

Awakn™ Clinics



Client
Information
Leaflet

Client Information Sheet for People Undergoing Ketamine-Assisted Psychotherapy at Awakn Clinics Bristol

Welcome to Awakn Clinics Bristol

We are the UK's leading provider of psychedelic-assisted psychotherapy, combining the proven therapeutic potential of ketamine with psychotherapy to treat Addiction, Anxiety, Depression, PTSD, and Eating Disorders. 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.

The Awakn clinical staff have extensive experience in psychedelic-assisted psychotherapy. Compounds used in psychedelic-assisted psychotherapy include ketamine, MDMA and psilocybin. The clinicians in the Bristol Awakn clinic have undergone formal training in MDMA and psilocybin therapy. Other members of the Awakn team have extensive experience in ketamine-assisted psychotherapy. 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.

Rationale behind the Awakn Ketamine-Assisted Psychotherapy course:

There are a lot of clinics (mainly in the USA) that provide intravenous (IV) infused ketamine as an antidepressant drug. Most of these clinics do not use the ketamine experience alongside psychotherapy. But all clients undergoing the Awakn Ketamine therapy course will receive ketamine together with psychotherapy sessions. At Awakn we utilise the non-ordinary (altered / psychedelic) state of consciousness to help you address your challenging psychological issues. This form of ketamine use is often referred to as Ketamine-Assisted Psychotherapy (KAP).

Who is KAP for at Awakn Clinics?

We use KAP for a wide range of psychiatric disorders, including Depression, Anxiety Disorders (including Generalised Anxiety Disorder, Obsessive-Compulsive Disorder and Panic Disorder), Post-Traumatic Stress Disorder (PTSD), Addictions and Eating Disorders. In all these conditions, the Awakn KAP course combines standard non-drug assisted face-to-face psychotherapy/counselling sessions, interspersed with drug-assisted ketamine sessions.

Enrolment in the Awakn KAP course:

All patients undergoing KAP must be under the care of a UK registered 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 KAP course. Some conditions would exclude you from treatment with psychedelics. People with unstable blood pressure, a history of cardiac disease, severe liver or kidney disease, pregnancy, breastfeeding, people over 65 years old, children under 18 years old, people with a history of psychosis (e.g. schizophrenia or bipolar 1 disorder) or those with a high suicide risk will likely not meet the eligibility criteria for psychedelic-assisted therapy. However, every case will be assessed individually and discussed with our clinicians before deciding whether to proceed with treatment. 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 KAP course.

At this point, you will be given the dates for all your visits.

The Structure of the Awakn KAP course:

You will receive 11 sessions of psychotherapy, spread over a 9-week course, which will include 4 ketamine-administrations (given intramuscularly, IM), 6 non-drug preparation and integration psychotherapy sessions and a final post-course evaluation session 3-weeks after the end of the therapeutic course. Over the course of the therapeutic sessions, the ketamine dose will be collaboratively adjusted according to your individual response. See *Appendix One for details of what happens at each clinic visit.*

All KAP and KARE psychotherapy sessions, both non-drug and drug-assisted, will take place face-to-face (in person) at the Bristol Awakn clinic. We do not offer remote/ Zoom sessions. This means clients must be either resident in Bristol or committed to travel on a regular basis throughout the therapeutic course. For the first 6 weeks of the 9 week course, sessions are at least weekly and on 4 occasions twice-weekly, with a next day session after each ketamine-assisted session.

How much does the Awakn KAP course cost?

Each client will be required to pay £250 for an initial medical assessment. The £250 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 KAP course for a cost of £5,750. Thus, the total cost for the course, including medical assessment is £6,000. Clients must therefore ensure funds are available for the full 9-week course. Preferably this will be paid in advance in a single payment. However, it may be paid in installments as per the below table:

SESSION 1	£1,250
SESSION 4	£1,500
SESSION 7	£1,500
SESSION 9	£1,500

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. There will always be help on hand. The whole course will be overseen by a senior medical professional who will ensure you are safe and feeling 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.

What Happens at the end of the Initial KAP Course?

The final session of the initial KAP course (session 11, on week 9) will be an opportunity for you and your therapist to review your progress so far. We expect most people to complete just one course of therapy. Depending on your clinical progress and, crucially, what you would like to do next, you have the option to repeat the full 9-week course or you could opt for a shorter (4-week, 2 ketamine sessions) course. See Appendix Two. Or you could take a break and consider further courses in the future.

If you have any further questions about the Awakn KAP course please feel free to call (Tel 0117 985 0439) to speak to one of our clinicians, or see the website for more details: www.awaknlifesciences.com/clinics

FAQs

Below are answers to some of the common questions that arise regarding ketamine-assisted therapy. We hope this is useful but please do ask one of our clinical staff if you have any further questions.

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 talk therapy, allow the client to experience a deeper and more effective form of talk therapy.

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?

Psychedelic experiences with 'classic' psychedelic drugs (such as LSD or psilocybin) can be potentially challenging. But when used clinically the client is always accompanied by an experienced therapist, who is there to help the client through the experience. 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 specialise in manufacturing the highest quality clinical medicines that meet all the necessary regulatory approvals to be used with clients.

The Awakn treatment

What conditions do you treat?

Depression, anxiety disorders, PTSD, eating disorders and addictions to multiple substances, including alcohol. Common to all of these conditions is often an underlying experience of past trauma and/or adversity – often going back to difficult childhood experiences. Psychedelic therapy is a good treatment for helping clients to address difficult past traumatic memories that they would usually avoid. Even if you have not experienced past trauma or adversity, this therapy can be particularly beneficial for helping you to gain new insights and perspectives to familiar problems.

Are there conditions that would exclude me from treatment?

Psychedelic drugs used clinically under monitored medical supervision are safe to use with most health conditions. However, some conditions would exclude you from treatment with psychedelics. People with unstable blood pressure, a history of cardiac disease, severe liver or kidney disease, pregnancy, breastfeeding, the elderly, children under 18 years old, people with a history of psychosis (e.g. schizophrenia or bipolar 1 disorder) or those with a high suicide risk will likely not meet the eligibility criteria for psychedelic-assisted therapy. However, every case will be assessed individually and discussed with our clinicians before deciding whether to proceed with 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 a medical assessment for psychedelic-assisted therapy.

Is this treatment covered under the NHS?

At present, the NHS has not chosen 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 their insurance companies) will have to self fund the treatments.

How should I prepare for the treatment?

When you make your referral, you will be asked to get a medical summary from your GP. This will be reviewed by the medical team before you are invited for a face-to-face medical assessment. 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. The other (non-drug) therapy sessions will be like ordinary therapy sessions.

What can I expect during the treatment?

The treatment course consists of eleven sessions of therapy over a nine-week course. You will not be required to stay overnight for any sessions. On four occasions your therapy session will involve being injected in the arm muscle with a solution of ketamine. The dose will vary across the four drug sessions depending on your clinical progress and in collaboration with yourself. Some people may desire or require higher doses. Others may wish to stay on lower doses. You will have control over how the therapy progresses.

Is ketamine licensed for KAP?

In the U.K. medicines are usually approved and licensed for specific health conditions. At present, ketamine is licensed for anesthesia 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) provide specific guidelines about off-label prescribing of medicines.

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 conditions such as depression, anxiety, PTSD, eating disorders and addictions, but could benefit from ketamine-assisted psychotherapy. Before your course of KAP 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 this treatment?

Ketamine can improve brain plasticity which means it becomes more interconnected. This can facilitate psychotherapy, as a person can more easily consider new perspectives to their difficulties. Thus, ketamine-assisted psychotherapy 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 50-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 leave to go home. You will not be able to drive yourself home after a drug session. We will request that you are accompanied home by a named individual whom you have identified in advance of starting the treatment.

General questions about ketamine

How many visits will I need to make?

You will visit the clinic for an initial assessment to get a better understanding of whether this treatment approach is suitable for you. If you are eligible and wish to proceed, you will attend nine sessions over six weeks. You will have an integration therapy session the day after each ketamine-assisted appointment. Three weeks after your treatment course, you will be offered a follow-up appointment to see how things are going and discuss next steps. You can therefore expect to make eleven visits to the clinic in total.

Is ketamine safe?

Ketamine is very safe. It is 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 it is used as an anaesthetic. All clients are carefully screened and fully monitored throughout. Safety is a priority.

How does ketamine work for therapy?

Ketamine is an NMDA-antagonist, working across multiple receptors in the brain. At very high doses it acts as an anaesthetic; putting you completely to sleep. At lower doses (as we use) it creates an altered state of consciousness that when combined with psychotherapy allows you to carry out effective and safe psychotherapy. Ketamine is understood to increase brain plasticity (flexibility) and connectivity meaning it can help a person become more adaptive and open to new perspectives.

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?

It 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, when combined with 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. 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 One: Initial Full KAP Course:

WEEK	CLINIC VISIT NO.	ACTIVITY	SESSION LENGTH	COMMENTS
1	1	Prep Session	60-mins	Non-drug preparation psychotherapy visit to explore your psychological issues and establish your intention for the course.
2	2	K1 IM	2-hours	Psychotherapy is carried out before, during and after the dose. 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 a identified supporter.
	3	Integration, Day after K1	60-mins	Non-drug psychotherapy integration visit, to discuss yesterday's session. A decision is made in collaboration with you about the dose for your next session.
3	4	K2 IM	2-hours	Psychotherapy is carried out before, during and after the dose. 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 a identified supporter.
	5	Integration, Day after K2	60-mins	Non-drug psychotherapy integration visit, to discuss yesterday's session. A decision is made in collaboration with you about the dose for your next session.
4	6	Integration	60-mins	Non-drug assisted preparation psychotherapy to further discuss your psychological issues and decide on the next dose.
5	7	K3 IM	2-hours	Psychotherapy is carried out before, during and after the dose. 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 a identified supporter.
	8	Integration, Day after K3	60-mins	Non-drug integration psychotherapy to discuss the material that emerged during yesterday's session. A decision is made in collaboration with the client about progressing to a higher dose for the next session.
6	9	K4 IM		Psychotherapy is carried out before, during and after the dose. 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 a identified supporter
	10	Integration, Day after K4	60-mins	Non-drug integration psychotherapy to discuss the material that emerged during yesterday's session.
9	11	Three-Week follow-up post-course	60-mins	3-weeks after the end of your last psychotherapy session, you will attend for a final non-drug follow-up appointment. You will discuss collaboratively with your therapist whether further courses of KAP are indicated.

Appendix Two: Follow-Up Brief KAP Course:

WEEK	CLINIC VISIT NO.	ACTIVITY	SESSION LENGTH	COMMENTS
1	1	Prep Session	60-mins	Non-drug preparation psychotherapy visit to explore your psychological issues and establish your intention for the course.
2	2	K1 IM	2-hours	Psychotherapy is carried out before, during and after the dose. 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 a identified supporter.
	3	Integration, Day after K1	60-mins	Non-drug psychotherapy integration visit, to discuss yesterday's session. A decision is made in collaboration with you about the dose for your next session.
3	4	K2 IM	2-hours	Psychotherapy is carried out before, during and after the dose. 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 a identified supporter.
	5	Integration, Day after K2	60-mins	Non-drug psychotherapy integration visit, to discuss yesterday's session. A decision is made in collaboration with you about the dose for your next session.
4	6	Integration	60-mins	Non-drug assisted preparation psychotherapy to further discuss your psychological issues. You will discuss collaboratively with your therapist whether further courses of KAP are indicated.

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