

## Participant Information Sheet for GOTHIC2: A 3-arm multi-centre randomised placebo-controlled trial of Glycopyrrolate or Hyoscine Hydrobromide for the treatment of clozapine-Induced hypersalivation

- You are invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve.
- Please take time to read the following information carefully or have someone read it to you. **Part 1** tells you why we are doing this study and what to expect. **Part 2** gives you more detailed information about the conduct of the study.
- You can ask a member of your clinical team (doctor, nurse) if anything is not clear, or if you would like more information.
- You may also discuss the study with friends, relatives and/or get independent advice via your local Patient Advice and Liaison Service (PALS) or equivalent. You can find your nearest PALS office on the NHS website: [www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals](http://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals). You can also ask your GP surgery, hospital or phone [NHS 111](tel:111) for details of your nearest PALS.
- Taking part is voluntary and it's fine if you prefer not to. There is no need to give a reason for not taking part.
- **GOTHIC2** is a study where we want to find good evidence to help patients with clozapine-induced hypersalivation ('drooling') by comparing medications used to treat drooling with a 'dummy' inactive capsule (placebo).
- We want 180 participants in England (both men and women) to take part in the GOTHIC2 study.
- The two medications that are being compared with placebo are hyoscine hydrobromide (Kwells) and glycopyrrolate (glycopyrronium bromide).

You will be in the study for 12 weeks and randomly assigned (by chance) to either hyoscine, glycopyrrolate or placebo. Neither you nor the researchers will know what treatment you are taking. This is called 'blinded'.

At week 12 you will be asked some questions about the trial treatment. You will then be told what treatment you have been on.

### How to contact the local study team

If you have any questions about this study, please talk to the research team:

**Principal Investigator:** <PI Name>

**Research Nurse:** <RN Name>

**Telephone:** <Number>

**Or visit the website:** <https://gothic2.co.uk/>

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# GOTHIC2: A 3-arm multi-centre randomised placebo-controlled trial of Glycopyrrolate or Hyoscine Hydrobromide for the treatment of clozapine-Induced hypersalivation

## PART 1: Purpose of the study and what will happen if you take part

### Why are we doing the GOTHIC2 study?

Clozapine is an antipsychotic medication used to help treat the symptoms of schizophrenia. Clozapine is also sometimes used to treat other mental health conditions. Clozapine is the most effective antipsychotic medication for many people and, for them, it is important to keep taking it. However, clozapine can cause different side effects and people who take clozapine tell us that one of the most upsetting is excessive drooling. Doctors call this 'clozapine-induced hypersalivation' (CIH) (or drooling).

People with CIH/drooling tell us they often have to wipe the saliva from their mouth during the day and their pillow becomes very wet at night which can sometimes make the skin on their face sore. CIH can be very embarrassing and lead to some patients wanting to stop clozapine treatment. For most patients this is not a good idea as their mental illness is likely to come back and they may need to be admitted to hospital. At the moment there is no proven treatment for CIH/drooling.

The medication that is usually prescribed for CIH/drooling is called hyoscine, but we do not know if hyoscine helps although doctors think it might. Also, hyoscine can cause unpleasant side effects such as bowel problems (constipation) and thinking problems (making attention and concentration worse). Some studies suggest that a different medication, called glycopyrrolate, might be helpful for CIH/drooling and may cause fewer thinking problems. However, it may still cause other side effects like constipation. Patients have told us that it is important for them to know which medications may improve CIH/drooling and what the side effects are so they can make an informed choice about whether or not to take any of these medicines, based on their mental illness symptoms and experience of side-effects.

Our study, GOTHIC2, will find out if either hyoscine or glycopyrrolate can improve CIH/drooling by comparing patients taking these medications with patients taking a dummy treatment (placebo). If hyoscine and glycopyrrolate both help reduce CIH/drooling, we will

compare the two medications to see which one causes fewer side effects and ask which one patients' prefer.

We hope the results from this study will be used to help improve treatments for patients with CIH/drooling and help doctors and patients in the future when making decisions about treatment for CIH/drooling.

### Why have I been chosen?

You have been invited to take part in this study because you may have clozapine-induced hypersalivation (CIH).

### Do I have to take part?

No, taking part is voluntary. It is up to you if you want to take part.

If you decide not to take part, you will still receive the usual treatment your hospital/GP offers.

If you decide to take part, you can also choose to stop at any time without giving a reason.

The decision you make about whether to take part or not will **not** change the care you receive now or in the future.

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

If you agree to take part, you will be asked to sign a consent form. This could be the consent form at the end of this information sheet or an electronic version. You will be given a copy of the consent form and this information sheet to keep.

Once you have signed the consent form, we will check that this study is suitable for you, and you will be invited to follow the study plan (see study timeline on page 4 and full study assessment table at the end of this information sheet).

At the start and end of the study, we will look at your medical notes and record how much clozapine is in your blood. We will also check your medical history and make a note of any medicines you are taking. We will ask you questions about your illness and the side effects of your

medicines. Together, all of these checks and questions are called 'assessments'. This will be done at a hospital or clozapine clinic visit.

If you are a woman who is 55 years of age or younger, we will also do a urine test at the start and end of the study. You will not be able to take part if you are pregnant or breastfeeding.

Participants must use contraception during the trial and for at least 5 days following the last dose of trial medication when engaging in sexual intercourse with someone of the opposite sex during the trial.

When you are entered into the study, you will randomly (by chance) be allocated to one of three treatments (hyoscine, glycopyrrolate or placebo). You will be asked to take capsules every day for 12 weeks. In the first week you will take one capsule twice a day. In the following 11 weeks you will take one capsule three times a day.

We want to make taking part in the study easy for you so will try to meet with you for the initial assessments at your usual clozapine clinic appointment if we can. We can also arrange to see you somewhere else if more convenient for you and if this is possible we will. There will be 3 further visits (and regular telephone assessments if you are in the community) during the 12-week 'blinded' study. If you are an in-patient, a nurse or researcher will see you instead of telephone calls. At each visit, we will repeat some or all of the assessments.

The assessments will be done face to face by research assistants before you start the study medication and then at weeks 4, 8 and 12 (with telephone assessments at weeks 1, 2 and 6 for community patients). We will do our best to make the assessment visits convenient for you and visits at home instead of the clozapine clinic can be arranged if you prefer.

At your study visits, we will invite you to complete some questionnaires. These are straightforward questionnaires which ask about your side effects, symptoms and your quality of life. We can help you with this if you would like us to.

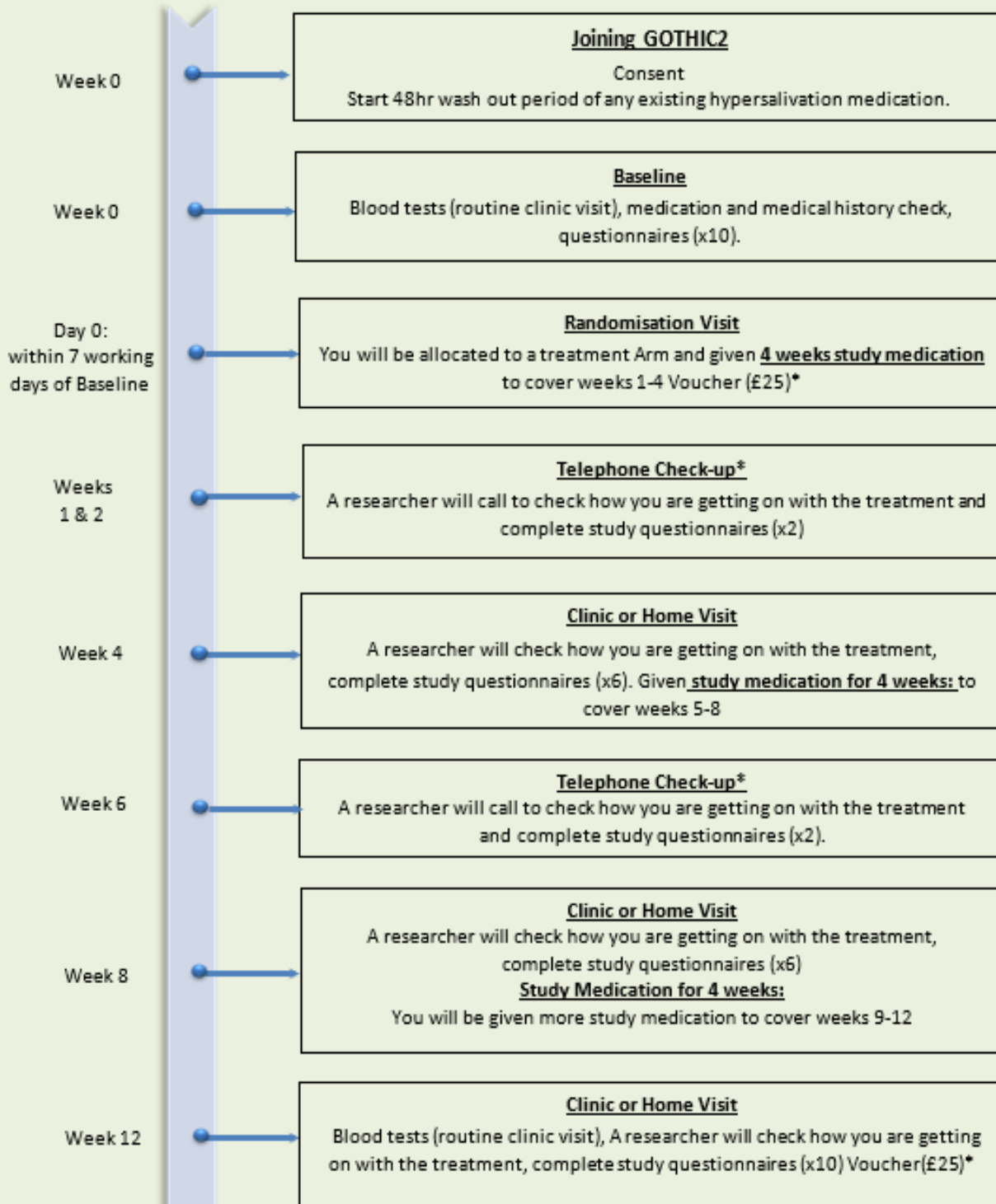
After 12 weeks you will be asked some questions about the trial treatment. Once these have been completed you will be 'unblinded' where you will be told which study medication you were on or if you were taking placebo.

At this stage you will leave the study and we will ask you if you want medication to be prescribed for CIH/drooling and make arrangements for this.

As a thank-you and in recognition of your time we will compensate you in vouchers\* to the value of £25 at the beginning and end of the trial (£25 after you have completed the study assessments at baseline and £25 after you have completed the study assessments at week 12). The maximum any person will receive is £50.

\*Alternative arrangements will be made for in-patients if vouchers are not permitted.

## Study Timetable



You will be asked a series of questions about the trial treatment. You will then be 'unblinded' and find out which medication you have been taking.

**End of your participation in GOTHIC2**

**\*Telephone Check-up Inpatients:**

For inpatients, the research assistant may liaise with a ward nurse to obtain this information.

**\*Participant recompense:**

Other arrangements will be made for in-patients if vouchers are not permitted.

## What are the medicines being tested?

The medicines being used in this trial are:

- Hyoscine Hydrobromide - this is a medicine that can be purchased over the counter for travel sickness and can be prescribed by a doctor
- Glycopyrronium bromide (Glycopyrrolate) – this is used in children with neurological problems to treat drooling and in anaesthetic medicine to stop people drooling during surgery.
- Placebo (dummy capsule)

All of the treatments are in capsule form and look identical.

You will be asked to take 1 capsule twice daily in week 1 and then 1 capsule three times daily in weeks 2-12.

## How will I know which treatment I'm going to have?

In research studies we often put patients into groups to see how different treatments work. In the GOTHIC2 study participants will be put in three treatment groups at random.

One group will receive hyoscine hydrobromide, another group will receive glycopyrronium bromide (glycopyrrolate) and a third group will receive a placebo.

It is very important that each group has a similar mix of patients in it, so we know that if one group of patients does better than the other it is very likely to be because of the treatment and not because there are differences in the types of patients in each group.

We use a computer programme that puts patients into groups 'at random' – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing. Neither you nor your doctor choose which group you are in.

In the GOTHIC2 study you are equally as likely to be in the group receiving hyoscine, as you are in the groups receiving glycopyrrolate or placebo.

This study is a type of trial called 'blinded' which means that neither you, your doctor or research assistants will know which treatment you will be receiving but the pharmacy team will know for treatment preparation. You will be told which treatment you were on at the end of week 12.

## What are the alternatives for treatment?

There are limited treatments available for CIH/drooling. In standard (routine) care, the medication that is usually prescribed is for drooling is hyoscine and there is no recommended alternative treatment at the moment.

## What are the benefits and risks of taking part?

There is no guarantee that you will benefit. We do not know whether the medicine you are given will have any benefits, but we hope that information from this study will help us improve treatment for patients with CIH Both hyoscine and glycopyrrolate are medications used in the NHS with a known safety record. Although the study medication may help you during the study, one (glycopyrrolate) may not be available at the end of the research (because it may not be available for prescription by either your GP/Mental Health Trust). Hyoscine will be available.

You might have side-effects from the medication and we will measure all side-effects whilst you are in the study.

### **Possible side effects of hyoscine include:**

Like all medicines, hyoscine can cause side effects, although not everybody gets them. Very common side effects (more than one person in 10 may get these) include feeling a bit sleepy or dizzy, eyesight being a bit blurry and having a dry mouth. It is also possible you may get constipated. All of these side effects can also happen with clozapine so you might not notice anything different. There is a very small chance that you might find it more difficult to concentrate or think clearly.

### **Possible side effects of Glycopyrrolate include:**

Like all medicines, glycopyrrolate can cause side effects, although not everybody gets them. Very common side effects (more than 1 person in 10 may get these) include dry mouth, constipation, diarrhoea, vomiting, flushed skin, nasal congestion, having difficulty emptying the bladder (urinary retention), feeling irritable and experiencing a reduction in chest secretions. Common side effects (experienced by one in 10 to 1 in 100 people) include chest infections (including pneumonia\*), urine infections, feeling agitated or drowsy, nose bleeds, rash and fever. \*Glycopyrronium should be discontinued if pneumonia is present.

### **Possible side effects of the placebo content:**

Side effects from placebo are unlikely as it is a dummy capsule with inactive ingredients. The main ingredient, magnesium stearate, is generally safe to consume but too much of it can have a laxative effect.

### **Risks from allergies:**

As with all medicines, some people may be allergic to the capsules. If you are allergic you might experience difficulty in breathing, coughing, wheezing or symptoms such as rash, itching and swelling. Please inform your doctor or nurse if this happens.

## **What happens if I change my mind?**

If at any point you decide to stop taking part in the study, you will still receive the usual, standard treatment and follow up by your clinical team.

If you do decide to stop taking part, we will ask you if you would like to:

- continue with study visits with reduced assessments **or**
- continue to complete follow up visits for the study **or**
- stop taking part with no more study visits.

Information on how we will use your information if you withdraw is in Part 2 of this Information Sheet.

## **What if new information becomes available?**

Sometimes during the course of a research project, important new information becomes available about the treatment/medicine that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw your doctor will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

On receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why, and your continuing care will be arranged.

## **What happens when the study stops?**

At the end of the study, you will likely continue to receive the usual treatment for your condition. Your doctor will be able to give you more information on the options available.

The results will be presented at conferences and published in medical journals so that we can explain to the medical and patient community what our research results have shown. Confidentiality will be ensured at all times and your details will not be identified in any publication.

Anonymous and non-identifying direct quotes may be used for publication and presentation purposes.

A brief summary report of the results will be made available to all study participants.

## **What if there is a problem?**

The research assistant can be contacted in the event of any problem and the research team will help to resolve any issues. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information is given in Part 2 of this information sheet.

## **Will my taking part in the study be kept confidential?**

Yes. All the confidential information about your participation in this study will be kept confidential. Detailed information on this is given in Part 2.

## PART 2: Detailed information about the conduct of the study

### Who is running the study?

The University of Liverpool (as Sponsor) and Mersey Care NHS FT are responsible for managing the trial. They are based in the United Kingdom. They have asked that the day-to-day running of the trial is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool).

The trial has been reviewed and authorised by the Medicines and Healthcare Products (MHRA) Regulatory Agency, the Health Research Authority and the National Research Ethics Service Committee to make sure that the trial is scientifically and ethically acceptable.

This study is funded by the National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme.

No drug companies are involved in the GOTHIC2 study in any way.

Your doctor will not receive any personal payment for including you in this trial. The hospital may receive additional funding to help with any extra costs that supporting this trial might incur.

### How will my information be collected and handled?

The University of Liverpool and Mersey Care NHS Foundation Trust are joint Data Controllers for this trial and will need to use information from you and your medical records for this research project.

This information will include your:

- Initials
- Name
- Age (month and year of birth)

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

Individuals from the University of Liverpool, the LCTC and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

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.

Data will be sent from your hospital/clozapine clinic to the LCTC.

- Main data: from study site → LCTC
- CANTAB: from participant → CANTAB European data centre → LCTC

Please note, if your full date of birth is entered on CANTAB then that date will be made available to us.

We will notify your GP and treating psychiatrist that you will be taking part in the trial for their information.

We will keep all information about you safe and secure.

A copy of your completed consent form will be kept in Liverpool Clinical Trials Centre [LCTC] (where it will be stored in a secure location) to allow confirmation that the consent was given.

Once we have finished the study, we will keep the data for 25 years so we can check the results. We will write our reports in a way that no-one can work out who took part in the study.

The University of Liverpool legal bases for data processing (task in the public interest) are laid out in the LCTC's Privacy Notice (see link below).

### What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason. We will keep information about you that we already have.

In some cases, however we may need to continue to collect limited information about any side-effects of the study treatment you may experience. We will only do this where we are required to do so by law.

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.

### Information sharing for other research

When you agree to take part in a research study, the information about your health and care may be beneficial to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or

companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

## Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients](http://www.hra.nhs.uk/information-about-patients)
- by asking one of the research team
- by sending an email to [site email address](mailto:site_email_address) or
- by calling us on [site phone number](tel:site_phone_number)
- in the Health Research Authority leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by contacting the University of Liverpool Data Protection Officer on [LegalServices@liverpool.ac.uk](mailto:LegalServices@liverpool.ac.uk)
- In the LCTC's "Privacy Notice" available from: <https://www.lctc.org.uk/privacy>
- By Contacting Mersey Care NHS Foundation Trust Data Protection Officer on [DPO@merseycare.nhs.uk](mailto:DPO@merseycare.nhs.uk)
- Mersey Care NHS Foundation Trust "Privacy Notice" <https://www.merseycare.nhs.uk/about-us/privacy>

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF ([www.ico.org.uk](http://www.ico.org.uk)).

## What will happen to the samples I give?

A urine sample for a pregnancy test will be taken from females below 55 years of age at the start and end of the study. These samples will not be stored and will be disposed of after use.

No genetic testing or analysis will be performed on these samples and both blood and urine samples will be destroyed and disposed of after testing.

These samples will be coded and the researchers carrying out tests on the samples will not be given information they do not need to carry out the tests and analyse the results. Coded is not the same as anonymous. It will be

possible to use the codes to identify that a result is from your sample. However, we do not plan to do this unless there is a good reason to do so. We will maintain this information so that we can properly manage the samples. For instance, sometimes we may need to update our record of your clinical details to help us interpret the results of tests. If you choose to withdraw from the study, we won't collect any more samples from you.

## What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of your research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient Advice and Liaison Service (PALS) or equivalent. Members of your local hospital team or GP surgery will be able to provide this information to you or you can find your nearest PALS office on the NHS website:

[www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals](http://www.nhs.uk/service-search/other-health-services/patient-advice-and-liaison-services-pals).

Or phone [NHS 111](tel:111) for details of your nearest PALS.

Every care will be taken in the course of this clinical trial. However, in the very unlikely event that you are harmed by taking part in this research project of the trial Sponsor (University of Liverpool), compensation may be available, and you may have to pay your related legal costs. University of Liverpool provides cover for no fault claims and the clinical trials insurance cover extends to risks related to the study drug and its effects in pregnant partners/babies.

Your hospital/clozapine clinic where you receive your treatment has a duty of care to you whether or not you agree to participate in the trial and the trial Sponsor accepts no liability for negligence on the part of your hospital's employees. However, if you are harmed and this is due to someone's negligence at the hospital, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated but you may have to pay for your legal costs. The normal National Health Service complaints procedures should be available to you.

## STUDY ASSESSMENT TABLE

When	Procedure	Description	Research Treatment or Standard of care
Screening and Baseline Face to Face	Informed Consent	You will be given time to read the consent form and ask any questions before you sign	<i>Research Treatment</i>
	Confirmation of Eligibility	Start 48hr wash out period of any existing hypersalivation medication	
	Blood Tests	Collection of blood sample to measure clozapine level	<b>Standard Care</b>
	Urine Test	Pregnancy test if you are a person of childbearing potential.	<i>Research Treatment</i>
	Medical Assessment and History	Assessment of medical history	<b>Standard Care</b>
		List of current medications	
	Questionnaires completed by you with the help of a research assistant if required	Drooling Rating Scale (DRS)	<i>Research Treatment</i>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
		Liverpool University Neuroleptic Side Effects Rating Scale (LUNSERS)	
		Liverpool Anticholinergic Side-effects Scale (LASS)	
		Patient Assessment of Constipation – Symptoms (PAC-SYM)	
		Rosenberg Self-Esteem scale (RSE)	
Digital cognitive assessments	Cambridge Neuropsychological Test Automated Battery (CANTAB) (Simple, user-friendly tasks completed by you on an interactive tablet device)	<i>Research Treatment</i>	
	Interview led assessments		
Personal and Social Performance Scale (PSP)		<i>Research Treatment</i>	
	Positive and Negative Syndrome Scale (PANSS)		
Within 7 working days of baseline assessment	Randomisation	You will be randomly allocated to a treatment Arm and issued with trial medication to cover weeks 1-4	<i>Research Treatment</i>
Weeks 1&2 Telephone Checks	Questionnaires	Drooling Rating Scale (DRS)	<i>Research Treatment</i>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
Assessments	Safety assessments of adverse events or reactions to trial medication		
Week 4 Face to Face	Questionnaires	Drooling Rating Scale (DRS)	<i>Research Treatment</i>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
		Liverpool University Neuroleptic Side Effects Rating Scale (LUNSERS)	
		Liverpool Anticholinergic Side-effects Scale (LASS)	
		Patient Assessment of Constipation – Symptoms (PAC-SYM)	
	Smoking status		
	Assessments	Safety assessments of adverse events or reactions to trial medication	<b>Standard Care</b>
Medication	Trial medicine review from weeks 1-4	<i>Research Treatment</i>	
	Issued with trial medication to cover weeks 5-8		
Week 6 Telephone Checks	Questionnaires	Drooling Rating Scale (DRS)	<i>Research Treatment</i>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
	Assessments	Safety assessments	

Week 8 Face to Face	Questionnaires	Drooling Rating Scale (DRS)	<b>Research Treatment</b>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
		Liverpool University Neuroleptic Side Effects Rating Scale (LUNSERS)	
		Liverpool Anticholinergic Side-effects Scale (LASS)	
		Patient Assessment of Constipation – Symptoms (PAC-SYM)	
		Smoking status	
Assessments	Safety assessments of adverse events or reactions to trial medication	<b>Standard Care</b>	
Medication	Trial medicine review from weeks 5-8	<b>Research Treatment</b>	
	Issued with trial medication to cover weeks 9-12		
Week 12 Face to Face	Blood Tests	Collection of blood sample to measure clozapine level (for Trusts who capture this measure more than once a year)	<b>Standard Care</b>
	Urine Test	Pregnancy test if you are a person of childbearing potential.	<b>Research Treatment</b>
	Assessments	Safety assessments of adverse events or reactions to trial medication	<b>Standard Care</b>
	Medication	Trial medicine review from weeks 9-12	<b>Research Treatment</b>
		Record changes in prescribed medication	<b>Standard Care</b>
	Questionnaires	Drooling Rating Scale (DRS)	<b>Research Treatment</b>
		Nocturnal Hypersalivation Rating Scale (NHRS)	
		Liverpool University Neuroleptic Side Effects Rating Scale (LUNSERS)	
		Liverpool Anticholinergic Side-effects Scale (LASS)	
		Patient Assessment of Constipation – Symptoms (PAC-SYM)	
		Rosenberg Self-Esteem scale (RSE)	
	Smoking status		
	Digital cognitive assessments	Cambridge Neuropsychological Test Automated Battery (CANTAB) (Simple, user-friendly tasks completed by you on an interactive tablet device)	<b>Research Treatment</b>
	Interview led assessments	Personal and Social Performance Scale (PSP)	
Positive and Negative Syndrome Scale (PANSS)			
Discussion	Record participant preference to stay on allocated medication or leave the trial		
Unblind	Reveal which study medication you have been taking	<b>Standard Care</b>	
Appointment	Appointment made for discussion with your clinical team about the best treatment options available to you for CIH		
Medication	Record changes in prescribed medication		

**Thank you for taking the time to read and consider this information sheet. Should you decide to take part in the study, you will be given a copy of this information sheet and signed consent form to keep.**

**FOR SITE USE ONLY:**

Site Name:												
Participant Trial Number:												
Participant Initials:				Participant DOB (MM/YYYY):								

## Participant Consent Form

*To be completed by the participant:*

Once you have read and understood each statement, please enter your initials in each box. Initial

1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.
2. I understand that participation is voluntary and that I am free to withdraw from the study at any time, without giving a reason, and without my care or legal rights being affected. However, the study team may need to collect some limited information for safety reasons.
3. I agree to take part in the above study.
4. I give permission for a copy of this fully completed consent form to be sent to the Liverpool Clinical Trials Centre [LCTC] (where it will be kept in a secure location) to allow confirmation that my consent was given.
5. I understand that relevant sections of my medical notes and any data collected during the study may be looked at by authorised individuals from the central study team and representatives of the Sponsor, regulatory authorities, and the local NHS Trust. I give permission for these individuals to have access to my records and data.
6. I agree to my GP and clozapine clinic, psychiatrist/Doctor being informed of my participation in the study and provide us with a list of the medication that I am on.
7. I agree for the relevant data on my NHS hospital admissions and treatment to be collected from my medical records for the purposes of this study.
8. I understand that my data will be kept by the University of Liverpool and at my hospital in a confidential manner for 25 years from the end of the study.

The statements below are **optional** (you can still take part in the study even if you do not wish to agree to these).  
 Please enter your initials in each box:

- |                                                                                                                                                                                                                                                       | YES                      | NO                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| 9. I agree that information and results from this study may be used for future healthcare and medical research. My personal identity will not be disclosed, and only coded (pseudonymised) data will be used, so that researchers cannot identify me. | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I agree that I may be contacted in the future in relation to this or other related studies.<br>(if you agree to this statement provide your details below):                                                                                       |                          |                          |
| Telephone number:                                                                                                                                                                                                                                     | <input type="checkbox"/> |                          |
| Email address:                                                                                                                                                                                                                                        | <input type="checkbox"/> |                          |

*To be completed by the participant:*

Your full name (please print):			
Your signature:		Date:	

<Trust/Site address 1>  
 <Trust/Site address 2>  
 <Trust/Site address 3>  
 <postcode>  
 Tel: <telephone number>

**FOR SITE USE ONLY:**

Site Name:												
Participant Trial Number:												
Participant Initials:				Participant DOB (MM/YYYY):			/					

**Participant Consent Form**

*To be completed by the Researcher (after participant has completed the form):*

Researcher full name (please print):												
Researcher signature:								Date:				

Please file the original wet ink copy in the GOTHIC2 Investigator Site File, and make three copies: one for the participant, one for the medical notes and one to be sent to the LCTC.