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Transcranial Direct Current Stimulation (tDCS) and Online Wellbeing Training Used at Home for Perinatal and Maternal Loss Patients with a Diagnosis of Depression: Depression, Real World-Functioning, and Quality of Life Outcomes

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Abstract

Background: There is a high prevalence of depression in the perinatal period and for women who experience maternal loss, which is linked to worse real-world functioning and quality of life. Research evidence indicates that transcranial direct current stimulation (tDCS) can reduce symptoms of depression. Flow FL-100 is a tDCS device self-administered by a patient at home in combination with a software application-delivered wellbeing behaviour therapy training. Training modules include: "Behaviour activation", "Mindfulness", "Exercise for your brain", "An anti-depression diet", and "Therapeutic sleep". **Purpose/Aim:** This study is the first to introduce Flow FL-100 tDCS in combination with a software application-delivered wellbeing behaviour therapy training into a Specialist Perinatal Mental Health Service and Maternal Mental Health Service. In addition to the support and interventions provided by these services, this study investigated the impact on depression, real-world functioning, and health-related quality of life for patients diagnosed with depression. **Methods:** An open-label patient cohort design with no control group. Baseline and 6-week follow-up assessments were completed using the participant self-report measures: Patient Health Questionnaire (PHQ-9), Work and Social Adjustment Scale (WSAS), and EuroQol five-dimension (EQ-5D-5L). **Results:** Twenty-five female patients completed six weeks of tDCS treatment. Their av-

erage age was 36 years, and their ages ranged from 27 to 42 years. Reliable improvement and remission rates for PHQ-9 were 64% and 52%, respectively. PHQ-9 and WSAS scores significantly improved, with large effect sizes. EQ-5D-5L results showed significant improvements in the EQ health index score and EQ-VAS score, with medium effect sizes. **Conclusion:** tDCS and online wellbeing behaviour therapy training can be successfully integrated into Perinatal Mental Health Service and Maternal Mental Health Service depression treatment offer. This study's findings provide evidence that tDCS and online wellbeing behaviour therapy training delivered in conjunction with the interventions provided by Specialist Perinatal Mental Health and Maternal Loss Psychology Services for patients with depression diagnosis can provide improvements in depression symptoms, functioning and quality of life. It is important to be able to offer an evidence-based addition and/or alternative to existing depression treatments (antidepressant medication and psychotherapies).

Keywords

Depression, Quality of Life, Functioning, Transcranial Direct Current Stimulation (tDCS), Perinatal, Maternal Loss

1. Introduction

Depression is defined as experiencing a low mood and loss of pleasure or interest in activities; symptoms include poor concentration, feelings of low self-worth, hopelessness, suicidality, disrupted sleep, and fatigue (World Health Organization, 2023). Depression symptoms can have a severe negative impact on people's everyday functioning and quality of life (Lépine & Briley, 2011; World Health Organization, 2023). Depression is the most common mental illness factor determinant of death by suicide (Vigo et al., 2016). The mortality risk for suicide among patients with major depression has been calculated to be 20 times that where major depression is not present (Harris & Barraclough, 1997).

A large proportion of women experience depression in the first year after birth (around 15% - 20%) (NICE, 2024), and there is evidence to suggest that perinatal depression may be commonly missed or undertreated in primary care general practice (GP) (RCGP/GPCPC, 2023). Depression following pregnancy is a major cause of disease burden for women and their families (Hahn-Holbrook et al., 2018), and is associated with negative effects on the foetus, infant and young child (Eastwood et al., 2017). Evidence shows that levels of depression following perinatal loss are significantly elevated compared to no-loss controls (live births, non-pregnant, or difficult live births) (Herbert et al., 2022; Mergl et al., 2023), with 8% - 20% of women showing symptoms for moderate depression (Farren et al., 2018).

The United Kingdom (UK) National Institute for Health and Care Excellence (NICE) produces guidance and recommendations for the UK National Health Service (NHS). NICE (2014) guidelines (Antenatal and postnatal mental health:

clinical management and service guidance [CG192]) state that women with persistent subthreshold depressive symptoms or mild to moderate depression in the postnatal period should be offered facilitated self-help-delivered as described in NICE's guideline on depression in adults (NICE, 2024). Self-help is available through the NHS "Talking Therapies" psychotherapy service, and it is open to all UK adults via self or healthcare professional referral. For women with moderate or severe depression in the postnatal period, there are three recommended options: a high-intensity psychological intervention (for example, cognitive behavioural therapy [CBT]), antidepressant medication (tricyclic antidepressants [TCA], selective serotonin reuptake inhibitors [SSRI] or serotonin and norepinephrine reuptake inhibitors [SNRI]), or a high intensity psychological intervention in combination with antidepressant medication. However, there are risks (negative side effects and withdrawal effects) associated with medication for women, unborn children and breastfed children (NICE, 2014). Patients and their healthcare advisors engage in risk/benefit considerations.

There are no specific NICE guidelines for women following perinatal loss. NICE (2024) recommends supporting patient choice, needs and preferences, taking into account any physical health problems, coexisting mental health problems, and previous treatment history, using the least intrusive and most resource efficient treatment appropriate for their clinical needs, or one that has worked in the past. Recommendations include guided self-help, psychotherapy and/or antidepressant medication (NICE, 2024). However, some women do not wish to try or do not respond to psychotherapy, and some do not wish to try antidepressants due to side effects or withdrawal effects or stop antidepressant medication when they find out they are pregnant (NICE (2014) states that healthcare professional should discuss stop taking antidepressants with pregnant women).

There are specialist Perinatal Mental Health (PMH) community services in all 44 local NHS areas for those struggling with their mental health during the perinatal period. The NICE (2016) quality standard and guideline on antenatal and postnatal mental health states that these services should be available to support women with mental health problems during pregnancy and/or the postnatal period. The PMH services provide advice support and deliver both psychological therapies and antidepressant medication. However, there is a need for other treatment options as not all patients with depression respond to psychological therapies and/or antidepressant medication (Cuijpers et al., 2021; Warren, 2020).

Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation by weak electrical currents (0.5 - 2.5 mA) (Grycuk et al., 2021). Electrode placement for treating depression is typically with the anode over the left dorsolateral prefrontal cortex (DLPFC) (F3) and cathode over the right DLPFC (F4) (Fregni et al., 2021). tDCS mechanisms of action include significant grey matter increases in brain regions functionally connected with the stimulation target, including the bilateral DLPFC, bilateral posterior cingulate cortex, subgenual anterior cingulate cortex, the right hippocampus, thalamus and left caudate brain re-

gions; tDCS leads to neurostructural changes at predetermined brain targets in depression, and plasticity effects may propagate over brain networks (Jog et al., 2023).

Meta-analyses of the results of randomised sham-controlled trials show tDCS can significantly improve depressive symptoms and clinical response, with remission being significantly better than placebo sham stimulation (Mutz et al., 2018, 2019; Moffa et al., 2020; Razza et al., 2020). tDCS is effective as a standalone treatment or in combination with other anti-depression treatments (Razza et al., 2020). tDCS is safe (Razza et al., 2020) and generally reported by patients as acceptable and well-tolerated, with mild and transient physical sensations that usually do not prevent use: burning sensations (16.2%), skin redness (12.3%), scalp pain (10.1%), itching (6.7%), and tingling (6.3%) (Chhabra et al., 2020; Grycuk et al., 2021; Gordon et al., 2021). NICE provides guidelines for the delivery of tDCS for depression in the NHS (NICE, 2015).

A randomised sham-controlled trial of Flow FL-100 in major depressive disorder (MDD) found significant improvement in depression symptoms following 10 weeks treatment, with clinical response of 58.3% and remission rate of 44.9% (Woodham et al., 2024). "Flow" combines tDCS (delivered by Flow FL-100 device) and software application wellbeing behaviour training (physical exercise, nutrition, mindfulness, sleep, and choosing actions). A "real-world" health service open-label primary care patient study of Flow found depression reliable improvement and remission rates of 58.1% and 32.3%, and significant improvement in depression, everyday functioning, and quality of life (Griffiths et al., 2024a, 2024b). Qualitative studies undertaken on experience of Flow found most patients reported that Flow improved depression symptoms, was acceptable, and that they would recommend it to others (Rimmer et al., 2022; Griffiths et al., 2023; Baukaite et al., 2024; Griffiths et al., 2024c).

Many women experience treatment resistant depression (TRD) following pregnancy (Cepeda et al., 2019). TRD can be defined as no response to at least two consecutive courses of antidepressant medication (Berlim & Turecki, 2007). A systematic review of evidence of tDCS for TRD found favourable evidence that tDCS is clinically effective as measured by response, symptom improvement, and remission in comparison to sham treatment (Li et al., 2024).

A systematic review to assess the effectiveness and safety of rTMS as a treatment option for postpartum and peripartum depression concluded that tDCS is a safe treatment with limited side effects and low dropout rates, with some evidence of effectiveness (Al-Shamali et al., 2022). Combining tDCS with antidepressant serotonin-norepinephrine reuptake inhibitor (SNRI) venlafaxine for treatment of postpartum depression compared to venlafaxine alone may enhance clinical efficacy (Wan et al., 2022). Specialist Perinatal Mental Health Service and Maternal Mental Health Service patients appreciated having tDCS as a non-medication treatment alternative and reported improvements in depressive symptoms, mood, sleep quality, and overall well-being (Baukaite et al., 2024).

This open-label patient cohort study investigated if Flow FL-100 tDCS and in combination with a software application delivered wellbeing behaviour therapy training can be introduced to a Specialist Perinatal Mental Health Service and Maternal Mental Health Service, and the impact of the addition to the support and interventions provided by these services for patients diagnosed with depression. The study addressed the question: "what are the depression reliable improvement and remission rates?", and "what is the impact on depressive symptoms, and real-world functioning (everyday, social and occupational functioning) and health-related quality of life?".

2. Methods

2.1. Design

Open-label patient cohort design with no control group.

2.2. Approval

The project was undertaken from September 2023 to January 2025. Ethical approval for the study was gained from the NHS Healthcare Trust Institutional Review Board (IRB) in which the services were based (reference for NHS trust ethical approval: Flow-Perinatal). The study was undertaken in accordance with the Declaration of Helsinki.

2.3. Setting

The sample was recruited from patients in a Specialist Perinatal Mental Health Service and Maternal Mental Health Service. Flow Neuroscience AB (manufacturer of Flow FL-100) provided staff with training.

2.4. Intervention

Flow FL-100 is a Conformite Européenne (CE) marked Class IIa medical device for the treatment of MDD. Flow can be purchased directly by anyone over the age of 18 via the manufacturer's website in the European Union and other European countries. Flow has been used by >15,000 users in UK/EU and is offered by >70 private healthcare institutions. There is only very limited availability through the NHS.

In the treatment protocol, the patient remains awake and self-administers at home five sessions per week for the first three weeks and then three sessions per week for the following three weeks: 24 sessions, with a maximum of one 30-minute session per day. After the initial six-week period, patients can choose to self-administer up to 3 sessions per week for as long as they choose.

Flow treatment was concurrent with any current treatment, e.g., antidepressant medication, face-to-face psychotherapy, or any online psychotherapy. The anode was positioned over the left dorsolateral prefrontal cortex (DLPFC) (F3 on the international 10/20 EEG system) and the cathode over the right DLPFC (F4); stimulation is 2 mA for 30 min. On the Flow mobile phone software app, seven

brief (around 20 minutes, pace of completion chosen by user) healthy lifestyle behaviour therapy training sessions are available for users to optionally engage with. These provide information about the links between behaviour and wellbeing and how to take actions to improve wellbeing and reduce depressive symptoms. They are titled: "The basics", "Choosing your actions", "Mindfulness meditation", "Exercise for your brain", "The anti-depression diet", "Therapeutic sleep", and "Looking back and planning ahead".

The Flow mobile phone software app is used to control the Bluetooth-connected Flow FL-100 tDCS headset via the user's smartphone. Flow also provides depression symptom level tracking that enables users to monitor their progress/symptoms. This is done by the completion of the nine-question Montgomery-Åsberg Depression Rating Scale Self-report (MADRS-S) (Montgomery & Åsberg, 1979) via the user's smartphone. Flow also provides an integrated platform for the patient's healthcare provider, with the ability to monitor patients, and customise protocols remotely. A patient can decide whether or not to allow their healthcare provider access to this information.

2.5. Inclusion/Exclusion Criteria

Participants were included if they were determined by service staff to have a diagnosis of depression, were aged 18 or over, had the mental capacity to consent, provided informed consent, and had the ability to understand verbal and written English. Participants remained on any prescribed medication they were taking and continued any current psychological interventions.

Exclusion criteria comprised: currently pregnant, epilepsy (or having a history of seizures), a defect in the neurocranium and/or an implant inside the skull, an active implanted medical device, a neurological condition, a history of hypomanic/manic episodes, and an open wound in the area of pad contact point on the forehead.

2.6. Procedure

Participants were selected if they met the inclusion/exclusion criteria and were provided with information about the treatment and evaluation. They continued any current medication and psychological interventions throughout the study. Informed consent was obtained by their mental health practitioner prior to beginning treatment. Following informed consent, participants were given the Flow device, along with instructions, and asked to complete three self-report measures. They were also made aware of the Flow Neuroscience AB website, which offers information, usage training, and email support. A supportive phone call was made between one to two weeks to address any concerns. Compliance was monitored through a web based clinical portal dashboard, tracking daily use of the Flow device and changes in depression scores. This information was made available to the patient's prescriber, if the participant had consented to share it. Follow-up self-report measures were collected after six weeks of treatment.

2.7. Measures

The primary outcome, Patient Health Questionnaire-9 (PHQ-9), is a self-report measure of depression; it has good sensitivity and specificity for major depression as well as good internal consistency (Kroenke et al., 2001); scores for depression severity are: 0 - 4 none, 5 - 9 mild, 10 - 14 moderate, 15 - 19 moderately severe, and 20 - 27 severe (Kroenke et al., 2007). Remission is defined as a score of 9 or less, and reliable improvement is a drop of 6 points (Richards & Borglin, 2011).

The Work and Social Adjustment Scale (WSAS) is a self-report measure of functional impairment attributable to an identified problem (e.g., depression) (Marks, 1986). The five questions on impairment to work, home management, social leisure, private leisure, and close social relationships are each scored zero (not at all) to eight (very severely). The WSAS is a reliable, valid, and sensitive to change outcome measure (Mundt et al., 2002). Severe functional impairment is 20 and over and scores below 10 are associated with subclinical populations; a score of 9 or below is the clinical (recovery) cut off (Hammond et al., 2012).

European Quality of Life Five Dimension (EQ-5D-5L) (EuroQol Group, 1990; van Hout et al., 2012) is a 5-item question and visual analogue scale (VAS) self-rated measure of health-related quality of life and overall health status developed by EuroQol Group to provide a simple, standardised measure for a clinical appraisal (EuroQol Group, 1990). It comprises five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each of which is measured within five levels (no problems, slight problems, moderate problems, severe problems, and extreme problems). The digits from the five dimensions are combined to create a five-digit number measuring the holistic health state. Each health state can be assigned an index score based on societal preference weights for the health state. Health state index scores 1 = the value of full health, with higher scores indicating higher health utility. The EQ VAS is a subjective measure of a participant's current health, ranging from 0 (worst health imaginable) to 100 (best health imaginable). The EQ-5D-5L has good construct validity and is sensitive to change in patients with depression and anxiety (Peasgood et al., 2012). The EQ-5D-5L is a validated measure of health status widely used in national health surveys worldwide and in clinical trials of health interventions (Brooks & EuroQol Group, 1996; Herdman et al., 2011), and EQ-5D is recommended by the UK's National Institute for Health and Care Excellence (NICE) to estimate health state utility weights for quality-adjusted life year (QALYs) (NICE, 2019).

2.8. Analysis

Data were analysed using the statistical software package SPSS Statistics 29.

3. Results

3.1. Participant Characteristics

Twenty-five female patients completed a six-week Flow tDCS treatment. Their

average age was 35.98 years (SD = 4.05, age range from 27 to 42 years). Eighteen patients (72%) were taking antidepressants, five were not (20%), and two did not provide this information (8%). Twenty patients (80%) patients were postnatal, and five had no live baby (20%). Patients' mean baseline scores were in the "moderately severe" range for depression (Kroenke et al., 2007). Baseline EQ-5D-5L crosswalk data values indicated patients had a low average holistic health index and EQ-VAS score compared to the general population; however, the dispersion was high. See Table 1 for baseline scores of outcome measures.

Table 1. Baseline characteristics.

Variable	N	Mean ± SD (Min-Max)
PHQ-9	25	17.68 ± 4.56 (7 - 25)
WSAS	25	27.04 ± 8.24 (8 - 39)
EQ Health Index	24	0.53 ± 0.26 (−0.20 - 0.85)
EQ VAS	21	52.33 ± 25.91 (0 - 90)

3.2. PHQ-9

The Shapiro-Wilk test found PHQ-9 scores to be normally distributed ($p > 0.05$) at both time points. The reduction in PHQ-9 scores from baseline (M = 17.68, SD = 4.56) to follow-up (M = 11.60, SD = 7.14) was statistically significant, t(24) = 6.410, $p < 0.001$, with a large effect size (Cohen's d = 1.28), 95% CI [4.12, 8.04]. On average, there was a drop of 6.08 points (SD = 4.74). The difference between the average mean at baseline (M = 0.88, SD = 0.83) and week 6 (M = 0.60, SD = 0.82) was reaching significance, t(24) = 1.661, $p = 0.055$). Reliable improvement and remission rates for PHQ-9 were 64.0% and 52.0%, respectively. Recovery (both remission and reliable improvement) was 44%. Sixteen patients (64%) reported at least some suicidal tendencies on item 9 of the PHQ-9 at baseline, which decreased to 11 (44%) at week 6.

3.3. WSAS

The Shapiro-Wilk test found WSAS scores to be normally distributed ($p > 0.05$) at both time points. The reduction in WSAS scores from baseline (M = 26.96, SD = 8.28) to follow-up (M = 18.60, SD = 10.80) was statistically significant, t(24) = 4.952, $p < 0.001$, a large effect size was observed (Cohen's d = 0.990), 95% CI [4.88, 11.84]. On average, there was a reduction of 8.36 points (SD = 8.44).

3.4. EQ-5D-5L

Table 2 illustrates the descriptive data for each of the five dimensions as well as the mean health index and VAS at baseline and after the six-week intervention. From baseline to week six, quality of life increased with an improvement of 0.11. Measured across ten years, this intervention adds 1.14 QALYs.

Table 2. Means and standard deviations within each dimension across time with corresponding mean variation, significance, and effect size.

EQ-5D-5L Dimension	Baseline	Week 6	*t*	*p*	*d*
	M (SD)	M (SD)			
Mobility	1.21 (0.42)	1.10 (0.81)	1.000	0.165	
Self-care	1.35 (0.58)	1.26 (0.65)	0.325	0.374	
Usual activity	2.32 (1.06)	2.21 (1.23)	0.490	0.315	
Pain/discomfort	1.53 (0.77)	1.52 (0.77)	0.000	0.500	
Anxiety/depression	3.63 (0.83)	2.89 (1.20)	4.379	<0.001*	0.733
Health index score	0.54 (0.26)	0.65 (0.28)	−3.36	0.001*	−0.681
EQ-VAS score	51.70 (25.40)	61.15 (23.00)	−1.906	0.036*	−0.426

*Significant at $p < 0.05$ level.

Data screening permitted the use of a paired-sample t-test to determine whether there was a statistically significant difference in patients' EQ dimensions, as well as their health index score and VAS at the six-week data collection point. The improvement was statistically significant for EQ dimension "anxiety/depression", and for the overall health index and VAS score, with medium effect sizes.

Table 3 illustrates the data collected from the EQ-5D-5L tool and broken down by level 1 (patients reported no issues on the dimension), level 2 (patients reported mild to moderate levels of issue), and level 3 (patients reporting severe to an

Table 3. Percentage reporting levels 1 to 3 on EQ-5D-5L by dimension and time.

EQ-5D-5L Dimension	Level	Baseline	Week 3
Mobility	1	76.3	95.0
	2	21.1	5.0
	3	2.6	0.0
Self-care	1	57.9	80.0
	2	42.1	20.0
	3	0.0	0.0
Usual activity	1	21.1	35.0
	2	60.5	50.0
	3	18.4	15.0
Pain/discomfort	1	52.6	55.0
	2	34.3	40.0
	3	13.1	5.0
Anxiety/depression	1	2.6	10.0
	2	78.9	60.00
	3	13.4	30.0

extreme level of issues). While only "anxiety/depression" dimension scores improved significantly, further improvements are observed in percentages of patients by levels of severity. For example, no patients reported severe or extreme levels of mobility or self-care issues, and only one patient had severe pain issues at week 6. Equally, the percentage of patients who reported no issues with mobility, self-care, and usual activity at week 6, increased by 18.7%, 22.1%, and 13.9%, respectively.

Level 1 consists of responses where no problems are reported. Level 2 indicated responses reporting a mild to moderate level of issues on a given dimension, and level 3 refers to severe to extreme issues reported.

3.5. Correlations

Pearson's correlation coefficients indicated statistically significant correlations between PHQ-9 and EQ-5D-5L (r = −0.601), PHQ-9 and WASA (r = 0.479), and EQ-5D-5L and WSAS (r = −0.610) at baseline. There was a statistically significant correlation between PHQ-9 and EQ-5D-5L (r = −0.741), PHQ-9 and WSAS (r = 0.744), and EQ-5D-5L and WSAS (r = −0.705) after six-weeks, all $p < 0.001$.

4. Discussion

This study found that Flow FL100 delivered tDCS can be provided to patients by a Specialist Perinatal Mental Health and Maternal Mental Health Service, and when offered most patients will choose to use tDCS. tDCS, in combination with a software application, delivered wellbeing behaviour therapy training when delivered in conjunction with the support, advice and interventions provided by these services was found to reduce impaired functioning and depression symptoms and increase health related quality of life in patients with depression. The outcomes add evidence to support the effectiveness of tDCS in reducing depression symptoms (Mutz et al., 2018, 2019; Moffa et al., 2020; Razza et al., 2020; Woodham et al., 2024; Al-Shamali et al., 2022). The outcomes support evidence of tDCS impact at six weeks course of treatment (Nikolin et al., 2023). This study's results underpin patient interview evidence of positive experience of tDCS in a Specialist Perinatal Mental Health Service and Maternal Mental Health Service (Baukaite et al., 2024).

This present study's sample had high average PHQ-9 baseline scores (depression in the "moderately severe" range). This demonstrates the potential value of tDCS for those with moderately severe depression. Many of the participants in this study would meet the definition of TRD. Therefore, the results add evidence to the value of tDCS in treating TRD (Li et al., 2024).

This study shows that tDCS can be combined with antidepressant medication, and previous research has shown this can possibly enhance overall outcomes (Razza et al., 2020; Wan et al., 2022). A systematic review and meta-analysis showed that tDCS plus SSRI antidepressant medication provided significant improvement in depression and achieved a significantly higher response rate than sham interven-

tion, and that this was more effective than tDCS treatment alone (Wang et al., 2021). This finding is important for clinical practice, as it indicates that patients should consider continuing their existing prescribed SSRI antidepressant use during tDCS treatment, and that patients can start using both tDCS and SSRIs at the same time (Wang et al., 2021).

This present study indicates that the use of tDCS may lead to relatively quick (six-week) improvement in depression symptoms. Another study showed tDCS produced good rates of remission at three weeks (Griffiths et al., 2024a). The time course of response of SNRIs and SSRIs antidepressants is around 2 to 4 weeks to achieve significant benefits; but it may take longer to achieve most of the improvement (Jakubovski et al., 2019). Therefore, tDCS might be considered as a treatment where a relatively quick relief of depression symptoms is required, of particular value in Specialist Perinatal Mental Health and Maternal Mental Health Service patients to address or prevent a mental crisis which may lead to suicide attempt, self-harm, or acute mental health ward admission.

Specialist Perinatal Mental Health and Maternal Mental Health Services are well-placed to deliver Flow tDCS treatment as they seek to understand a patient's individual circumstances and provide individualised support and treatment. Some participants did not experience remission or reliable change following the use of tDCS, and it is not effective for everyone. Due to Specialist Perinatal Mental Health and Maternal Loss Psychology Service active engagement with their patients, they can prepare their patients for this potential outcome and ensure that patients receive ongoing support, and suggest other potential depression treatment if tDCS does not provide relief from depression symptoms. Patients are told they may need to try a number of treatment options and combination of treatments.

5. Limitations

There were several limitations of the study. There was no control group, small sample size, and the treatment with Flow FL100 tDCS was open-label and adjunct to any existing depression or other treatments or therapies. Additional diagnosis was not reported, and analysis was not split based on depression severity or treatment resistance. This study collected outcome measures after six weeks of treatment, with no later follow-up data collection; it is recommended that future studies employ additional follow-up data collection points, for example, 12, 24 and 36 weeks. The participants were from a single UK county, reducing generalisability.

6. Conclusion

This study demonstrated that Flow FL100 delivered tDCS could be fully and effectively integrated into Specialist Perinatal Mental Health and Maternal Loss Psychology Service depression treatment. The services were able to offer, and their patients chose to use Flow, providing evidence of the acceptability of and demand for Flow FL-100 delivered tDCS and software app behaviour change wellbeing

training. This study's findings provide evidence that tDCS delivered in conjunction with the advice, support and interventions provided by Specialist Perinatal Mental Health and Maternal Loss Psychology Services for patients with depression diagnosis can be effective against depression symptoms. Treating depression symptoms improving functioning and quality of life using tDCS may allow discharge from Specialist Perinatal Mental Health and Maternal Loss Psychology Services to care of a GP, prevent mental health in-patient admission, reduce A&E attendance, and prevent the need for more costly antidepressant treatment such as transcranial magnetic stimulation (TMS) or electroconvulsive therapy (ECT) (Magnezi et al., 2016); and, therefore, may reduce healthcare costs.

It is important to be able to offer patients a wide choice of effective depression treatment options. Evidence indicates extending tDCS treatment from six to ten weeks might provide further improvements (Nikolin et al., 2023; Woodham et al., 2024). In many countries, people can buy and use Flow-delivered tDCS or other tDCS devices themselves or through private healthcare, but the cost is prohibitive for some. Availability through free-to-access universal healthcare systems such as the UK NHS would address inequality of access issues. More evidence would be valuable on the long-term effectiveness of tDCS for perinatal and maternal loss mental health patients experiencing depression and the potential need for ongoing maintenance sessions to sustain any benefits.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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