

Do I have to take part?

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

4. Your personal information

What information will you collect about me?

Alongside the questionnaires we will also collect information about your health and care from your medical records. We may need to collect data in this way until the end of the study period, even if you have completed your final questionnaires.

Data from me – questionnaires:

We will ask you to complete 3 questionnaires over a total of 3 months. Some participants will also be asked to complete a questionnaire at 6 months. The questionnaire will include questions about your health, quality of life, and your use of care providers.

The first questionnaire would be completed at the meeting with the researcher, either at your home or at your GP Surgery, and the researcher can help you to complete this. The same questionnaire would then be posted to your home address or sent to you as a link by email or text at 1 month, 3 months and potentially 6 months after you agree to take part. This is to see if anything has changed since you answered the questions at the meeting with the researcher. You can complete the questionnaire by yourself and return it via a free-post envelope, or submit it online. If you would like help in completing

the questionnaires, we can arrange for a researcher to either contact you to complete them over the phone, visit you at your home or meet you at the Surgery if you prefer. Please let us know if you change address or living circumstances.

If we don't receive your questionnaire, we will contact you by text message, phone or email to see if you need any help completing the questionnaire and check you are happy to continue in the study.

Data from me – phone calls:

We will call you when questionnaires are to be completed at 1 month, 3 months and potentially 6 months to ask you a couple of questions about your physical ability. If you have chosen for a researcher to help you complete questionnaires, the researcher will ask you these questions at the same time.

Data about me:

We would like to obtain information about you held within your medical records to avoid asking you more questions about your recent care. This may include any attendances, admissions, referrals, specialist care, and reported health and health conditions.

5. What if we are socially distancing?

Certain steps will not be possible if social distancing rules are enforced.

We would not be able to visit you at your home or at your GP Surgery when you agree to take part. In this case, we would collect your consent and data over the phone. Your consent form would be completed on your behalf and you would be sent a copy.

If your GP Surgery is in the "intervention" group, you would not be able to attend a face-to-face appointment with a GP. Instead, this appointment would be arranged remotely, either over the phone or via video chat.

We would not be able to visit you to help you complete questionnaires. We would phone you instead.

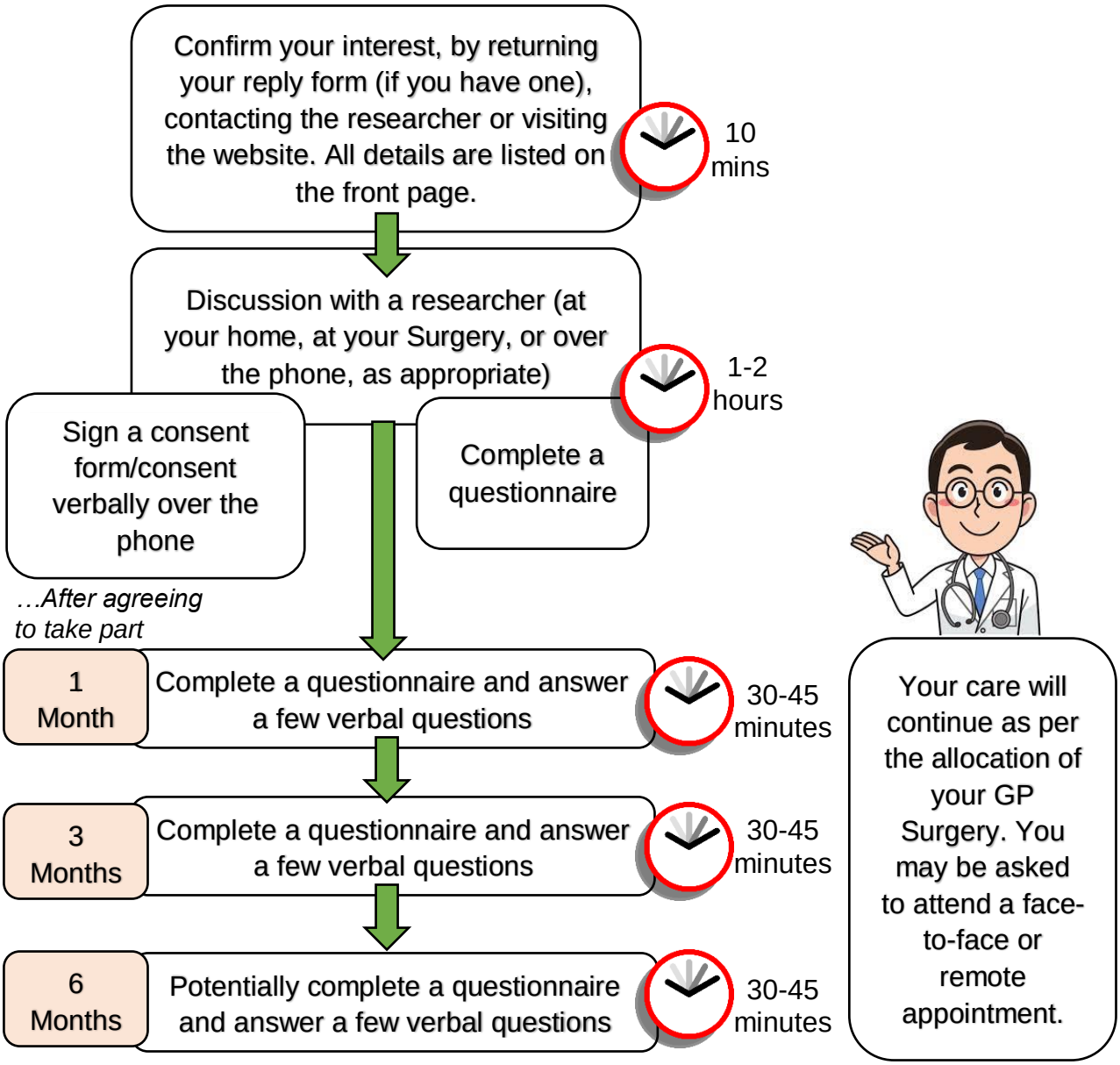
If social distancing rules are not enforced, but you don't feel comfortable with face-to-face contact, the above options will be available to you. Phone/video conversations will not be recorded.

6. 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 these can be effectively managed by the appropriate professional. However, we cannot say that you will experience an improvement in the care you receive, although your involvement in this study may help with how people with cancer are looked after in the future.

Agreeing to take part in this study will mean giving up some of your time to complete questionnaires, and allow the study team to obtain information about you from your medical records. Some, but not all, participants will also be requested to attend a GP/nurse appointment at their GP Surgery or at home.

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



7. 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. GPs and patients like you are also involved in organising the study.

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

This study is funded by Yorkshire Cancer Research.

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

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say.

Before deciding to stop, we ask you to talk to your GP Surgery or researcher. They can advise you and may be able to deal with any concerns that you have. If you decide to stop taking part at any time it will not affect the standard of care you receive.

If you decide not to take part anymore, we will keep the information we already have on file and this will be included in the final study analysis.

If you choose to stop taking part in the study, we won't collect any further data from you personally, but we would like to continue collecting information about your health from your medical records. If you do not want this to happen, tell us and we will stop.

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 happens if new information about the study becomes available?

Sometimes during the course of a study, new information becomes available. If this happens, the study team or your GP will let you know about it and you can decide if you want to continue in the study.

If you wanted to speak to anyone in the study team at any point about your participation, please use the contact details on the first page of this information sheet.

Will my GP be informed?

Your GP, and other doctors involved in your healthcare, will be kept informed of your participation in this study. However, we will not share information that you give to us with your GP, unless you disclose anything to us that we feel puts you or anyone else at risk.

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 GP.

Thank you for taking the time to read about the CANAssess study.

Please read Part 2 to find out about how your information will be used.

Part 2 – How will my information be used?

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

- Name
- Initials
- Date of birth
- NHS number
- Contact details

People will use this information to do the research or to check your records 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 secure electronic means), 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 or GP Surgery to the CTRU.

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 along with your date of birth and initials to identify you on each paper form. 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.

Your name, address, phone number, and email (if you have one) are collected on a contact details form for us to send questionnaires and updates about the study to your home address, send you a link by email or text, and to phone you to collect some additional data and/or help you with completing the questionnaires. If you are happy to receive text, phone or email reminders, these contact details are also collected. This form is sent to CTRU by post, or secure electronic means.

Every effort will be made to ensure that any further information about you that leaves the GP Surgery will have information removed so that you cannot be recognised from it; this information will usually be removed by a researcher, but may also be removed by the CTRU upon receipt.

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.

Your medical records may be looked at by authorised individuals from the research team, the University of Hull (the study Sponsor) or the regulatory authorities to check that the study is being carried out correctly.

Who is managing my information?

Under UK Data Protection law 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 and your medical records in order to undertake this study. This means that we are legally responsible for looking after information we collect about you and using it properly. We will keep identifiable

information about for at least 5 years after the study has finished.

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.

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. To safeguard your rights, we will use the minimum personally-identifiable information possible. We would like to continue collecting information about your health from your medical records. If you do not want this to happen, tell us and we will stop.

If your clinical care team determine that you have lost the ability to make your own decisions, you will be withdrawn from the study and we will keep the information we have already collected. However, no further study information will be collected.

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

As universities we use personally-identifiable information to conduct research to improve health, care and services. As publicly-funded organisations, 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.

What if I have a concern about the use of my information?

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer can be contacted using the following details:

- Email: DPO@leeds.ac.uk
- General postal address: University of Leeds, Leeds LS2 9JT, UK
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT
- Telephone number: +44 (0)113 243 1751

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.

Using your information for further research

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 will include sharing the information collected about your health and care with researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-egislation/uk-policy-framework-health-social-care-research/).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Thank you for taking the time to read about the CANAssess study.

What do I do now?

If you do not wish to participate**,** it would be helpful for us to understand your reasons if you would be happy to share them with us. If so, please complete the reply form (if you have one) letting us know and we will not contact you further. Alternatively, please contact us using the details on page 1 to let us know.

If you would like to participate**,** then please contact our research team by:

- Completing the reply slip and returning in the envelope provided (if applicable),
  OR
- Contacting us using the details provided on page 1

  OR
- Submitting your interest on the website