DEPARTMENT OF EXPERIMENTAL PSYCHOLOGY
Anna Watts Building, Woodstock Rd, Oxford, OX2 6GG

Supervisor: Prof Nele Demeyere
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Primary researcher: John Kinley [MSc Psychological Research Student]
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PARTICIPANT INFORMATION SHEET

STUDY TITLE: Investigating the role of planning strategies to improve mood post-stroke

1. You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others 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 you wish to take part. Please note that you will only complete the below tasks if you are found eligible following a study screen. **Why is this research being conducted?**

People who have had a stroke can suffer from depression and low mood. At the moment, there are no treatments specifically recommended for stroke survivors. This is a problem because people who have experienced stroke can sometimes face barriers in typically offered talking therapies. For example, they may find it harder to concentrate for long times than people that have not had a stroke.

In order to develop treatments specifically designed for people who have had a stroke, researchers at the Translational Neuropsychology Laboratory are investigating how well certain types of therapy work for stroke survivors. In a recent study, people with strokes who did more meaningful activities had improved mood. This approach is called Behavioural Activation. Here, we are looking into whether planning abilities (*executive functions*) play a role in benefitting from increases in activity levels.

2. Why have I been invited to take part?

You have been invited to take part because you responded to our study advertisements about taking part in a research study. We are looking for people who are over 18 years of age, have a diagnosis of stroke and live in the UK, and who identify as having low mood or being sad a lot. If we find you to be eligible to participate following a telephone screen, you will be invited to take part in the main study.

3. Do I have to take part?

No, you do not have to take part, and you can ask questions about participating before deciding to take part. You have the right to withdraw from this study **at any time up until the data is pooled for analysis.** You do not need to give a reason and your data will be destroyed.

4. What will happen to me if I take part?

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The purpose of this study will be to compare two ways of increasing activity levels. We do not know if either way is better than the other at increasing activities or mood. The difference is the way in which the activity will be planned. One set of participants will practice a strategy for enhancing activity planning. The other set will not do this and plan the activity as they would normally. You would be sorted into groups randomly – neither the researchers nor you will control what group you are put into.

In this study, you will meet a researcher online using videoconferencing for all sessions. The sessions will work like this:

Session 1 (approximately 60 – 90 minutes)

In the first session, you will meet a member of the research team and discuss the study. You will get a chance to ask any questions and then you will be asked again if you want to take part in the study. We will first go through this information sheet with you and if you choose to take part, complete a consent form.

We will then ask you some basic demographic information, specifically:

- Information about your stroke
- Address and postcode
- GP contact details
- Emergency contact name and number, if available
- Next of kin name and contact number, if available

These are collected in case any emergencies arise online and we need to arrange emergency services.

You will then be asked to complete a reasoning task and complete some questionnaires about your mood, activity levels, sense of control over your day-to-day life, and your functional abilities. There will be some questions that you will be asked to complete on your own, and some questions that will be asked by us. There will be time for any questions (or to explain the tasks more) during the session if you'd like.

After this, you will be randomly assigned to one of two groups:

Group 1 – Activities and Executive Function

If you are in this group, you will be given some information on the link between activities and mood. We will work together to identify an activity that you find meaningful or enjoyable. We will then plan together for you to do this activity over the next week, before session 2. In this group, you will also receive some information on executive functions after stroke and how it relates to the activity you planned.

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Group 2 – Activities Practice

If you are in this group, you will be given some information on the link between activities and mood. We will work together to identify an activity that you find meaningful or enjoyable. We will then plan together for you to do this activity over the next week, before session 2. In this group, we will also discuss local activity options with you.

At the end of session one, we will book the other sessions in the study.

- Session 2 must be approximately 1 week after session 1
- Session 3 must be approximately 1 week after session 2

Session 2 – Follow Up (approximately 30 minutes)

Roughly 1 week after session 1, we will meet again online. We will ask you to complete some questionnaires as in Session 1. We will discuss how the activity that was planned last session went. We will then repeat the same activity planning exercises from session 1.

Session 3 – Final Session (approximately 30 minutes)

Roughly 1 week after session 2, we will meet again online. We will discuss how doing the planned activity went and how the overall study has gone for you. When the session is over, you will be asked to fill out two of the questionnaires that we did in Session 1.

At the end of the study, we will provide you with information about UK mental health resources if you found talking with us helpful.

5. What are possible disadvantages and risks of taking part?

There is a small risk that discussing distressing things such as your stroke may impact your mood. There are protocols in place to deal with this in the unlikely event that it happens.

6. Are there any benefits in taking part?

The focus of this research is on activities and how they relate to mood, which may be helpful for you. However, the main aim is to do research which might be of benefit to other stroke survivors. Therefore, there may be no direct benefit to you in participating.

7. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

With your permission, we will record the study sessions. This is so that other members of the team can check that the researcher followed the protocol for this study. This is **not** to check anything to do with you.

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We will use an audio only recorder to record the sessions and will not collect any video recordings. The recording will be transferred to a password-protected secure server on the Medical Science Division IT research drive and be accessible only by the research team.

At the end of the study, **all** recordings will be destroyed. If you do not want your sessions recorded, you can still take part in the study.

Any information you provide as part of this study is research data. Data that you can be identified from, including your contact details, home and GP address, demographic information, consent form, audio recordings, and telephone screen consent is called personal data.

Research data will be stored confidentially. All of your responses on questionnaires and tasks will be labelled with a code instead of your name.. All data will be stored on password protected computers.

There is identifiable data included in your electronic consent form (your name) and on the electronic linkage list (name and contact information). These electronic forms and list will be password protected and stored, separate from the research data, on password protected computers. Audio recordings will be assessed as described above and then, once all assessments have taken place, deleted entirely.

All research data (including screening information and consent forms) will be stored for 3 years after publication or public release of the research. Your contact information will be deleted after all data are analysed, unless you have agreed to the retention of your contact details for the purpose of informing you about future research studies that you might be eligible for. We will keep a copy of your consent form with this database, as your consent is our legal basis for re-contacting you under UK data protection law.

While every reasonable effort will be taken (e.g. only using University of Oxford approved software), confidentiality during online sessions cannot be guaranteed.

Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

8. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will/may be written in an academic dissertation, an academic publication and for a conference presentation. No participants will be identifiable in any of

these. You have the right to withdraw from the study at any point up until the data is pooled for analysis. After this point, it will not be possible to withdraw from the study.

At the end of the project, the *anonymised* data only will be made available in an Open Science archive for the benefit of society, with your permission. We share anonymised research data so that new questions about stroke can be answered in a more efficient way.

9. Are there any circumstances where you would share my Identifiable Information to anyone outside the research team?

The Translational Neuropsychology Lab has clear policies about confidentiality. Anything you say in emails, phone conversations or online will be kept confidential and only discussed with members of the team involved in the study. However, we have a duty of care to research volunteers. Therefore, if there is a medical emergency, or if you are at risk of harm to yourself or to someone else, we may have to break confidentiality and share your personal information. This means that if we are worried about your safety, or the safety of someone else, we might have to contact your GP or emergency services, for example. We would try to inform you about this before we do it but sometimes this is not possible (e.g., if we cannot reach you in an emergency). You should only take part if you understand these limits on confidentiality.

Apart from this rare exception, your data will be kept confidential. Only members of the research team will be able to access any study-related data.

10. Can I get access to my study results?

As a policy, we do not share individual results and work with data at the group average level. If you have concerns about some of the questionnaires and tasks during this study, please discuss these with the researcher.

11. Who is organising and funding the research?

This study is led by researchers Prof. Nele Demeyere and Dr. Andrea Kusec at the Translational Neuropsychology Laboratory, a part of the University of Oxford. The Department of Experimental Psychology is funding the research.

12. Who has reviewed this study?

This study was reviewed by, and received ethics clearance through, a subcommittee of the University of Oxford Central University Research Ethics Committee (reference: R85920/RE001).

13. Who do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this study, please contact John Kinley (john.kinley@wadham.ox.ac.uk), Andrea Kusec (andrea.kusec@psy.ox.ac.uk), or Nele Demeyere (nele.demeyere@ndcn.ox.ac.uk), and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

14. Data Protection

The University of Oxford is the data controller with respect to your personal data and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights.

15. Further Information and Contact Details

If you have any questions, you can contact:

Primary Researcher:

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You can find out more about the Translational Neuropsychology lab here:
http://www.demeyerelab.org/

The people in the principal research team for this study are:

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