Flow Clinician Overview

FLOW
NEUROSCIENCE

Treat Depression. Differently.

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.

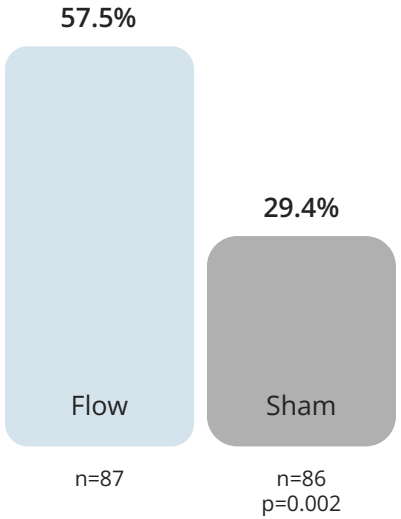
Mechanism of action

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, improving mood and emotional regulation.

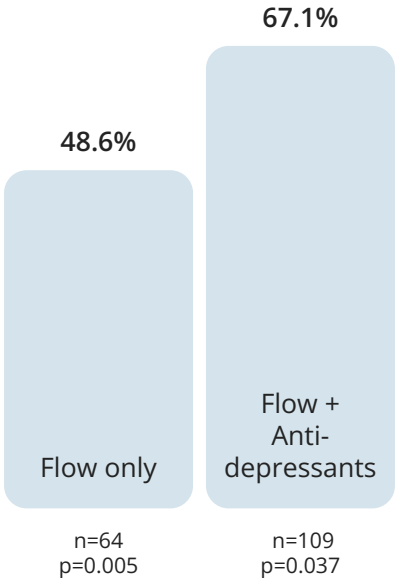
Efficacy

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]

Overall remission rates at 10 weeks:



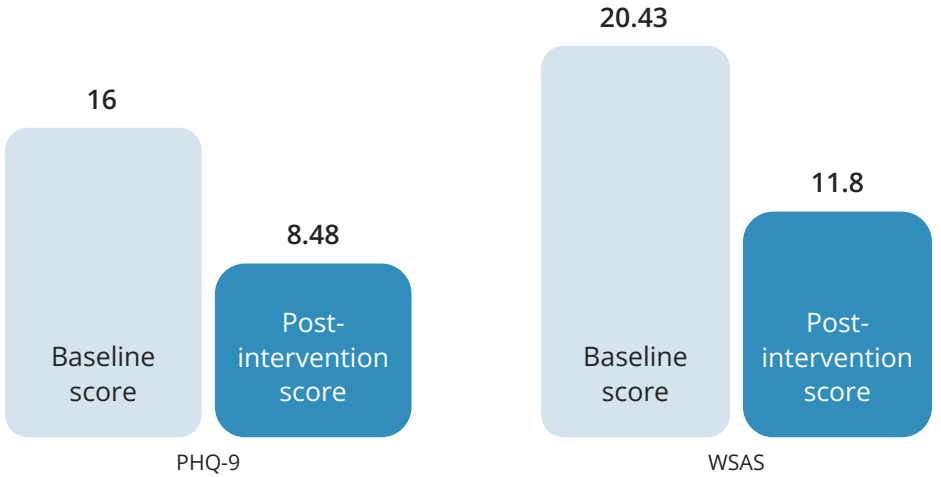
Remission rate when used as standalone and adjunct:



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

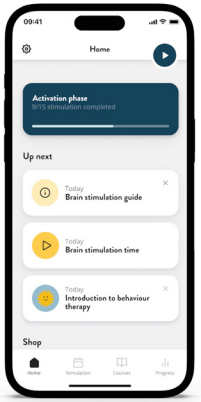
- Includes 5 stimulations a week
- Introduces optional behavioral therapy courses via the app

Strengthening Phase:
Week 4 onwards

- Includes up to 2 stimulations a week
- Continues to strengthen and preserve results
- Continue behavioural therapy courses

Behavioural therapy

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



Contraindications

No universal 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; used 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 favourable against antidepressants.

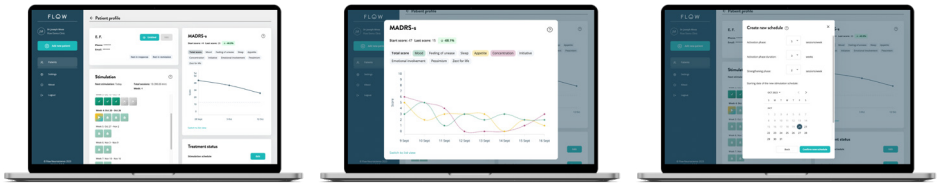
Side effect	Incidence	Probable duration	Recommendations to reduce intensity and/or duration
Skin irritation (including tingling, stinging redness	≥ 10% to < 20%	Less than a day. Rarer cases up to 3 days	Avoid stimulating on irritated skin • new pads with each stimulation • well-moisturised skin • well-hydrated • 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

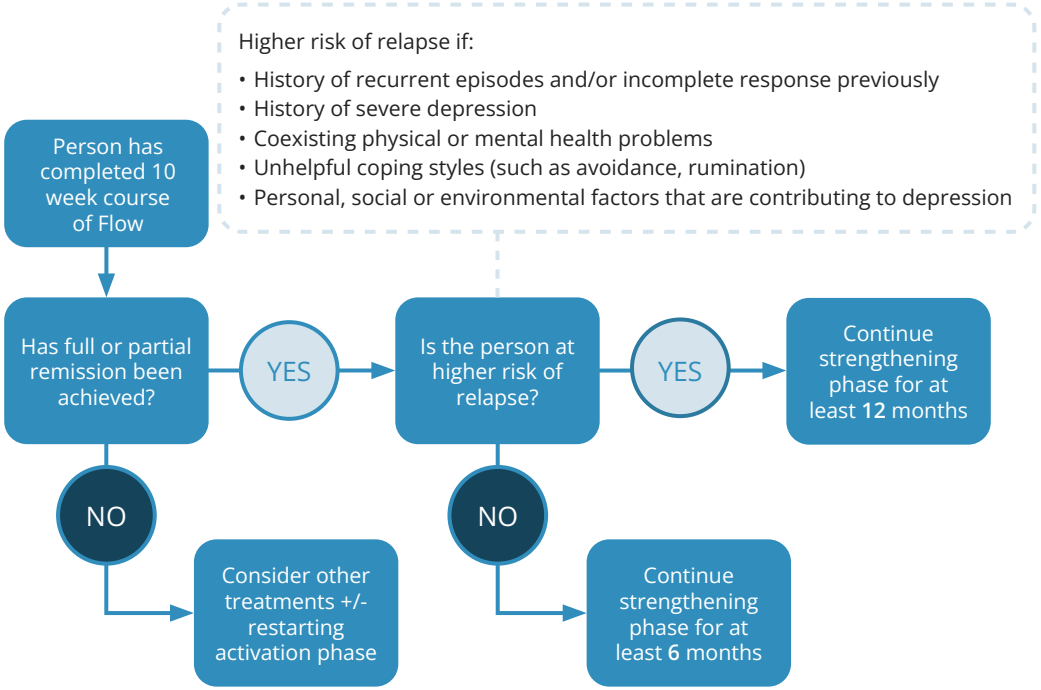
Adverse events should also be reported to Flow Neuroscience by emailing support@flowneuroscience.com.

Clinician review and customisation

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 judgement to address individual patient needs. This setup ensures personalised treatment adjustments to help optimise 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.

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

www.flowneuroscience.com

References:

1. Woodham, R. D. et al. (2023) "Home-based transcranial direct current stimulation RCT in major depression," bioRxiv. PREPRINT
2. Griffiths, C. et al. (2024) "'Flow' Transcranial direct current stimulation (tDCS) for depression treatment in a primary healthcare general practice - Depression, functioning, and health-related quality of life outcomes." *Open Journal of Depression*. 13(02), 25–39.

Class IIa medical device
CE 673331
UKCA 776047
Holder: Flow Neuroscience AB,
Södra Tullgatan 3, 21140 Malmö

www.flowneuroscience.com