Awakn Clinics Bristol

Inspection report

1 Regent Street
Clifton
Bristol
BS8 4HW
Tel: 07950892788

Date of inspection visit: 15 February 2023
Date of publication: 30/03/2023

This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	Good
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Good

Overall summary

This service is rated as Good overall.

The key questions are rated as:

Are services safe? – Good

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an unannounced comprehensive inspection at the registered location Awakn Clinics Bristol on 15th February 2023, as the service had not been previously inspected.

Awakn clinics Bristol provides a consultant led outpatient service that assesses and treats patients with depression, anxiety, post-traumatic stress disorder and addiction who are treatment resistant. The treatment involves intravenous use of a controlled drug called Ketamine alongside psychotherapy. This form of Ketamine use is often referred to as Ketamine-Assisted Psychotherapy (KAP).

The clinic director is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

We reviewed feedback that the provider had collated since opening the service in 2021.

Comments were positive and described the service as being life-changing. Patients we spoke with were also complimentary about the service. They described the consultant psychiatrist as being supportive, made them feel at ease and the treatment had vastly improved their quality of life.

Our key findings were:

- The service provided safe care and treatment. The provider ensured that patients had comprehensive assessments for both their mental and physical health prior to treatment.
- The service safely managed medicines. The consultant psychiatrist prescribed medicines and they were administered to patients in line with legal requirements and current national guidance.
- Staff supported patients to make informed decisions about treatment. The service ensured that patients were given information that included how the treatment works and the costs involved. Patients we spoke with told us that they were given enough time to ask questions before they committed to starting treatment.
- Access into the service was easy. The provider's website clearly set out how patients could contact the service. The service responded promptly to enquiries and ensured patients were seen in a timely manner.
- The service had enough qualified staff to provide high quality care and treatment to patients.

However:

Overall summary

- Governance systems that should have monitored the quality and safety of the service were not thorough. For example, not all routine audits were completed within the organisation's time-frames.
- Not all policies were up to date.

We saw the following outstanding practice:

The service offered a 25% discount for people receiving certain income related benefits as well as people with disabilities. This meant the treatment was made more accessible to people who were unable to meet the full cost of treatment.

The areas where the provider **should** make improvements are:

- The provider should ensure oversight of audit schedules and completeness.
- The provider should ensure all policies are up to date.
- The provider should ensure the Safeguarding policy outlines staff training competencies.

Our inspection team

Our inspection team was led by a CQC lead inspector, a CQC support inspector and a member of the CQC medicines team. The team had access to advice from a specialist advisor when required.

Background to Awakn Clinics Bristol

The service is provided by Awakn Clinics Bristol

Awakn Clinics Bristol is registered to provide the following regulated activitiy:

- Treatment of disease, disorder or injury

Awakn Clinics Bristol provides treatment to adults who have treatment resistant depression, anxiety, post-traumatic stress disorder, mental health problems and substance and alcohol dependency. The treatment involves using a controlled drug called Ketamine that is passed into a person's blood stream via an intravenous injection.

Treatment is delivered to patients in a clinical setting and the patient is closely monitored throughout treatment and for a period of time after treatment before being discharged.

An experienced consultant psychiatrist prescribed the Ketamine and experienced psychotherapists trained in psychedelic assisted therapy provided therapeutic intervention during scheduled sessions.

Patients were required to complete assessments prior to treatment including a physical health assessment, and relevant information was sought from the patient's GP.

The service registered with the CQC in November 2020 and has not been inspected before. The service employed a consultant psychiatrist, psychotherapists, registered mental health nurses, a GP and staff to provide leadership and oversight of the service.

Staff received appraisals and regular supervision which was undertaken by leaders within the service and also by peers.

The clinic was open between 9:30am and 5:30pm Monday to Friday for treatment, the service was closed on Saturdays and Sundays.

How we inspected this service

During the inspection visit to the service, the inspection team:

• spoke with two patients who had used the service

• reviewed feedback from 12 patient questionnaires

• spoke with staff such as the registered manager, consultant psychiatrist, psychotherapists and the quality safety and risk lead

• reviewed six treatment records

• checked how medicines were managed

• reviewed information and documents relating to the operation and management of the service.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

• Is it safe?

• Is it effective?

• Is it caring?

• Is it responsive to people's needs?

• Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection

Good

Are services safe?

We rated safe as Good because:

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse.

The provider had appropriate safety policies which were regularly reviewed and communicated to staff. However, not all policies had been reviewed regularly. For example, we reviewed the provider's policy schedule and found a number of policies out of date, including the medicines policy and respecting and involving patient policy. We were told there was a project underway to review all policies and naming conventions.

The service had standard operating procedures to support the running of the service and treatment being delivered. Staff received safety information from the service as part of their induction.

The service had systems to safeguard adults at risk of abuse . All members of staff had received level two safeguarding adults and children training and all patient facing staff had completed level three safeguarding adults and children training. All other staff had been offered level three safeguarding adults and children training.

Guidance on how to raise a safeguarding alert and who to report a concern to was outlined within the provider's safeguarding adult's and children policy. However, we reviewed the policy and this did not identify the level of training required for staff members.

The provider told us they carried out thorough recruitment checks prior to employment and on an ongoing basis where appropriate. The service was small in size and employed eight members of staff which included the lead psychiatrist and the quality and safety lead. We were not able to review employment records as these were held off site.

All permanent staff received up-to-date mandatory training appropriate to their role. They knew how to identify and report concerns. Staff were required to complete a range of mandatory training courses including information governance, mental capacity training and basic life support.

There was an effective system to manage infection prevention and control. The provider carried out monthly infection control audits to ensure the environment adhered to infection control principles. The provider had an infection control policy which was due to be updated shortly.

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

There were arrangements for planning and monitoring the number and mix of staff needed. The therapists booked appointments when required after discussing the referral at the multidisciplinary team meeting.

There was an effective induction system for staff tailored to their role. All members of staff had received an induction. This included how to use the electronic patient record system, mandatory training and the general running of the service.

Good

Are services safe?

Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly. The service had a medical emergency policy in place that guided staff in how to respond to an unwell patient. The service had a defibrillator on site.

Patient risk was assessed at the point of referral into the service and during the assessment stage. In all six records reviewed, patients had received appropriate physical health and mental health assessments prior to treatment commencing. The service requested a full medical history from their GP prior to commencing treatment.

There were appropriate indemnity arrangements in place. Indemnity arrangements covered the clinical practice as well as insurance indemnity cover for the provider.

The provider had an emergency contact for each patient and made sure an appropriate individual was available to assist the client after any treatment that included Ketamine medication.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

Staff ensured that individual care records were written in a way that kept patients safe. Records demonstrated correspondence had been sent to individual patients, their GP or other healthcare professionals involved in their care.

In all six records reviewed we found that the records included the introductory emails that had been sent from the service to the individual patients. We reviewed triage information for each person used to determine whether their treatment programme was appropriate for the individual. We also found the service had ensured that correspondence sent to other healthcare professionals had been saved into the individual patient records.

The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment. The service only did this when the patient had given consent to share their information. In six records reviewed, consent for their personal information to be shared, or not, was recorded.

Safe and appropriate use of medicines

The service had reliable systems for appropriate and safe handling of medicines.

The service managed medicines safely, including controlled drugs and emergency medicines. The provider had a comprehensive medicines management policy to ensure staff adhered to local policy and national guidance.

Medicines were stored in a locked clinic room with secure access only to authorised staff. The clinic room temperature was monitored and recorded during clinic opening hours and was within the recommended range. Staff were aware of what appropriate action to take if deviation in temperature occurred.

Controlled drugs were managed effectively and stored safely and securely. Checks were undertaken and recorded to ensure safe storage. The service had a Home Office licence to ensure that they were able to obtain and store Ketamine as a stock medicine, in compliance with the law. The provider managed the waste of medicines safely. The service had the right protocols in place to safely manage the disposal of controlled medicines.

Good

Are services safe?

Emergency medicines were available if needed. Checks were undertaken to ensure the medicines were within date and safe to use in an emergency.

The service carried out medicines audits to ensure prescribing was in line with best practice guidelines for safe prescribing. The service regularly audited the use of controlled drugs administered to ensure adherence to legislation.

Staff prescribed and administered medicines to patients in line with legal requirements and current national guidance. They recorded the batch numbers and expiry dates of medicines that had been administered. Maintaining records of medicines administered ensured that in the event of a drugs recall, the provider would be able to refer back to the medicines the service had administered and take action if required.

There was a system in place to ensure that patients' medicines were accurately recorded prior to treatment. Allergy statuses of clients were routinely recorded on all records seen. Weights were recorded which is important for calculating the correct dose of Ketamine to administer.

The clinic used Ketamine as an 'off-label' medicine. 'Off label' means the medicine has a licence for treating some conditions, however the prescriber wanted to prescribe the medicine to use it in a different way than that stated in the licence. The provider ensured that patients were aware of this before they consented to treatment.

Physical health monitoring checks were undertaken prior to prescribing and administering medicines to patients. We reviewed six treatment records and found that patient's physical health was monitored before, during and after treatment. Physical health checks included the monitoring of blood pressure, heart rate and breathing rate.

The provider had an effective system to check patients' identity. The service requested patients to confirm their name, date of birth and address prior to treatment and required patients to show photographic ID. In all six records reviewed we observed the correct checks for ID.

Track record on safety and incidents

The service had a good safety record.

There had been no serious incidents reported at the service. The service had appropriate policies and procedures in place to manage an incident if they were to occur.

The service monitored and reviewed their activity. The service had a clinical governance meeting every month and discussed the running of the service including any incidents that had occurred.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so. Following an event where controlled drugs were delivered to a local pharmacy by the supply company, meaning there was a potential for the medication to be given to the wrong person, the service made improvements to processes for controlled drug delivery to the service. For example, telling the supplier to deliver only to the clinic location.

Good

Are services safe?

There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified and took action to improve safety in the service.

The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents. The provider had a duty of candour policy in place that guided staff in how to ensure the duty of candour principles were upheld. We reviewed a recent example of where the service had applied the Duty of Candour.

The service had an effective mechanism in place to disseminate alerts to all members of the team. The clinical governance and business meeting was the main forum in which safety alerts were discussed and recorded.

Good

Are services effective?

We rated effective as Good because:

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence-based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance.

Staff appropriately assessed patient need and delivered care in line with the most reliable and up to date evidence based research available. Patients were assessed and treated in line with National Institute for Health and Care Excellence (NICE) guidance.

Although the evidence base for using Ketamine as a treatment for treatment resistant depression, anxiety and post-traumatic stress disorder is still in its infancy in the UK, the lead psychiatrist was involved in conversations about the treatment with UK based researchers and experts in the field.

Patients' immediate and ongoing needs were fully assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing. Experienced therapists assessed suitability for treatment, and discussed with clinicians during multidisciplinary meetings, to ensure the service had enough information about the patient before treatment was given.

We saw no evidence of discrimination when making care and treatment decisions. In the six records we reviewed, we did not see any evidence of discrimination.

Monitoring care and treatment

The service was actively involved in quality improvement activity

The service used information about care and treatment to make improvements. After discharge patients were asked to complete feedback about their treatment. Some feedback described a long wait to see the nurse after treatment. This led to the service training all therapists in physical observations so that the client did not have to wait at the end of a treatment session.

The provider had a system in place to monitor patients' mental wellbeing and mood after treatment. Patients were required to complete a mood monitoring questionnaire. This was partly to assess whether the treatment was effective and to also engage with the patient after treatment.

The service collected outcome scales at the end of each treatment session. This allowed patients to see their progression through the course of treatment and the service to measure the effectiveness of treatment.

The service told us they made improvements through the use of completed audits. However, we reviewed the audit programme and not all regular audits were completed, or were completed and not updated on the audit programme. A number of audits were completed at a later date, some months later. For example, there were gaps in the last two months for a number of audits including the controlled drug key safe audit, drug administration audit and cleaning and infection prevention control audits. This meant the service could not assure themselves that improvements were being made and

that staff were following the provider policies. The provider was not aware at the time of the inspection that the audit programme had not been completed. However, there had been no impact on patients or safety. The quality and risk lead told us the audit programme and policy review was being discussed at the following clinical risk meeting and will address the issues highlighted.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. The lead psychiatrist was registered with the General Medical Council and was up to date with re-validation.

The provider understood the learning needs of staff and provided protected time and training to meet them. Up to date records of skills, qualifications and training were maintained.

Coordinating patient care and information sharing

Staff worked together, and worked well with other organisations, to deliver effective care and treatment.

Patients received coordinated and person-centred care. Staff referred to, and communicated effectively with other services such as GPs and other healthcare professionals when appropriate.

Before providing treatment, the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. In all six records reviewed we found patients' previous treatments and medical records.

All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. We were told it was rare for a patient to decline their information to be shared. We were told they would not offer or carry out treatment on patients who did not give consent to share information with their GP or another healthcare professional. Where patients agreed to share their information, we saw evidence of correspondence sent to their registered GP in line with General Medical Council guidance.

Patient information was shared appropriately, and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.

The service monitored the process for seeking consent appropriately. The provider monitored consent as part of the clinical record audit.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.

Where appropriate, staff gave people advice so they could self-care. The service provided patients with information on how to integrate the treatment into their lives and suggested activities that supported this such as yoga, reflection and healthy eating. We observed therapists discussing coping activities with clients.

Good

Are services effective?

Risk factors were identified and highlighted to patients and where appropriate to their normal care provider. During the assessment process any risks relating to the patients physical or mental health would be taken into account before treatment was considered. Therapists completed risks assessments before each treatment session.

Consent to care and treatment

The service obtained consent to care and treatment in line with legislation and guidance.

Staff understood the requirements of legislation and guidance when considering consent and decision making. At every assessment and prior to treatment the service required the patient to give consent. In all six records reviewed we found evidence that patients had consented to treatment.

Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision. When a client first enquired about the service therapists ensured that patients understood the criteria for treatment. If a client was triaged to be suitable for treatment their treatment plan would be discussed at the morning multidisciplinary meeting.

All patients we spoke with told us that they were given enough time to ask questions and make their decision about the treatment.

Good

Are services caring?

We rated caring as Good because:

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

The service sought feedback on the quality of treatment patients received. The service asked patients to complete feedback via a leaflet called 'Your Views Count' following treatment. One service user we spoke to told us they also completed a review on 'Google' to inform others of their positive experience.

Patients were positive about the way staff treated people. Patients described the service as being really caring, considerate and that the treatment they had received provided them with a better quality of life.

Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients. Patients told us they felt comfortable knowing the decisions they made before and during treatment was their own, and staff respected their preferences and decisions.

The service gave patients timely support and information. Patients told us that the service was flexible in their approach. One patient told us that the service respected their wishes to not go ahead with treatment immediately and ensured they had time to make their decision.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

The service did not provide interpreters for patients who did not have English as a first language. However, if an interpreter was required the service assisted patients to arrange this. Staff told us they ensured interpreters were able to understand and relay detailed information about the treatment offered, so the person was able to make an informed decision.

All patients we spoke with reported that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.

Staff involved patients in the assessment and planning of care and treatment. Patients told us that clinicians were contactable for further advice and support outside of the appointment time.

Privacy and Dignity

The service respected patients' privacy and dignity.

Staff recognised the importance of people's dignity and respect. Patients told us that staff were kind and made them feel at ease. Patients told us the environment was calming and staff went out of their way to ensure they were comfortable.

Patients were treated in one of the three dedicated treatment rooms within the building. After treatment, patients remained in the room to recover until it was deemed safe for them leave upon completion of their session.

Good

Are services responsive to people's needs?

We rated responsive as Good because:

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

Staff understood the needs of their patients and supported their needs. Staff were aware that patients attending the service had not been successful in treating their mental health condition in the past and that some patients were at risk because of this. The consultant psychiatrist ensured that mood monitoring results were reviewed and followed up promptly.

The facilities and premises were appropriate for the services delivered.

Reasonable adjustments had been made for disabled people so that they could access the service on an equal basis to others. An additional entrance was located on the lower level of the property, this ensured people with mobility aids were able to access the treatment rooms.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

Patients had timely access to initial assessment, test results and treatment.

Waiting times, delays and cancellations were minimal and managed appropriately. The service did not have a formal target for scheduling initial assessments. The service aimed to assess patients promptly after they had completed the pre-consultation questionnaires and shared their medical history.

Patients with the most urgent needs had their care and treatment prioritised.

Patients reported that accessing the service was easy. Patients told us the service offered an initial call soon after they had enquired about treatment.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

Information about how to make a complaint, give compliments or raise concerns was available in a patient information booklet.

The service had complaint policy and procedures in place. The service aimed to provide an initial response to a complaint within 48 hours and a final response within 28 days.

Good

Are services responsive to people's needs?

The provider had received one complaint which resulted in full reimbursement of fees. Learning from this complaint resulted in additional double glazing being installed to block out any traffic noise, and psychology were introduced into the initial assessment process to ensure therapeutic considerations were acknowledged during assessment.

Good

Are services well-led?

We rated well-led as Good because:

Leadership capacity and capability;

Leaders had the capacity and skills to deliver high-quality, sustainable care.

Leaders were knowledgeable about issues and priorities relating to the quality and future of services. The service held regular governance and business meetings which addressed matters to the running of the clinic. However, a standing agenda item 'Clinical Audits' stated there were no updates. This meant oversight of issues relating to missed audits was not prioritised or actioned. Multi-disciplinary team (MDT) meetings were also regularly held to discuss matters relating to treatment that patients were receiving at the clinic.

Leaders were visible and approachable. The consultant psychiatrist and registered manager worked closely with all staff to ensure a good quality service.

Vision and strategy

The service had a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

There was a clear vision and set of values. The aims of the service were outlined within the clinics policies and procedures. The consultant psychiatrist's long-term goal was to work with health care partners such as the NHS and enable free access to Ketamine therapy for those who would benefit from it.

The service developed its vision, values and strategy jointly with staff.

Culture

The service had a culture of high-quality sustainable care.

Staff felt respected, supported and valued. They were proud to work for the service.

The service focused on the needs of patients. Staff were passionate about achieving positive outcomes for patients and spoke enthusiastically about the future of the model of treatment used.

Openness, honesty and transparency were demonstrated when responding to complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.

Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.

There were processes for providing all staff with the development they needed. This included appraisal and career development conversations. All staff received annual appraisals and regular supervisions. Staff were supported to meet the requirements of professional re-validation where necessary. All staff were considered valued members of the team. They were given protected time for professional time and for professional development and evaluation of their clinical work.

Good

Are services well-led?

There was a strong emphasis on the safety and well-being of all staff. The provider ensured staff had received health and safety training as well as fire safety training.

The service actively promoted equality and diversity. Staff had received equality and diversity training.

There were positive relationships between staff and teams. Staff told us that the workplace felt like a family.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management. However, during the inspection, we found not all governance processes were complete and evident.

Structures, processes and systems to support good governance and management were clearly set out and understood. However, we saw not all audits were completed within the organisations' schedule. This meant it was not possible to provide assurance that issues were addressed and improvements were made. The quality and risk lead told us the audit schedule would be addressed as an agenda item at the next monthly risk governance meeting and actioned appropriately.

The governance and management of partnerships, joint working arrangements and shared services promoted interactive and co-ordinated person-centred care.

Staff were clear on their roles and accountabilities. However, policies and procedures to ensure safety and assure themselves that they were operating as intended were not thorough and up to date. At the time of our inspection, the policies were being updated to address these issues.

Managing risks, issues and performance

There were clear and effective processes for managing risks, issues and performance.

There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety. The service held regular meetings named 'Town hall meetings' with the CEO and other Awakn Clinics. During these meetings, emerging risks and performance data was discussed, as well as sharing of information to improve patient experience.

The quality, safety and risk lead worked in partnership with senior staff at the clinic to address highlighted areas of risk. The service had a risk register that clearly outlined known and potential risks with mitigating actions in place to ensure safety.

The service had processes to manage current and future performance. Leaders had oversight of safety alerts, incidents, and complaints.

There was some evidence of action taken to improve the service. For example, a defibrillator had been purchased for the clinic to ensure immediate access, and the provider had always stocked medicines to support patients experiencing a cardiac arrest, anaphylaxis and opiate overdose.

Good

Are services well-led?

The service had enough suitably trained staff in place to ensure the service could resume in the event of staff absences.

Appropriate and accurate information

The service acted on appropriate and accurate information.

Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.

Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information. Senior leaders were sighted on clinical matters.

Engagement with patients, the public, staff and external partners

The service involved patients, the public, staff and external partners to support high-quality sustainable services.

The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them when required. For example, we were told about open evenings to engage members of the public and external health professionals where information was available about treatments offered and relevant clinic information.

Staff could describe to us the systems in place to give feedback. The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

There were systems and processes for learning, continuous improvement and innovation.

There was a focus on continuous learning and improvement. The consultant psychiatrist gave examples of research being undertaken by Awakn Clinic stakeholders that involved clinical trials at different phases. Some staff members were involved in this collaborative work and leaders were keen for continuous improvement to be a key feature of the service.