

Aims and hypothesis

A post-marketing informed consent service evaluation of the use of Flow tDCS within Perinatal Mental Health Service for patients with a diagnosis of post-natal depression who had either no or minimal benefit from antidepressant medication or wanted an alternative whilst breastfeeding.

Background

Flow is a transcranial direct current stimulation (tDCS) treatment for depression that patients use at home. Over 30 years of research/clinical use show tDCS is safe and is generally reported by patients as acceptable and well-tolerated, with mild and transient physical sensations (Razza et al. 2020). Flow is CE-marked for treating depression in Europe. Meta-analyses of randomised sham-controlled trials (RCT) show tDCS is associated with significant improvements in depressive symptoms and high rates of clinical response and remission relative to sham stimulation (Mutz et al., 2018; 2019; Moffa et al., 2020; Razza et al. 2020). Flow RCT depression remission rates of 45% (Woodham et al. 2024); patients describe improved depression symptoms and functioning (Rimmer et al., 2022, Griffiths et al., 2023; 2024).

In the first year after birth 15-20% of women will experience depression and 30-50% of these women continue to present with major depression throughout their child's first year of life and beyond.

For some women the need for antidepressant medication may be a barrier to breastfeeding and as there is no evidence that tDCS has any effect on breastmilk, this treatment could prove to be an alternative for patients who would rather not be treated with medication whilst breastfeeding. It could also be used as an adjunct to medication or as an alternative for women who have had minimal benefit from medication. TDCS has been used to good effect in the general population however has not been trialled sufficiently in the perinatal population.

The advantages of delivering tDCS via a portable device are that the patient can self-administer at a time of their choosing and remain awake throughout the treatment therefore it is accessible for new parents.

Method

We conducted a service evaluation of the use of tDCS in 18 postnatal women with depression

Patients were assessed using PHQ-9, after a diagnosis of depression was confirmed through a clinical interview. The inclusion and exclusion criteria were assessed, and the patient was offered the treatment if appropriate.

Outcome measure data was collected at baseline and again at the 6-week follow-up point. Self-report measures used were the PHQ-9, the Work and Social Adjustment Scale (WSAS) and the Montgomery-Asberg Depression Rating Scale (MADRS).

Results

PHQ9 mean at baseline was 16.4 ± 7.06 and 5.88 ± 7.94 at week 6. This is a statistically significant improvement ($p < .001$).

A significant reduction was also observed in the frequency of people who reported suicidal tendencies (question 9 on the PHQ scale).

A depression drop from average 'Moderately Severe' to 'Mild'

On the PHQ-9, 30% experienced depression remission (no longer meeting criteria for having depression) and 44% reliable improvement (PHQ-9 score improvement by 6 points or more), 28% experienced no change and no one got worse.

WSAS functioning scores decreased significantly ($p < .001$) from 21.0 ± 12.7 at baseline to 10.2 ± 12.2 in week 6.

Of those that adhered, 58% of patients went into remission or response by Week 6. This is particularly interesting given that 100% of the patients had previously tried antidepressants or psychotherapy, and 77% had tried both antidepressants or psychotherapy.

Of those that adhered, 100% saw an improvement of 5 points or more on the MADRS-s scale. Though not everyone reached remission, the depression severity distribution of your population has fundamentally changed. If a patient did not reach remission, in many cases their depression has been downgraded from moderate to mild.

Some Side effects were reported, all participants various physical sensations during and after using the Flow device, including tingling, burning sensation, and itching, primarily concentrated around the areas where the pads were placed. Some likened these sensations to pins and needles or small electric shocks, but for all but one, they did not find them severe enough to discontinue use.

Patients gave feedback on the use of the device

All thirteen participants highlighted the effectiveness of Flow tDCS, They used language such as "smooth", "fine", "quick", "easy", and "straightforward" to depict the process. Additionally, seven participants specifically underscored the efficiency and helpfulness of the professionals providing the treatment

Quote : "Yes, everything went really smoothly for me, everything was explained to me and I had leaflets and I the app and everything... it was brilliant..."

Conclusions

The results suggest that Flow tDCS treatment is a valuable and acceptable intervention for women who are experiencing postnatal depression.

References :

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