Part 1

1. **What is the purpose of the study?**

The aim of this study is to determine if altering the pattern of your sleep and having light therapy can speed up the treatment of your depression.

2. **Why have I been chosen?**

You have been chosen because you are currently suffering from depression.

3. **Do I have to take part?**

No, it is entirely up to you to decide whether to take part. If you do not want to take part that’s OK. Your decision will not affect the quality of care you receive. We will
give you an opportunity to ask any questions you may have. We will then give you this information sheet to read in your own time.

If you agree to take part, we will ask you to sign a consent form to show you have agreed to take part. However, even after giving consent to take part; you are free to withdraw at any time, without giving a reason, by contacting the researchers at the end of this information leaflet.

4. What will I need to do if I take part?

If you decide to take part, you will be interviewed by a research worker who will ask about your condition and to complete various questionnaires. If you are taking medication for depression, this should be kept at the same dose. You and your doctor should not be planning to change the dose of your current medication or to start a new medication for depression in the next 4 weeks. You should continue to receive any talking therapy or other treatments for depression.

If you choose to participate, you will be given a wristband to wear for 3 days before the new treatment begins and for 7 days after the treatment. During this time you will also be asked to rate your mood on a daily basis. You will be allocated by chance to one of the two new treatments described below. This is illustrated with the flowchart on the next page:

1) **Sleep Therapy and a Light Box:** You will be given information and advice on how to get a good night’s sleep. You will be also given a light box to use in the morning for 1 week. For the light box, you will be asked to sit about one foot away from a light box. You will be free to have breakfast, read or use a computer while facing towards the light. Treatment with a light box will last 30 minutes when you get up. You may continue to have any treatment as usual (for example medication or talking therapies).

2) **Wake therapy and a Light Box:** You will be helped to change the pattern of your sleep by depriving you of sleep for one night.

*On Day 1* (e.g. a Monday), you will be supported to stay up all night and the following day at the Hospital. We will arrange various activities to help you stay awake accompanied by a nursing assistant during the night and the following day.

You can go to bed by 5pm at your home **on Day 2** (e.g. Tuesday). You will need to get up by about 1am and return to the hospital to be supported to stay awake.

You will then go to bed at 7pm **on Day 3** (e.g. Wednesday).

You will be asked to sleep until 3am and then stay awake at home until bed at 9pm **on Day 4** (Thursday).

You will then get up by 5am **on Day 5** (Friday) and stay awake until 11pm to resume a normal sleep routine waking by 7am **on Day 6** (Saturday).

You will also be given a light box to use each morning. For the light box, you will be asked to sit about one foot away from a light box. You will be free to
have breakfast, read or use a computer while facing towards the light. Treatment with a light box will last 30 minutes. You may continue to have treatment as usual (for example medication or talking therapies).

- You will be asked to complete various questionnaires and be interviewed at 1 week, 2 weeks, 4 weeks, 8 weeks and at 6 months after starting.
- You will be asked to make 6 extra visits to the research team at the hospital over and above those needed for your normal care.
- We can pay the public travel expenses for these visits. Alternatively, the interview can be completed over the telephone and the questionnaires can be completed over the internet.

**FLOWCHART**

You will then be allocated by chance to one of two treatments

Group 1: Sleep and Light Therapy for 7 days

Group 2: Wake and Light Therapy for 7 days

Follow up with measures at 1 week, 2 weeks, 4 weeks, 8 weeks and at 6 months
5. What are the side effects of taking part?

Possible side effects include tiredness after altering your pattern of sleep. A few people may experience nausea or headache after beginning light therapy. In this case, the time in front of the light may decrease by 10 minutes. The frequency of any side effects from the treatment will be monitored and your doctor or therapists would continue with treatment as usual.

6. What are the possible disadvantages or risks of taking part?

One of the possible disadvantages may be the time and burden to complete the questionnaires and attend the research interview. The only potential risk of treatment is of triggering an episode of mania, but this should be a rare occurrence as we are excluding from this study people with bipolar disorder.

7. What are the possible benefits of taking part?

We cannot promise this treatment will help you, but it may help some people with depression. Information we get from this study will help us better understand whether it can be a practical treatment in the community and whether it is worth doing a larger study.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

9. What happens when the research study stops?

A summary of the results of this research will be made available to all those taking part who would like to receive this. You will be provided with a summary of the main research findings. Your anonymized data will be kept for a maximum of 10 years while publication and further research procedures might take place.

10. Will my taking part in this study be kept confidential?

Yes. Your medical information will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. The researchers may need to check information in your medical notes.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.
PART 2

1. What will happen if I don’t want to carry on with the study?

You can withdraw from the study at any time without giving a reason and without your current care being affected. Any identifiable data collected will be destroyed. Data that is not identifiable may still be used.

If you do not wish to take part in the research study then you may still carry on with the routine care.

2. What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to Professor David Veale who will do his best to answer your questions (see contact details below). If you remain unsatisfied and wish to complain formally, you can do this through the NHS Complaints mechanism. You can obtain advice and information on making a complaint from the Patient Advice and Liaison Service (PALS). You can contact the Maudsley PALS on Freephone 0800 731 2864 or by email at pals@slam.nhs.uk. In the event, that something does go wrong and you are harmed during the research and this is due to someone’s negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs.

3. What will happen to the results of the research study?

Findings from the research will be published in scientific journals and publicised in the media. You will be sent a summary of the results and may request a copy of the paper. You will not be identified in any report or publication arising from the research.

4. Will my taking part in this study be kept confidential?

All information about you, which is collected during the research, will be kept confidential. All data will be anonymous. You will be assigned a participation code at the beginning of the study and the list linking the names of participants to their code will be kept separate from the data, in a locked filing cabinet. Only staff working on the project will have access to the data you provide. Electronic copies of data are stored on computers with username and password security required to gain access. No electronic copies of data will be transferred to portable data devices. Hard paper copies of any information you share with us will be kept in folders in a locked filing cabinet. No personally identifiable information is at any time being transferred outside of the hospital. Both computers and filing cabinets are stored in the clinic building at the Maudsley Hospital, which is locked with a security code and alarm system.

You may be asked if you would like your GP to be informed of your participation in the research. This is because it can be useful for your medical records to note any form of treatment you have received. However, this decision will be yours, and if you do decide that it is OK for us to inform your GP, this information will remain confidential in line with patient information legislation. You are also being asked to...
consent to your data (for example the outcome of the rating scales) being shared anonymously with other researchers, for example if they request to check on our analysis.

5. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and been given favorable opinion by London - Bromley Research Ethics Committee (Reference 17/LO/1567).

6. What will happen if those running the study become concerned for my safety?

If those conducting the research become concerned for your safety (for example a risk of suicide) they will be bound by a duty of care and limitations to confidentiality to report any concerns to a third-party professional. As examples, a third party may refer to a GP or a staff member at accident and emergency.

Contact for Further Information

For further information, please do not hesitate to discuss the study with the research worker who has assessed you or the Chief Investigator, Professor David Veale.

Dr Clara Humpston, Research Associate
By email: Clara.Humpston@kcl.ac.uk
By telephone: 07553 518853

By email:  David.Veale@kcl.ac.uk
By post:  Professor David Veale
          Centre for Anxiety Disorders and Trauma
          The Maudsley Hospital
          99 Denmark Hill
          London SE5 8AZ
By telephone:  020 3228 3461

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for considering taking part in the study.