Participant Information Sheet

(Version 1.1 22/08/2024)

Title of study:	Psychological therapy Readiness and resourcing in Oncology – Support to Promote an Enhanced Response (PROSPER): a randomised clinical trial
Chief Investigator:	Dr Sam Malins

****Contact details of the researchers are given at the end****

Would you be interested in joining the PROSPER study?

- We are inviting you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.
- One of our team members will go through this information sheet with you and answer any questions you may have. Talk to others about the study if you wish, and ask us if there is anything that is not clear.
- Please take time to read the following information carefully and talk it through with others to decide if you would like to participate or not.

What is the purpose of the study?

Many patients receiving care for cancer experience mental health difficulties like depression. These difficulties can be helped with psychological therapies.

People who seek psychological support for these difficulties often face long waiting times before starting treatment, during which their mental health may worsen.

We have developed a Therapy Preparation Intervention that will aim to support cancer patients who are waiting for psychological treatment.

The intervention includes a session at the start of the wait, involving an explanation of what can help people gain the most benefit from psychological therapy sessions, goal setting, and automated text reminders of the session's content until psychological therapy begins.

This study aims to evaluate the effectiveness of such an intervention and assess whether a therapy preparation intervention combined with standard care is more effective than standard care alone.

Am I eligible to take part?

You have been invited to take part because:

(1) You have been accessing cancer care services.

(2) You reported that you are experiencing difficulties with symptoms of depression.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign an online consent form. If you decide to take part but then change your mind, you can withdraw at any time and without giving a reason. This would not affect your legal rights or access to care.

If you do not have access to the internet, we will receive your consent verbally over the phone. This consent process will be audio recorded. This recording serves as a clear record that you were informed about the study's details and provided your consent, ensuring transparency and compliance with ethical standards in research. The online consent form will be completed on your behalf and signed by the researcher. A copy of the signed consent form will be posted to you.

After consenting to take part in the study, with your consent, your GP will receive a letter letting them know that you are participating in the study and if you withdraw from it. This is standard practice in research studies.

What will I be asked to do?

Once we receive your consent:

- We will allocate you a unique study ID. This study ID will be used instead of your name to protect your confidentiality. Your name and contact details and your unique study ID will be stored in a spreadsheet, this is so that we can reidentify you if we need to. Access to the spreadsheet will be restricted to members of the research team and it will be destroyed at the end of the study.
- You will be emailed a link to complete an online questionnaire about your symptoms of depression, anxiety, general wellbeing, and use of health services (taking around 30 minutes).
- If you do not have access to the internet, a study researcher will call you at an agreed suitable time to complete the questionnaire with you.

After completion of the questionnaire, you will be put into one of two groups:

The process of determining which group you are allocated to will be completely at random and like tossing a coin, you will have a 50/50 chance of which group you are allocated to. We will do this because we want to see if the intervention is more effective in reducing depressive symptoms after psychological therapy compared to people who only receive psychological therapy. The random allocation to a group is used in research to make sure that the results are fair and reliable.

If put into Group 1:

You will receive an invitation to participate in the therapy preparation intervention whilst you are waiting for psychological therapy.

During the waiting period for psychological therapy, you will attend a remote therapy preparation session with a clinician from the East Midland Cancer Alliance Centre for Psychological Health. The session will last approximately 60 minutes.

This session will cover factors that could help you get the most out of psychological therapy, as well as helping you identify strategies to improve your experience of therapy.

After the session, you will receive personalised smart-texts from an automated system called Florence whilst you wait for your therapy sessions to start, reminding you about key parts of the session content:

First, you will receive a text message asking you to confirm that you would like to use the service. If you reply with the word "YES" you will receive the personalised smart-messages, every day or every other day three days a week. If at any time you would like to stop the smart-messages you can text the word "STOP" to 64711 and you will not receive any further messages. You never have to pay for any messages you send to the Florence system regardless of your mobile phone contract.

You will be asked if you are happy for the session to be audio/video recorded. You can ask for the recording to be stopped at any time without having to give a reason. The therapy preparation session or the remote interview recordings will be transcribed (as a Microsoft word document) for analysis. The transcription will be conducted using an automated system within the University of Nottingham, or by an NHS Trust-approved transcriber who has signed a confidentiality agreement After ensuring the accuracy of the transcripts and removing any identifiable information, such as names and places, the audio/video recordings will be promptly deleted by the research team. This process of checking, anonymising the transcripts and deleting the audio recording will take up to 15 working days. The psychological therapy will commence within four to ten weeks.

In addition, we will conduct remote interviews with some participants who take part in the PROSPER study. These interviews will last approximately 30 minutes. Taking part in the interview is optional. You can select your preference to take part in it or not on the participant consent form. We aim to interview between 20 and 30 participants. Interviews will be recorded and transcribed for analysis.

Individuals in Group 1 who provide consent to take part in the interview will be requested to complete a brief online feedback form immediately after the 60-90 minute session, sharing insights into what they found beneficial. This Feedback form will be used as a reminder of your thoughts about the session prior to and/or during the interview, as it is scheduled to occur after you complete your last questionnaire at 24-weeks.

If put into Group 2:

You will not be asked to take part in the Therapy Preparation Intervention but will receive your usual care.

The psychological therapy will commence within four to ten weeks.

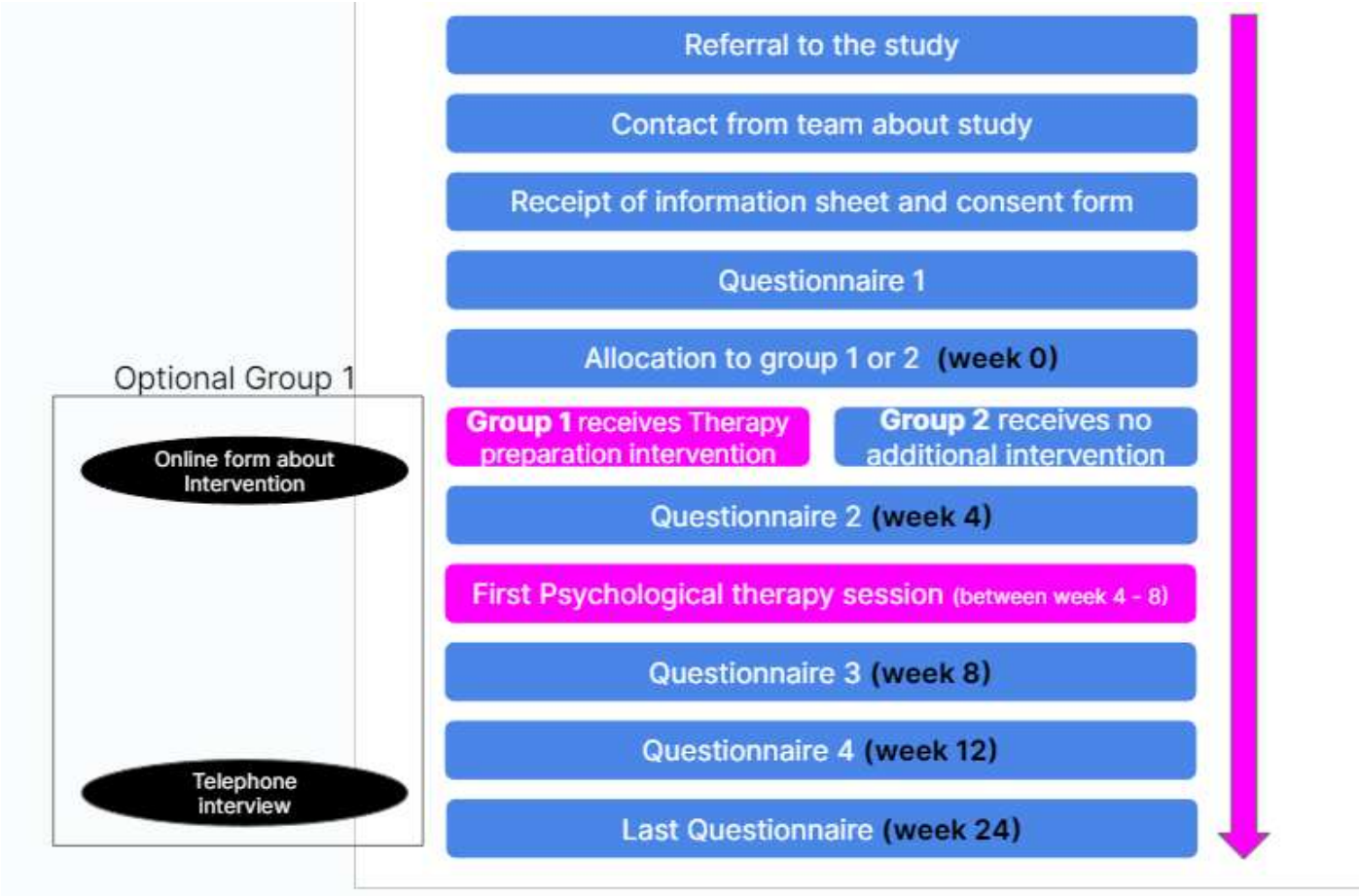
Whichever group you are in:

You will be asked to complete a questionnaire after 4, 8, 12 and 24 weeks. These can be completed over the phone or online, whichever is most suitable for you.

The questionnaires will be similar to the first one that you completed and should take between 20 and 30 minutes.

Taking part in this study will not influence or delay your normal care. After you finish the study, you will continue to receive your usual care.

Participant's journey throughout the study.



Will I be paid expenses for taking part?

Participation in the study is voluntary. Upon completion or exit, you will be given a £50 worth of Love to Shop voucher as a token of appreciation, £25 for completing the first survey questionnaire and £25 for completion of follow-up questionnaires. The vouchers are redeemable online. The vouchers will be emailed within two weeks following baseline completion/ the completion of the study activities. For those who do not have access to the internet the voucher code will be shared with them via text message.

Participants who prefer not to receive a voucher/reward can choose to opt out by contacting the research team. Contact details are available at the end of this information sheet.

What are the possible benefits of taking part?

Whilst we cannot guarantee personal benefits from participating in the study, the insights gained will inform our decision on whether this intervention could be offered as part of routine NHS care.

Your involvement in this study could contribute to enhancing psychological treatment options for individuals dealing with cancer.

What are the possible disadvantages and risks to taking part?

Taking part will require your time as detailed above and may therefore be inconvenient. However, because the intervention is delivered remotely, you will not need to travel or attend in-person sessions, which should save you some time and make it easier to fit into your schedule.

The regular texts may be perceived as unsolicited or inconvenient to you. You can request these to stop at any time.

For those in group 1, attending the Therapy Preparation Session, it is possible that thinking about current needs, hopes, and reasons for seeking therapy may be upsetting. However, you can stop at any time if you do not wish to continue.

If you find any aspect of the study assessments or interview distressing you can contact your usual care team, including your GP for support. If you would like faster access to support you can contact NHS 111 services or the Samaritans [116123]. If you require urgent, immediate support please contact 999 emergency services or your local Emergency Department.

How will we use information about you?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept strictly confidential, stored in a secure and password protected database. Under UK Data Protection laws Nottinghamshire Healthcare NHS Foundation Trust is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named below) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally identifiable information possible. You can find out more about how we use your information and to read our privacy notice at: (nottinghamshirehealthcare.nhs.uk)

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All personal identifiable information will be stored securely on University of Nottingham secure servers and will only be accessible to appropriately authorised staff, and may include the study sponsor or regulatory bodies if required.

The information we collect about you during this study will not only contribute to our current research but may also be used to support future research studies. To ensure your privacy, any data shared with other researchers will be completely anonymised, meaning that all identifying details will be removed. This ensures that your identity remains confidential while still allowing your information to contribute to further scientific knowledge.

The research team will not access your medical records or extract any data from them, access to medical records by the sponsor may be required for auditing/monitoring purposes. All individuals who have access to your information have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies. This information will be kept separately from the research data collected and only those who need to will have access to it. Please let us know if you don't want to be contacted.

During the conduct of the study, any personal information that you provide or that we collect will be kept confidential and will not be shared with anyone outside of the study team without your consent unless:

- You share information which suggests that there might be a risk of harm to you or someone else, or
- we are required to do so by law or,
- as the result of a court order.

What are your choices about how your information is used?

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 collected.

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.

Where can you find out more about how your information is used?

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team (contact details below)
- by emailing the sponsor's Data Protection Officer at DPOenquiries@nottshc.nhs.uk

Where will my data be stored?

The data obtained from the study will be stored securely on the University of Nottingham's cloud storage platform in password protected files and only the study researchers will have access to it. These security measures ensure that only authorised study researchers will have access to your data, maintaining the confidentiality and integrity of your information.

The final anonymous dataset from this study may be put in an Open Access repository for other researchers to use in future research. If so, responses will remain unidentifiable with any personal information (e.g., contact details) removed.

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

You are free to withdraw at any time, without giving a reason. If you want to withdraw from the study, please contact the study team using the contact information at the bottom of this information sheet, and your participation will be concluded).

If you choose to withdraw from the study, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained. This is because we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you choose to withdraw from the study, you will receive an optional online form seeking additional details about the reasons for your withdrawal. If you choose to complete the form, you will not be asked

to provide any personal information. Feedback about the reasons why people withdraw from research studies is valuable and will assist us in enhancing the delivery of this study and future studies.

Withdrawing from the PROSPER study will not affect your access to psychological therapy sessions for which you were originally referred. You will remain on the waiting list or proceed with your psychological therapy as planned with your therapist.

What will happen to the results of the research study?

The study outcomes will be used to determine the potential of the therapy preparation intervention in enhancing psychological therapy benefits for patients in cancer care. The results will also be written up as a report to the project funders and may be published in academic journals and/or presented at conferences. While anonymised quotes from participants may be used in these publications, your identity will remain confidential, and you will not be identifiable in any reports or publications.

When consenting to participate in the study, participants can choose to receive a lay summary of the study results and/or an invitation to a dissemination event where the study's findings will be presented.

Who is organising and funding the research?

This research is being conducted by the Nottinghamshire HealthCare NHS Foundation Trust and is being funded by the East Midland Cancer Alliance (EMCA) and supported by the Applied Research Collaboration East Midlands (ARC-EM) at the University of Nottingham.

Who has reviewed the study?

All research conducted within the Nottinghamshire Healthcare NHS Foundation Trust is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Bromley Research Ethics committee. The approval reference is: 24/LO/0610

The project has also been reviewed by the Health Research Authority, the Research and Evidence department at Nottinghamshire Healthcare Foundation Trust, researchers from the University of Nottingham who are specialised in mental health research, and the National Institute for Health and Care Research Applied Research Collaboration East Midlands (NIHR ARC-EM) scientific committee.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers, who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, using the details below.

Further information and contact details

Study shared mailbox: prosper@nottingham.ac.uk

Research coordinator:

Clement Boutry

clem.boutry@nottingham.ac.uk

Chief Investigator:

Dr Sam Malins

sam.malins@nottingham.ac.uk

Information compliance

Nottinghamshire Healthcare NHS Foundation Trust is the lead organisation and sponsor for this study and, will be the Data Controller for this study. This means that we are responsible for looking after your information and using it properly in accordance with the UK GDPR and the Data Protection Act (2018).

If you wish to make a complaint about the conduct of this study you can contact your Patient Experience Team (PALs).

You can also make complaints directly to the Information Commissioner's Office (ICO). The ICO is the independent authority upholding information rights for the UK. Their website is ico.org.uk and their telephone helpline number is 0303 123 1113.