



Information sheet: “Assessing the impact of acute 5-hydroxytryptophan supplementation on distractibility”

We are inviting you to take part in a research project. Before you decide whether to participate it is important for you to understand why the research is being done and what participation involves. Please read the following information carefully and ask us if there is anything you do not understand or would like more information about. Take time to decide whether or not you wish to participate.

Project purpose:

The aim of this project is to look at the impact of 5-Hydroxytryptophan (5-HTP) on distractibility. 5-HTP is the precursor to the neurotransmitter serotonin, and is a chemical that your body produces naturally. There is evidence that distractibility is associated with a decreased level of serotonin. This research aims to see if giving people 5-HTP will alter their distractibility, which will form part of an initial assessment as to whether 5-HTP could be used to support people with attention deficits. This research will also contribute to a PhD thesis.

Why have I been chosen?:

We have screened a large number of people for the study and have included people with a range of scores on our measures. We are looking to recruit 50 participants in each group, meaning around 100 people will complete this study.

Do I have to take part?:

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information to keep and will be asked to sign a consent form. You can withdraw your consent at any time without providing reason, and you will be able to leave the study without any negative consequences. You do not have to provide a reason. Due to data anonymization, you will be unable to withdraw data from the study once testing has completed.

What will happen to me if I take part?

You will be invited to book a session slot at the University of Sheffield to attend the study. The session will take around 2.5 hours. We will not be able to reimburse you for travel costs to the university.

We will send you a reminder about your session by email 36 hours before the study starts. For the 2 days before the study, we ask that you fill out a digital food diary of everything you eat and drink. This is because some foods may affect the amount of 5-HTP you have in your body, and other things such as caffeine or alcohol may affect your responses. On the day of the study, please refrain from eating or drinking anything but water in the two hours before your session. This is to allow us to assess the sole effect of 5-HTP.

When you arrive at the university, you will meet with the researcher and be escorted to a quiet room with a computer. You will complete two simple computer tasks, which will take around 30 minutes to complete. Full instructions to the tasks will be given on the day.

After completing the first set of computer tasks, you will be given a dose of 5-HTP or a placebo with a glass of water. You will not know which one you have been given, so we can assess the effectiveness of 5-HTP properly. There will then be a 90 minute wait whilst the 5-HTP is digested. You can bring a book, headphones or something to occupy yourself during this wait. You will not be allowed to eat, but you can drink water.

After 90 minutes the researcher will collect you and take you back to the computer room to repeat the computer tasks. This will take around another half an hour. After the test, you will be able to have a snack and a chat with the researcher, and then you will be allowed to leave. Upon completion, you will be compensated for your time in the study with a £30 Amazon voucher or 8 SONA participation credits.

What are disadvantages and risks to taking part?

- Because of the nature of the study, you will have to fast for 2 hours before taking part.
- Sitting in front of a computer may cause eye strain. We will make sure the screen has an appropriate brightness and that tasks take no longer than half an hour. If you need glasses, please bring them.
- 5-HTP may cause nausea and tiredness in some individuals. We have determined a dose to try and prevent this as best as possible, but if you do start to feel sick or tired during the study, please let your researcher know. We advise against using heavy machinery or driving following the experiment.

What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will help in the development of new treatments for people with attentional problems.

Confidentiality:

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. Before completing the study, you will have been provided with a participant number. All data that you provide in the course of the study will be associated with the participant number; data such as your name, date of birth or other personal details will not be held and your information will be anonymized. You will not be identifiable in any subsequent reports or publication. Any personal information provided throughout the course of the study will be stored securely and held in accordance with the GDPR and data protection policy of the University of Sheffield. If you agree to us sharing the information you provide with other researchers (e.g., by making it available in a data archive), then your personal details will not be included.

What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice

<https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

'As we will be collecting some data that is defined in the legislation as more sensitive (information about medical diagnoses and prescription medications), we also need to let you know that we are applying the following condition in law: that the use of your data is 'necessary for scientific or historical research purposes'

What will happen to the results of the research project?

We will use the data we have collected to calculate if 5-HTP has a statistically significant effect on people's distractibility. Data collected will be anonymized prior to any data sharing that may occur. Results of the research are likely to be published. If you wish to be informed of any publications as a result of this study, please provide the researcher with a corresponding email address. Due to anonymization, we will be unable to tell you whether you took 5-HTP or placebo after the study.

Data will be stored in the university of sheffield ORDA (open research database) repository, meaning that other researchers will be able to use the data in answering future research questions. We will ask for explicit permission for your data to be shared in this way. All data will be stored on a long term basis for the standard University of Sheffield retention period of 10 years following the project.

Who is organising and funding the research?:

The University of Sheffield is responsible for organising and funding the research.

Who is the data controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

Who has ethically reviewed the project?

This project has been ethically approved via the University of Sheffield's ethics review procedure, as administered by the department of Psychology.

What if something goes wrong and I wish to complain about the research?

If you feel that you have been mistreated or were upset by anything in the study, please contact the project supervisor (details provided below), who will be able to handle your complaint. If this is not handled to your satisfaction, you may contact the head of the Department of psychology, who will escalate the issue accordingly. If you have a complaint with regards to the handling of your personal data, information on how to raise a complaint can be found in the university's privacy notice.

<https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

Contact details for further information:

Eleanor Jackson, researcher and PhD candidate at the University of Sheffield.

Email: EFJackson1@sheffield.ac.uk

Address: Eleanor Jackson
Floor 2, ICOSS Building
219 Portobello,
Sheffield
S1 4DP

Professor Paul Overton, project supervisor

Email: p.g.overton@sheffield.ac.uk

Address: Professor Paul Overton
ICOSS Building
219 Portobello,
Sheffield
S1 4DP

Dr Chris Martin, Head of the department of psychology

Email: psy-hod@sheffield.ac.uk