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**Participant Information Sheet**

**Title:**

**Lisdexamfetamine Dimesylate, taste, and brain activity**

**Contact persons**: Elizabeth Schneider

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Other investigators UoB: Elizabeth Martin, Prof Suzanne Higgs, Dr Colin Dourish, Dr Maartje Spetter, and Dr Pia Rotshtein

**Invitation**

You are being invited to take part in a research study. Before you decide if you would like to participate, 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. Thank you for reading this information sheet.

**What is the purpose of this study?**

We are interested in finding out about how certain drugs can affect taste and the way they can affect how our brain responds. In this study we are investigating lisdexamfetamine dimesylate (LDX). We believe this drug may have effects on taste and brain functions that can be detected in the brain by using functional magnetic resonance imaging (fMRI). Looking at how LDX affects taste and the corresponding effects in the human brain, could allow us to understand more about the way taste works in the human brain.

**What is LDX?**

LDX is a drug that acts as a stimulant on the brain, meaning it increases activity in the brain causing more alertness and energy. It is primarily used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). Taken once by mouth, such as what will be used in this study, participants have safely tolerated doses up to 250mg of LDX. Our doses will be 50mg. Possible side effects of LDX include temporary loss of appetite anxiety, diarrhoea, dry mouth, feeling jittery, insomnia, and nausea. Once consumed, LDX converts to the stimulant. This gradual process means the drug is not likely to be addictive, especially when taken only once.

**What is fMRI?**

fMRI is a safe, non-invasive brain imaging technique that can identify changes in blood flow in different parts of the brain that are active when people perform simple tasks (such as looking at pictures). It uses the same methods that are used for MRI brain scanning which provides detailed pictures of the brain.

**Why have I been invited?**

You have been invited to take part in the study, as you are a healthy female volunteer who has expressed an interest in participating.

**Who is eligible to take part?**

A total of 35 healthy female participants will take part in this study. Participants must be fluent English speakers, possess a minimum body mass index (BMI) of 18.5, and have binge-eating symptoms. Binge-eating symptoms will be determined using the BES a questionnaire. You must meet a minimum score to continue on with this study. Participants must be aged 18-55 and non-smokers.

You are unable to participate if you have/are: symptoms or diagnosis of Anorexia Nervosa or Bulimia Nervosa, neuropsychological disorders (e.g., Attention-Deficit Hyperactivity Disorder), metabolic disorders (e.g., metabolic disorder, diabetes), psychological disorders (e.g., depression), neurological disorders (e.g., Alzheimer’s disease, stroke, Parkinson’s Disease), illegal substance dependence in the past year, lifetime history of stimulant abuse or dependence, intake of any medication that can interfere with LDX, lifetime history of mania or psychosis, psychotherapy/pharmacotherapy for binge-eating three months prior to this study, smoking, history of heart problems, moderate or severe hypertension, pregnant or breastfeeding, unable to receive medical clearance from your doctor, food allergies, and dietary restrictions (e.g., vegetarian, vegan, gluten-intolerance).

For the fMRI scans, you will only be eligible if you are right handed, and do not have the following: heart pacemaker, tattoos older than 10 years, limited or increased perception of temperature changes, pathological hearing ability or increased sensitivity to sounds, surgical operation less than 3 months ago, moderate or severe head injury, acute illness or infection in the last 4 weeks, claustrophobia, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if you carry pieces of metal that have accidentally entered your body. This is to ensure that we do not take the risk of metal being in your body when you go into the scanner. Participants exceeding 336 pounds will be unable to participate, due to fMRI capacity restrictions. Also, it is not possible to wear normal glasses in the scanner. However, we can provide scanner-safe glasses for most prescriptions. Before going into the scanner the operator will go through the procedure with you and ensure that you are safe to go into the scanner. Additionally, in the event that the results of fMRI scan indicate pathological findings, you must be willing to be informed of these results.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you decide to take part, you would be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw until the end of the experiment without giving a reason. This will not affect any current or future treatment within the NHS. Your GP will also be informed of your participation and will notify us if they are aware of any medical reason as to why you cannot take part. This may involve the GP disclosing relevant medical information about you to the research team.

**What would happen to me if I take part?**

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part in the study we will ask you to sign a consent form. You are free to withdraw until the end of the experiment without giving reason. If you decide to take part in the study we will invite you to come to the School of Psychology, for a screening session. This session will last approximately 1.5 hours, and will comprise of the following:

* Signing a consent form
* Filling in an fMRI safety form to ensure eligibility
* Other questionnaires
* Measurement of height, weight, and BMI
* Consumption of test meal
* Computerised task
* Meeting with a physician

If, following the screening, you are suitable and willing to proceed with the study, we will arrange two test days for you to attend. Each test day is separated approximately a week apart, and both follow approximately the same protocol.

For both test sessions, you will arrive at the Centre for Human Brain Health around 9:00 and leave at approximately 15:00. On the first test day, you will be further screened on the morning - for your physical health and to test for pregnancy - before you are able to proceed with the testing session.

Each testing session will last approximately 6 hours, in which you will undergo the following:

- Questionnaires

- A brief physical examination

- A pregnancy test

- Two fMRI scans (each just under an hour)

- Administration of either 50mg LDX or placebo. The placebo used in this study is a lactose tablet. Both the LDX and placebo tablets will be encased in a gelatine capsule (of animal origin), which are unsuitable for vegetarians & vegans

- Three blood samples to be taken during the course of the day. The total amount of blood taken will be around 6 teaspoons

- Consumption of pasta and a snack of cookies, whilst making ratings on a computer (for both foods, you will be free to eat as much as you like, until you feel comfortably full).

- Six behavioural tasks that will measure various facets of cognitive processing, preferences, and psychoemotional functioning

You are advised not to drive or operate heavy machinery for 24 hours after leaving the research unit and not to consume alcohol for 24 hours after taking the study drug.

On both test days, you will complete some questionnaires (often completing multiple versions of the same one). These questionnaires will relate to things such as: how you think about food and how you eat, your mood both at present and in the past, your lifestyle and personality.

Please note that:

* You can decide to withdraw until the end of the experiment, and you will be compensated with course credits or cash for the time you completed.
* Your name will be removed from the information gathered in the study and it will not be possible to identify anyone from our reports on the study.
* Your medical notes and data collected during the study may be looked at by individuals on the study team, staff from the Centre for Human Brain Health, authorities, or members of the University of Birmingham where it is relevant to your taking part in the research.
* Your GP will be notified of your study participation and may need to disclose relevant medical information to the study research team.

**What will I have to do?**

As well as completing the above visits, you must also:

* Not consume any recreational drugs or other medications that affect the way you feel from the screening visit until the end of the study. These include any antibiotics, painkillers, anti-depressants, or any prescription or over the counter medications. If you are prescribed antibiotics by your GP then please continue to take these and contact a member of the research team who will arrange an alternative study date after the completion of your course of antibiotics.
* Not consume any alcoholic beverages on the day of the study, or for 24 hours after taking the drug.
* Not take part in any other drug studies within 3 months of taking part in this study.
* Not have blood draws for one month while taking part in this study.
* You must use an effective means of contraception for the duration of your involvement in the study, for example: the contraceptive pill, condoms, etc. If you are unsure about your method of contraception please speak to a member of the research team.

**What will I have to do for the study?**

The flowchart below shows an outline of your progress through the study.

Compensated 1.5 course credits or £10 for your time

**13:25**

-Lunch

**14:50**

-Final Blood Draw  
-Taxi Home

If not eligible

**09:00**-Arrive at CHBH  
-Medical check, Urine test, Blood draw  
-LDX given

**14:05**

-Complete Cognitive task

**12:20**

-fMRI Scan  
-Blood draw

**09:30**

-Complete Questionnaires

-Break

**(Pre)Screening**

-Questionnaires used to determine eligibility  
-Consumption of test meal

-Meeting with a physician

If eligible

**11:30**

-Complete cognitive tasks

**What are the possible risks and benefits of taking part?**

Whilst LDX is a safe drug and generally well tolerated, it has *possible* side effects which include: temporary loss of appetite anxiety, diarrhoea, dry mouth, feeling jittery, insomnia, and nausea.

As a precaution, you should not take part in this study if you are pregnant, suspect you might be pregnant, or if you are trying to become pregnant. As mentioned above, if you are a female of childbearing age, you must be using an effective means of contraception, and you will be asked to take a pregnancy test on the test day of the study.

There are no direct benefits to taking part in the study. However, you will be making a contribution to our scientific understanding of the mechanisms underlying taste and brain signals. You may also request an image of your brain from the MRI scan if desired.

**What if there is a problem?**

If you wish to report grievances about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Chief Investigator (Elizabeth Schneider: bhamstudies@contacts.bham.ac.uk).

**Expenses and payments**

If you take part in this study, you will be given £125 (or the option of 12 course credits for Psychology students), upon completion of the study. We will also arrange for a paid taxi to take you home after the test days.

**Would my taking part in this study be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential. You will be assigned a number and data will therefore not include your name. We will anonymise the data fully once all test sessions have been completed. We are obliged to keep all anonymised data for a period of 10 years. After this time, it will be destroyed.

**What will happen to the results of the research?**

Any research publication would not identify you individually. If you wish to obtain a copy of the published results, please inform the researcher by ticking the appropriate box on the consent form, and we would be delighted to send you a summary of the results in lay language.

**Insurance**

The University of Birmingham has arrangements in place to provide for harm arising from participation in the study, for which the University is the research sponsor.

**Who has reviewed the study?**

The study was reviewed and given a favourable opinion, by the National Research Ethics Service (NRES – NHS ethics service).

**Who is sponsoring and funding the study?**

The study is being sponsored by the University of Birmingham. Funding will be provided by the University of Birmingham, BBSRC & P1vital. P1vital is a Clinical Research Organisation specialising in experimental medicine for Central Nervous System (CNS) disorders and obesity, but does not produce the test drug. Dr Colin Dourish is the Chief Executive officer of P1vital, as well as the industrial PhD supervisor of Elizabeth Martin and Elizabeth Schneider, and is interested in the development of an experimental medicine model for anti-obesity drugs.

**Contact for further information**

If you have any further questions about this research, please contact Elizabeth Schneider using the email address above.

If you wish to contact an independent point at the University, you can phone or email University of Birmingham’s Research Ethics:

Phone - 0121 414 8825

Email - ethics-queries@contacts.bham.ac.uk

**NOTE:** This is not the contact if you wish to arrange to take part in the study.

The Patient Advice and Liaison Service (PALS) offers confidential advice, support and information on health-related matters. They provide a point of contact for patients, their families and their carers. PALS can also help you in making a complaint regarding NHS services. You can reach a local branch of PALS by telephone:

Phone - 0121 371 3280

Website: <https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/>

**Thank you for taking the time to read this information sheet and considering whether to take part in this research.**

**You will be given a copy of this information sheet and a signed consent form to keep if you do take part.**