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Trial title: A multi-centre investigation of increasing alcohol abstinence with ketamine-assisted psychological therapy in severe alcohol use disorder.

MORE-KARE DETAILED PARTICIPANT INFORMATION SHEET

EXCLUDING BACtrack SKYN

We would like to invite you to take part in the MORE-KARE trial which is sponsored by the University of Exeter, with funding from the National Institute for Health and Care Research (NIHR) and Awakn Life Sciences (Part of Solvonis Therapeutics). Before you decide to take part, it is important to explain why we are doing this research and what it will involve, so please take some time to carefully read the following information and do not hesitate to contact us if you have any further questions. One of our team will go through the information sheet with you and answer any questions you have.

Your participation is entirely voluntary, and you will be given time to decide if you would like to join this trial or not. Please ask the trial team any questions you have, and we encourage you to discuss the trial with your friends, family or other services you are working with. You can choose to stop taking part in this trial at any time, it will not affect the care you receive or your legal rights and do not have to give a reason why you do not wish to take part.

1. Why are we doing this trial?

Over half a million adults in the UK have alcohol problems that require treatment.

Just 1 in 4 people with an alcohol problem get treatment, and current treatment methods often are not very good at stopping people returning to heavy drinking in the long term.

A growing body of research suggests that ketamine has promising applications in the treatment of alcohol problems. This trial aims to find out if ketamine combined with psychological therapy can help increase alcohol abstinence.

2. Why have I been invited to take part in this trial?

You have been invited to take part because you have stopped, or have expressed a desire to reduce or stop, drinking alcohol. This trial aims to recruit 280 participants from approximately 10 research centres across the UK.

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

You will be supplied with this information sheet and the research team will explain the trial in detail and give you a chance to ask any questions. If you would like to, you can discuss whether to take part with others, such as family and friends.

If you agree to take part in the trial, you will be asked to sign an Informed Consent Form and be given a copy of this to take away. Copies of the consent form will be filed in your patient notes, the trial records, be sent to your GP and Exeter Clinical Trials Unit.

- You will be asked to fill in a self-assessment questionnaire online and have a screening telephone call with a relevant member of the trial team.
- If it appears that you may be suitable for the trial, you will be asked to attend one **screening visit** at your nearest participating research centre.
- You will also have four support calls with the site therapist over 2-4 weeks between screening and your first treatment visit to prepare for the trial and ask you about your drinking. You will be provided with a booklet to complete prior to these calls.
- If you appear to be eligible based on your screening visit assessments, you will be invited to your first treatment visit. On this day some screening assessments will be repeated e.g. breathalyser and urine drug testing (including alcohol). If you are eligible based on these results you will be entered into the trial.
- You will be invited to attend seven **treatment visits** and two **follow up visits** at your nearest participating research centre.
- Your treatment visits will consist of seven **psychological support sessions** with the trial therapist and **three infusions** (via a tube inserted into your vein) of the trial drug, ketamine.
- After the treatment period is complete, you will be invited to attend a 3- and 6-month follow-up visit, and your research team will contact you before these to check you are still able to attend these appointments.
- You will be asked to self-breathalyse every day.
- You will be asked to keep an alcohol diary every day after you finish treatment until your final trial visit.

After your participation in the main trial has finished, i.e., after your six month follow up:

- Everyone can opt in to take part in a voluntary online support forum, where you can discuss aspects of the trial and your experiences with fellow trial participants.

You will also be asked whether you would like to opt in to:

- A voluntary interview with a member of the University of Exeter to talk about your experiences of the trial over the phone or a video call. This interview would be within 3 months of your final visit.
- A further voluntary online follow up visit, at around one year after your first infusion visit.

4. What is Ketamine?

Ketamine is a dissociative anaesthetic drug that is widely used in general hospitals. Ketamine can make you feel very strange, like you are outside of your body, or have strange changes to vision and hearing. In this trial smaller doses of ketamine will be used rather than anaesthetic doses. At the doses being used in this trial, ketamine can function as a rapid acting anti-depressant, which has been found to reduce depressive symptoms in people with alcohol problems up to 6 months after treatment.

In this trial, you will receive one of two doses of ketamine; either 0.8mg/kg or 0.05mg/kg over 40 minutes intravenously. You will be randomly assigned to one of these two groups by a computer and neither you nor the research team delivering the infusion will know which group you are in.

5. What are the psychological support sessions?

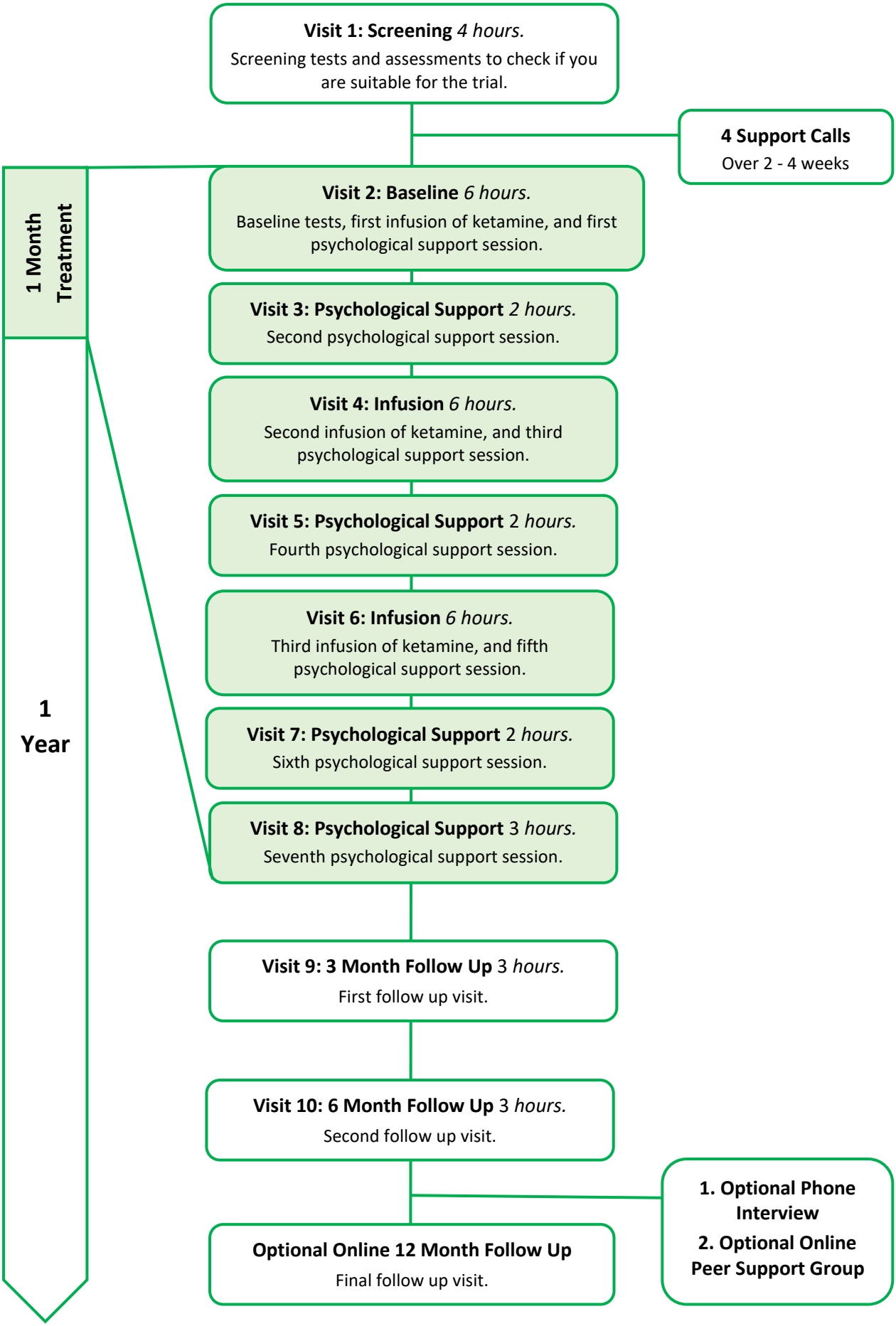
You will receive 7 sessions of psychological support during the trial, which could be either therapy or alcohol education. Both the therapy and alcohol education will be delivered by a therapist. These sessions are included in the trial as they can help some people reduce their drinking or remain sober. The therapy and education sessions will involve working through a structured booklet with a therapist and exploring practical strategies to manage alcohol. All participants will be encouraged to journal and privately write about their trial experiences.

The type of psychological support you receive will be randomly assigned by a computer. All sessions will be audio recorded; the recordings will be kept confidential and securely stored by the University of Exeter and only accessed by the trial therapist team. In the interest of ensuring yours and others safety, confidentiality would only be broken if the therapist felt that either you or someone else's health, safety or welfare would otherwise be put at risk. This would be discussed with you first unless it was not possible or safe to do so.

6. What will happen at each trial visit?

Pre-Screening

If you are interested in taking part in the trial, you must complete an online self-assessment questionnaire on the trial website https://sites.exeter.ac.uk/morekare/. However, if you do not have internet access, those referring you to the trial can print the trial documents for you and give the contact details for your local research team so that you can contact them directly. No information will be stored about you from your self-assessment questionnaire answers. If it appears that you may be suitable for the trial based on your answers to the online questionnaire, you will be given the contact details for your local research team, and they will arrange a suitable date and time to have a pre-screening phone call. During this phone call the research team will discuss the trial further with you and further confirm your potential suitability for the trial. If after this phone call you would still like to take part, the research team will arrange an in-person screening visit for you at the research centre.


Visit 1: Screening 4 hours.
Screening tests and assessments to check if you are suitable for the trial.
4 Support Calls
Over 2 - 4 weeks
1 Month Treatment
Visit 2: Baseline 6 hours.
Baseline tests, first infusion of ketamine, and first psychological support session.
Visit 3: Psychological Support 2 hours.
Second psychological support session.
Visit 4: Infusion 6 hours.
Second infusion of ketamine, and third psychological support session.
Visit 5: Psychological Support 2 hours.
Fourth psychological support session.
Visit 6: Infusion 6 hours.
Third infusion of ketamine, and fifth psychological support session.
Visit 7: Psychological Support 2 hours.
Sixth psychological support session.
Visit 8: Psychological Support 3 hours.
Seventh psychological support session.
1 Year
Visit 9: 3 Month Follow Up 3 hours.
First follow up visit.
Visit 10: 6 Month Follow Up 3 hours.
Second follow up visit.
1. Optional Phone Interview
2. Optional Online Peer Support Group
Optional Online 12 Month Follow Up
Final follow up visit.

Screening

At the screening visit a member of your local research team will talk through the trial in more detail, and answer any questions you may have, before asking you to give your consent to take part by signing an informed consent form. They will then go through screening tests and assessments with you, including:

- A breathalyser test.
- Your medical history.
- A physical examination of your height and weight, and heart, breathing, digestive and nervous system function.
- A check of your vital signs, including your temperature, resting heart rate, blood oxygen level, and blood pressure.
- Blood tests to check your general health. Three small tubes of blood (about a teaspoon each) will be taken from a vein.
- A urine drug screening (including alcohol).
- A pregnancy test, only if applicable.
- A review of your current medications.
- Several questionnaires about your psychological health, mood, feelings towards alcohol and history of alcohol and recreational drug use.

Self-breathalysing and drink diaries

As part of this trial, you will be asked to keep a drink diary and self-breathalyse every day from your first infusion visit onwards. You will be supplied with a breathalyser to use. Each day after you wake up, you should blow into the breathalyser and record your reading in a diary we will supply. The breathalyser will store some readings as well. We would also like you to keep a record of how much alcohol you drink each day on this diary. The research team will ask to see your breathalyser data and drink diary at each visit to make a record of these readings.

We will not be able to confirm whether you are eligible for the trial at the screening visit as we will need to wait for the results of your blood tests and your urine drug results to inform us that it is safe for you to receive ketamine. This usually takes a minimum of 24 hours. The research team will contact you to let you know whether your first treatment visit can be booked. We will also write to your GP after your screening visit to say that you would like to take part in this trial. Some screening assessments e.g. breathalyser and urine tests, will also be repeated at subsequent treatment visit. Positive results will be communicated back to you.

After screening you will be asked to return to the research centre to start your treatment visits within 28 days. You can only start treatment if you are completely abstinent from alcohol and ideally for a minimum of 2 weeks. If this is not possible within the 28 days, you will need to repeat the screening visit to take part. It is important that you safely reduce your alcohol consumption. A medical detoxification may be needed, or in other circumstances support may be needed from your local alcohol services or GP.

You may be found not to be suitable for the trial based on test results taken at screening, such as elevated blood pressure, blood tests that are outside of the normal range, and positive drug

screening. In this case it may be possible to repeat these screening tests depending on the nature of the results at the discretion of the research team at the centre.

Support Calls

You will receive four video/telephone calls over the course of 2 to 4 weeks between your screening and baseline visit from the trial therapist. These calls will involve a check in about your alcohol use and other discussions to support you in preparing to take part in the trial. You will be provided with a booklet to complete before these calls, which will include a drink diary and space to reflect on topics which may be relevant to your participation. The trial therapist will discuss your answers with you on these calls in preparation for your first infusion visit and your booklets should be brought along to visit 2 (baseline visit).

Randomisation

All the people in this trial will be treated with a dose of ketamine with either psychological therapy or alcohol education. A computer will randomly decide which treatment you receive. You have an equal chance of being allocated to the different treatment options. Neither you, nor the doctors/nurses, or the research team can choose which treatment you receive. This is so we can make a fair and unbiased assessment about which treatment option is best for people with alcohol problems. It is important to only take part in this trial if you are happy to receive any of the treatments.

Blinding

This trial is a 'double-blind' trial, which means that neither you nor the team administering the trial drug will know which treatment you are receiving. The therapist will however know which psychological support sessions they are delivering but will not give this information to you. This trial is designed in this way to avoid bias about which treatment you are receiving in case knowing what treatment you are receiving affects the results of the trial in some way.

Visit Plan

Timing of assessments	What will happen
Visit 1 **i.e., screening visit**	• Informed consent process • Physical examination, medical and medication history • Vital signs check, blood tests and breathalyser reading • Urine drug test including alcohol (to include a pregnancy test in people of childbearing potential) • Questionnaire/interview assessments looking at psychological health, mood, feelings towards alcohol and history of alcohol and recreational drug use •

Visit 2 **i.e., baseline visit**	• Vital signs check, blood tests (before and after infusion) and breathalyser reading • Urine drug test including alcohol (to include a pregnancy test in people of childbearing potential) • Medication history • Questionnaire/interview assessments • Enrolment into the trial • Psychological support session • Trial drug infusion
Visit 3	• Vital signs check and breathalyser reading • Urine drug test including alcohol • Medication history • Questionnaire/interview assessments • Psychological support session
Visit 4	• Same procedures as visit 2 but with slightly fewer questionnaires/interviews
Visit 5	• Same procedures as visit 3
Visit 6	• Same procedures as visit 2 but with slightly fewer questionnaires/interviews
Visit 7	• Same procedures as visit 3
Visit 8	• Vital signs check, blood tests and breathalyser reading • Urine test • Medication history • Questionnaire/interview assessments • Psychological support session • Drink diary given and discussed
Visit 9 **i.e., 3 month follow-up**	• Blood tests and breathalyser reading • Urine test • Medication history • Questionnaire/interview assessments • Drink diary reviewed and discussed
Visit 10 **i.e., 6 month follow-up**	• Same procedures at visit 9

Infusions

At visits 2, 4, and 6, you will receive a dose of ketamine over the course of 40 minutes. A very thin tube called a cannula will be inserted into a vein in your arm or hand, allowing the drug to be slowly pumped into your blood. Some people can experience dissociative effects which make you feel very strange, like you are outside of your body, or have strange changes to vision and hearing. These effects only last for a short time and wear off quickly after the infusion is stopped.

Before coming to each infusion visit you can have a light breakfast but must **then fast up until (excluding water) for two hours before the infusion**, which means no food, fruit juices, or milk can be consumed in that time. You should also avoid drinking grapefruit juice at all on infusion visit days. Examples of a light breakfast include cereals such as rice crispies, cornflakes, porridge or ready break with milk, bread or toast (white or brown) with a small amount of butter and jam or marmalade,

scrambled egg or omelette, Ovaltine or Horlicks drinks, tea, coffee, milk, squash, cocoa, build up drinks. <You may bring your own lunch for after the infusion, or food may be provided at the site>. You should wear loose fitting, comfortable clothing, or bring a change of clothes with you.

During the infusion you will lie down or be reclined in a chair and will be given the choice to listen to music. A member of the research team will stay with you throughout the infusion. You will have to stay in the research centre for a minimum of 2 hours after receiving the trial drug, until your research team are happy that any potential side effects have gone.

Your infusion visits will be scheduled at weekly intervals, however there is some flexibility if this is not possible for you or the research team. Infusion visits can be between 4-21 days apart.

Psychological Support

You will receive seven psychological support sessions each lasting about an hour to an hour and a half with your trial therapist from visit 2 to visit 8. These sessions could either be therapy or alcohol education; and, as with the ketamine dose, will be randomly assigned following your screening visit. All psychological support sessions will be recorded for review by the lead therapists, but all recordings will remain confidential with access restricted to only those who need it.

Your follow-up psychological support sessions (visits 3, 5 and 7) will be scheduled for the day after each infusion visit, however there is some flexibility if this is not possible for you or the research team. These visits will be between 1 to 5 days after an infusion visit.

In Person Follow Up

At around 3 and 6 months after your visit 2, your research team will contact you to check that you would be happy to attend for your follow up visits and remind you to complete your alcohol diaries. These visits will not involve any treatments with the trial drug or psychological support. Please see the visit plan table for an outline of what will happen at these visits.

Qualitative Interviews

If you have undertaken the trial, you will be invited to take part in a voluntary interview over the phone/video call/zoom/Microsoft teams which will take place within the first 3 months after your visit 10 follow up. The interview should take no longer than 30 minutes. This will give you an opportunity to talk about your personal experiences of the trial treatment with a researcher from the University of Exeter. Your participation in this interview is optional and will not affect your opportunity to take part in the trial. There is a separate part of the consent form about this part of the trial.

Typed copies will be made (transcripts) of the recorded interviews. We will ensure all the information in these copies is anonymous by removing all named references to you or your family and friends to protect confidentiality. Once a written copy of your interview is made the audio recording will be deleted. .

Online Peer Support Group

If you took part in the trial, you will be invited to take part in a voluntary online peer support group with other trial participants to provide a space to discuss your trial experiences with others who have gone through the trial. It was recommended after our previous trial by past participants that having such a forum could be beneficial to future participants. You do not however have to take part in these sessions, and they will be conducted outside of the trial and will be participant led.

Online Follow Up

If you were enrolled into the trial within the first year and a half of recruitment, you will have the opportunity to collect a further 6-months of drink diary information for the trial. You will also be sent an online questionnaire to complete a year after your first treatment visit to provide us with information about your drinking. A member of your research team will also call you to ask you some further questions.

7. What are the benefits of participating?

We hope that your participation in the trial helps you with your own aims to reduce or quit drinking alcohol. You will also be offered psychological support which can help some people reduce their drinking or remain sober.

Whilst participation may or may not have direct benefits for you, taking part in this research could lead to improvements in future understanding and treatment of alcohol use disorders, and help people to remain abstinent for longer.

8. Are there any potential risks to me?

Ketamine is safe and well tolerated in humans at the doses chosen for this trial. However, like all medicines, ketamine can cause effects on the body; most of these effects are mild and resolve quickly after the infusion of the medication has finished. In this trial we are using lower doses of ketamine than those used in anaesthesia. Ketamine has different effects on different people, however common effects at this dose (affecting 1 in 10 people) are likely to include dissociative effects which may feel strange, like you are outside of your body, or have strange changes to hearing or vision. Some people can feel nauseous or be sick when they recieve ketamine and their breathing, blood pressure and heart rate can quicken. You may also experience a mild rash or redness of the skin following the infusion, this will resolve after the infusion stops. You will be closely watched throughout and after each infusion to check for any effects. The effects only last for a short time and wear off quickly after the infusion is stopped.

Other effects of ketamine that have occurred in patients who are given ketamine at higher doses, for example in anaesthesia, which are uncommon (affecting 1 in 100 people) include slowing of the heart rate, changes in heart rhythm, pain or inflammation of the skin at the injection site, loss of appetite, lowered blood pressure, anxiety, a slowing of breathing rate, and/or blocking of the voice box. Rare effects of ketamine (affecting less than 1 in 1000 people) at anaesthetic doses include increased salivation, sleep problems and cystitis. As with most medicines there is a possibility that an allergic reaction might occur, however severe allergic reactions to ketamine appear to be rare. There are also some effects which have never been observed at this low dose we are using in this trial but have been found at much higher doses of ketamine or with prolonged daily usage of ketamine: abnormal liver function tests and raised pressure in the eyes.

You should not take ketamine recreationally outside of the infusions you will receive during the trial. As we have outlined above, we will carry out urine drug screens including alcohol, during the trial and unfortunately if you test positive for ketamine you will be withdrawn from treatment in the trial but invited to continue to come to the 3-month and 6-month follow-up visits. Other positive urine tests will be reported back to you.

Pregnancy

It is possible that if the treatment is given to a pregnant person, it could harm the unborn child. Pregnant people must therefore not take part in this trial; neither should a person who plans to become pregnant during the trial or anyone who is currently breastfeeding. All trial participants should use effective forms of contraception during the trial and must inform the local trial team if pregnancy occurs for you or a sexual partner. People of childbearing potential will be asked to take a pregnancy test before taking part and prior to each infusion. If you become pregnant during the trial, we will ask you permission to follow the pregnancy to its completion and collect information. If your sexual partner becomes pregnant, we will supply a pregnant partner information sheet and ask their permission to follow the pregnancy to its completion. Any information that needs to be shared with the trial Sponsor, ethics committee or UK regulatory body for medicines will be anonymised so neither the child nor mother can be identified.

Driving

On the days of the ketamine infusion, you **must not drive or use heavy machinery** in the 24 hours following the infusion. We recommend that a responsible adult takes you home on infusion visits, or we can cover the cost of taxis and public transport for you.

Current Medications and Health Conditions

There are some medicines that can interact with ketamine, and so anyone taking certain medications every day would not be able to take part in this trial. Please tell your local trial team if you are taking any medications, including over the counter medication, vitamins and herbal supplements who will check whether they are safe to be taken with ketamine.

There are some health conditions in which ketamine is not recommended to be used. The local site team will ask you lots of questions about your physical and mental health at your screening visit and subsequent visits. Please tell the team if you have any medical conditions and they will check whether it is safe for you to receive ketamine.

With your permission, we will also write to your GP after your screening visit to notify them you are taking part in this trial and will provide a copy of your consent form. We will also request information on any medical conditions or medications you are taking that could put you at risk if you took part in this trial.

Blood Sampling and Cannulation

We will ask you for a blood sample at several time points during this trial, please see the visit plan table above. These blood tests involve a needle and can be a little uncomfortable. At each of the 3 infusion visits, a medic or nurse will also insert a tube into your vein to allow the infusion of ketamine (a procedure called cannulation). This will be a different needle to the one used to take your blood sample. At infusion visits blood samples will be taken both before and after your infusion. Some people experience discomfort, bruising or fainting. In rare cases, you may get an infection. If you have ever suffered from complications when giving a blood sample or have a severe fear of needles, you should **not** take part in this trial.

Psychological Support

You will have several sessions of psychological therapy or alcohol education in this trial. Most people find this a positive and helpful process however during psychological support sessions you may experience memories and feelings that are uncomfortable or painful for you. You do not have to discuss anything that you do not wish to, and the therapist will only talk to you about that which you are happy to talk about. Anything you do discuss will be completely confidential between you and the therapist team. Sessions will be audio-recorded but this is so another therapist in the team can confirm that the psychological therapy is being conducted correctly. The only instance where the therapist is under obligation to disclose information is if they feel there is a serious risk to you or another person's health, safety or welfare. Any breach would be discussed with you first unless it was not possible or safe to do so.

Before taking part in the trial, you should consider whether your participation will affect any health insurance you have and seek advice if necessary.

9. Will I receive any expenses or payments?

We are able to arrange travel for you or can reimburse you for travel expenses incurred to attend your trial visits. If you live a long way from your nearest participating research centre, it can be

considered whether we can arrange accommodation for an overnight stay or reimburse you for these expenses. Reimbursement will be via bank transfer through the University of Exeter.

As a token of appreciation for you taking part, we will offer you high street shopping vouchers. We will offer a voucher for £52 after Visit 8. Then if you complete Visits 9 and 10 we will offer you an additional £100 voucher after each follow-up visit. This means the total amount available to you is £252 of vouchers. The vouchers are optional, so you do not have to accept them. You will have the option of a voucher card or a digital code to use online. Receiving these vouchers for your participation in this trial could have tax implications. To check whether this will affect you please refer to the HMRC website.

10. What are the alternatives for treatment?

Your doctor may have discussed alternative treatments with you. These are likely to include other drug treatments including acamprosate and disulfiram and may also include some form of talking therapy.

11. Who is organising this trial?

The University of Exeter is the Sponsor for the trial and has overall responsibility for the trial. The trial is being organised and run on their behalf by Exeter Clinical Trials Unit, University of Exeter. Dr Stepehen Kaar from Greater Manchester Mental Health NHS Foundation Trust is the Chief Investigator and is overseeing the trial. This trial is funded by the National Institute for Health and Care Research – Efficacy and Mechanism Evaluation (NIHR150193) and Awakn Life Sciences (Part of Solvonis Therapeutics). Before this trial, some of the team ran a smaller trial using ketamine with therapy. Awakn has the licence to use the therapy manual for treating mental health problems. Members of the research team who helped create the therapy manual for that trial receive money from Awakn Life Sciences (Part of Solvonis Therapeutics) via the University for use of this manual.

Any research conducted in the United Kingdom is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. The MORE-KARE trial has been reviewed and approved by London – London Bridge Research Ethics Committee.

12. How will we use information about you?

The University of Exeter is the Sponsor for this trial. We are responsible for looking after you and your information and using it properly. Your data will be stored and used in compliance with data protection legislation. In 2018 changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018).

Since the UK left the EU, key principles of EU GDPR have been adopted in a UK-only version (UK GDPR) and the DPA 2018 still applies.

The University of Exeter's lawful basis to process personal data for research is 'public interest'.

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

This information will include your name, date of birth, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. This may include people from the clinical trial site, University of Exeter and regulatory authorities where it is relevant to the research.

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, called a participant ID, instead. We will keep all information about you safe and secure.

Information collected about you for the trial ('trial data') will be entered onto a trial database hosted by the University of Exeter. You will be identified by your participant ID, you can see this ID on your consent form. This database will also hold your contact details and a copy of your consent form with your name visible, this will be accessible to authorised members of the study team that have a need to see your details.

Once we have finished the trial, 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 trial.

If you agree, information collected about you will be used to support other research in the future and shared anonymously with other researchers.

In line with University of Exeter policy, at the end of the trial, your data including the interview transcript will be securely archived for a minimum of 10 years. Arrangements for confidential destruction will then be made.

13. What are my choices about how my information is used?

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

As 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.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one the research team, or
- by contacting the University Data Protection Officer, details available at https://www.exeter.ac.uk/about/oursite/dataprotection/dpo/

15. What happens with my samples?

Your urine samples provided at trial visits will be analysed by the research team, before being destroyed. Most of the blood samples you provide us with will be sent to a local hospital NHS laboratory for testing and analysis, before being safely destroyed.

Some of your blood samples will be transferred *via* a secure courier to the 'Analytical Services International' in London, England, for further testing and analysis. This laboratory will be performing a check on the ketamine levels in your blood. These samples will be labelled only with a code number only, no personal identifiable data will be shared with the laboratory. The results from these tests will not be fed back to your doctors or other professionals outside the research team.

16. What if I don't want to carry on in the trial?

If you decide you do not want to carry on with the trial you may withdraw at any time and without giving a reason. However, we may ask you for a reason, to help us design better studies for the future, it is up to you whether you are happy to supply a reason or not. If you choose to stop taking part, we will still keep records relating to the treatment given to you, as this is valuable to the trial and your safety. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive, or your legal rights.

If you opted in to receive a copy of the results of the trial, we will still share the results with you unless you express you no longer wish to receive these. If you would like to know your treatment allocation you should communicate this to the trial team.

17. What if relevant new information becomes available?

Sometimes during a trial new information about the treatment being investigated becomes available. If this happens, one of the research team will discuss this new information with you and any necessary further action. If you have withdrawn from the trial, if such information becomes available it may be necessary to contact you to discuss this with you.

18. What happens at the end of the trial?

You will not receive any further treatment with this drug or therapy as part of this trial, however, you will have the opportunity to take part in an online voluntary peer support group with other trial participants. These would be optional online sessions outside of the trial. Whether you decide to take part in these sessions will not impact on your opportunity to take part in the trial.

After the final follow up visit, if you would like to receive further help or advice about your alcohol use, we will be happy to help you find further services that are available to you.

As this is a double-blind trial, we will not be able to tell you which treatment you received until the results have been published. If you wish to find out the results of the trial, you should complete the relevant section of the informed consent form. If you would like to be made aware of your treatment allocation, please let the research team know at Visit 10 and this information can be supplied once all participants have completed the trial.

19. What if there is a problem or I have any complaints?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be taken seriously. If you have any concerns about any aspect of this trial you should speak to your trial doctor who will do their best to answer your questions, their contact details are listed in section 20 of this information sheet.

We do not expect that you will be placed at any greater risk by taking part in this trial. However, in the unlikely event that you are injured as a result of the managing organisation (the University of Exeter), compensation may be available and you many have to pay your related legal costs. The clinical trial site where you receive your treatment has a duty of care to you, and the University of Exeter accepts no liability for negligence or misconduct on the part of the clinical trial site's employees. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the Sponsor (the University of Exeter) or the clinical trial site, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you can do this through the Sponsor of the trial, the University of Exeter, details in section 20.

[Select text as per NHS or non-NHS site as appropriate]

For NHS sites:

Alternatively, you can use the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your hospital on <insert number>, or make a

formal complaint by writing to <insert address>. This will not affect your hospital treatment in any way.

For non-NHS sites:

Alternatively, if you wish to speak with someone not directly involved with the research study, or if you wish to make a complaint, you should contact the Private institutioanl arrangements at: 02038914862 or qualityteam@clerkenwellhealth.com

Participants are expected to treat all staff and fellow participants with respect. We operate a zero tolerance policy towards abusive, threatening, discriminatory or harassing behaviour. Anyone behaving in such a way may have their participation withdrawn.

20. How to contact us

Your Principal Investigator: {insert name} Phone: Email:	Your Research Therapist: {insert name} Phone: Email:
Your Research Nurse: {insert name} Phone: Email:	Sponsor's representative: Suzy Wignall, Research Ethics and Governance Office, University Corporate Services, University of Exeter Phone: 01392 726621 Email: res-sponsor@exeter.ac.uk

Alternatively, if you or your relatives have any questions about this trial you may wish to contact your GP/local alcohol service which are independent of the research centre at which you are being treated.

We will give you a card (the same size as a credit card) with the research teams contact details (both in and out of hours) for you to always carry while you are on the trial. If you see a doctor while you are taking part in the trial, you should show this to them so that they can treat you appropriately.

Thank you for taking the time to read this participant information sheet.

We encourage you to ask as many questions as you wish, before, during and after your participation.

If you have any questions about the trial, please speak to your research nurse or doctor.