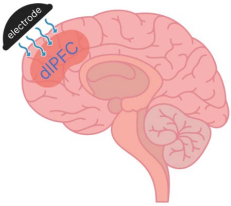
Clinician guide

Indications for use

Major depressive disorder (unipolar): Treatment of unipolar major depressive disorder (MDD) in adults, either as standalone treatment or in combination with antidepressants and/or psychological therapy.

Mechanism of action

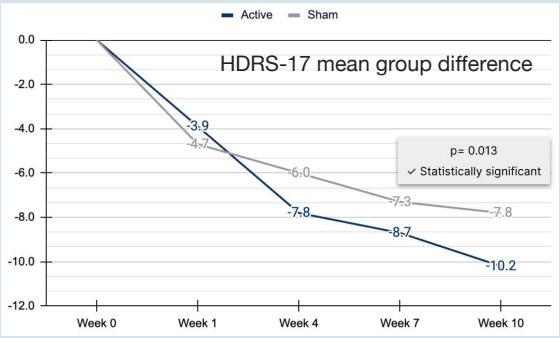
The Flow headset delivers a gentle electric current (transcranial direct current stimulation, tDCS) to the left dorsolateral prefrontal cortex, a region of the brain which plays a significant role in regulating emotions. There is a well-established link to depression when this region is hypoactive - the application of a current encourages more neurons to fire, and this gradual increase in neuronal activity can help counteract the hypoactivity associated with depression, leading to an improvement in mood and emotional regulation.

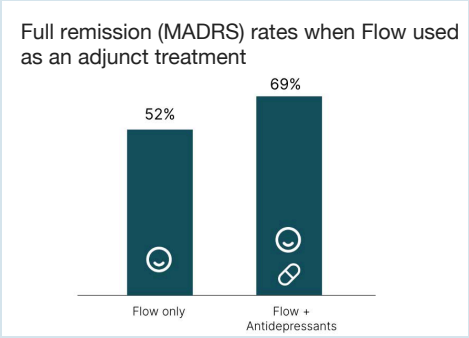


The headset is partnered with the Flow app which offers over 50 behavioral therapy modules. Users of Flow complete a weekly MADRS-s assessment (a self-reported depression test comprising of 9 questions, similar to a PHQ-9) and this is tracked over time to judge the response of the treatment.

Efficacy

Results at 10 weeks from a recent double-blind placebo-controlled randomized control trial were statistically significant for both primary and secondary endpoints. Flow achieved a **45%** remission rate using the HDRS-17 scale, **57%** using the MADRS scale, (n=173)





Treatment schedule

The standard treatment is split into 2 phases - activation and strengthening. Each session (termed stimulation) is 30 minutes long. Users cannot stimulate more than once per day. Users complete a MADRS-s survey at the beginning of each week to monitor progress. They are able to reset the schedule no earlier than 9 weeks.

Activation Phase

Weeks 1-3

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

Strengthening Phase:

Weeks 4+

- Includes up to 2 stimulations a week
- Further implements practices from the app
- Continues to strengthen and preserve results, reducing risk of relapse

Adverse reactions

Based on real world evidence from >17,000 users, the incidence rate of adverse reactions is **3.7%**, which is favorable versus antidepressants

Adverse reaction	Incidence	Duration	Techniques to reduce incidence
Headache	1.1%	During and up to a few hours after stimulation	Correct placement on head Relaxed environment Adequate hydration
Skin irritation (itching, tingling, mild erythema)	0.9%	During and resolves within a few hours	Avoid vigorous cleaning of skin before treatment (no more than a gentle wipe needed). Ensure pads are moist and not reused Cooling the skin after treatment with an ice pack
Tinnitus	0.5%	Most resolve within a few days. Small number of cases where persisting for weeks	Correct placement on head
Skin burn (1st degree)	0.3%	Can take 48 hours to resolve	Avoid vigorous cleaning of skin before treatment (no more than a gentle wipe needed) Ensure pads are moist and not reused Cooling the skin after treatment with an ice pack
Increased anxiety	0.2%	Can be a delayed response and last up to 48 hours	Correct placement on head Relaxed environment

Contraindications

There are no universal contraindications to using Flow.

Warnings/Precautions

Broken/inflamed/infected skin (including, for example, psoriasis) at the electrode site

Cranial or intracranial implant

Following neurosurgery e.g. after craniectomy

An active implanted medical, metallic or electronic device (such as a cardiac pacemaker, spinal cord stimulator, cochlear implant, implanted hearing aid or defibrillator)

Epilepsy or a history of seizures

History of hypomania or mania

Children and adolescents

Flow is not licensed for use in children. There have been some studies of using tDCS in children aged over 14 without adverse effects. Research in this group is ongoing.

Pregnancy

Flow is not licensed for use in pregnancy. Data from tDCS studies published to date have not raised safety concerns. Research in this group is ongoing.

Breastfeeding

Flow is safe to use while breastfeeding. Due to the mechanism of action there is no effect on breast milk production.

Postpartum

Flow is licensed for the treatment of Major Depressive Disorder, which there is significant crossover with Postpartum depression - Flow has been safely used in this population (including as a pilot in an NHS trust) and has seen high uptake as it is a drug-free option and safe to use while breastfeeding.

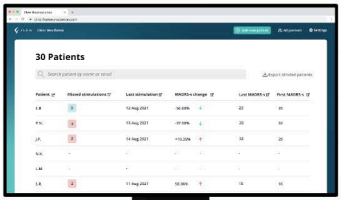
Other chronic conditions

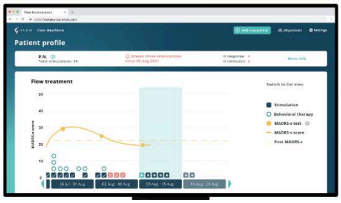
Due to the mechanism of action, there are no interactions with medications and it is safe to use in individuals with chronic conditions including diabetes, heart disease, hypertension, asthma and if they suffer with other mental health conditions alongside unipolar MDD. Additionally, individuals who have congenital, acquired and degenerative brain injuries/disorders or are neurodivergent have used Flow without any safety concerns.

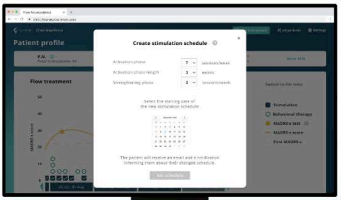
Monitoring

Users complete an in-app MADRS-s survey at the end of each week to monitor their progress.

You are also able to review their progress and stimulation history through a secure clinician portal (called the Flow Clinician Platform Portal (CPP)) which also allows you to customize their treatment protocol. For example you may wish to extend the activation phase, modify the number of stimulations or reset the schedule.







A determination on how to continue with Flow is recommended at 10 weeks: