



## Participant Information Sheet

### **Design of two new cancer measures: the Cancer Treatment Satisfaction Questionnaire (CancerTSQ) and the Cancer Symptom Rating Questionnaire (CancerSRQ).**

#### **Invitation**

*You are being invited to take part in the above research study. If you think you might be interested, it is important for you to understand why the research is being done and what it involves. Please read the following information carefully and discuss it with friends, relatives and relevant health professionals if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

*Thank you for reading this.*

#### **What is the purpose of the study?**

The core aim of this study is to improve the measurement and understanding of cancer treatment satisfaction and the frequency and impact of different symptoms of cancer and its effect on the individual. The aim of this study is to develop questionnaires that will enable treatment satisfaction and the impact of symptoms to be measured in people receiving treatment for cancer.

To do this, we are developing the Cancer Treatment Satisfaction Questionnaire (CancerTSQ) and the Cancer Symptom Rating Questionnaire (CancerSRQ). We expect that both of these questionnaires will improve routine cancer care and the evaluation of new cancer treatments. These measures will also provide a way of monitoring the impact of cancer and its treatments on patients' lives. We hope this will allow health professionals to support patients better.

The CancerTSQ and the CancerSRQ are being designed by Professor Clare Bradley and her research team. Her company, Health Psychology Research Ltd (HPR Ltd), manages the creation of new language versions and licenses her questionnaires for clinical and research use including use in pharmaceutical company clinical trials. One of the aims of this study is to validate the CancerTSQ and the CancerSRQ for use. This will allow new cancer treatments to be evaluated, helping identify which treatments are associated with greater treatment satisfaction and fewest symptoms.

We also aim to explore the relationships between the new CancerTSQ and CancerSRQ measures, and measures of cancer-related quality of life and general well-being.

#### **Why have I been given this invitation?**

You have been given this invitation because we understand you have received a cancer diagnosis, are undergoing treatment for cancer or have had treatment for cancer in the past 2 years, are over 18 years old and are fluent in English.

#### **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 you will be asked to sign a consent form. If you

decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If you decide not to take part, it will not affect your care. If you decide to withdraw from the study any information already collected from you will be retained and may be used in the study unless you request for your data to be withdrawn. No further data will be collected from you. If you withdraw from the study after you have participated you can request to have your data withdrawn, although this would need to happen prior to the data being used in analysis. In the very unlikely event that you were to lose capacity to take part during the study your data would be withdrawn in full.

### **What will happen to me if I take part?**

If you agree to take part in the study you may be asked to take part in an online or telephone interview, or alternatively, to complete some questionnaires.

#### *Taking part in an online/telephone interview*

If you agree to take part in an online/telephone interview, you will be asked questions about your cancer, its treatment and any symptoms or side-effects you have experienced as a result of cancer and/or its treatment. Taking part in an interview will also involve completion of a demographic information sheet and draft versions of the CancerTSQ and the CancerSRQ. The questionnaires will ask about your satisfaction with your cancer treatment and about the presence and impact of any symptoms you have experienced as a result of your cancer and/or its treatment. You can decide not to answer any question if you prefer not to.

You will be asked to provide some general feedback about how you found the questionnaires and will also be asked questions about your experience of filling them out. This will help us to improve the questionnaires for future use. The aim is to identify any questions that need to be added, are not that relevant or need a change of wording.

We will also ask you to look at the Well-being Questionnaire (W-BQ), which was developed previously by Professor Bradley and her research team. The W-BQ has been adapted for online use. During interviews we will ask for your views on the layout, response options and format of the electronic version of the questionnaire.

We expect the whole interview to take about 1 hour. We will ask for your permission to audio or video record the interview. We will only record the interview if you give your consent to do so.

#### *Taking part by completing questionnaires*

If you do not wish to take part in an online/telephone interview, or if we already have enough volunteers for this part of the study, you can volunteer to complete a pack of questionnaires. The questionnaires will include a demographic information sheet and the CancerTSQ and CancerSRQ. We will also ask you to complete two additional questionnaires which ask about your quality of life, using the Cancer Dependent Quality of Life questionnaire (CancerDQoL) and general well-being, using the W-BQ. We will send the questionnaires to you by email after we have completed the interview phase of the research.

You will not be required to have additional tests or receive extra drugs/medicines.

### **What are the possible disadvantages and risks of taking part?**

There are no risks to your health and your treatment will not be affected whether or not you agree to take part in this study. It is possible that some of the questions could cause distress, however in our experience of developing such questionnaires for people with other conditions, we have found this is unlikely. In the event that the questionnaires do cause upset and you require support, we will not contact your GP or your consultant oncologist. Instead, we will advise that you contact your local Maggie's Centre, the medical team involved in your cancer care, and/or your GP.

**What are the possible benefits of taking part?**

There are no direct benefits from taking part in the study but we hope that this research will help lots of people in the future. The two new questionnaires will offer a way of assessing patient satisfaction with cancer treatments and the frequency and impact of cancer symptoms. We expect they will help to optimise routine care and find new treatments that patients see as beneficial.

**What will happen after my participation?**

In this stage of the study we will be interviewing approximately 30 people with different types of cancer and revising the draft version of the CancerTSQ and CancerSRQ to take their feedback into account. Then, the questionnaires will be given to a larger number of patients who have experienced cancer and its treatment in the past two years, and the results will be analysed to check that the questionnaires are working as expected.

If you would like to find out about the progress of the study you can visit [www.healthpsychologyresearch.com](http://www.healthpsychologyresearch.com) for news of the project. The website will include a news item initially and, in due course, abstracts, posters and publications.

**What if something goes wrong?**

It is very unlikely that anything will go wrong. However, if you have any concerns about the study, you can contact a member of the research team using the contact details at the end of this information sheet.

If you are harmed in any way by taking part in this research project, there are no special compensation arrangements. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the research team.

**How will my data be stored?**

Your data will be collected and stored in accordance with the Data Protection Act 2018. All information which is collected about you during the course of the research will be kept strictly confidential and will be used only for research purposes. The researchers alone will have access to the questionnaires you complete and, in the computerised data, your data will be referred to only by a number. Any information about you will be stored separately from your signed consent form and your name and address so that you cannot be recognised from the information you provided. We may use some of your feedback about your experience of a diagnosis of cancer to assist in the drafting of future questionnaires. However, no confidential information will be shared outside of this study.

Your personal data will be kept for at least 5 years once the current research has ended. The personal data will be stored securely electronically at Health Psychology Research (HPR) Ltd and deleted after that time. Unnamed digital recordings of the interviews, completed questionnaires and notes will be kept for 10 years or until dissemination is complete whichever is the longer. The interview recordings are kept for 10 years or until dissemination is complete to allow time to analyse and publish the results of the study, as well as to respond to any queries. All research data will be unnamed, identified only by a number, and stored securely to ensure confidentiality.

There is a possibility that the study will be audited by independent bodies, to verify that the research has been carried out in accordance with NHS Health Research Authority protocol and in line with the Data Protection Act 2018. They may have access to the consent forms, transcripts and questionnaire data.

**Who is the Sponsor and Data Controller for this project?**

Health Psychology Research Limited (HPR Ltd) is the sponsor for this study. HPR Ltd is also the Data Controller for this project. HPR Ltd has responsibility for the protection of any personal information collected for this study and to ensure that it is used properly. The Data Controller has legal accountabilities to ensure that this study is compliant with the Data Protection Act 2018.

**What will happen to the results of the research study?**

It is anticipated that the results of this study will be published in a national or international journal. You will not be identified in any report or publication.

**Who is organising and funding the research?**

HPR Ltd will fund some of the costs of the study. The study is being carried out by Dr Michelle Taylor, Dr Charles Gilbride and Professor Clare Bradley. The project has been organised in collaboration with Dr Lesley Howells, Lead Consultant Clinical Psychologist and Research Manager at Maggie's and Dr Melanie Powell, Dr Virginia Wolstenholme and Dr Karen Tipples, Consultant Clinical Oncologists at St Bartholomew's Hospital, London. The professionals collaborating in this research will not receive any payments for their input other than their usual salaries.

**Who has reviewed the study?**

All research is looked at by a group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the Dulwich Research Ethics Committee (Reference no. 22/LO/0490).

**Contacts for Further Information**

If you require additional information, please contact:

Dr Michelle Taylor

Email: [mt@healthpsychologyresearch.com](mailto:mt@healthpsychologyresearch.com)

Dr Charles Gilbride

Email: [cjg@healthpsychologyresearch.com](mailto:cjg@healthpsychologyresearch.com)

or, Professor Clare Bradley

Email: [cb@healthpsychologyresearch.com](mailto:cb@healthpsychologyresearch.com)

Address: Health Psychology Research Limited, 188 High Street, Egham, Surrey, TW20 9ED

Telephone: 01784 818888

**Thank you for reading this.  
We hope you agree to take part in this study**

**You will be given a copy of this information sheet and a signed consent form to keep for reference and in case you wish to contact us with any queries.**