Can Talk: A study to compare usual treatment with a talking therapy to see which is more helpful to improve mood in people with cancer

Patient Information Sheet

We are inviting you to take part in a research study, because low mood is common in people with cancer. It is important to read this information sheet first as it explains why the research is being done and what is will involve. Please do ask if there is anything that is not clear, or if you would like more information.

Purpose of the study
The Department of Health aims to improve the care of people with cancer who may have low mood. We have developed a study to comparing Treatment As Usual (TAU), (which might or might not include counselling), with TAU plus CBT for low mood; CBT is a talking therapy that is widely used to help improve mood.

Why you have been chosen
You have been chosen because you have a diagnosis of cancer and may have low mood. We aim to recruit 240 people, from cancer clinics in London and from GP practices in London as well as locations across the UK.

Do I have to take part?
No it is up to you to decide whether or not to take part. Your decision will not affect the care that you receive. Should you decline, please be assured that no further effort will be made to make you reconsider.

Taking part in the study
If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form after 48 hours. Even if you do decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the care that you receive. If you withdraw from the study, we will still use the information given in your questionnaires unless you request otherwise, in which case, the data will be destroyed.

What if there is a problem?
We do not anticipate anybody to come to any harm by taking part in this study. However, information is included at the end of this sheet informing you about the process of dealing with any complaints or harm you feel you may have encountered in relation to the trial.

What do I have to do?
All participants at the beginning of the study will complete 5 questionnaires about your health and healthcare, with the help of a researcher, which will take about 45 minutes. You will then be allocated by chance into one of 2 groups.

Which treatment group?
You have a 50:50 chance of being put into either group. It is important what we have 2 groups in order to compare what happens to people in each group, to help us to decide which treatment is most helpful for people with low mood. Participants in the first group will continue to have treatment as usual, their normal care. If you are allocated to the talking therapy (CBT) group you will continue to have your usual care and be offered in addition up to 12 sessions of CBT each up to 1 hour long over a period of 3 months. This will be given by a CBT specialist locally.

How long will I be in the study?
The length of time that you will be in the study is 6 months for participants in both groups. You will be asked to complete some follow-up questionnaires at 6, 12, 18 and 24 weeks either in person with the researcher, or on the phone or online, whichever is more convenient.

Benefits of taking part
The main benefit of taking part is to identify people with low mood and see which treatment is of most help. This will also ensure that other people in a similar situation are helped in the future.

Harm of taking part
The talking therapy CBT is not known to cause any harm. The only disadvantage is that it will take up a little of your time.

What if there is a problem?
Every care will be taken during the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects you may have experienced due to your participation in the research you should speak to the chief investigator Dr Marc Serfaty on 0207 679 9712 who will do his best to answer your questions. If you remain unhappy and suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation formally. You must firstly discuss this with your research doctor then if you wish to make a claim you must do so in writing to Dr Marc Serfaty, Chief Investigator for the CanTalk study, based at the Division of Psychiatry, University College London. He will pass the claim to the Sponsor's Insurer's, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this. You are also entitled to complain through the NHS Complaints Procedure. Please ask your research doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk

Confidentiality
All information that is collected about you during the course of the research will be kept strictly confidential. Any personal/medical information will have your name and address removed so that you cannot be identified from it. All data will be handled, processed, stored and destroyed in accordance with the Data Protection Act (1998).

Results of the research study
The results of the study will be published in scientific journals and at academic meetings. All information collected during the study will be added together to form the results, so it will not be possible to identify any individual in any report or publication. If you would like a copy of the results, these will be available from Dr Marc Serfaty, UCL Division of Psychiatry, First Floor Charles Bell House, 67-73 Riding House Street, London W1W 7EJ.

Funding and review of the research study
This research is funded by the Department of Health. It has been approved by an Ethics Committee – NRES Committee London- Camberwell St Giles.

Contact for further information
For further information please contact the CanTalk researchers (Kirsty Bennett, Georgina Forden or Cate Barlow), Division of Psychiatry, UCL, Telephone 0207 679 9717. Or you can contact the Trial Manager, Deborah Haworth on 0207 679 9209.

Thank you for your time reading this information sheet and for considering taking part in this study.