FLOW
NEUROSCIENCE

The Flow Data Pack

Welcome to the Flow Data Pack!

This is the Flow tDCS device

Using electric currents to treat ailments is not exactly modern technology. For example, Scribonius Largus describes how ancient Romans used electric discharges from the torpedo fish to treat nerve pain.

However, the packaging and procedure has been improved quite a lot since then.

The specific technique used in Flow Neuroscience's brain stimulation device is called transcranial Direct Current Stimulation (tDCS). There is class A evidence (definite effect) for the ability of tDCS to improve depressive symptoms.

The research behind tDCS technology indicates a link between depression and hypoactivity in the left dorsolateral prefrontal cortex of the brain (the DLPFC). The Flow tDCS device uses the neurons' favourite tool of communication – electricity – to restore brain function in the area.

The device delivers a gentle electric current to the left DLPFC, which significantly increases the neurons' ability to reach action potential.

In contrast to Transcranial Magnetic Stimulation (TMS) or Electroconvulsive Therapy (ECT), the tDCS technique offers sub-threshold stimulation. The extremely mild current of 2 mA does not force neurons to fire, but rather *encourages* them to do so.

Over time, neurons in the targeted brain area are more likely to fire together and increase activity, thereby relieving depressive symptoms.

The gentleness of this treatment ensures that it's completely non-invasive and that side effects remain unusually rare and mild in comparison to other treatments. It also means that patients may need to wait 2-4 weeks to notice an improvement in their depression.

For a majority of patients, it's well worth the wait.

A recent RCT study showed that the Flow tDCS device offered full remission for 57% of the 173 depressed participants at 10 weeks. 63% of the patients reported a 50% or more reduction of symptoms.

Read more about **How effective is the Flow treatment** below.

Quality control of the Flow tDCS device

In the past, tDCS treatment was only available in-clinic under the direct supervision of a trained professional. Consequently, the treatment required time and resources.

To help clinicians meet the demands of a constantly growing depressed population, Flow Neuroscience has made tDCS available for patients to use at home.

Today, clinics can monitor more patients in less time thanks to the thorough review processes which ensure that the Flow tDCS device is completely safe and effective for at-home use.

The Flow tDCS device is currently approved as a medical device for at-home depression treatment in:

- **The EU, the UK and Switzerland (since 2019)**
- **Brazil (since 2020)**

An FDA approval for at-home use in the USA is in progress.

The British Standards Institution (BSI) evaluates the safety and efficacy of the Flow tDCS device. The BSI review is supported by several large-scale RCTs demonstrating the effectiveness and impact of tDCS. See the clinical trials below.

The Flow tDCS device is CE-marked as a Class IIa medical device. In contrast to Class I devices, the BSI has thoroughly reviewed clinical studies and published safety reports in order to conclude that the Flow tDCS device treats depression effectively and safely.

After-market data. Since receiving the CE-marking, the Flow tDCS device has been used by over 16 000 people in Europe. As part of the certification, Flow collects extensive data from these patients and reports it to the BSI annually. The procedure ensures that the real-world effects of using the Flow tDCS device align with the effects reported in the literature.

Thanks to a unique safety system, the Flow tDCS device has proven absolutely safe to use. It has been tested according to IEC 60601 for electrical medical device safety.

The Flow tDCS device received FDA Breakthrough Device Designation for at-home depression treatment in 2022. It's the first and only tDCS device to do so.

The National Institute for Health and Care Excellence (NICE) has developed a medtech innovation briefing (MIB) on the Flow tDCS treatment. It includes a review of published evidence and expert statements about the usefulness and cost saving potential of Flow.

"There is high-quality, comparative evidence from the UK that Flow can improve symptoms of depression and lead to remission."

Pending approvals

Flow Neuroscience is targeting full FDA approval before the end of 2024.

How effective is the Flow treatment?

– Clinical trials and real world results

There are over 9000 peer-reviewed publications on tDCS, including numerous large-scale studies and meta-analyses. And the number increases each year.

tDCS's popularity surge is probably due to four main factors:

1. **Efficacy**
2. **Tolerability**
3. **Affordability**
4. **Ease of use**

Since 2020, there has been class A evidence (definite effect) for the ability of tDCS to improve depression.

Though it would be nearly impossible to mention all significant publications, below are a few important ones:

2013 – Brunoni et al: Clinical trial with 120 patients demonstrated that tDCS was significantly superior to placebo and even more effective when combined with an SSRI (Sertraline).

2016 – Bikson et al: An ambitious study found tDCS to be absolutely safe to use across a variety of populations and over 33 000 tDCS sessions. The team concluded:

"The use of conventional tDCS protocols in human trials (≤40 min, ≤4 milliamperes, ≤7.2 Coulombs) has not produced any reports of a Serious Adverse Effect or irreversible injury across over 33,200 sessions and 1000 subjects with repeated sessions. This includes a wide variety of subjects, including persons from potentially vulnerable populations."

2019 – Mutz et al: Systematic review, including a combined group of 6,750 patients, demonstrated that tDCS is comparable to TMS in efficacy. The authors concluded:

"Given that tDCS tends to be a less expensive treatment than transcranial magnetic stimulation, ECT, or psychotherapy, this finding is particularly relevant for policy makers who might consider tDCS as a clinical therapy outside the research setting."
Indeed, TMS devices are typically priced at a significantly higher cost than the Flow tDCS device.

2020 – Razza et al: Meta-analysis of 1,092 patients demonstrated that tDCS is superior to placebo.

2020 – Fregni et al: tDCS was classified as definitely effective for depression (Level A evidence). In addition, tDCS reached Level B evidence (probably effective) for a wide range of other conditions, such as:

- Neuropathic pain
- Fibromyalgia
- Migraine
- Epilepsy
- Parkinson's disease
- Schizophrenia
- Alcohol addiction

Please note: *The careful process behind the CE marking of the Flow tDCS device ensures that the effects of using Flow align with the effects seen in the literature.*

2020–2023: Flow Neuroscience conducted its own pilot studies and RCT to investigate the safety and efficacy of the Flow tDCS device.

The Flow Neuroscience RCT Results

June 2023 – Flow Neuroscience finished enrollment for one of the largest randomised placebo-controlled tDCS trials ever conducted for depression.

It showed that active stimulation with the Flow tDCS device was superior to sham stimulation for the treatment of Major Depressive Disorder (MDD) when used at home.

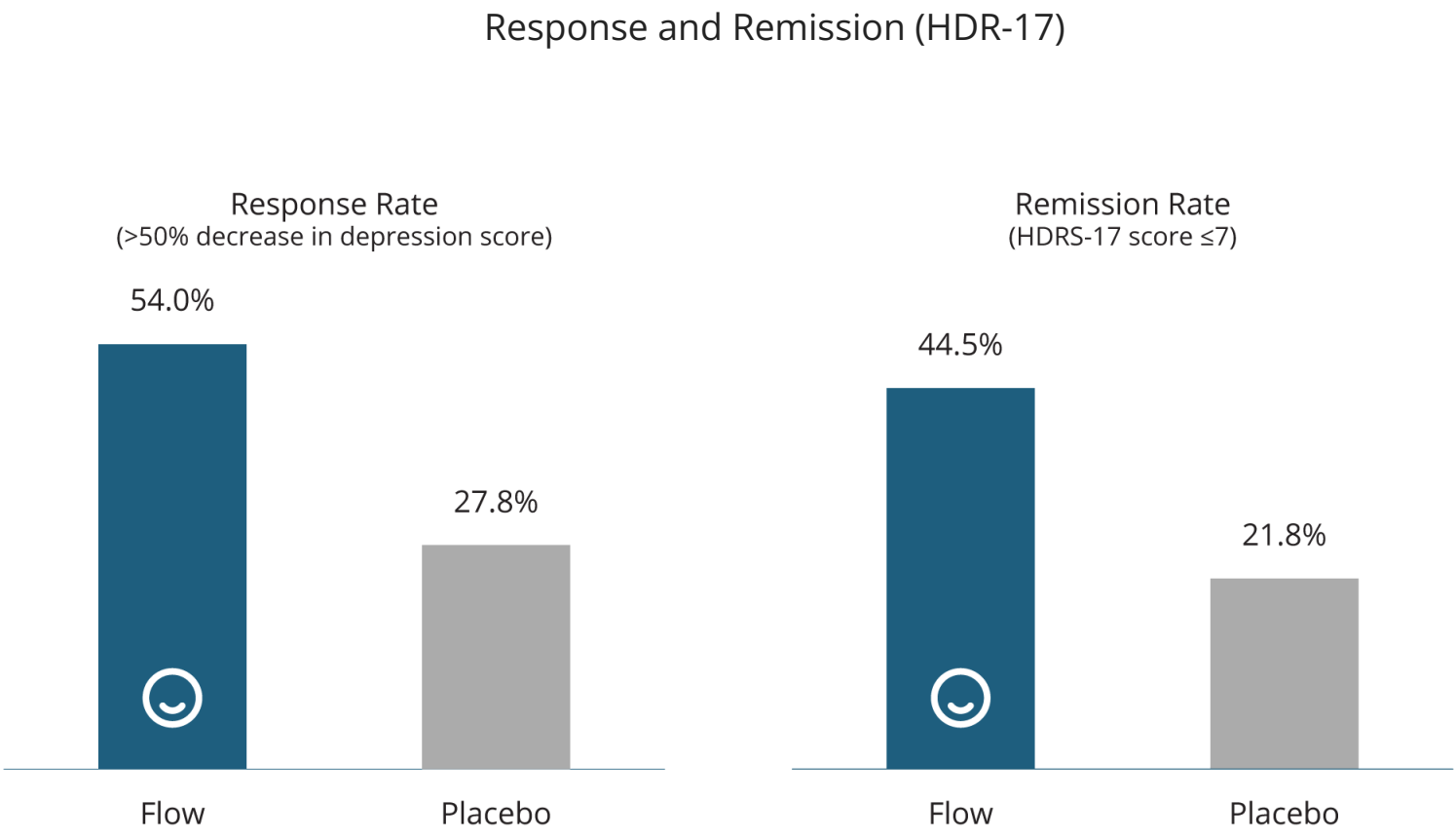
The study was double-blinded and involved two research centres – the University of East London (UK) and the University of Texas (US).

173 participants with moderate to severe depression used the Flow tDCS device in the comfort of their own homes. The treatment protocol included 10 weeks of treatment with 3-5 stimulation sessions a week. Each session was 30 minutes long.

Outcomes were measured using the HDRS-17 and MADRS depression surveys.

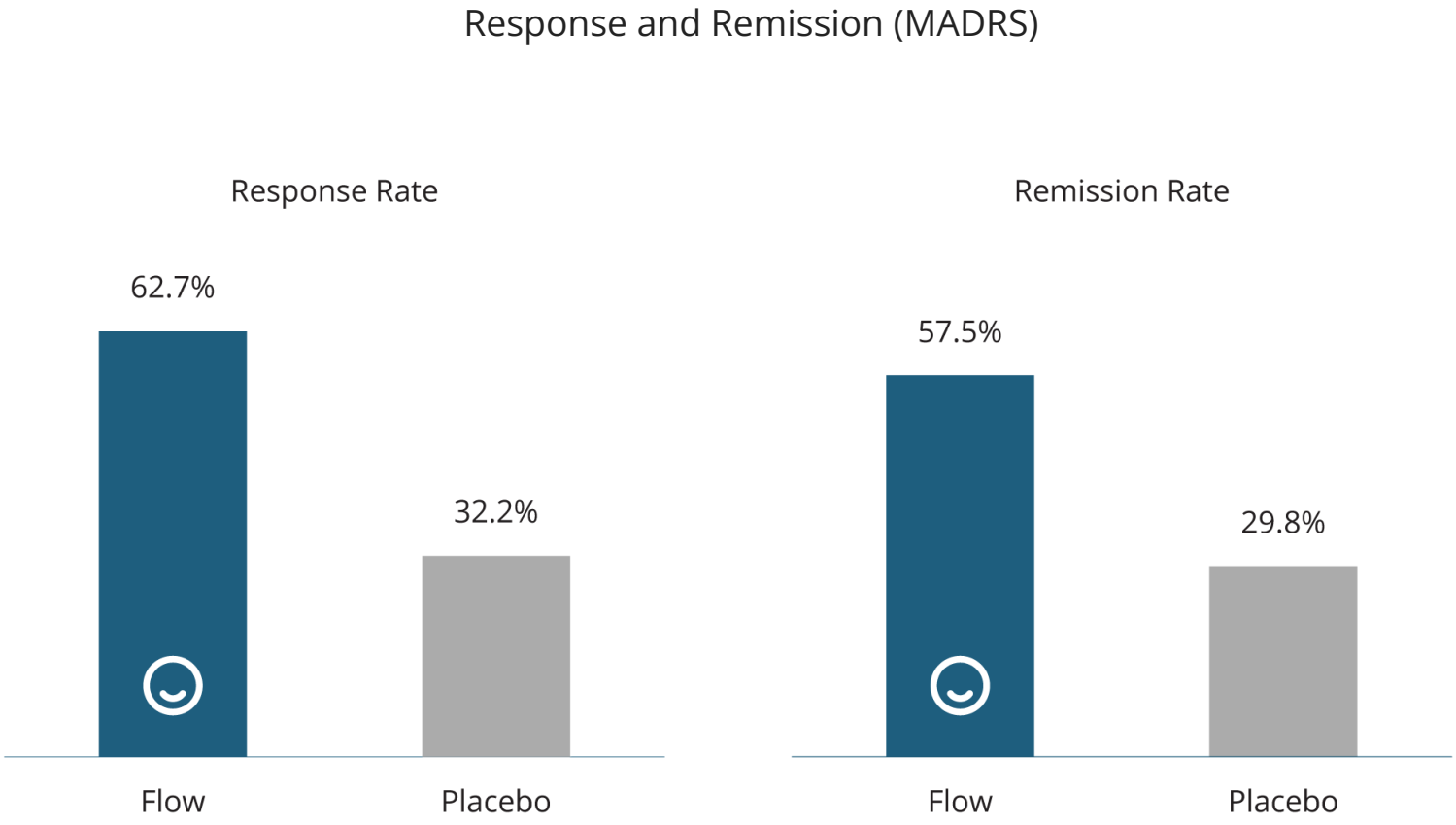
Results:

- **Results based on HDRS-17:** 44.5% Remission (vs 21.8% placebo) and 54.0% Response rate (vs 27.8% placebo) at week 10.

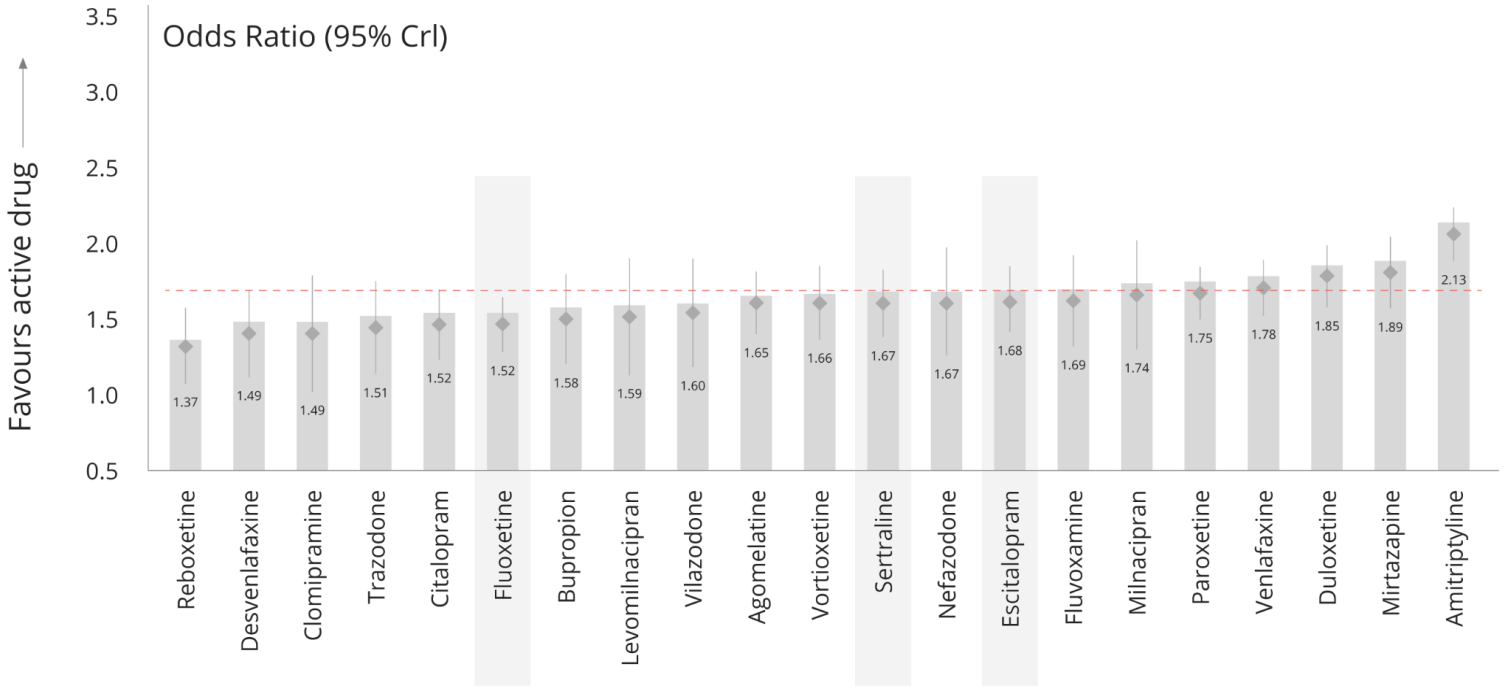


** p>0,025

- **Results based on MADRS:** 57.5% Remission (vs 29.8% placebo) and 62.7% Response rate (vs 32.2% placebo) at week 10.



- Odds ratios of **3.05** (based on the HDRS-17 results) and **3.56** (based on the MADRS results) indicate that the Flow treatment was approximately twice as effective as the best-selling antidepressants (view [the trials for the 21 best-selling antidepressants]).



Source: 116,000-patient and 500+ study meta analysis. Cipriani, Furukawa, Salanti et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with MDD: meta-analysis. 2018.

- No serious adverse effects were reported.
- More information on the trial can be found here.

The NHS Qualitative Study Results

July 2023 – Griffiths and colleagues performed a qualitative study using the Flow tDCS treatment in primary care within the United Kingdom's National Health Service (NHS).

The aim of the study was to explore the experience and value of using the Flow tDCS treatment for depression at home.

The patients were offered six weeks of the Flow treatment by their General Practitioner (GP). In addition to 24 home-based brain stimulation sessions, patients were offered to engage in the behaviour therapy training sessions included in the Flow app.

The results of the study provided support for offering Flow as a treatment option for depression in primary care.

The research team concluded:

"Flow has been successfully integrated into a primary care service depression treatment. It is important to offer patients an evidence-based alternative to existing depression treatments (antidepressant medication and talking therapies). The results support the use of Flow as a treatment option for people with symptoms of depression."

Of the 47 patients using the Flow treatment, 18 agreed to in-depth interviews about their experience.

Results:

Following the analysis of the interview data, four main themes emerged:

1. **Feasibility**
2. **Useability**
3. **Acceptability**
4. **Value**

Feasibility
The patients described how Flow was easily and conveniently integrated and used in combination with other treatments such as medication and talking therapies.

The initial process of getting Flow was easy, convenient, and patient friendly. Patients also described setting it up as user-friendly.

Useability
The patients found that they could fit Flow into their day-to-day routine, without too many problems. Side effects such as itching and tingling could easily be managed.

"It's dead simple to be honest, once the app is on there, which is easy to download. I mean, I'm not particularly techie. Because I think anybody, especially when you get older… so simple…" (NHS patient)

The behaviour therapy training facilitated some positive behaviour changes. A majority of patients found it helpful.

"It gives you suggestions for habits and you know it is almost like a mini therapist, I really like that element and I'm finding it most helpful." (NHS patient)

"I did love the therapeutic sleep training. It has made a massive difference to my sleep. I've since had no TV on, I've done my meditation before bed, and then it's been like pitch black…" (NHS patient)

Acceptability

For the majority of the patients, the fact that Flow was an alternative to medication to treat their depression was an important factor.

For those still on medication, Flow was perceived by some as a means to eventually help them come off their medication.

Flow was perceived to be something that worked. Many of the patients felt very strongly about keeping Flow.

"Because I felt it was making a huge difference. After six weeks, I stopped using it with the idea of giving it back. But after a week, I could feel that my mood was going backward again. Then I used it for the following couple of days. And I was back to being how I was. So yeah, then I was, no it's mine you are not having it back!" (NHS patient)

Value

The Flow treatment had a significant positive impact on patients' depression and anxiety.

Several talked about feeling like their old self. Others felt it had relieved them of their depression and anxiety completely.

In addition, patients reported improvements in mood, optimism, confidence, sleep and motivation.

"The effect it's [Flow] had on me, and I think it's been quite groundbreaking for me and my depression and anxiety, it's been a life changer." (NHS patient)

"I don't feel sad anymore. I feel a lot more optimistic, and happier. I have just got a better outlook on things. Using the Flow changes your train of thought. My thinking is now positive rather than negative all of the time... and I feel better in my mood." (NHS patient)

More information about the study can be found here.

Real-world Results

In addition to conducting clinical trials, Flow Neuroscience collects data from the > 16 000 patients on the Flow platform (via the Flow app).

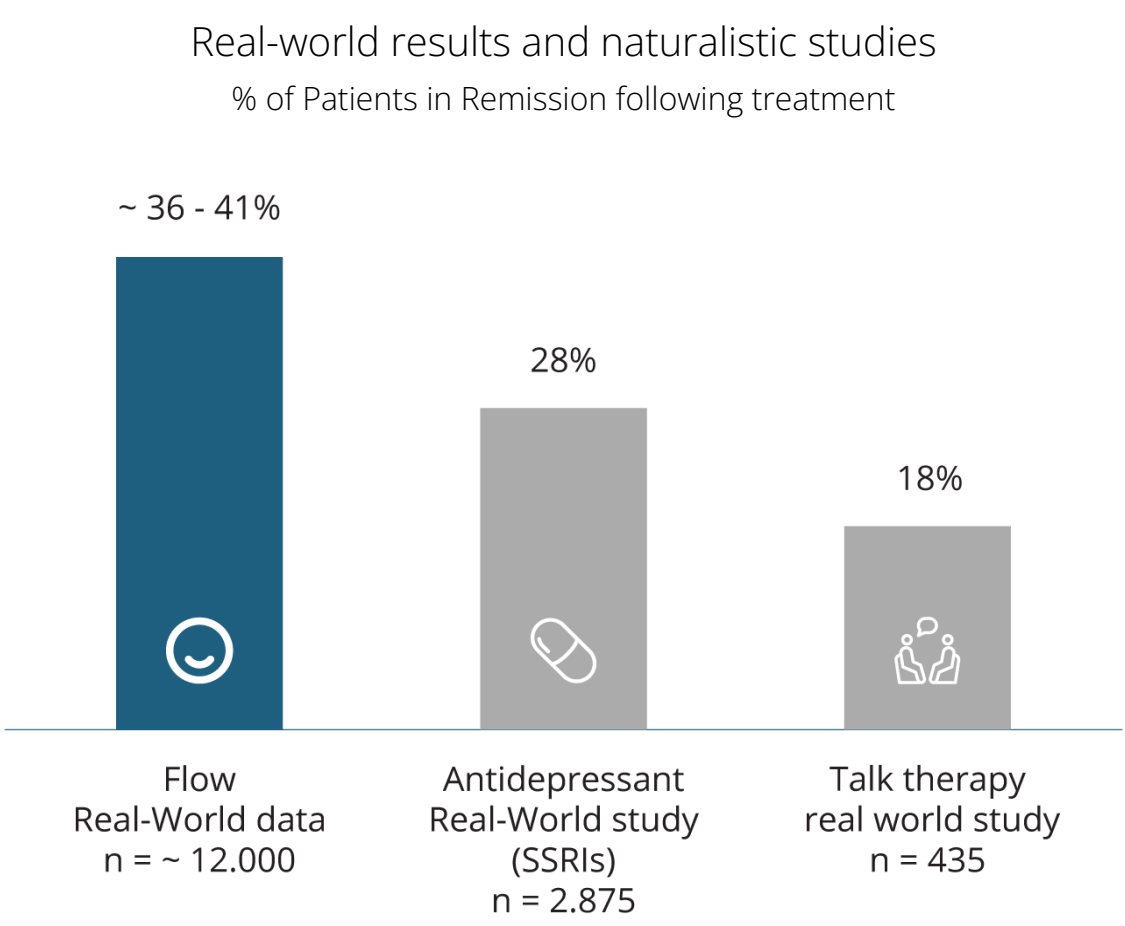
Depression scores are collected weekly from all patients using the Montgomery and Åsberg Depression Rating Scale (MADRS-s) – a reputable and clinically-validated questionnaire for measuring depressive symptoms.

The data suggest that the Flow tDCS treatment currently outperforms existing treatments in terms of real world remission rates.

This is particularly noteworthy considering that around 92% of Flow patients report that they have already tried one or several treatments before choosing Flow. A consistent theme in patient feedback and interviews is that antidepressant medication and/or psychotherapy have had little or no effect (or have been unmanageable due to side effects or waiting times).

Consequently, treatment resistance may be over-represented among Flow patients. And one should typically expect to see lower remission and response rates for these patients.

Please note: *The Flow remission rates vary with time because of the constantly growing number of patients.*



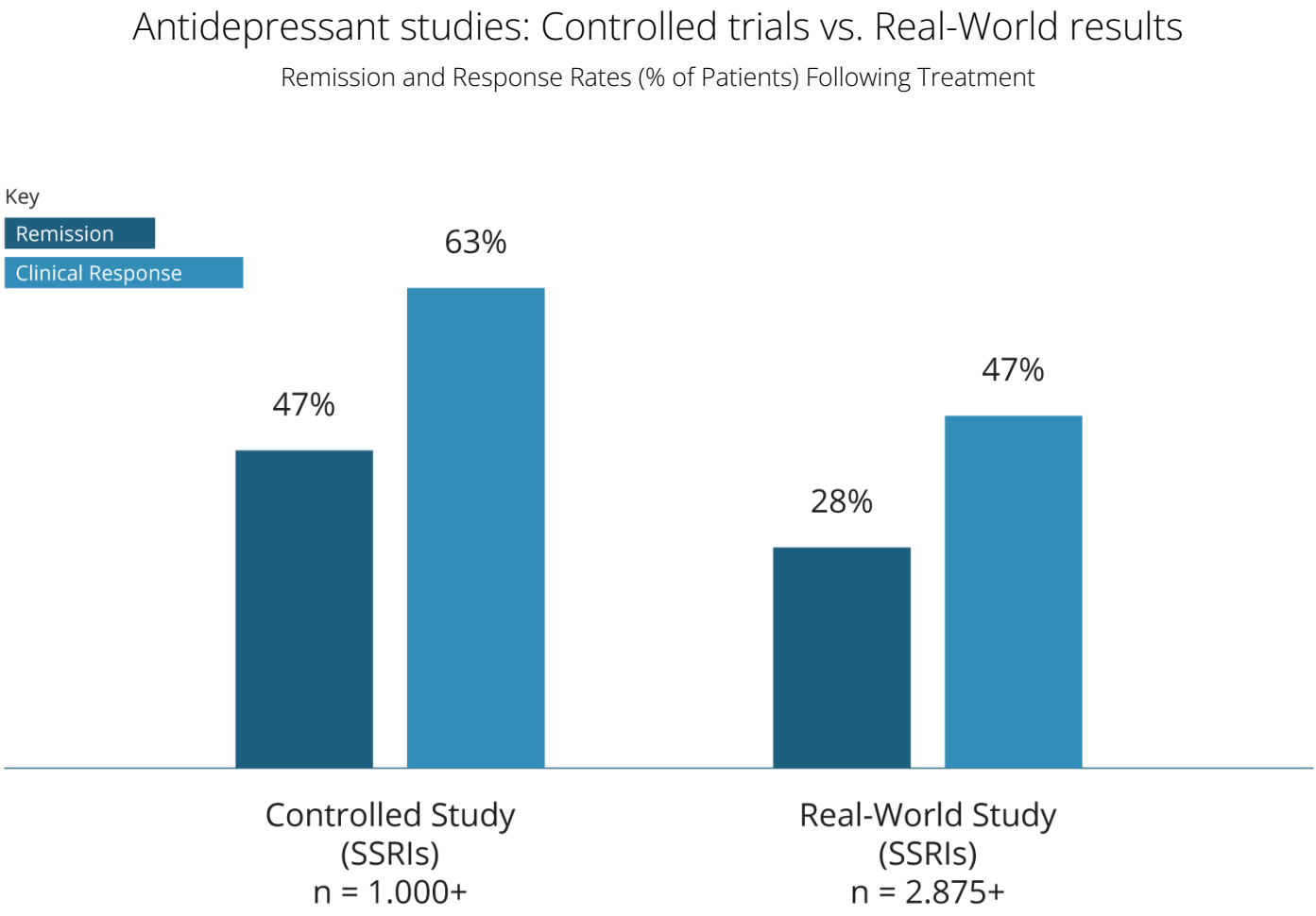
Why are the real-world results different from the clinical trial results?

In general, real-world results are expected to underperform controlled trials for depression treatment. This is typically due to:

1. **Patient selection in trials:** Real-world results usually include patients with multiple comorbidities, which can complicate results and make it more difficult to achieve an impact on depression scores.

2. **Clinician influence:** In clinical trials, clinicians usually administer depression score questionnaires and supervise patients through the treatment protocol. When it comes to real world data, patients report symptoms themselves. Clinicians tend to report bigger improvements in depression scores than patients.

The same phenomenon can be observed across different studies for antidepressant medication:



References: Controlled study by Thase et al., Real-World results by Trivedi et al.

Side effects

One of the most tangible benefits of the Flow tDCS treatment is the astonishing absence of side effects.

Real-world reports

Over 16 000 people have used the Flow tDCS device. Very few have reported any side effects at all.

This list includes known side effects from the Flow tDCS device (until August 2023):

- Headache (~1,5 %)
- Skin irritation (~1.2%)
- Tinnitus (~0.6%)
- Mild skin burn (~0.5%)
- Worsening of symptoms (~0.4%)
- Increased anxiety (~0.3%)
- Skin redness (~0.15%)
- Stinging (~0,07%)

Please note: *The percentages may vary slightly with time because of the constantly growing number of patients.*

The high tolerability of tDCS is repeated across clinical trials where drop out rates usually don't differ between treatment group and sham/control group.

Clinical evidence

Clinical studies, such as the one performed by Bikson and colleagues examining over 33 000 tDCS sessions, show that the current used in tDCS treatment protocols is not strong enough to cause any damage to the brain.

A 2020 study, examining adverse effects of over 2000 tDCS sessions, found side effects to be mild, transient and well-tolerated. The most commonly reported side effects included:

- Burning sensations (16.2%)
- Skin redness (12.3%)
- Scalp pain (10.1%)
- Itching (6.7%)
- Tingling (6.3%)

Antidepressants. In comparison, a large international cohort including people from 38 different countries showed that a majority of antidepressant users experienced several adverse effects.

61% of the users reported at least 10 adverse effects. Some of the most common ones are listed below:

- Feeling emotionally numb (reported by 71%)
- Feeling foggy or detached (70%)
- Feeling not like myself (66%)
- Sexual difficulties (66%)
- Drowsiness (63%)
- Reduction in positive feelings (60%)
- Suicidality (50%)

In addition, withdrawal effects were reported by 59% and 40% reported an addiction to the drug.

Contraindications

tDCS should NOT be used in the following cases:

- The patient has a cranial or intracranial implant
- The patient's skull is not intact
- The patient has a skin condition, for example psoriasis

The following conditions are not contraindications, but may require extra precautions – such as careful monitoring:

- Bipolar disorder (or a history of hypomanic/manic episodes)
- Epilepsy (or a history of seizures)
- Heart disease
- Neurological conditions
- A recent surgical procedure
- An active implanted medical, metallic or electronic device (such as a cardiac pacemaker, spinal cord stimulator, cochlear implant, implanted hearing aid or defibrillator)

Use during pregnancy

There is no evidence to suggest that tDCS treatment could be harmful to use during pregnancy. The electric current targets the brain directly without affecting the hormonal or digestive systems, making tDCS a tempting option for treating depression during the peripartum period.

However, more large-scale controlled trials are needed before any definitive conclusions can be drawn.

Today, the option to use tDCS during the peripartum period should be carefully evaluated in each individual case.

Encouraging research results for tDCS during pregnancy:

2022 – Laurin et al: A systematic review including seven studies and 33 women. No serious adverse effects for the mothers or children.

2019 – Vigod et al: A pilot randomised controlled trial showing promising results for tDCS during pregnancy. There were no serious adverse events.

2018 – Kurzeck et al: A systematic review concluding that the scientific evidence for tDCS during pregnancy is sparse but promising.

Long-term use

Clinical trials indicate that tDCS sessions can be used for at least 6 months without any changes in side effects, suggesting the treatment is suitable for long-term use.

There is no evidence to suggest that side effects would increase beyond 6 months, but few such long-term studies exist.

In comparison, most clinical studies on antidepressant medication follow up for a maximum of 5 months.

The following studies indicate the safety and efficacy of tDCS long-term treatment:

2022 – Woodham et al: An open-label, single-arm feasibility study with long term outcomes investigated home-based tDCS treatment for depression.

At week 6, 22 participants (91.7%) showed a clinical response. 21 participants (87.5%) achieved remission.

At the 6-month follow up, clinical response was 21 out of 23 participants (91.3%). Remission was 17 out of 23 participants (73.9%).

The treatment was described as “very acceptable” or “quite acceptable” by all participants (n=24).

2021 – Razza et al: A systematic review and meta analysis investigated the follow-up effects of tDCS for depression. The analysis included 11 studies and showed that depressive symptoms continued to improve during the tDCS follow-up phase. It suggested that maintenance treatment might further improve the gains from acute tDCS treatment.

2019 – Aparicio et al: A 6-month follow-up clinical trial investigated the effects of tDCS for preventing depression relapse. The study included 24 patients who had responded to tDCS treatment in the acute treatment phase (15 tDCS sessions over 3 weeks). The participants were followed for up to 6 months.

The maintenance treatment included 2 weekly tDCS sessions.

tDCS was well tolerated, both during the acute phase and the follow up phase. No adverse events were reported.

The studies main findings were:

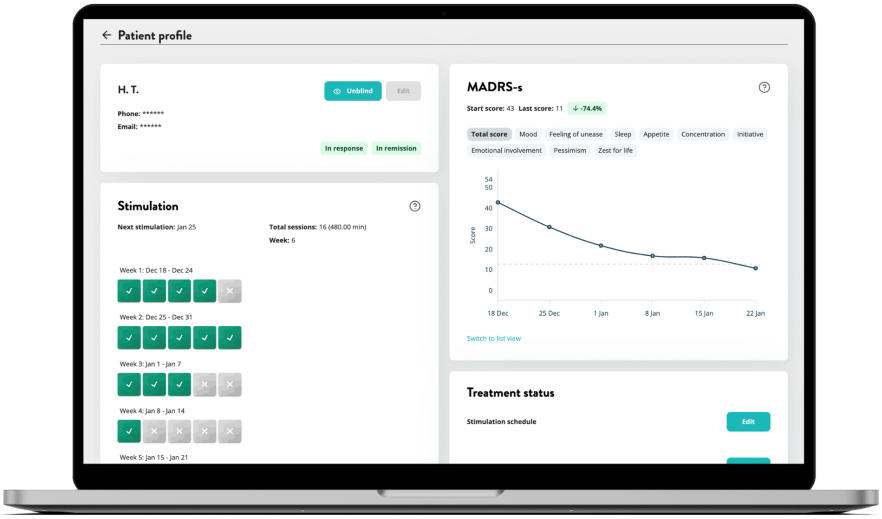
1) Patients presented approximately a 50% improvement in depression during the follow up phase.
2) The overall relapse rate was 26.5%.
3) Antidepressants treatment-resistant depression was associated with higher levels of relapse.

2013 – Valiengo et al: The SELECT-TDCS trial followed participants for 6 months and found that tDCS was effective both as a treatment in the acute phase of depression and as relapse prevention.

However, the relapse rate was higher in comparison to Aparicio's study (53% vs 26.5%). According to Aparicio (2019), the probable explanation was that the SELECT trial included significantly fewer maintenance sessions.

The Treatment protocol

The Flow tDCS treatment protocol is simple to follow. Flow offers all patients a standard treatment plan based on the protocols most commonly used in clinical studies. That way, safety and efficacy is ensured.



However, the Flow Clinician Platform enables clinics to monitor patient progress and personalise the treatment protocol for each patient. After all, patients are different and some might benefit from more frequent stimulation sessions.

The standard treatment plan

As a starting point, the following protocol is recommended for all patients:

First 3 weeks of treatment: 5 stimulation sessions a week.
Beyond 3 weeks: 2-3 stimulation sessions a week.

In case the patient experiences a return of symptoms as the treatment protocol is reduced to 2-3 sessions a week – consider increasing the number of stimulation sessions to 5 for another few weeks, or for the whole duration of the treatment.

Patients usually see results within the first 3 weeks of treatment. A recent RCT study showed that 57% of participants with moderate to severe depression reached remission within 10 weeks.

Maintenance treatment for a minimum of 6 months is recommended.

Maintenance protocols

Patients with a high risk of depression relapse are recommended a slightly different protocol than patients with a low risk of relapse.

High risk factors include:

- Childhood maltreatment (such as abuse, neglect, family violence)
- A history of depressive episodes
- Chronic physical or mental health disorders

Low risk of relapse patients are exempt from these risk factors.

The maintenance protocol is based on how the patient responds to the Flow tDCS treatment during the initial 10 weeks. Below, you'll find the recommended protocols for three common scenarios.

Scenario #1: The patient reaches remission by week 10

Recommendations for high risk of relapse patients: 3 or more stimulation sessions a week for a minimum of 12 months to help maintain remission.

For low risk of relapse patients: 2-3 stimulation sessions a week for a minimum of 6 months to help maintain remission.

Scenario #2: The patient achieves a 50% reduction of symptoms (but not full remission) by week 10

For all such patients: Consider increasing the number of stimulation sessions per week.

For high risk of relapse patients: Continue the treatment for a minimum of 12 months to maintain the results.

For low risk of relapse patients: Continue the treatment for a minimum of 6 months to maintain the results.

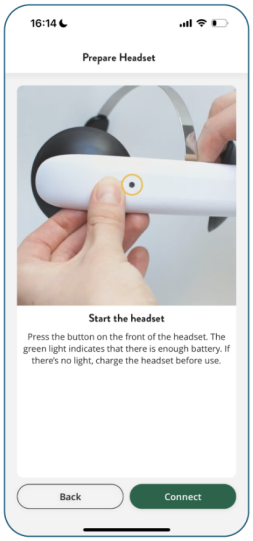
Scenario #3: The patient does not reach response or remission by week 10

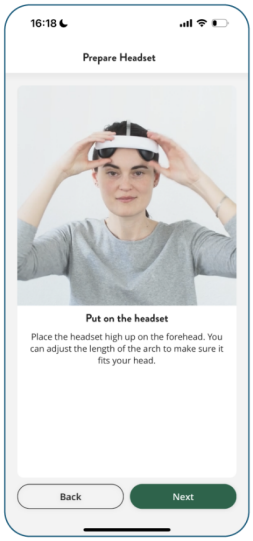
For all such patients: Re-evaluate the use of the Flow treatment.

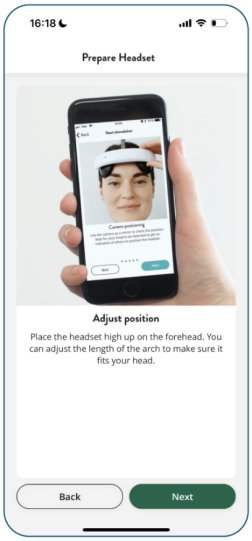
How to start the Flow tDCS treatment

Step 1. Patients will need access to a Flow tDCS device to use at home.

Step 2. With the device available, they simply download the Flow Neuroscience app for Android or Apple and follow the instructions.







Explaining tDCS to patients

The following 3-minute video can be used to explain tDCS to patients with depression: What is tDCS?

Future uses of tDCS

To date, the only tDCS treatment with Level A evidence (definite effect) is the treatment of Major Depressive Disorder (MDD).

The Flow tDCS device is solely classified as a Class IIa medical device for the treatment of depression.

Should a clinic choose to use the Flow tDCS device to treat any other condition, this would be classified as “off-label” use with the accompanying risks.

Level B evidence

There is currently Level B evidence (probable effect) for the use of tDCS on several conditions. A few of these conditions are treated by targeting the same area as the Flow tDCS device – the left dorsolateral prefrontal cortex (DLPFC).

tDCS treatment usually targets the left DLPFC in:

- Cognitive symptoms of Parkinson's disease
- Auditory hallucinations in Schizophrenia (however the cathode is placed differently – over the left temporoparietal area)

A minority of studies have used the left DLPFC as a target for the treatment of pain disorders.

tDCS treatment usually targets other brain areas in:

- Alcohol addiction (usually the **right** DLPFC)
- Epilepsy (cathode placed over the affected area)
- Neuropathic pain (motor cortex)
- Migraine (motor cortex)
- Fibromyalgia (motor cortex)
- Stroke rehabilitation (motor cortex)

Level C evidence

There is currently Level C evidence (possible effect) for the use of tDCS in:

- Obsessive-Compulsive Disorder (targeting the pre−SMA)
- Aphasia (various placements, some targeting Broca's area)

ADHD

There is promising and growing evidence for tDCS treatment of ADHD symptoms.

In 2022, a randomised, double-blind, controlled trial showed that at-home tDCS treatment significantly improved attention in 64 adult patients with ADHD. The treatment used the anode over the right DLPFC.

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