ToSCA – Trial of Sertraline versus Cognitive Behavioural Therapy for generalized Anxiety disorder

Participant Information Sheet

This information sheet is designed to give you information about a research study comparing whether a medication (Sertraline) or a talking therapy (Cognitive Behavioural Therapy) is the better treatment for people with generalised anxiety disorder.

Invitation to take part

You are being invited to take part in our research study exploring treatment of Generalised Anxiety Disorder (GAD). Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please read the following information carefully and discuss it with others, such as your family or friends if you wish. Take your time to decide whether or not you wish to take part. If you are interested in taking part a member of the research teams will go through this information with you and answer any questions. Thank you for reading this.

Why are we doing the study?

GAD is common, causes unpleasant symptoms and affects people's functioning.

It is often chronic and may be accompanied by depression or other anxiety disorders.

Those taking part will have already had low intensity psychological therapy for this condition, but still continue to experience a certain level of symptoms. There are two treatments recommended for GAD when treatment of the kind you have already had has not helped enough. One is a type of medication (Sertraline), the other is a psychological therapy (CBT). Both have been found in many research studies to be effective, but they have never been directly compared. This is a national study comparing these two kinds of treatment to see whether one is more effective. We are very keen to find out more about patients' experiences of treatment and recovery and will be following all participants over the course of a year.

This research will inform future treatment of GAD. We will compare the clinical and cost effectiveness of the two treatments after one year. Findings from the research will help clinicians and service providers to choose the best treatment for people with GAD.

Why have I been chosen to take part?

We are approaching people who are aged 18 years and older who have attended local psychology (IAPT) services for low intensity treatment, but who are still experiencing symptoms likely to be due to GAD. We would like to offer such people further, more intensive, treatment. We are hoping to recruit 360 people nationally to take part.

Do I have to take part?

No, it is up to you whether or not you take part in this study. Whether or not you decide to be involved will not affect the care you receive from your general practice or local psychology service (IAPT). If you would like more information to help you make a decision, please contact the research team using their contact details on the back page.

If you are interested in taking part you will be contacted by a researcher who will arrange a time to go through the study in more detail at a location convenient for you. At this point you will also have the opportunity to raise any questions about the study. You do not have to take part unless you feel completely happy with what you are being asked to do. If you agree to take part, the researcher will ask you to complete a consent form and you will be given a copy. You are free to withdraw at any time without giving a reason. If you do decide to stop taking part we will destroy all identifiable information about you and any recordings.

What will taking part involve?

As you have said you may be interested in the study the research team will contact you shortly by phone, email or letter (whichever suits you best) offering you an appointment to meet with a member of the team. At that appointment you will be given the chance to ask any questions which you may have about the trial and we will make sure that you understand what the research is about.

If you would like to take part in the trial after this discussion we will need to check that you meet a few entry requirements. We have already asked for your permission to contact your GP to ensure there are no medical reasons why you cannot be involved.

We will ask you to sign a consent form before checking your worry and anxiety symptoms to see whether you are suitable to take part. If you are suitable and still want to be involved we will also ask you to complete a few simple questionnaires asking about symptoms of anxiety, depression,

quality of life and your general functioning at this first meeting. This whole interview and assessment should take about one hour.

Women of child bearing potential will be asked to complete a urine pregnancy test at the initial interview, before completing the study assessments, to make sure that they are not pregnant when entering the study. This test will be provided by the researcher.

This is because there is uncertainty about the effect of sertraline on the unborn child and we will therefore not be including any women who are pregnant or planning pregnancy in the near future or breastfeeding, in case they are allocated to the medication group of the trial. For this reason we advise use of contraception for anyone included in the medication arm of the trial in order to avoid pregnancy.

You will be asked to complete the brief questionnaires asking about anxiety, depression and quality of life again at 3 monthly intervals during the year that you are involved in the trial. These will be sent to you by post or email – whichever you prefer. You will be asked to have a further meeting with a member of the research team to review how things have gone 12 months after your first appointment and will be asked to complete the same questionnaires again, as well as the measure of your general functioning. This should take about one hour and can take place at a location that suits you best.

How do you decide which treatment group I am in?

This study is what we call a 'randomised trial'. At the moment we do not know whether the medication Sertraline or CBT will be more helpful in improving people's worry and anxiety in the longer term. We need to compare the two by choosing people to receive one of these two approaches. A computer will be used to pick names at random and put them into one of the two groups. The computer has no information about people, so selection is by chance. You will be told which group you are in by the research team within two working days of the first meeting.

If you are in the group receiving the medication Sertraline

You will be asked to see your GP for this – the research team will have already checked that your general practice is happy to provide this medication for you and will let them know that you are in this trial group. We will ask the GPs prescribing Sertraline and the participants taking this medication to continue doing so for 12 months if possible, in order to investigate its longer-term effectiveness. You will be reviewed regularly by your GP over this time, who will be acting in your best interests at all times. In order to do this, they will ask you to attend for six visits over the 12 months of the study.

Sertraline has been prescribed for many millions of people worldwide for symptoms such as depression and panic and found to be very safe. However, it does not yet have marketing authorisation specifically for treating generalised anxiety, so your GP will need to check that you understand this before prescribing it for you. This does not mean that the medication is unsafe; indeed, many studies have shown it to be safe and effective and it has been selected by the

National Institute for Clinical Excellence (NICE) as the medication most likely to be effective for generalised anxiety. If you are in this group we advise use of contraception while you are taking part in the trial to avoid pregnancy.

If you are in the group receiving Cognitive Behavioural Therapy (CBT)

You will be asked to attend between 14 and 16 weekly sessions of about an hour each with a specially trained therapist. Sessions will be tape recorded to ensure that everyone taking part receives the same quality treatment. These recordings may be used in the supervision sessions for the therapists – this is usual clinical practice with this form of therapy. You will also be asked to complete some standard brief questionnaires at each of the weekly sessions.

How will this affect my usual treatment from my GP?

Taking part in this trial should not affect the treatment you get from your GP in any way. People being prescribed the medication Sertraline by their GP will be regularly reviewed for this and should feel free to discuss any concerns they may have about this treatment or any other medical problems they may be experiencing. Those receiving CBT should feel free to attend their GP as usual.

Are there any disadvantages in taking part?

You will be asked to complete some questionnaires every three months for a year but we will keep these as short and simple as possible, so they should only take 10 to 15 minutes to complete each time. All information will be kept confidential and identifiable only by a special code number, not your name.

Do the treatments have any side-effects?

Some people can get side-effects when starting to take the medication Sertraline, such as feeling giddy, a bit sick or getting a headache, but these are usually mild and short-lived. In a few cases it can make people's anxiety worse to start with, but we are asking people who will be taking the medication to start on a very low dose to minimize the chance of them getting any of these side-effects. Any possible side-effects will be listed on the leaflet accompanying the treatment when prescribed and your GP will be happy to discuss these with you. You will also be given a telephone number to contact the research team if you are concerned.

It is rare to get side-effects from talking or psychological treatments, but some people occasionally find it upsetting talking about their problems with another person, although this usually improves as you get to know them better. If you find it very upsetting you should discuss this with the therapist, and may also wish to mention it to your GP or to the research team via the contact number you will be given.

What are the possible benefits of taking part?

Both treatments offered in this trial are likely to be effective in helping treat your anxiety symptoms, so you should benefit from whichever treatment you are given. The reason we are running this trial is because we are unsure which of the two treatments is best for whom. We will ensure that both treatments are delivered to the highest clinical and quality standards and we will be monitoring your progress throughout.

What are the alternatives for treatment?

If you decide that you are unhappy with the treatment you are offered or think that it isn't effective, you should discuss this with your GP who can suggest a different medication or psychological therapy for you to try. Possible alternative treatments suggested by NICE include several other medications or an addition to the CBT called applied relaxation. (Other psychological/talking therapies have not been recommended by NICE because of a lack of evidence). The two treatments we are using in this trial were given the highest effectiveness ratings for GAD by the NICE panel which is why we are testing them against each other.

What if relevant new information becomes available?

Sometimes we get new information about the treatments being studied. We don't think this is very likely to be the case, but if it happens, we will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, we will make arrangements for your care to continue. If you decide to continue in the study we will ask you to sign an updated consent form. If the study is stopped for any other reason, we will tell you why and arrange your continuing care.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the study will be kept strictly confidential and in accordance with the Data Protection Act 1998. Any information about you that we collect will have your name and any other identifiable details removed and will be given a special code number. This code number will also be used to identify the questionnaires that you are sent, and the key to the code will be kept in a locked cabinet at the research centre at University College London. Any identifiable information will be stored separately and securely at the research centre at UCL. Only members of the research team and responsible people authorized by the Sponsor, regulatory authorities or from the NHS Trusts involved will have access to this data. All essential documents will be kept in a safe and secure place for a minimum of 5 years after completion of the trial, in case there are any queries raised about the data collected.

Although your GP will be aware that you are taking part in the study, and will know which treatment you are receiving, (s)he will not have access to any other data you provide as part of the research study (e.g. your answers to the questionnaires).

What happens when the research study stops?

We hope that by the time the research study is finished, you will be feeling better, however, if you are not, you will be able to talk to your GP about this and they will be able to arrange for you to have any further treatment necessary.

What will happen to the results of the research study?

None of the people taking part in the study will be identified in reports or publications. The study results will be presented at conferences and published in relevant medical journals. We will send you a brief summary of the results at the end of the study. Copies of any publications can be obtained from the study organisers and sent to any study participants and GPs who wish to have them.

Who is organising and funding the research?

The study is being organised by the Research Department of Primary Care and Population Health, University College London. Funding is from the National Institute for Health Research (NIHR) Health Technology Assessment. Researchers are not paid above their normal salaries if you take part in the study.

Who has reviewed this study?

This study has been reviewed and approved for its scientific methods by independent researchers in the field appointed by the research funder.

In addition, all research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Brent Research Ethics Committee (REC reference 14/LO/2105).

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions – please see details below.

If you remain unhappy and wish to complain formally, you can do this through your local Clinical Commissioning Group (CCG) Complaints Procedure. Details can be obtained from the relevant CCG. A member of the research team can help you to get these.

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) negligence then you may be able to claim compensation.

After discussing this with a member of the research team, please make the claim in writing to Dr Marta Buszewicz who is the Chief Investigator for the clinical trial and is based at the

Department of Primary Care and Population Health at University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, 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.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with a member of the research team (details given at the end of this letter) in the same way as above.

Regardless of this, 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 (adverse events) you may have experienced due to your participation in the clinical trial, the normal National Health Service complaints mechanisms are available to you. Please ask your study 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.

What if I have any questions or concerns about the study?

We are providing contact details and telephone numbers and email addresses so you can contact us if you have any questions at any point. We will be happy to ring you back if you wish.

Thank you for taking the time to read this.

Yours sincerely,

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