Scientific Research Publishing

Open Journal of Depression, 2023, 12, 65-86
https://www.scirp.org/journal/ojd
ISSN Online: 2169-9674
ISSN Print: 2169-9658

A Qualitative Study Exploring the Experience and Value of "Flow" Transcranial Direct Current Stimulation (tDCS) Device and Behaviour Therapy Training Software Application at Home for Symptoms of Depression

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How to cite this paper: Griffiths, C., Walker, K., Jiang, H., Noel-Johnson, A., & Zafar, A. (2023). A Qualitative Study Exploring the Experience and Value of "Flow" Transcranial Direct Current Stimulation (tDCS) Device and Behaviour Therapy Training Software Application at Home for Symptoms of Depression. *Open Journal of Depression, 12,* 65-86.
https://doi.org/10.4236/ojd.2023.124007

Received: September 27, 2023
Accepted: October 28, 2023
Published: November 1, 2023

Abstract

Background: Flow FL-100 is a self-administered transcranial direct current stimulation (tDCS) device used in combination with a software application delivered well-being behaviour therapy training, which has evidence of effectiveness in treating symptoms of depression. In this study, the combined Flow FL-100 and well-being behaviour therapy training app, an intervention known as "Flow", was offered by a participant's general practitioner (GP) in a United Kingdom (UK) primary care setting to those who experienced depressive symptoms. Participants completed six weeks of use of Flow. This study explored participants' experiences and views on the feasibility, acceptability, useability, and value of Flow. **Methods:** A qualitative approach was employed, involving in-depth semi-structured interviews. Thematic and content analyses were applied. Out of a sample of 47 participants using Flow, 18 participants consented to be interviewed. The age range of the participants was 23 - 75 years (M = 52.78, SD = 16.27); 10 (55.6%) were female and 8 (44.4%) male. **Results:** There was support for the feasibility, acceptability, useability and value of combined Flow FL-100 and well-being behaviour therapy training. Most participants described a positive impact on depressive symptoms, sleep, and functioning. Findings provide support for the approach of delivering together both tDCS and evidence-backed well-being behaviour therapy training. **Conclusion:** Flow has been successfully integrated into a primary care service depression treatment. It is important to offer patients an evi-

dence-based alternative to existing depression treatments (anti-depressant medication and talking therapies). The results support the use of Flow as a treatment option for people with symptoms of depression.

Keywords

Depression, Primary Care, General Practice, Transcranial Direct Current Stimulation (tDCS)

1. Introduction

Depression is ranked as the largest contributor to global disability, responsible for 7.5% of all years lived with disability (World Health Organization, 2017). Depression can have a severe negative impact on the quality of life (Lépine & Briley, 2011) and is the main determinant of deaths by suicide (Vigo et al., 2016). There is a global trend of increasing depression prevalence, indicating that the detrimental effects on people's quality of life and mortality excess will keep growing (Moreno-Agostino et al., 2021). Within the context of this study's setting in Great Britain, in 2022 around 1 in 6 (16%) adults experienced moderate to severe depressive symptoms, which is a rise from 1 in 10 (10%) in 2019; the effects of the Covid-19 pandemic, along with the rising cost of living and a resulting decline in disposable income, may have been contributing factors for this trend (Office for National Statistics, 2022).

tDCS is a non-invasive brain stimulation technique administered via a portable device that delivers weak electrical currents (0.5 - 2.5 mA) to the brain (Grycuk et al., 2021) which can be used to treat depression (Razza et al., 2020). Meta-analyses of randomized sham-controlled trials show that tDCS is associated with significant improvements in depressive symptoms, with high rates of clinical response and remission relative to placebo sham stimulation (Mutz et al., 2018; 2019). A subsequent meta-analysis revealed that compared with sham, active tDCS significantly improved depression (Moffa et al., 2020). A systematic review and meta-analysis of 23 randomised controlled trials (RCTs) involving 1092 participants investigating the effects of tDCS in depressive episodes, reported that tDCS is modestly effective in treating depressive episodes, with active tDCS being clinically superior (Razza et al., 2020). tDCS is a depression treatment that is safe, it is an effective standalone treatment or can be used in combination with other anti-depression treatments (Razza et al., 2020).

tDCS is generally reported as acceptable and well-tolerated, with side effects being mild and transient. These side effects may include burning sensations (16.2%), skin redness (12.3%), scalp pain (10.1%), itching (6.7%), and tingling (6.3%) (Chhabra et al., 2020). Qualitative research has been undertaken on experiences of tDCS (Gordon et al., 2021; Grycuk et al., 2021). Exploring the experiences and perceptions of tDCS to reduce weight gain for patients with schizophrenia, through interviews with 12 participants, revealed that all partici-

pants described tDCS use as uncomfortable, but that unpleasant sensations only lasted for a short time; participants mentioned feeling happier and having improved relaxation, motivation, and concentration (Grycuk et al., 2021). Acceptability and side effects for patients having tDCS for a binge eating disorder have also been successfully investigated, this study found minor and transient sensations and side effects attributed to tDCS but that tDCS was an acceptable treatment (Gordon et al., 2021).

The commercially available product "Flow", which is combined tDCS (delivered by Flow FL-100) and software app-based well-being behaviour training (exercise, nutrition, mindfulness, sleep, choosing actions), has been subject to investigation. In a case series study, reliable change index (RCI) improvements were reported in depressive symptoms in five out of seven patients with depression (Sobral et al., 2022). In a 24-participant open-label single-arm feasibility study, there was a significant improvement in depressive symptoms after 6 weeks of treatment, which was maintained at 3 and 6 months, with most participants stating that Flow was acceptable and that they would recommend it (Woodham et al., 2022; Rimmer et al., 2022). Perceived effectiveness (i.e., How helpful do you think the tDCS sessions may be for improving your depressive symptoms?) was reported by participants on a seven-point scale from "very unhelpful" to "very helpful". At 6 weeks and 6 months 30% found it "quite helpful; at 6 weeks, 40% found it "very helpful"; at 6 months, 50% found it "very helpful"; and at 6 months all participants reported it had been helpful to some extent (Woodham et al., 2022).

There is currently a lack of qualitative research into the impact of Flow on people experiencing depressive symptoms. This is the first study to explore the patient experience and value of using Flow through in-depth interviews. This study takes a qualitative approach to answer the question: "What is the experience (feasibility, acceptability and useability) and value of using Flow for primary care patients with symptoms of depression?".

2. Methods

2.1. Design

Participants were recruited from a post-marketing evaluation study employing an open-label patient cohort design with no control group. A qualitative approach was employed using semi-structured in-depth interviews with participants. The interview questions created were informed by relevant research literature and the aims of the study.

2.2. Ethical Approval

The study was approved by the NHS Primary Care Provider Consortium. Ethics committee name—Ideas Forum: reference IFFLOW1. All participants provided informed consent. The study was delivered in accordance with the Declaration of Helsinki.

2.3. Medical Records

Following informed consent, demographic information (gender and date of birth) was extracted from clinical records containing routinely collected data.

2.4. Participants

The sample was recruited from people using a primary care service within the United Kingdom's (UK) National Health Service (NHS). Participants were included if they were determined by their GP to have symptoms of depression, were aged 18 or over, had the mental capacity to consent, provided informed consent, and had the ability to understand verbal English. Participants remained on any prescribed medication they were taking and continued any current psychological interventions.

Exclusion criteria comprised: epilepsy (or a history of seizures); neurocranium defects and/or an implant inside the skull; an active, implanted medical device (e.g., cardiac pacemaker, spinal cord stimulator, vagal nerve stimulator, auricular stimulator, deep brain stimulating electrodes, cochlear implant, implanted hearing aid or defibrillator) or other implanted, metallic or electronic device; or a history of hypomanic/manic episodes.

Out of the 47 participants who used Flow, 18 were interviewed: the age range was 22 - 75 years ($M = 52.78$, $SD = 16.27$); 10 (55.6%) were female and 8 (44.4%) were male. All participants reported their ethnicity as "White British".

2.5. Setting

The intervention was offered through primary care and delivered at home by participants (under the care of a GP) living in the community in Northamptonshire, UK.

2.6. Intervention

Flow FL-100 is a Conformite Europeene (CE) marked Class IIa medical device for the treatment of major depressive disorder (MDD) and received U.S. Food and Drug Administration (FDA) "Breakthrough Device" designation in July 2022, indicating its potential to provide effective treatment. Flow can be purchased directly by anyone in the European Union and other European countries, it is available for purchase from the manufacturer's website. Flow has been used by >10,000 users in UK/EU and is offered by >70 private healthcare institutions.

Flow is controlled by an accompanying software app, which limits how often the device can be used and for how long. In the treatment protocol, the patient remains awake and self-administers up to 5 sessions per week for the first 3 weeks and then 3 sessions per week for the following 3 weeks, receiving a maximum of 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. This was Flow Neuroscience AB's standard protocol.

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. Seven briefs (around 20 minutes, the pace of completion chosen by the user) well-being behaviour therapy training sessions are available for users to optionally engage with. These provide learnings about the links between behaviour and well-being and how to take actions to improve well-being 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 app is used to control the Bluetooth-connected Flow FL-100 tDCS headset via the user's smartphone and incorporates the well-being behaviour therapy training. 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 prior to a tDCS session. Flow also provides an integrated platform for the patient's GP, with the ability to monitor patients, derive insights, and customise protocols remotely. Flow has comprehensive user training and support available via its dedicated website and support team, participants were made aware of this.

2.7. Procedure

The project was undertaken from January 2023 to July 2023. Participants were identified as having symptoms of depression by their GP and asked if they would like to try using Flow for these symptoms. Participants were selected if they met inclusion/exclusion criteria, and they were then provided with information about Flow. Informed consent was sought and required to begin using Flow. Participants could withdraw consent or stop engagement with Flow at any point without the need to provide a reason. Following completion of the intervention (6 - 8 week point), participants were asked if they would like to complete an in-depth interview. For those who agreed, the interviewer contacted the participant to arrange a time to complete the interview. All of the interviews were completed via telephone and were audio-recorded using an encrypted audio recorder. As soon as the interviews were transcribed and anonymised, the audio recordings were deleted.

2.8. Methodology and Analysis

The methodology was underpinned by ontological and epistemological assumptions aligned with constructivism and interpretivism. Constructivism takes an approach of understanding each participant's subjective experience, acknowledging that human reality is constructed through individuals' interactions with the world and others and their interpretations of this (Crotty, 1998). Social real-

ity is therefore interpreted through the meanings participants produce, and so interpretivism looks to understand experiences and phenomena by looking to access meanings participants assign to them (Blaikie & Priest, 2019).

As there were no studies exploring experiences of using Flow, thematic analysis was chosen as the methodological framework, as theories can be applied flexibly (Braun & Clarke, 2006), with or without any prior theoretical assumptions (Willig, 2001). Thematic analysis enables the researcher to interpret the patients' experiences as well as the situations and contexts within which they arise.

The thematic analysis was data-driven and inductive (to explore experiences, perspectives, and meanings of the participants in relation to feasibility, useability, acceptability, and value) and focused on the semantic level to capture explicitly expressed meaning (Braun & Clarke, 2021). The six-phase guide advocated by Braun & Clarke (Braun & Clarke, 2021) was implemented and comprised: 1) familiarisation with the data, (reading and re-reading, noting initial observations); 2) initial code generation taken from important features in the data; 3) theme development extracted from meaningful patterns in the data; 4) reviewing the themes assessing for consistency; 5) naming themes; and 6) writing up a coherent account of the data.

Initial analysis of the data was conducted by one of the researchers, supported by an individual with lived experience of depression, who undertook initial reading and coding of a proportion of the interviews (phase i and ii of thematic analysis). The themes were then further categorised into subthemes by the two researchers working on the project, who collaborated to refine finalised themes. Verbatim quotes were reported to promote verifiability (Silverman, 2015). To promote credibility and confirmability of the research, and to make sure that the findings were the experiences of those interviewed, Shenton's (Shenton, 2004) strategies for ensuring trustworthiness were followed.

3. Results

Following the analysis of the interview data, the experiences of the patients were aligned to four areas: "Feasibility", Useability", "Acceptability" and "Value".

3.1. Content Analysis

Content analysis was undertaken on responses to a series of direct questions about the use of Flow. Results are presented in **Table 1**.

3.2. Thematic Analysis

The themes that were developed within the four assessment areas (feasibility, useability, acceptability and value) are illustrated below in **Figure 1**.

Feasibility

Feasibility was defined as ease of adoption. This organising theme was represented by two sub-themes: "*Flow easily integrated into existing treatment*" and "*Patient-friendly process getting Flow*".

Table 1. Feasibility, useability, acceptability and value.

Question	Yes *N* (%)	Exemplar Quotes	No *N* (%)	Exemplar Quotes
Feasibility: Did you stick to the protocol of use: 5 times a week for 3 weeks, 3 times a week for 3 weeks?	12 (66.7)	P10: *Yeah. I've stuck to it. I've made sure that I'm making myself available at the correct time to do it.*	6 (33.3)	P11: *When I first got it, I was so excited to use it. I used it five days in a row, and then I didn't use it for I think 10 or 11 days.* P15: *Some days I would forget and get to the end of the week and it's like ok I should have done that, I will admit that last week I haven't used it at all.*
Usability: Did you have any practical problems using the Flow?	5 (27.8)	P6: *… a couple of occasions where we just couldn't get the Bluetooth to pair.* *P7: Better for it to warn me [insufficient charge] before [session start]* P12: *Securing the pads, the little black plastic thing that you clip them in, they don't always bite in correctly.*	13 (72.2)	P5: *I found it very easy, very straightforward.*
Usability: Did you have any practical problems using the Flow software app?	0 (0)		18 (100%)	P9: *No, the app was really good. Easy to download and use.*
Acceptability: Did you use the following app training?:				
• Mindfulness meditation	10 (55.6)	P5: *I found it very helpful.* P13: *I found the technique used on there was incredibly straightforward and easy to follow.* P18: *It is just calming.*	8 (44.4)	P11: *I've never really done any meditation. It's not to say I wouldn't do it.*
• The anti-depression diet	13 (72.2)	P1: *It was interesting to see the foods that were good for you.* P10: *I found it helpful, you know, because there's obviously there's good food, bad food, and I was eating a lot of bad food.* *P:18 We moved across to… a Mediterranean diet*	5 (27.8)	
• Looking back and planning ahead	8 (44.4)	P2: *It was useful looking at what I had been doing and how I'd felt and made me realise what things did affect me more than others.* P3: *I did, yes, because it was nice to look back at how far I've come. And I like planning ahead.*	10 (55.6)	
• Choosing your actions	10 (55.6)	P3: *I liked the choosing the actions because it gave you options to choose from. And I am like oh, yeah, that one's achievable. I can do that one.* P10: *Flow brought that to my attention, and I could see the reasoning behind it.*	8 (44.4)	
• Exercise for your brain	11 (61.1)	*P5: Actually doing the exercise itself makes me feel better, definitely. It makes me feel energised.* *P18: I try to keep mentally active.*	7 (38.9)	

Continued

• Therapeutic sleep	11 (61.1)	P3: *I did love the therapeutic sleep training. It has made a massive difference to my sleep.* P13: *I have done that one. And I think it's working because I'm sleeping better.*	7 (38.9)	P12: *No, to be honest, sleeping is not a thing I have a great issue with. I can get to sleep easily enough.*
Acceptability: Did you experience any side effects from using the Flow	15 (83.3)	P15: *I had less headaches when using Flow… I can't think of anything that caused an issue.* P10: *There were no side effects or negative effects while using the Flow or after the Flow that I experienced.*	3 (16.7)	P4: *The first, probably the first week, I got headaches after [using it].*
Acceptability: Would you want to keep the flow	17 (94.4)	P2: *I'd like to keep going with it… hopefully not take medication and just try with Flow.* P12: *I would like to keep it because I think a) it's helping me, and b) I would like to keep it because ultimately, I'd like to be able to come off antidepressants if I could.*	1 (5.6)	P6: *I'll probably say no. Only that I feel it would benefit somebody else… it's had a positive effect… I'd like somebody else to benefit from it really.*
Value: Did you notice any improvements after using the Flow?	17 (94.4)	P6: *Yes, I feel it did, give improvements without a doubt.*	1 (5.6)	P17: *I didn't, to be truthful with you, I didn't really notice any significant change at all.*
What was the length of time following use, to notice improvements?	4 (22.2)	**Within the first week** P13: *I say my sleeping improved pretty quickly, after using it…. I think within the first week*		
	8 (44.4)	**Two weeks** P10: *Two weeks after using the Flow regularly for five nights.*		
	4 (22.2)	**Three weeks** P4: *Yeah, it was probably about, three weeks. For three weeks, I remember being at work and having a good day.*		
	1 (5.6)	**Five weeks** P5: *Five weeks is when I have most noticed that I have started to look at things differently, that I am behaving differently in myself, and actually looking forward to things.*		

Flow easily integrated into existing treatment

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

P11: *Flow helped when I was going to my therapy sessions. I could wear my Flow during those sessions and that was helpful.*

By being able to easily add another type of treatment, participants felt they were better at addressing their depression and anxiety:

P12: *I say psychotherapy… a sort of wellbeing coach. He deals with stress and anxiety and all that sort of stuff… now I'm back on Citalopram, for the sort of depression part of it, so I'm really sort of feeling, with the ability to easily include the Flow as well, I'm attacking it from all sides.*

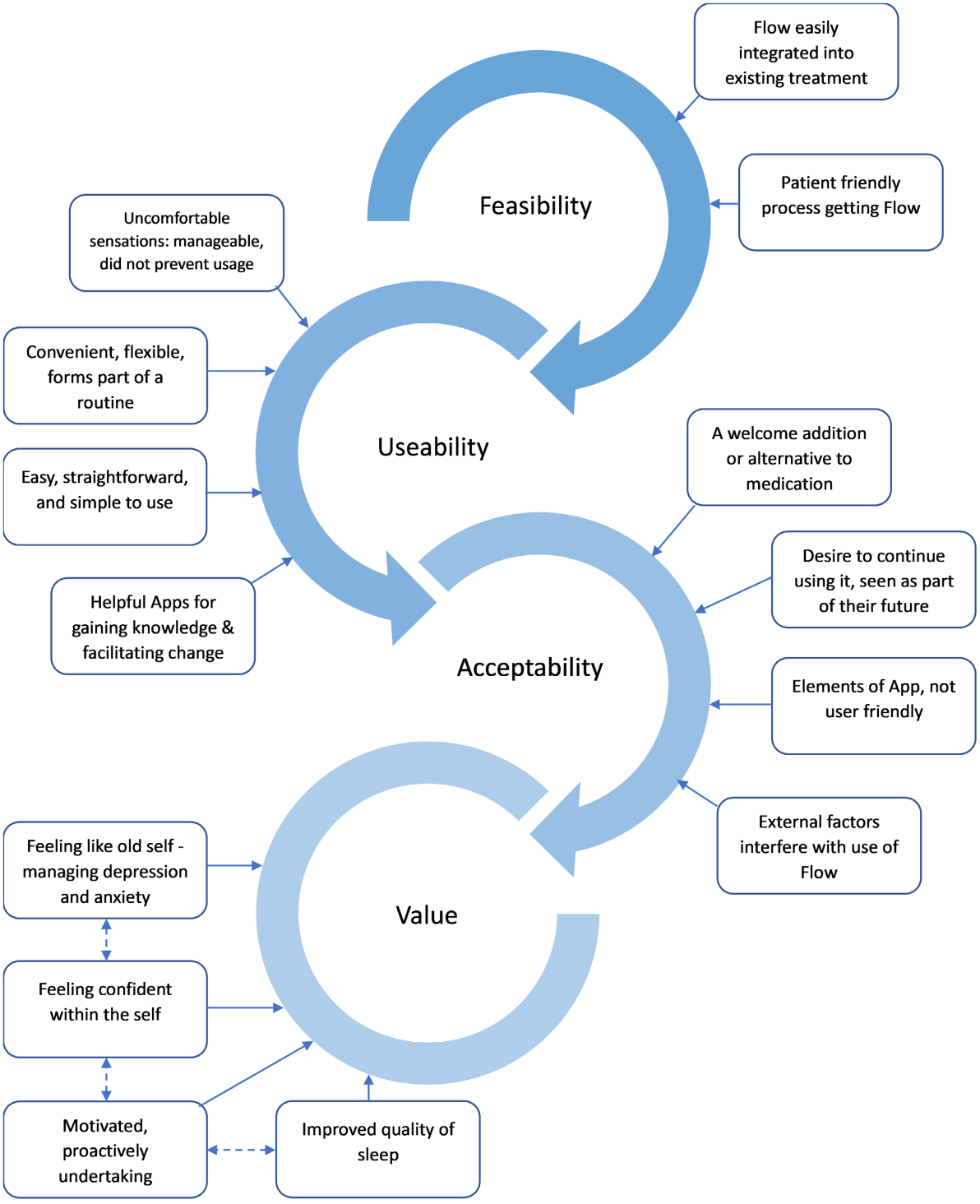

Figure 1. Themes represent the patient's experience of Flow.

Patient-friendly process getting Flow

The initial process of getting Flow was easy, convenient, and patient friendly:

P2: *It was fairly straightforward to get hold of it... I had an email from the doctors, I responded straight away, and within 10 minutes, I went down to the doctors and picked it up… it was brilliant.*

Patients also described setting it up as user-friendly. Patients were given information and advice and were able to ask questions, so that they could take Flow away, set it up and start using it.

P13: *It was quite simple, booked an appointment at my GPs to see* [*nurses*]*, and they gave… a discussion about how to start up. So, it's all quite simple through the app.*

Useability

This theme is represented by four sub-themes that are associated with the useability of the device such as design factors that influence experience, ease of use, and user satisfaction.

Convenient, flexible, forms part of a routine

The patients found Flow easy to use. They found that they could fit it into their day-to-day routine, without too many problems. For many of them, it had positive impact and so was not perceived as a burden.

P5: *Now I do it at bedtime because I log on and I do all of the programs… once I have completed those, I'll do the stimulation and I'll lay down and I actually fall asleep while it's working…. it has become part of my routine, which I really like.*

For others, it was convenient in that it could be used when they chose, and they could still continue to do required tasks.

P7: *We sat watching television while we were doing it... If the dog wanted to go out in the garden, got up and let him out in the garden… it didn't stop me from doing that.*

Some patients talked about using it while engaging with chores (e.g., P4: "*I use it when pottering, putting a wash load on, mopping the floor*"), others when they found a quiet time to themselves to engage with it, for some patients when they were reading.

Easy, straightforward and simple to use

Patients highlighted how the device was user-friendly: it was easy to set up, engage with, and use.

P12: *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…*

P4: *It's pretty easy to use… you don't even have to type anything in, it gives you the option to just press a button and go like…, every three days, you have to do a questionnaire, I would literally forget, but it tells me, I can't go any further until I do it.*

Another factor that was highlighted was the time needed for using it was relatively short, and so not prohibitive of its use:

P7: *How easy it is to use because of how long it takes, it doesn't take long for each time. It's only 30 minutes.*

Some uncomfortable sensations: manageable, did not prevent use

The types of sensations described by some patients included: "*Lots of little pins sort of stabbing in your head, but not really pain*" (P2); "*It was so itchy*"

(P4); "*Stinging, pinpricks*" (P5); "*Slight burning sensation*" (P10); "*Pins and needle burning effect*" (P18); "*Left [temporary] great big red circles on my forehead*" (P3), and *"…that last 30 seconds is… uncomfortable… real tingle on your forehead"* (P1). The uncomfortable sensations were not prohibitive of use:

P6: *A little bit of heat or, and itchiness around the pads. The itching is the worst. You do feel like you want to scratch it at times, and that's quite frustrating. But that was all. It was a little bit uncomfortable at times, but not that often. It really wasn't that bad. It wasn't prohibitive at all.*

These side effects could be managed by the patients, they got used to them, did not last long, or didn't continue over the full course of the six weeks of Flow treatment.

P5: *It was just, the first few times it was just uncomfortable, and it was just getting used to that feeling.*

Helpful apps for gaining knowledge and facilitating beneficial change

Part of the design feature that influenced the user's experience was the training apps, which the majority of the patients found helpful.

P5: *I have found it very interesting in the foods that can cause depression… to see what food to eat to try and get you out of that depression… I have never really thought about food as a trigger* [*for depression*].

Participants commented that the apps raised awareness:

P2: *It [looking back and planning app] sort of made me aware of things that made me anxious… and I learned to sort of deal with them slightly better.*

added to their knowledge:

P13: *It's giving you the knowledge and then… you made some changes which have helped.*

and offered advice:

P8: *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.*

P10: *You don't get this type of information… I've learned from the modules… by anyone… It's made me think about things I need to do, like… socialising.*

The training apps facilitated some positive behaviour changes. Participants valued information on "why it's important" (P3) to make suggested changes. For example, in relation to diet:

P9: *I think that [the anti-depression diet app] did help me, and I thought we should eat more fish and stuff like that, and healthier foods. So, I have implemented things.*

and sleep:

P3: *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…*

Acceptability

This organising theme collates the themes associated with the acceptability of Flow, factors influencing the willingness to use Flow and engage with the train-

ing apps. It is made up of five interlinked sub-themes.

A welcome addition or alternative to medication

For the majority of the participants, the fact that this was an alternative to medication to treat their anxiety and depression was an important factor that influenced their desire to use and try Flow.

P1: *I was very up for it, I mean, to be honest, I was up for anything that wasn't medication.*

A rationale for using Flow as an alternative form of treatment was that many did not like anti-depressant medication side effects.

P3: *I don't like taking medication. I hate the side effects. I think the side effects are awful.*

For those still on medication, Flow was perceived by some as a means to eventually help them come off their medication; in time the device could be used on its own to treat their depression.

P13: *I don't want to be on medication for the rest of my life. And if I can find something that helps that and helps me come off the medication, then that'd be great for me…, a key one for me was finding an alternative to medication.*

Desire to continue using it, seen as part of their future

For most of the patients, Flow was seen as being part of their future treatment. Flow was perceived to be something that worked, so influencing willingness to engage with it now and to continue to do so in the future. Many of the patients felt very strongly about keeping Flow.

P3: *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!*

Flow was also seen to be part of future treatment enabling them to eventually stop taking medication, but still giving them an effective form of depression treatment.

P13: *It might be something that could hopefully help me get off the medication.*

Elements of apps are not user-friendly

Around half of the patients interviewed highlighted that there were elements of the training apps that were not user-friendly. In some cases, they discussed how they could not relate to the training apps.

P1: *The little bot on the app is called Flow, which is fine. But then it asks you a question, but it tells you what the answer is, and it's so annoying.*

However, others liked this approach (predetermined and choice of predetermined answers to posed questions) and found it to be user-friendly. Some disliked the 'amusing animal photos' that appeared at the end of a session as a 'reward', and questioned appropriateness for someone experiencing depressive symptoms.

One patient struggled to engage with the material on it; they found it was not

aligned to how they would best learn.

P11: *But then I clicked on it [the app], and I was like—no, this is boring. I felt like, there was just too much information. It was kind of like information overload. Like there were no pictures or anything. Like I'm quite a visual learner.*

External factors interfere with the use of Flow

Some patients experienced situations or factors that got in the way of using Flow. However, these were either short-term issues, or issues that could be managed and so then not necessarily prevent its use. This included issues such as physical illness:

P1: *I literally couldn't stop being sick…. I just crashed in bed. I just thought there was no way I could do that today. I just couldn't stand that. So being ill prevented me from using Flow.*

their social life:

P6: *Last week and this week we haven't done any, because of our social life.*

and other priorities and commitments:

P4: *I haven't done a lot of the things on it really. Just like it's time, I have like five dogs, got a house of kids like, and people and work. I have two jobs. I think I'll do that tomorrow. I'll do it later and I just never do.*

Value

This organising theme relates to patients' perceptions of the degree to which Flow produced positive results and improvements for them. This is represented by four sub-themes, which are all interlinked: improvement in one area is likely to be associated with improvement in another area.

Feeling like old self, managing depression

The patients discussed how Flow had a significant positive effect on their depression and anxiety symptoms:

P14: *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.*

P11: *I didn't have as many suicidal thoughts*

P12: It's had a positive effect on my depression… it's probably made, helps my low points be fewer and shorter… when I get into the real depths of despair, it is as deep, about as bad as we can get. And I haven't got that bad for long, for a, well certainly not since I have been on the Flow.

Several talked about feeling like their old self, e.g., '*I just feel back to my old self, back to being calm and being able to think through things before I… lose the plot.*' (P3), '… feeling like myself again' (P14), and '*I got back to normal, I'm my normal cheerful self*' (P16). Others felt it had relieved them of their depression and anxiety completely:

P16: *I don't feel depressed, I don't feel worried about the future…*

A lot of the patients made an association between using Flow and giving them the ability to manage and cope with their depression and anxiety, enabling them to put strategies in place:

P6: *It calms my thinking and made me look at what the issues are… and ac-*

cept the fact that I'm yes, I'm back in depression and I need to do something about it, and address all the other things that are not right, that, without them becoming overwhelming… which is part of the depression problem in the first place.

Patients reported improvements in mood and optimism:

P5: *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.*

P3: *I'm energetic. I am motivated, I'm less miserable, less grumpy… I'm happier. I look forward to things, I get excited by things.*

P10: I said to my daughter… I think the Flow device is definitely working, I've never laughed so much as I have laughed today.

Feeling confident

Patients talked about how they felt their confidence improved:

P14: *I'm feeling better in myself. I feel more confident, and I feel less anxious about being myself, and I'll chat with people in the supermarket.*

P:5 I was always putting myself down and that element has been lifted.

Several of the participants talked about feeling more confident in relation to social situations, being able to deal with situations at home and work, and engaging generally more with life:

P3: *I can hold a conversation now. Whereas previously, I… couldn't think of how to keep a conversation going.*

P4: *I was messaging my friends saying like, we haven't seen each other for ages do you want to get together?*

P5: *I feel more confident, I feel a little bit stronger in myself… rather than hiding myself away…*

P6: *I do seem to be able to cope [with challenges] a lot easier.*

P10: *I've gained confidence. You know the fact that I'm actually making sure that I, I do take part in life now and not just withdraw.*

Improved quality of sleep

All apart from two of the participants discussed how they associated improved sleep with the use of Flow. This seemed to manifest in relation to falling asleep:

P10: *I can drop off to sleep quicker... it's definitely helped me to fall asleep, quickly, because I've always found it difficult to fall asleep straightaway because my brain is just going over and over things.*

getting back to sleep if waking up during the night:

P2: *I do sleep better, I was sort of waking up and struggling to get back to sleep, and maybe waking up about three or four in the morning. But now I sometimes do wake up, but I feel that I'm able to you know get back to sleep easier.*

sleeping for longer:

P16: *I go to bed at about 11 o'clock and I wake up at 6 o'clock, whereas I was only sleeping for two perhaps three hours at the most.*

and experiencing improved quality of sleep:

P3: *Massive impact on my sleep. I'm getting better quality sleep... before my restful sleeping was absolutely horrific. It was constantly up, and down. Whereas now I get quite a big block of restful sleep.*

Participants reported that the resultant good-quality sleep was beneficial:

P5: *Waking up quite refreshed in the morning.*

P13: *Sleeping has improved quite dramatically… so a bit more energy.*

Several of the patients also discussed the knock-on effect, in that the improvements in their sleep, would result in improvements in their anxiety, depression, mood, and/or well-being, which helped them function day to day.

P18: *Sleeping well, just makes you feel generally better anyway. And directly then related to that is just general improvement in mood during the day.*

Motivated, proactively undertaking activities

Most participants reported improved motivation, which translated into actions:

P11: *I find it's given me a lot more motivation.*

P5: *Motivation comes through not being so overwhelmed and I feel I can tackle these things… because I am not tired, because I'm feeling a lot better within myself.*

P1: *Using the Flow, I'm more positive. It's like a combination of things, that you're feeling better, you're sleeping better… And then because of all of that, you're more likely to want to do things, and you are more motivated to do things.*

P7: *I just found myself doing more.*

P8: *I have been more motivated to do my uni work and look for jobs.*

P13: *I'm utilising my time a bit better… just giving myself a bit of structure… trying to be a bit more of a better dad.*

P15: *It's had a tremendous impact in terms of positivity in terms of wanting to get involved in doing things.*

P18: *I think and just feel that things are sort of worth doing.*

Participants described feeling motivated to do things and proactively undertake activities, many included routine chores within the home, that they previously neglected.

P3: *So since using it, I'm happy. I'm energetic. I am motivated, I was more motivated to do things because I used to spend a lot of time just sitting on my bum on the sofa, mindlessly scrolling through my phone. Whereas now I'm like, well, the bathroom needs cleaning so let's do that. Whereas previously, there would be no way in hell I'd be getting up to clean bathrooms.*

P16: *Yeah I'm more motivated to do things, I don't sit down and think I can't be bothered, now I'll get up and get on, I'm gonna be decorating a bedroom this week and I mean before the Flow there's no way I would've done it, I would have found an excuse not to do it but I'm not looking for excuses anymore…*

Another area where the patients seemed to be motivated was physical exercise

and activities; for example, going to the gym, playing sports, and doing yoga—which they previously had not been motivated to do.

P6: *I've always been very active… from June last year, I stopped doing it. Couldn't be bothered… I'm back training again… loving it. Getting the, feeling the benefit already.*

Several discussed being motivated to increase their walking as a way of doing exercise and keeping active.

P4: *I have better levels of motivation. Just walking home from work before I was like—oh I'm just going to get the bus. But I'm walking to work and walking home from work. I'm walking the dogs more often.*

For some their motivation was around engaging with others:

P3: *I've got a 10-year-old… and she's obsessed with TikTok and all of that, and she is like 'Mum do dances with me' and I'm like no, whereas now… I'll dance…*

P15: *I think I'm happy mixing with people again.*

4. Discussion

This is the first study to qualitatively examine through in-depth interviews the experience and value of using Flow by individuals with symptoms of depression. It provides support for the acceptability, feasibility, useability, and value of Flow, suggesting that successful integration of the Flow as part of patient's depression treatment can be achieved and can be beneficial. The content analysis and themes that emerged offered insights into side effects, and how people use Flow and gain beneficial outcomes. Participants found engagement with Flow was enabled through the useability of the device: it was easy to use, reliable, could be embedded into their daily routine, and did not have any adverse side effects preventing use. The findings add to and align with previous evidence of some uncomfortable but temporary side effects, acceptability, and improved relaxation and motivation found in other qualitative tDCS studies (Gordon et al., 2021; Grycuk et al., 2021). The findings also support evidence of perceived helpfulness for improving depressive symptoms (Woodham et al., 2022).

RCTs have shown the effectiveness of Flow on valid measures of depression (Mutz et al., 2018; 2019; Moffa et al., 2020; Razza et al., 2020), but participant's perceptions of their recovery are also important. Many participants in this study reported returning to their "normal" or "old" selves, i.e., they felt like they did before their episode of depression, some stating that they no longer had depressive symptoms. There were reported improvements in mood, optimism, positivity, energy, motivation, confidence, sleep, and physical activity attributed to the use of Flow. These factors translated into reported improvements in functioning such as socialising, doing day-to-day activities, studying, undertaking physical activities, and generally engaging in life.

Engaging in increased physical activity where depression is present may be particularly valuable, as evidence shows that aerobic exercise can be as effective

as taking antidepressant medication or undergoing psychotherapy (Babyak et al., 2000; Singh et al., 2023). Regular physical activity of sufficient intensity and duration can prevent many chronic medical conditions and is associated with improved cognition, functioning, and mental and physical health (Mittal et al., 2017; Rhodes et al., 2017; World Health Organization, 2020). Also, an increase in sociability could be of particular benefit, as positive and supportive social relationships are associated with better well-being, resilience, coping, realisation of goals, positive affect, and motivation, and the development of positive identities (Ferragina, 2010; Langford et al., 1997; Thoits, 2011; Webber et al., 2015).

The side effects reported aligned with those listed by Chhabra et al. (Chhabra et al. 2020), and did not prevent the use of Flow FL100, unlike antidepressants where side effects can become prohibitive of their use. An important factor for participants was being able to fit the use of Flow FL-100 into their lives; 30 minutes was felt to be an acceptable amount of time (not too burdensome) and allowed them to engage in other activities whilst using it if they desired. The time required for Flow FL-100 use is less than the time commitment for face-to-face talking therapies or transcranial magnetic stimulation (TMS) (requires daily outpatient appointments across a number of weeks), and home use means no travel is required for treatment.

Though not everyone used all of the training modules, overall, the training (which is based on evidence on what reduces depression symptoms and enhances well-being) raised awareness, added to patient's knowledge, provided useful advice, and facilitated positive behaviour changes. This supports evidence that Flow combined tDCS and software app-based well-being behaviour training (exercise, nutrition, mindfulness, sleep, choosing actions) is beneficial (Sobral et al., 2022; Woodham et al., 2022; Rimmer et al., 2022).

Participants reported improvements in sleep quality, duration, and getting back to sleep if they woke during the night, and that resultant good quality sleep was described as beneficial in terms of functioning and well-being. Effective sleep is important for enabling occupational, social, emotional, cognitive, and healthy functioning (Cappuccio et al., 2010; Kripke et al., 2002). Effective nighttime sleep duration and quality can improve physical health (reducing risk for mortality, diabetes, cardiovascular disease, stroke, coronary heart disease, and obesity) (Chaput et al., 2013; Jike et al., 2018), and improve mental health (Palagini et al., 2022). There is a bidirectional relationship between depressive symptoms and disturbed sleep, highlighting the value of participants reporting Flow's positive effect on sleep (Hertenstein et al., 2022).

Many participants reported that their sleep issues were resolved by Flow and its sleep hygiene training app. For the treatment of short-term insomnia, the National Institute for Health and Care Excellence (NICE) recommends nonpharmacological interventions, e.g., insomnia cognitive behavioural therapy (iCBT), as the first method and, where this fails, a follow-up with a brief course of a non-benzodiazepine hypnotic prescription (NICE, 2020). Following further re-

search, Flow offers a possible alternative for insomnia treatment where a depression diagnosis is present, which is potentially cheaper than iCBT and does not have the side effects associated with some hypnotic prescriptions.

The positive benefits described by the participants were interlinked, providing insights into mechanisms that reduce depressive symptoms and improve well-being. Flow use was associated by participants with breaking the negative cycles of depression and promoting positive cycles of mental health, well-being, recovery, and engagement in life.

The findings that Flow was acceptable, had good usability, could be easily embedded into daily routine, brought benefits, and did not have any adverse side effects that prevented use and promoted treatment compliance align with Woodham et al., (Woodham et al. 2022) and Rimmer et al., (Rimmer et al.2022). Medication for depression can have significant side effects that can cause treatment failure (Sundbom & Bingefors, 2013); and the comparative lack of Flow FL-100 side effects assists treatment adherence potentially reduces health care service requirement to have appointments to address depression following treatment failure and the need to consider alternative treatments.

The reported ease with which Flow integrated with and was used in combination with other treatments such as medication and talking therapies is valuable because many people with depression will be taking antidepressant medication and/or receiving talking therapies. Some participants felt they were better addressing their depression and anxiety by adding Flow to their current depression treatments, adding to evidence that tDCS can be used in combination with other treatments (Razza et al. 2020); further research could be valuable to investigate this further.

Many people who are on antidepressant medication have a desire to stop using them, due to factors such as side effects, dependence, and wishing to have a "medication-free" life, but withdrawal can be problematic (Hengartner et al., 2020). Information provided by participants indicated that Flow could offer a means of coming off their antidepressant medication; either through removing depressive symptoms or as a replacement to treat their depression. Some participants perceived Flow as a preferred alternative to medication.

Some minor practical issues with the device were identified but these did not prevent use. A couple of participants disliked aspects of the training app, and these are factors that could be possible areas of product development to enhance user engagement and value.

Due to recruitment through an NHS primary care service in a single county of the UK, generalisability to other settings is reduced. Furthermore, all participants self-identified as White British, limiting generalisability to other ethnic groups. It is worth noting that participants in this study self-selected, which can introduce bias, as more people with a positive experience may be willing to be interviewed and their experiences and perceptions may differ from those who did not wish to be or felt unable to be interviewed. Future research could specifi-

cally target those who did not have a positive experience. Eighteen is a sufficient number for a qualitative in-depth interview study as saturation often occurs at around twelve participants in relatively homogeneous groups (Guest et al., 2006). The sample herein was a fairly homogeneous group in terms of diagnosis.

5. Conclusion

The protocol set up by the study team to offer and provide Flow to patients with symptoms of depression was reported as working well by the patients. The majority of patients interviewed reported a beneficial effect, with most reporting some side effects that did not prevent use. These findings provide support for the approach of delivering tDCS and at the same time wellbeing behaviour therapy training. Some people do not wish to try or respond to particular treatment modalities, so it is vital to offer as wide as possible choice of effective evidence-backed depression treatments so that people can find an approach that works for them. The results of this study provide support for offering Flow as a primary care-delivered treatment option for people with symptoms of depression. Access to Flow should not be restricted by being able to afford to buy it.

Acknowledgements

General practice alliance (GPA) research and training academy Northampton in delivery of the intervention and support in recruitment.

Funding

Funding was provided by Flow Neuroscience AB, but study design, analysis, interpretation, and reporting was independent of Flow Neuroscience AB's involvement.

Conflicts of Interest

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

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