FLOW

NEUROSCIENCE

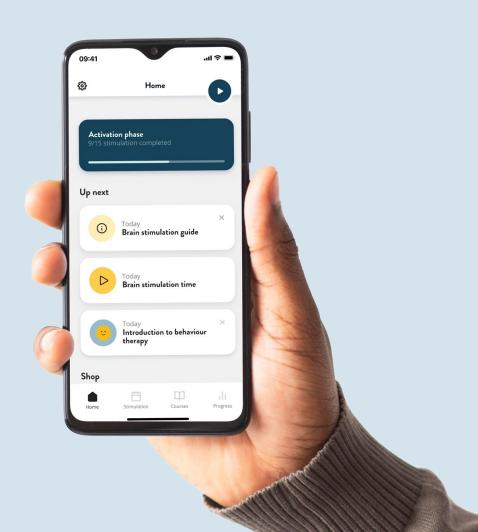




Web: www.flowneuroscience.com E-mail: sam@flowneuroscience.com

Agenda

- Recap: The Treatment and Evidence
- Overview of Flow-NHS Programs
- Overview of Key NHS Results
- NICE
- Next steps



The Treatment



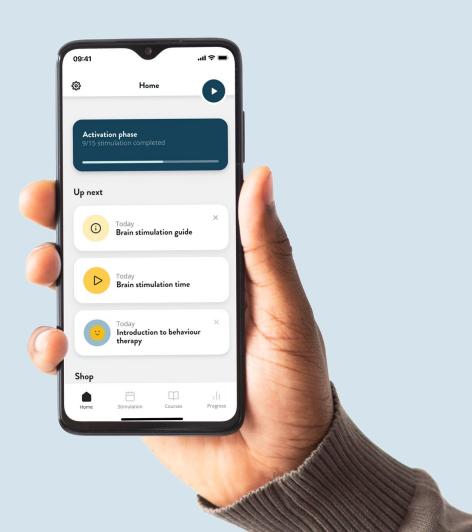
The headset delivers a small electrical current into the prefrontal cortex.

By stimulating this part of the brain, it's possible to raise activity levels and relieve the symptoms of depression.



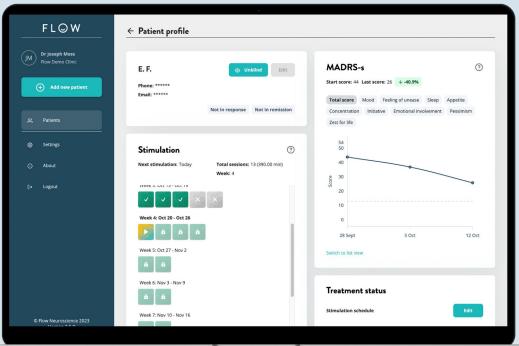
The Flow app completes several functions:

- Restricts abuse, limiting the no. of times patient can use headset
- Tracks patient reported outcomes
- Provides behavioral therapy content modules



Using Flow's Clinical Platform, clinicians can **remote monitor** a patient's depressive symptoms

over time, helping to plan timing of interventions.



Results

There are over 9000 peer-reviewed **publications on tDCS**, including numerous large-scale studies and meta-analyses.

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

Transcranial Direct Current Stimulation

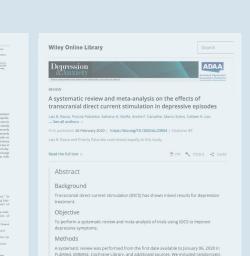
A Double-Blind Randomized

Sham-Controlled Trial

for Treatment-Resistant Major Depression:

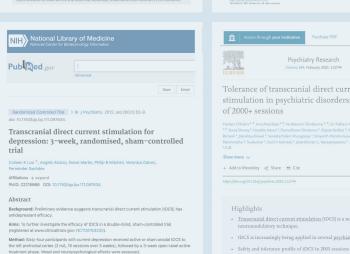
suptom relief, however, technical challenges and the amount | however, technical challenges and the amount | however, technical challenges and the amount |

Elham Sharafi¹, Arsia Taghva², Mohammad Arbabi¹, Afsaneh Dadarkhah²,



sham-controlled clinical trials (RCTs) enrolling participants with an acute depressive

episode and compared the efficacy of active versus sham tDCS, including association with











What Flow has done is taken this bank of research and turned it into a **safe**, **regulatory approved**, **intuitive**, treatment that can be **used at home** by the patient.







Flow 100

Flow Companion App

Flow Clinician Portal

NICE concluded that:

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

The Maudsley have confirmed that tDCS will now be included in their **2024 depression treatment guidelines**.

58%

Flow RCT Remission

40%

Flow Real World Remission

Flow and the NHS

The next step was to demonstrate that Flow could be successfully **integrated into NHS treatment pathways**.

In 2023 Flow launched programs with the NHS in:

- Primary care
- Community Mental Health
- Perinatal Mental Health



Primary Care

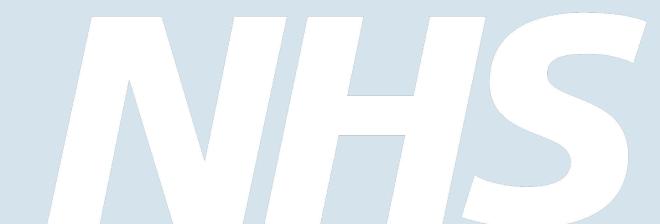
- 100 NHS patients with depression
- 4 GP Clinics in Northamptonshire
- Flow offered as alternative to antidepressants

- 50 NHS clinicians with depression
- NHS Practitioner Health
- Flow offered as alternative to antidepressants



Community Mental Health

- 50 patients
- 2 CMH Teams in Northamptonshire
- Flow offered in combination with antidepressants and therapy, and as an alternative to more expensive forms of care like TMS



Perinatal Mental Health

- 50 patients
- 1 Perinatal Mental Health Service in Northamptonshire
- Flow offered as an alternative to antidepressants



Patient Outcomes

A significant percentage of patients went into remission or response within 10 weeks

Remission = <12 on the MADRS-S Scale

Response = >50% reduction in MADRS-S Score 57%

Remission or Response within 10 weeks

Patient Primary Care 35%

Remission or Response within 10 weeks

Community Mental Health tDCS was integrated into community mental health without requiring any additional clinical resource and without having to make any major changes to the treatment pathway.

"It's so easy to use. I think that's the key bit.
I'm a bit of a technophobe but it's very easy to use...
now, it's just like second nature."

Henry

I feel less like the future is like a black void that's never going to come about,
I feel less worthless...
I feel more genuinely happy about things.

I think it's massively helped my depression.

I just wish it had been offered years ago.

Giles

Three months ago I was suicidal,
I just wasn't functioning as a person.
I was non communicative with my partner.
Everything now just feels brighter,
and I feel a lot more present in life.

Emma

NHFT published Study 1 NHFT Published Study 2

Oliver

tDCS was integrated into community mental health without requiring any additional clinical resource and without having to make any major changes to the treatment pathway.

"Flow has received overwhelmingly positive feedback from our patients, who have reported improvements in their emotional well-being, increased energy levels, and overall functioning."

Azar Zafar [GPA Director of Research and GP1

"The Flow application is easy to use as is the headset, the treatment can be conducted from home and patients find this a very useful treatment"

Alex O'Neill-Kerr [Ex-medical director for Northamptonshire and medical director for Transforming Mind Solutions]:

"Being able to offer Flow has been very well received from our patient group....Many of our patients are interested in an intervention which is not a medication or CBT. The choice is very valuable to them.....From a service perspective the headset has been easy to offer"

Will McIlhiney [Non-Medical Prescriber for Rural Parks CMHT]:

This work has led to the development of a **blueprint** for deploying Flow into the NHS:

- 1. How to train the team
- 2. How and when to offer Flow to patients
- 3. How to offer Flow without incurring any additional resource
- 4. Etc.

This blueprint is now being deployed by other facilities in Northamptonshire and there is now demand across the NHS to set up similar programs



NICE



NICE helps practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer.

They do this by:

- Producing useful and usable guidance for health and care practitioners
- Providing rigorous, independent assessment of complex evidence for new health technologies
- Developing recommendations that focus on what matters most and drive innovation into the hands of health and care practitioners
- Encouraging the uptake of best practice to improve outcomes for everyone





1 Recommendations

- 1.1 Semaglutide is recommended as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity in adults, only if:
 - it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and
 - they have at least 1 weight-related comorbidity and:
 - a body mass index (BMI) of at least 35.0 kg/m², or
 - a BMI of 30.0 kg/m² to 34.9 kg/m² and meet the criteria for referral to specialist weight management services in <u>NICE's guideline on obesity:</u> identification, assessment and management.
 - the company provides semaglutide according to the commercial arrangement.

Use lower BMI thresholds (usually reduced by 2.5 kg/m²) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds.

1.2 Consider stopping semaglutide if less than 5% of the initial weight has been lost after 6 months of treatment. NICE TAG for use of Smegultide Ozempic/Wegovy





NICE Medtech Innovation Briefings

"MIBs are NICE advice, designed to support NHS and social care commissioners and staff when considering using new medical devices and other medical or diagnostic technologies. Our advice products provide a critical assessment of relevant evidence to aid decision-making"





NICE Technology appraisal guidelines (TAG)

"The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals.

When NICE recommends a treatment 'as an option', the NHS must make sure it is available within 3 months (unless otherwise specified) of its date of publication"





NICE Medtech Innovation Briefings

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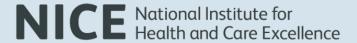




NICE Medtech Innovation Briefings

The information provided in a briefing includes:

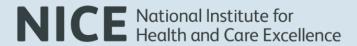
- A description of the technology
- How the technology is used
- The potential role in the treatment pathway
- A review of relevant published evidence
- The likely costs of using the technology





NICE MIB 324 - Flow Neuroscience

- "There is high-quality, comparative evidence from the UK that Flow can improve symptoms of depression and lead to remission."
- "All the clinical experts agreed that Flow would particularly benefit people whose symptoms have not responded to existing interventions or who experience side effects with commonly prescribed medication, such as antidepressants."
- "None of the clinical experts were aware of any issues that could prevent this technology or procedure from being adopted in the NHS. They also advised that no change in facilities is needed for adopting Flow, but a short training session is needed for clinicians."



NHS: Why is it so key



"the NHS was rated as the world's best healthcare system in terms of efficiency, effective care, safe care, coordinated care, patient-centred care and cost-related problems, according to a study conducted by the Commonwealth Fund, a private US foundation.

Compared to healthcare systems of other developed countries, the NHS is very efficient.



Michael Branagan-Harris · 2nd
Founder & CEO Device Access UK - MedTech Market Access - 50+
NICE approvals - Getting Great Technologies To Patients Faster
Chilworth, England, United Kingdom · Contact info
500+ connections



What's Next

Whats next?

More data

- Publication of more results across the different NHS programs [4 more papers expected]
- Publication of Flow RCT results expected in Q2

Improved access

- Flow will be on NHS Supply Chain from March 2024
- Establishment of new Flow programs with 4 other NHS trusts expected in next 3 months
- Implementation of small scale commissioned services E.g PCN's
- Drug Tariff submission

Further work with NICE

NICE TAG



How to get involved

