The University Of Sheffield.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Participant Information Sheet

Cognitive Behavioural Therapy Software for the Treatment of Depression in People with Multiple Sclerosis: pilot trial

Invitation
You are being invited to take part in a research study which is being carried out by the University of Sheffield. It is important that you understand why this research is being done and what is involved. Please take time to read the following information.

What is the purpose of the project?
We would like to know how a treatment for depression, computerised cognitive behavioural therapy (CCBT), works for people with MS.

Why have I been chosen?
We want 24 people to complete eight weekly sessions of CCBT. This information can help us to design a much larger clinical trial which will confirm whether CCBT is an effective treatment for depression in people with multiple sclerosis. You have been asked to participate because you have MS, you experience low mood and may benefit from CCBT. Anyone assessed as suffering with severe depression or seriously contemplating suicide would not be recruited to this study.

Do I have to take part?
It is up to you to decide whether or not to be involved with this research. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You are free to withdraw at any time without giving a reason.

What will happen to me if I agree to take part?
We will ask you to start using a software package called *Beating The Blues* either now or in six months time. If you are asked to start immediately, we will tell you whether we want you to use the software at home or in a primary care facility. We will ask you to arrange a schedule of eight sessions. We expect that using the software and feeding back to us will take about an hour each week. We will contact you after the first week to check that you are okay to continue: this will take about five minutes. We also want to carry out a short telephone interview after you finish using *Beating The Blues*. We will ask for your permission to tape record the interview so that we can use the information that you share with us in our research. You will be asked to fill in five short forms evaluating different aspects of your health and quality of life at the beginning of the study, after eight weeks and after a further three months.

Why do you want to ask my consultant about my MS?
We want to ensure that CCBT is appropriate for all people with MS. With this in mind we need to select people with all types of MS and with different levels of disability.

Why do you want to tell my GP that I am taking part in the study?
It essential to notify a participant's GP so they are aware of what treatment you are receiving.

Will my taking part in this project otherwise be kept confidential?
All information that you provide will be strictly confidential and no individuals will be identifiable in any reports or publications. No information collected will be shown to anyone apart from the University of Sheffield research team and your consultant neurologist. If, during screening or the study itself, we

become concerned that you may be actively contemplating suicide, we will inform your consultant neurologist. Transcripts and recordings will be kept in a locked cabinet. Transcripts will be anonymised and parts in which participants might be identified will be avoided in publications. For regulatory purposes, data from the study will be stored securely for at least 5 years following the study and destroyed as confidential waste thereafter.

What are the possible disadvantages and risks of taking part in this research?

As with any psychological intervention, it is possible that thinking about your feelings and emotions may cause you some distress. Additionally, while CCBT is recommended NHS treatment for adults with mild to moderate depression, it does not work for everybody.

What if I am Harmed?

If you are harmed by your participation in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action.

What if something else goes wrong?

If there is a problem with our research please contact the *study manager, Dr. Daniel Hind*, at the University of Sheffield on the contact number given below. If your complaint is not handled to your satisfaction then please contact Dr. David Fletcher the 'Registrar and Secretary' of the University of Sheffield by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN) telephone (0114 222 1100) or e-mail (D.E.Fletcher@sheffield.ac.uk).

Who is funding the research?

The MS Society is funding this research and it is being undertaken by the University of Sheffield. The project has received ethical approval from the NHS National Research Ethics Service.

Will you pay travel expenses incurred through participation?

The costs of public transport to and from sessions will be fully reimbursed; car drivers will be reimbursed at the rate of 40p per mile.

What will happen to the results of the research study?

This research will take place over a year, after which the results will be presented to the MS Society in a report. The information will also be presented at academic conferences and will be published in research journals. You will also be able to access the results of the study on the University of Sheffield website at: *www.shef.ac.uk/ctru*

Contact for further information:

Dr. Daniel Hind, Clinical Trials Research Unit, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA, Tel: 0114 2220707

This information sheet is for you to keep. Thank you for your time and help.