

**Can and How a Nasal Spray Reduce Your Heroin Cravings?**

**Investigating the mechanism mediating the effects of oxytocin on opioid craving: A proof of concept study**

You are being invited to take part in a research study. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read this information sheet carefully and decide if you would like to take part or not.

**What is the study about?**

![counselling[1]]()The aim of this study is to understand what happens to opioid cravings and attention when a nasal spray of a hormone called oxytocin is used. In total, about 30 people will take part in the study. Everyone will receive a nasal spray of both oxytocin and a placebo but nobody will know which one they receive first. The study will last between 4 and 8 weeks in total depending how often you want your appointments. You can choose weekly or fortnightly appointments.

**Why have I been asked to take part in this study?**

You have been invited to take part because your care team has identified that you are male, currently using heroin, stable of methadone or buprenorphine (including Espranor, Subutex and Suboxone) and may be interested. We’re sorry but oxytocin works differently with females so we cannot invite females to take part in the research but females are more than welcome to help us tell people about the results if you would like.

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

* If you decide to take part, you will be asked to sign a consent form (you will be given a copy to keep along with this information sheet).
* You will be asked to attend four times in total. You can choose whether to have weekly or fortnightly appointments. Each visit will last between around 45 minutes to two hours, it depends on how long you want to stay afterwards.
* At your first visit you will complete a research assessment, which will involve answering some questions about your life (nationality, education, employment status etc). Craving and attention will also be measured.
* You will then be randomly allocated to receive either a nasal spray of oxytocin or placebo first. This will be done by computer and we won’t know which one you have had until the study is finished. Random allocation means by chance, a bit like flipping a coin. This is to make sure the study is a fair test.
* On your second and third visits you will receive either a nasal spray of oxytocin or placebo (you will receive both during the study) and then tested for craving and attention in the same way as the first visit.
* At the fourth visit we would like to interview you about your experience and using heroin in general. This will be recorded digitally but will remain anonymous and confidential. Your care co-ordinator will not be informed of what you tell us.
* You have the right to withdraw from the study at any stage without having to explain your decision.

**How will you test craving?** 

* We will show you a video of a man injecting heroin once and then ask you to tell us how it makes you feel using a rating scale. We will also test your attention using a computer program. We show the video once on visits one, two and three only. You will be asked to complete the craving test four times on visit one, two and three. Each craving test lasts for one minute. You will be asked to complete the attention test three times on visit one, two and three. Each test takes about 5 minutes. You will also continue to receive your usual care from your care team. Participating in the study will not interfere with the usual care you receive from your keyworker so you could have your study visits on the same day as your keyworking visits so you don’t have to attend any more than you normally do.
* At the end of each visit we will invite you to stay in the service until you feel you are ok to leave. This is why the visits could take up to one and a half hours but you are free to leave before this if you feel ok. We ask you to stay in case you continue to crave heroin and want to be in a safe place with support options. We will also give you a Naloxone pen.

**Do I have to take part?**

No. Participation is entirely voluntary, which means it is up to you whether you want to take part. *If you do decide to take part, but later change your mind, you are free to withdraw at any time without giving a reason. If you decide not to take part in the study, or later withdraw from the study, this will not in any way affect the normal care you receive.*

**Will I be compensated for my time?**

You will be compensated with shopping vouchers after visit four. There will be four visits in total. You will receive one voucher per attended visit. For example if you only completed three visits then you would only receive three vouchers.

You will also have bus fare, or train fare from the surrounding area only, reimbursed for attendance at every clinic visit if you show us the receipt or ticket.

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

The main disadvantage is that the video will make you crave heroin when you wouldn’t have done normally. For the research assessments, there are no right or wrong answers and you do not have to answer any questions you do not want to. You are free to ask the interviewer to move on to another subject or to stop the session altogether if you find any of the questions upsetting.

**What are the side-effects of nasal oxytocin and placebo?**

There are no major side-effects known with nasal oxytocin and nasal oxytocin has been used on other studies with drug users without adverse event. Like all medications some people have bad reactions. You may experience mild light headedness/vertigo, drowsiness, dry throat/mouth, nasal irritation, runny nose, abdominal/stomach pain, anxiety, euphoria, calm and headache. These are the same side-effects you may experience when you take the placebo and you have the same chance of experiencing them with both oxytocin and placebo.

If you experience any side-effects you can stay at the treatment centre until you feel better where trained staff will be available to support you. You can also withdraw from the study at any time.

**What are the possible advantages or benefits of taking part?**

The nasal spray used in this study is a new type of medication. For this reason we do not know whether or not it will be helpful. By taking part in the study you will be helping us to learn if this is helpful in reducing cravings and how it may work. This information will help us to prepare for a future bigger project that will give us a better idea whether the nasal spray is helpful or not, and if we should design a bigger study.

![confidential[1]]()**Will my responses be confidential?**

Yes. All data collected will be kept confidential, and identified only by an anonymous identification code that will not personally identify you. No names will be used when the results of the study are published or talked about so your identity will never be revealed in any reports based on this study.

 If you tell the research assistant something that makes them concerned for your safety, or the safety of others, they will have to share this information with your care team

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

The results of the study will be published in an academic journal and a lay summary of the findings will also be written. You are welcome to have a copy of the results of the study once it is completed, if you wish.

 **Who is organising and funding the research?**

This research is being funded by St. Georges University of London and Kings College London. Surrey and Borders NHS Foundation Trust is the sponsor for the research.

**Who has reviewed the study?**

This research was reviewed and funded by St. Georges University of London and Kings College London. People with experience of using three different drug and alcohol services have provided advice on study procedures and documents so that the study will be carried out in the best possible way. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion (approved) by the London - Brent Research Ethics Committee.

**How will we use information about you?**

We will need to use information from you, your drug and alcohol treatment records and your GP for this research project.

This information will include your:

* Full name
* Contact details
* Medical history including details of all medications currently prescribed
* Risk assessment created by the drug & alcohol service
* Pharmacy where you collect your methadone/buprenorphine/Espranor details
* Whether you have been in contact with your keyworker during the study period

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to research@sabp.nhs.uk, or
* by ringing us on 01932 453000.

**What should I do if I have questions or concerns about the research?**

![telephone-image[1]]()If you have any concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. If you would rather speak to someone else then you can contact Dr Christos Kouimtsidis at Surrey and Borders Partnership NHS Foundation Trust on 01932 453000. If you wish to complain formally, you can do this through the NHS Complaints Procedure. You can call the **Patient Advice and Liaison Service (PALS) freephone on 0800 731 2864 for information on how to do this.**

**I would like to speak to the research assistant about taking part!**

If you would like to speak to the research assistant about taking part you can either ask your keyworker to pass on the message or leave your name and contact number below then pass *this page only* back to reception who will give it to the research assistant. The research assistant will contact you by any of the ways you agree to be contacted then store this document in a folder in a locked cupboard to keep your details safe.

Please initial box

1. I give consent for you to contact me by telephone and you can get my number by looking at my case file
2. I give consent for you to contact me by text message and you can get my phone number by looking at my case file
3. I give consent for you to contact me at my pharmacy and you can get their number by looking at my case file.
4. I give consent for you to contact me at my next keywork appointment and you can get this date by speaking to my keyworker.
5. I understand I am under no obligation to enter the study, I would just like to know more

Name of Participant Date Signature