

KARE: Client Information Leaflet



Awakn™ Clinics

Client information leaflet for people undergoing KARE Therapy (ketamine for the Reduction of Alcoholic Relapse) at Awakn Clinics

Welcome to Awakn Clinics

We are the UK's leading provider of psychedelic-assisted psychotherapy, combining the proven therapeutic potential of ketamine with psychological therapy to treat Addiction. We believe that care should always be client-centred and want you to be well informed about the clinic and the therapy options available. This leaflet provides information about the treatment we offer to help answer some of the questions you may have.

If you have any questions, please review the FAQs at the end of this document or talk to a member of our clinical staff.

What is ketamine?

Ketamine is a synthetic drug that has been used extensively in medicine since the 1970s. It is used every day in emergency departments all over the world at high doses as an effective and safe anaesthetic agent for carrying out brief surgical procedures. It has more recently been discovered that at much lower doses it has both antidepressant and psychedelic properties.

What is KARE?

KARE is the world's first evidence-based ketamine-assisted psychotherapy and Awakn Clinics are the only organisation in the world with the license to deliver this treatment for people with alcohol problems. Many clinics provide intravenous (IV) infused ketamine as an antidepressant drug. Most of these clinics do not use ketamine alongside psychotherapy and do not follow evidence-based protocols in the way KARE does. Research has demonstrated that ketamine can have a profoundly enhancing

effect on the brain's ability to grow new neural pathways. This means that in the days following the ketamine experience, people can think in new ways about problems they might be facing in their lives. In the KARE protocol, we utilise this enhanced creative state that ketamine provides, alongside an adapted but established psychotherapy methodology to help people find ways to overcome and move on from their problem drinking. The efficacy of the KARE treatment protocol has been demonstrated in a Phase II Clinical trial, a form of highly regulated clinical trial considered the gold standard of medical research and shown to be considerably more effective than therapy alone.

Who is KARE for at Awakn Clinics?

KARE is an alcohol relapse prevention intervention that has been developed to help people maintain sobriety. This means that to undergo this treatment clients will need to have reduced to the levels they can stop safely at the start of treatment. We realise that many people will still be drinking when they come to us, so in this case we will support people to access the appropriate support to achieve sobriety before starting KARE.

Enrolment in the Awakn KARE treatment

All patients undergoing KARE must be registered with a UK GP. This is essential for us to communicate medical issues between Awakn and your GP.

There are some eligibility criteria you must meet before being considered for the Awakn KARE course. Some conditions would indicate that ketamine assisted psychotherapy may not be safe or appropriate for you. Once you have been screened and you meet the criteria to progress, you will be assigned a 1:1 therapist, who will be with you throughout your KARE therapy. At this point, you will be given the dates for all your visits.

The structure of the Awakn KARE course

Following your initial inquiry with Awakn we will contact you and request further information regarding your medical history. This information will be reviewed by our multidisciplinary team for an initial screening. Following this you will be invited to attend an 'Initial Medical Assessment' for further screening and a discussion regarding treatment options.

If you are deemed safe to undertake the treatment then your therapist will arrange a series of 'support calls', to assist you in achieving or maintaining abstinence in the run-up to starting therapy.

KARE therapy is a seven session programme with three high dose injections. The programme runs over a minimum of four weeks but the length of time between treatment sessions can be adjusted to fit your schedule. Each treatment week you will come into the clinic where you will have a therapy and mindfulness session followed immediately by a ketamine dosing session (this is a high 1.0 mg/kg intramuscular ketamine injection). After each dosing session, you will return to our clinic the following day for an integration session to build on any thoughts or new perspectives you may have gained from the previous day. On this follow-up day, you will also have further therapy. This pattern runs for the first three treatment blocks of KARE, on the final week you will have an evaluation therapy session to consolidate and complete treatment and assess the need for further treatment. A graphical representation of the treatment protocol can be found in the appendix.

Support during clinic visits:

At every visit to the Awakn Clinic, you will be closely monitored and cared for by an attendant nurse and your 1:1 therapist who is trained in delivering ketamine assisted therapy. There will always be help at hand. The whole course will be overseen by a senior medical professional who will ensure you are safe and feel comfortable.

Questionnaires and outcome measures

To assess how well the course is working for you, we will carry out baseline questionnaires at the initial screening appointment, at every weekly session and again at the end of the course to see how you have progressed.

How much does the Awakn KARE treatment course cost?

Each client will be required to pay £350 for an initial medical assessment. The £350 for the medical assessment is non-refundable, whether you go onto the therapeutic course or not. Upon completion of a successful medical assessment, the client shall be entered into the Awakn KARE course for a cost of £4,995 in Bristol and £6,995 in London, which can either be paid as one single payment, or paid in four instalments ahead of sessions 1,4,6 and 8 of your treatment protocol as follows:

Bristol payment instalments (optional)

Session 1	£240
Session 4	£1,356
Session 6	£1,356
Session 8	£1,693

London payment instalments (optional)

Session 1	£500
Session 4	£1,892
Session 6	£1,892
Session 8	£2,361

Get in touch

If you have any further questions about the Awakn KARE course, you can contact our London clinic on 020 7387 2596, or our Bristol clinic on 0117 985 0439 where you will have the opportunity to speak with one of our clinicians. Alternatively you can visit our website for more details: www.awaknlifesciences.com/clinics

FAQs

This section contains the answers to some of the common questions that arise regarding ketamine-assisted psychotherapy.



General information about psychedelic therapy

What is psychedelic therapy?

Psychedelic therapy refers to using drugs that alter consciousness, combined with psychotherapy, to offer clients the opportunity to address difficult psychological issues, supported by their therapist. The drugs, in combination with talking therapy, allow the client to experience a deeper and more effective therapeutic experience.

Aren't psychedelics drugs of abuse? How is this different?

Historically many drugs that have therapeutic benefits have been banned by governments. However, current research shows that many such drugs do have important therapeutic properties and can be used safely as treatments for a wide range of medical conditions. The way many drugs (e.g. cannabis, MDMA, psilocybin (magic mushrooms), LSD and ketamine) are used recreationally is very different from how they are used in controlled medical settings. In the medical context, the drugs used are pure without adulterants and clients are closely monitored before, during and after drug sessions, making psychedelic therapy very safe.

What about scary or 'bad' trips?

Some people can have scary experiences on ketamine, such as thinking they have gone mad, or that the experience will never end. It is often through experiencing these challenges that the client 'breaks through' and tackles rigid patterns of thinking that have maintained their lifelong psychological issues.

Who are your providers?

All the medicines used are produced by legal chemists who specialize in manufacturing the highest quality clinical medicines that meet all the necessary regulatory approvals to be used with clients.

Is the treatment covered under the NHS?

At present, the NHS has chosen not to fund this kind of treatment. This is something we hope will change in the near future. The NHS often takes a long time to approve new treatments. For the time being, clients (or insurance companies) will fund the treatment.

Do I need a referral? How can I get a referral from my GP?

You do not need a formal referral from your GP. Anyone may self-refer to the clinic to be assessed for possible treatment. We will need to see a record of your medical history (which you can request from your GP practice) so we can assess in advance whether you meet the criteria for an initial medical assessment for psychedelic-assisted therapy.

Are there conditions that would exclude me from treatment?

Ketamine used clinically, under monitored medical supervision, is safe to use. However, some conditions would exclude you from treatment with psychedelics. Our assessment process will check many aspects of your health and health history to ensure that this treatment is safe for you.

How should I prepare for the treatment?

During visits for the treatment, you are advised to wear comfortable clothing. You may feel nauseous which is why you are advised to eat only a light meal before your ketamine administration sessions, and to fast for six hours prior to each Dosing session. The other (non-drug) therapy sessions will be like ordinary therapy sessions.

Is ketamine licensed for KARE?

In the UK, medicines are usually approved and licensed for specific health conditions. At present, ketamine is licensed for anaesthesia and also (in the form of esketamine) for the psychiatric condition, 'treatment resistant depression'. However, it is also common practice that doctors may prescribe medicines for conditions for which they are not specifically licensed. This practice is referred to as 'Off-label prescribing'. The Medicines and Healthcare Products

Regulatory Agency (MHRA) provides specific guidelines about off-label prescribing of medicines. KARE has been through Phase II clinical trials which means it is on the pathway to being approved.

Before prescribing off-label treatments, the doctor must ascertain that the patient has already tried other, licensed treatments (e.g. other drug or therapy options) but without success at managing their condition. The doctor must also be aware of the available evidence for the off-label use of a medicine and satisfy themselves that off-label treatment is in the best interests of their patient.

At Awakn, we recognise that clients may not have responded to typical, licensed treatments for relapse prevention, but may benefit from psychedelic-assisted therapy. Before your KARE course starts we will ask for your consent to use ketamine in an off-label manner as described above.

How will the ketamine be administered?

We will be using intramuscular (IM) injections of ketamine, which is given into the shoulder muscle - much like a vaccine is given.

What are the benefits of the treatment?

In our clinical trial, KARE therapy produced 86% abstinence from alcohol at six months, in patients who were drinking every day before entering the study.

Ketamine can improve brain plasticity, which is the ability of our brains to change through growth and reorganisation. This can facilitate psychotherapy, as a person can more easily consider new perspectives on their difficulties. This ketamine-assisted therapy can help people to become 'unstuck' by adopting new, more flexible ways of thinking and behaving. It is important to put the new learning and insights from the therapy into practice in your daily life to maintain the benefits. Your therapist will support you to do this.

How long does a treatment visit take?

Non-drug sessions are 75-minutes long. The drug sessions are 2-hours long. After each drug session you will be able to stay in the clinic until you feel able to go home. You will not be able to drive yourself home after a drug session and we will request that you are accompanied home by a named individual whom you have identified in advance of starting the treatment.

How many visits will I need to make?

Following a successful initial medical assessment you will be invited to attend four preparation sessions and seven treatment days over four weeks. You will have a preparation session and a ketamine session on one day, with an integration and therapy session the day after each ketamine dosing appointment. You can therefore expect to make eight visits to the clinic in total.

How does ketamine work for therapy?

We think ketamine may help therapy in many ways. Ketamine has been found to increase brain plasticity (flexibility) and connectivity, meaning it can help a person to learn new things and become more adaptable which is part of what is required in psychotherapy. The subjective state associated with ketamine, where people often feel they are looking from outside of their bodies, may also facilitate taking new perspectives on old problems.

Is ketamine safe?

Ketamine is very safe. Is it used every day in casualty departments all over the world as a safe and effective anaesthetic for performing minor surgical procedures. We will be using ketamine at much lower doses than those administered for anaesthetic purposes. All clients are carefully screened and monitored throughout. Safety is a priority.

How long will it take for ketamine to be felt in my system?

The effects start after five minutes and last for around 90 minutes. You will be supported throughout the experience. You can then 'chill out' in our comfortable clinic surroundings before going home.

How does ketamine feel?

Ketamine is described as a "dissociative" drug, meaning the client experiences a sense of detachment from their usual self. Sometimes referred to as an 'out of body' type experience. This experience, alongside psychotherapy, allows the client to see their psychological problems in a new light and, together with support from their therapist, reflect upon and address their issues.

Is ketamine addictive?

In the lower, infrequent doses we use clinically there is a very low risk of addiction. However, in large, repeated doses (as some people use the drug recreationally) it is possible to become addicted to ketamine.

Does ketamine have any side effects or risks?

COMMON EFFECTS: In the short term, you may feel somewhat dissociated (or 'spaced out' where your mind feels separate from your body). There is a possibility of some initial anxiety that will pass and you will always be supported by your therapist to help to manage this. People sometimes describe feeling a bit light-headed or dizzy. You may feel nauseous which is why we will advise you to fast for 6 hours before your ketamine administration. Ketamine can increase blood pressure, therefore we are careful about screening people for pre-existing unstable blood pressure. People often describe feeling tired afterwards, so it is a good idea not to make plans for the rest of the day.

UNCOMMON EFFECTS: Much less commonly, people report feeling low in mood or manic immediately following treatment. You must let the clinical team know immediately if you notice these experiences so we can support you.

You will be closely monitored throughout your treatment and clinicians will use a questionnaire to monitor any side effects and how long they last (most typically resolve within an hour). Ketamine administered in a clinical environment, alongside therapeutic support enhances safety.

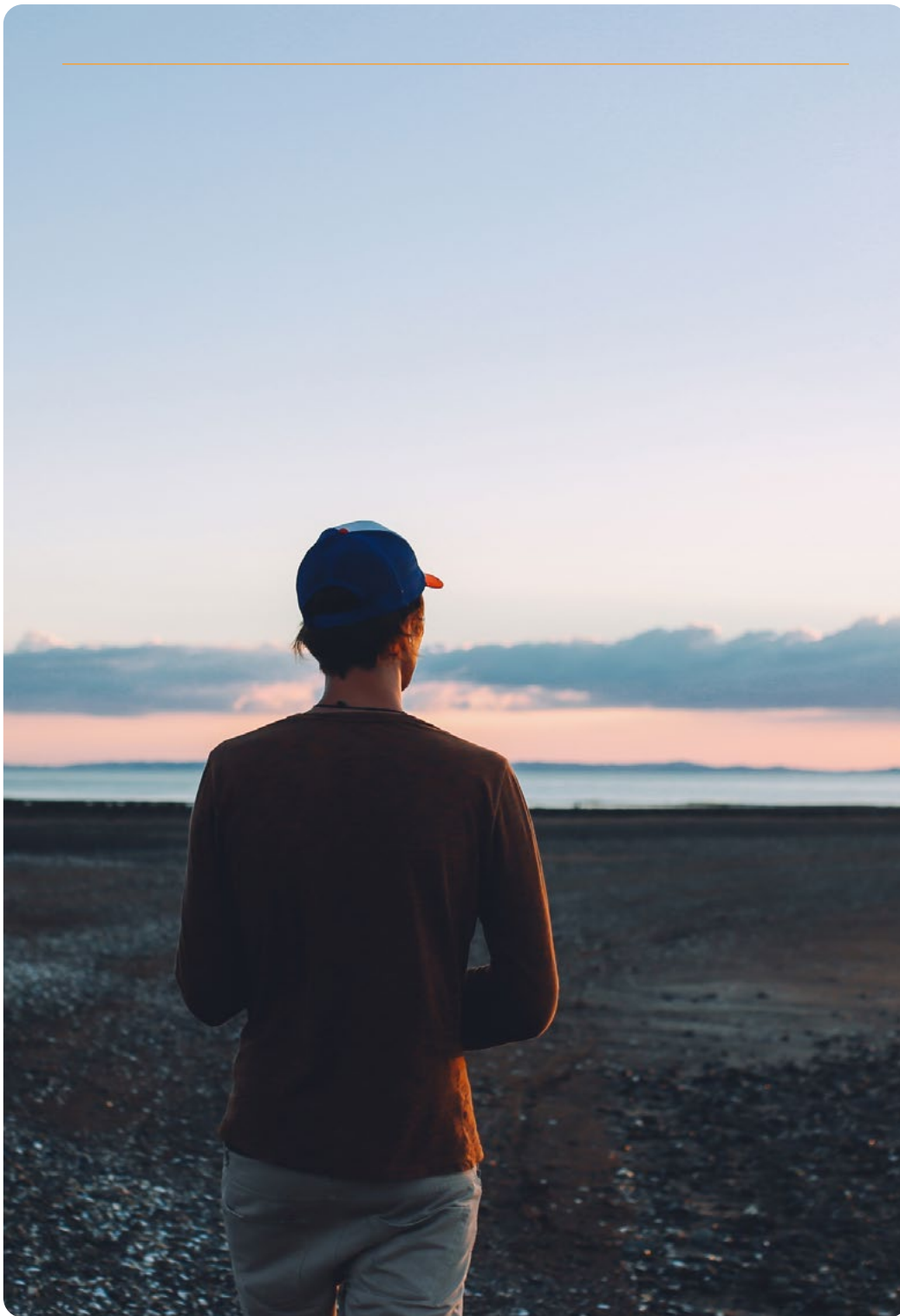
Appendix:

KARE Course:

Cost = £4,995 in Bristol and
£6,995 in London

Prior to beginning treatment, you may require a period of reducing your alcohol consumption, or may need to maintain a lower level of consumption or abstinence whilst waiting for therapy. At Awakn we offer a package of support calls to help people during this period. These are optional but recommended as it might be that your circumstances mean starting KARE therapy immediately without the calls is preferable. Should you need them, the support calls are typically four, thirty-minute video or telephone-based calls. They are not a substitute for a medically supervised detox should you need one, but you and your therapist can use this time to help organise support if need it, and also develop a more detailed shared understanding of your experience of recovery. The time allowance for these calls may be distributed as you and your therapist see fit, depending on your individual circumstance.

Week	Day	Activity	Length	Comments
N/A	N/A	Non- Drug Support Calls	4×30 min	Your therapist will support you in the reduction of your alcohol consumption, or in maintaining abstinence prior to starting therapy. This time can be really useful for sharing your story, helping you develop you motivation and focus for therapy, and also in developing the therapeutic alliance between yourself and your therapist.



Week	Day	Activity	Session length	Comments
1	1	KARE Session 1 Non-drug Psychotherapy and Preparation Session	 60 min	Your therapist will help clarify your understanding of the KARE Programme. You'll spend some time developing your goals and the vision of your sober life. Your therapist will help you think of ways to identify and manage risks to this alongside building positive wellbeing-focused behaviors. Your therapist will then help you prepare for your first ketamine dose.
		KARE Dosing 1 Ketamine- assisted Psychotherapy	 2 hrs	Your therapist will help you get comfortable and then you will receive your first dose of ketamine. Your therapist will remain with you throughout the dosing. You will remain in the clinic in the recovery area until ready to go home. You are instructed not to drive, but rather you must be accompanied home by an identified supporter.
	2	KARE Session 2 Non-drug Psychotherapy Integration Visit	 60 min	You and your therapist will discuss yesterday's session and anything it brought up for you. You and your therapist will further develop your ideas around managing high risk situations, promoting wellbeing and considering other essential resources for sobriety. A decision will also be made in collaboration with you about the dose for your next session.
2	1	KARE Session 3 Non-drug Psychotherapy and Preparation Session	 60 min	Your therapist will help consider how your cognitions (thoughts and thought processes) might impact on your drinking behaviour and how you might help manage this. They will also discuss how this can support sobriety. Your therapist will then help you prepare for your second dosing session.
		KARE Dosing 2 Ketamine- assisted Psychotherapy	 2 hrs	Your therapist will help you get comfortable and then you will receive your first dose of ketamine. Your therapist will remain with you throughout the dosing. You will remain in the clinic in the recovery area until ready to go home. You are instructed not to drive, but rather you must be accompanied home by an identified supporter.

Week	Day	Activity	Session length	Comments
2	2	KARE Session 4 Non-drug Psychotherapy Integration Visit	 60 min	You and your therapist will discuss yesterday's session and anything it brought up for you. You and your therapist will further develop your ideas around managing high risk situations, promoting wellbeing and considering other essential resources for sobriety. A decision will also be made in collaboration with you about the dose for your next session.
3	1	KARE Session 5 Non-drug Psychotherapy and Preparation Session	 60 min	You and your therapist will be building on the concepts covered in previous sessions and preparing for your final dosing.
		KARE Dosing 3 Ketamine- assisted Psychotherapy	 2 hrs	Your therapist will help you get comfortable and then you will receive your second dose of ketamine. Your therapist will remain with you throughout the dosing. You will remain in the clinic in the recovery area until ready to go home. You are instructed not to drive, but rather you must be accompanied home by an identified supporter.
	2	KARE Session 6 Non-drug Psychotherapy Integration Visit	 60 min	You and your therapist will discuss yesterday's session and anything it brought up for you. You will explore 'valued roles' and you will develop a lapse management plan to help you have something in place for the future should you need it.
4	1	KARE Session 7 Non-drug Psychotherapy Evaluation Session	 60 min	This will be your final therapy session. You and your therapist will discuss the ways in which you can enrich the roles that you value within your life. You will consider how to take forward the learning you have gained from the therapy and plan for the coming months to support your continued sobriety. Finally, you will revisit the goals and hopes you identified at the beginning of the treatment course, and reflect on the progress you have made towards them.



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