
# FLOW NEUROSCIENCE Flow Headset Medically Approved Brain Stimulation Instructions



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## FLOW NEUROSCIENCE Flow Headset Medically Approved Brain

## Product Information

**Specifications:**

- Product Name: Flow Clinician
- Classification: Class IIa medical device
- Intended Use: Treatment of unipolar major depressive disorder (MDD) in adults
- Mechanism: Transcranial Direct Current Stimulation (tDCS)
- Current Strength: 2mA
- Treatment Sessions: 30 minutes each

## Product Usage Instructions

**Mechanism of Action:**

The Flow headset delivers a 2mA electric current to the left dorsolateral prefrontal cortex, enhancing neuronal activity to improve mood and emotional regulation.

**Efficacy:**

Flow has shown significant results in treating depression, achieving a 57.5% remission rate in 10 weeks. It can be used as a standalone therapy or with antidepressants.

**Treatment Schedule:**

The standard treatment includes an activation phase for weeks 1-3 and a strengthening phase from week 4 onwards, with each session lasting 30 minutes.

**Behavioural Therapy:**

The Flow app offers optional behavioral therapy courses such as activation, exercise, meditation, diet, and sleep hygiene, complementing the stimulation protocol.

**Contraindications:**

No absolute contraindications reported for Flow Clinician.

**Warnings and Precautions:**

Flow Clinician can be used by individuals with various chronic conditions. It is not licensed for use in pregnancy but appears safe for breastfeeding and postpartum depression.

**Adverse Reactions:**

Common side effects may include skin irritation, headaches, and rare cases of worsening depression or anxiety symptoms.

## Frequently Asked Questions

- **Q: Can Flow Clinician be used by children and adolescents?**
  - A: Flow Clinician is not licensed for use in children and adolescents, but studies are ongoing for ages 14+.
- **Q: Are there any known interactions with medications?**
  - A: Flow Clinician has no known interactions with medications, making it suitable for individuals with various chronic conditions.

**Indication**

Class IIa medical device approved for the treatment of unipolar major depressive disorder (MDD) in adults, either as monotherapy or as an adjunct with antidepressants and psychological therapies.

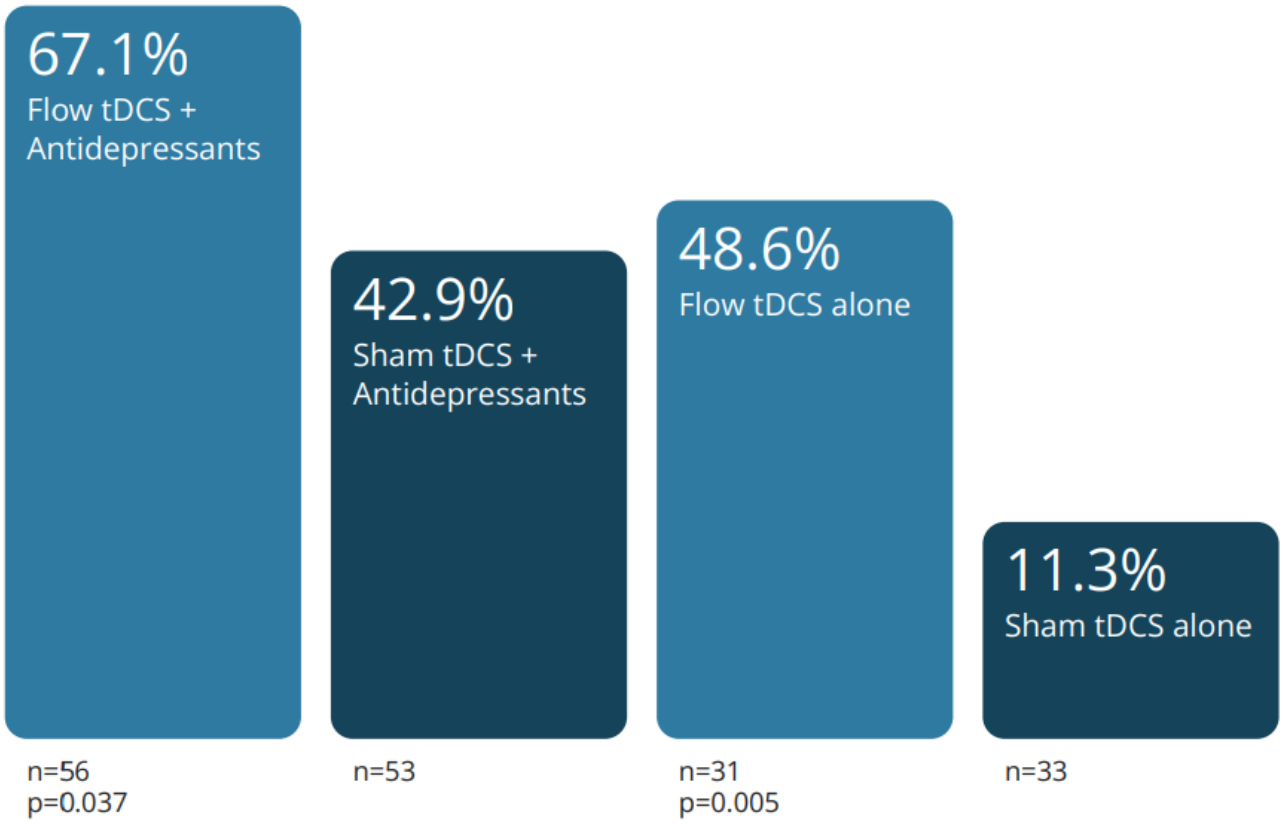
## Mechanism of action

The Flow headset delivers a gentle 2mA electric current (transcranial Direct Current Stimulation, tDCS) to the left dorsolateral prefrontal cortex. This region is crucial for emotional regulation and is often hypoactive in individuals with depression. tDCS enhances neuronal activity in this area, counteracting hypoactivity, and improving mood and emotional regulation.

**Efficacy**

Results at 10 weeks from a multisite, double-blind placebo-controlled randomised superiority trial were statistically significant for both primary and secondary endpoints. Flow achieved a 57.5% remission rate using the MADRS scale and was effective as both standalone and adjunctive therapy.1

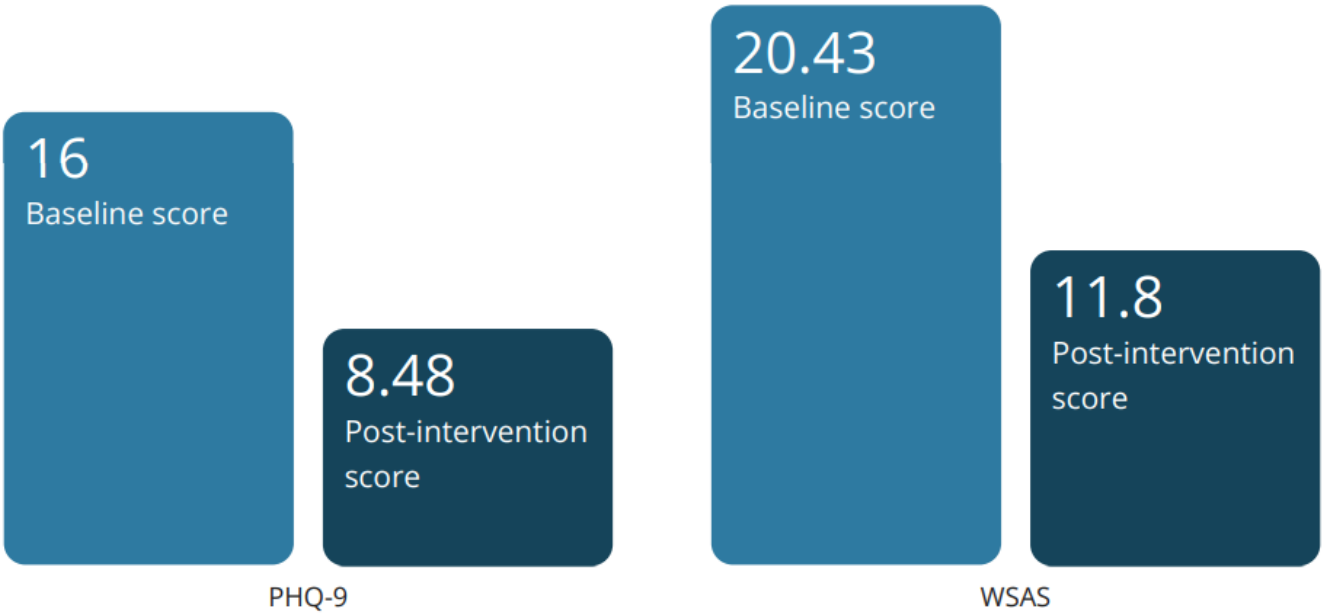
**Remission rate when used as standalone and adjunct:**




Open-label patient cohort study in an NHS primary care general practice found at 6 weeks: 2

- 58.1% of patients showed reliable improvement, and 32.3% achieved remission using the PHQ-9
- Significant improvements were observed in functioning (WSAS) and health-related quality of life (EQ-5D-5L)

**Improvements in Depression Severity and Functional Impairment**




### Treatment schedule

The standard treatment is split into 2 phases – activation and strengthening. Each session (termed stimulation) is 30 minutes long. Patients complete a MADRS-s survey at the beginning of each week to monitor progress



**Activation Phase**

Weeks 1-3

- Includes 5 stimulations a week
- Introduces optional behavioral therapy courses via the app

**Strengthening Phase:**

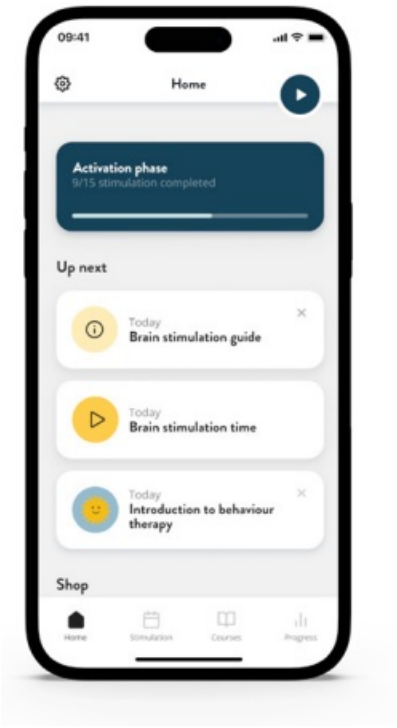
Week 4 onwards

- Includes up to 2 stimulations a week

- Continues to strengthen and preserve results
- Continue behavioral therapy courses

**Behavioural therapy**

The Flow app includes 7 behavioral therapy courses including behavioral activation, exercise, meditation, diet, and sleep hygiene, totaling over 50 short therapy sessions. These courses are entirely optional and do not interfere with the Flow stimulation protocol.




**Contraindications**

No absolute contraindications.

## Warnings and Precautions

- Broken/inflamed/infected skin (including, for example, psoriasis) at the electrode site
- Cranial or intracranial implant (e.g. brain clips, deep brain stimulators)
- Craniofacial abnormalities (e.g., congenital deformities, severe trauma, or reconstructive surgeries) which may affect electrode placement
- Epilepsy or history of seizures
- Active suicidal ideation (requires closer monitoring)
- History of hypomania or mania (may require closer monitoring)

**Special populations**

- Other chronic conditions: No known interactions with medications; use by individuals with diabetes, heart disease, hypertension, asthma, co-occurring mental health conditions, neurodivergence, and brain injuries/ disorders without reported safety concerns.
- Pregnancy: Not licensed for use; no safety concerns identified in existing studies, research ongoing.
- Breastfeeding: Safe to use; no effect on breast milk production.

- Postpartum: Appears safe for postpartum depression and successfully used in NHS pilots.
- Children and Adolescents: Not licensed for use; studies ongoing for ages 14+

**Adverse reactions**

Based on real world evidence from >20,000 users, the incidence rate of adverse reactions is 4.5%, which is favorable against antidepressants

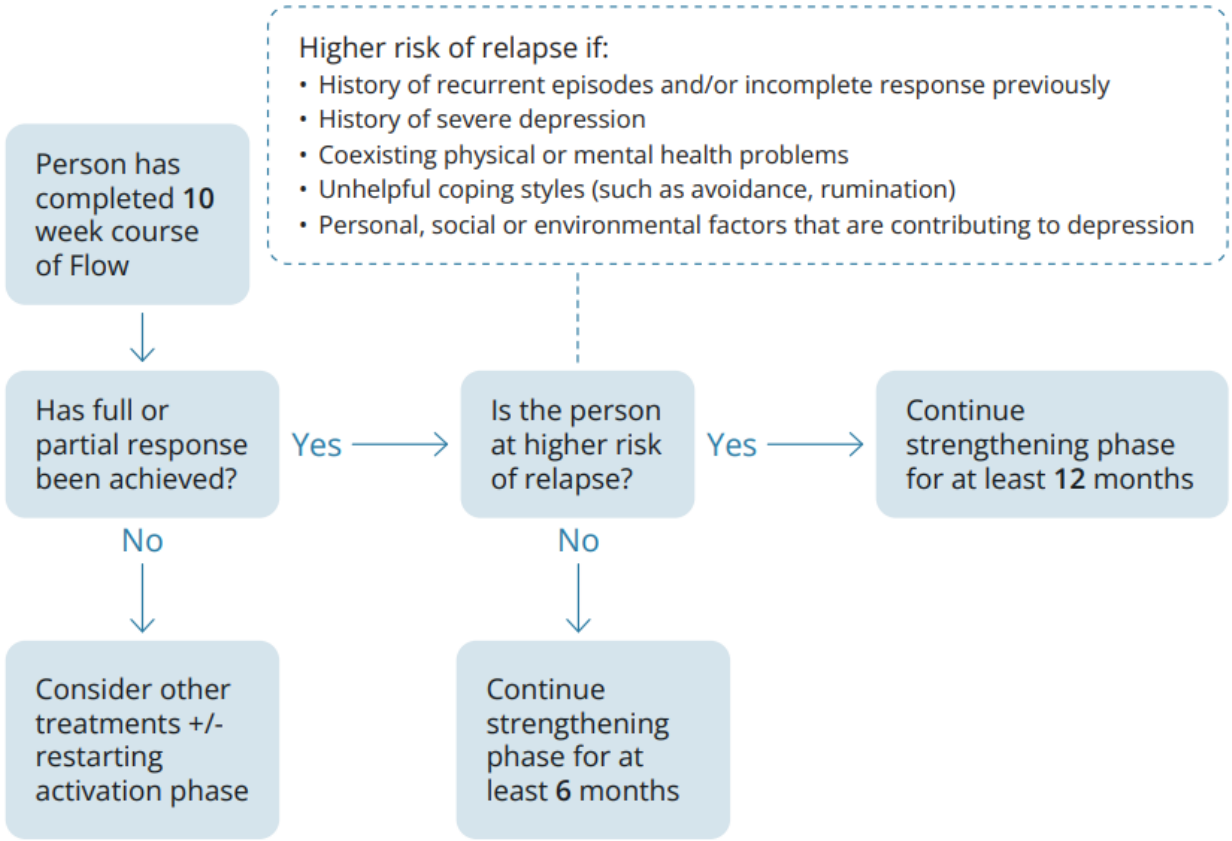
| Side effect | Incidence | Probable duration | Recommendations to reduce intensity and/or duration |
|---|---|---|---|
| Skin irritation (including tingling, stinging redness | ≥ 10% to < 20% | Less than a day. Rarer cases up to 3 days | Avoid stimulating on irritated skin • new pads with each stimulation • well-moisturized skin • well-hydrated • ice pack following stimulation • correct electrode placement |
| Headaches | ≥ 10% to < 20% | Less than a day | Adequate hydration • relaxed environment • correct electrode and headset placement • post-stimulation rest |
| Worsening depression symptoms and/or anxiety | ≥ 1% to < 10% | Up to several days. Usually only occurs in the first few weeks of treatment | Relaxed environment • correct electrode placement |
| Fatigue, malaise and sleep disturbances | ≥ 1% to < 10% | Up to several days | Changing/fixing time of day of stimulation • relaxed environment |
| Tinnitus | ≥ 0.1% to < 1% | Less than a day. In rare cases persisting for a few weeks | Correct electrode placement • monitoring during session and stop use if persisting |
| 1st degree skin burns | ≥ 0.1% to < 1% | Up to 3 days | New pads with each session • avoid stimulating on irritated skin • well-moisturised skin • Well-hydrated |
| Photopsia (Flashes of Light) | ≥ 0.1% to < 1% | Up to a minute | Ensuring correct electrode contact and placement • not removing headset without powering down |
| Hypomania/ Mania | < 0.01% | Up to several days | Closer monitoring if history of bipolar disorder |

- Adverse events should be reported. Report forms and information can be found at [www.mhra.gov.uk/yellowcard](www.mhra.gov.uk/yellowcard)
- Adverse events should also be reported to Flow Neuroscience by emailing [support@flowneuroscience.com](mailto:support@flowneuroscience.com).

**Clinician review and customization**

Review your patients' progress and adherence through the Flow Clinician Platform (CPP). Accessible anytime and anywhere through a secure web browser, this platform streamlines patient visits by providing informed insights. It also allows for the customisation of treatment protocols
(maximum 1 per day, 7 per week) based on clinical judgment to address individual patient needs. This setup ensures personalized treatment adjustments to help optimize patient outcomes.

The suggested initial treatment duration is 10 weeks. Following 10 weeks, patients' response should be assessed and length of continued treatment determined, taking into consideration the effectiveness to date and the risk of relapse.




## Support and contact information

For technical support and assistance, patients can contact [support@flowneuroscience.com](mailto:support@flowneuroscience.com). Clinicians can

enquire about setup, pricing, and training support by contacting clinical@flowneuroscience.com.

- www.flowneuroscience.com

**References:**


1. Woodham, R.D., Selvaraj, S., Lajmi, N. et al. Nat Med (2024).
2. Griffiths, C. et al. (2024). Open Journal of Depression. 13(02), 25–39.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## Documents / Resources

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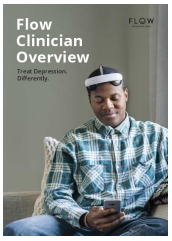
|  | FLOW NEUROSCIENCE Flow Headset Medically Approved Brain Stimulation [pdf] Instructions<br>Flow Headset Medically Approved Brain Stimulation, Medically Approved Brain Stimulation, Approved Brain Stimulation, Brain Stimulation, Stimulation |

## References

- tDCS depression treatment - Flow Neuroscience
- tDCS depression treatment - Flow Neuroscience
- User Manual