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NEUROTECH

Beta CUE1 User Testing - Long term use in a home setting

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Prepared by Charco Neurotech

The aim of this study was to test the Beta version of the CUE1 device in a home setting over a prolonged period of time. A mixture of quantitative and qualitative methods were used to assess the potential impact on the lives of people with Parkinson's (PwP). Parkinson's disease (PD) is a neurodegenerative disease that leads to postural, balance, and movement disorder. Symptom management remains one of the most important concerns of the Parkinson's community as the disorder has profound effects on their daily lives [1]. The use of focused vibrotactile stimulation leads to the neuromodulation of proprioceptive information required for motor control and performance [5,6]. In addition, patients in cueing studies exhibited significant postural improvements and were able to retain the benefits for weeks after an initial period of cueing [13-16]. In this study we observe the experience of 8 participants over a combined total of 13.5 months with the CUE1 device. The participants of this study have reported improvements in gait, speed, stiffness, fatigue, tremor, freezing, movement, posture and confidence. In the absence of the CUE1, the participants reported rigidity, fatigue, anxiety, balance issues, irregular gait and decreased confidence.

1. Introduction

Parkinson's disease (PD) is a neurodegenerative disorder distinguished by the loss of dopaminergic neurons in the striatum leading to complications in posture, balance, and movement. Initially, symptoms can be so mild that they are overlooked. Early symptoms include slight tremors, stiffness, and slower movement. There have also been reports of bloating, sleep disturbance, anosmia and clumsiness. Symptom management remains one of the most important areas that concern the Parkinson's community as the disorder has profound effects on their daily lives [1]. PD can be extremely debilitating and result in those afflicted becoming increasingly dependent on external assistance.

In contrast to current interventions such as levodopa-based medications and Deep-Brain Stimulation, both focused vibrotactile stimulation and cueing offer a novel, non-invasive, non-pharmacological approach to help manage symptoms. The implementation of focused vibrotactile stimulation has been shown to exert a positive effect in the neurorehabilitation of Parkinson's as well as stroke, cerebral palsy and multiple sclerosis [2-4]. The stimulation of specific muscle groups through vibration leads to the neuromodulation of proprioceptive information required for motor control and performance [5,6]. External cues, also known as cueing, have also been well-established in alleviating gait symptoms in patients with PD [7-9].

Cueing can be delivered through projecting lines onto the floor (visual), listening to a metronome (auditory), or feeling vibrations against the skin (somatosensory) [10]. A study conducted on those three strategies revealed that auditory and somatosensory cueing were most effective in decreasing the number and length of freezing episodes while on medication [11]. It was also suggested that externally or internally derived cues may trigger a plan in the brain to execute movement, thus ameliorating movement pathology experienced in PD [12]. Furthermore, patients in cueing studies exhibited significant postural improvements and were able to retain the benefits for weeks after an initial period of cueing [13-16].

Despite the success of auditory cueing, the same level of effectiveness may not be attainable in a non-controlled setting. This method relies on the user being conscious of the auditory cues which might prove to be challenging in a noisy environment and has the potential to distract the user from avoiding dangerous situations. In contrast, somatosensory stimulation has the capacity to be discreet in terms of its application and placement. Rhythmic somatosensory cueing has been shown in numerous studies to benefit patients afflicted with Parkinson's. The improvement in cadence evident in the participants of a rhythmic tactile cueing study was comparable to that displayed in rhythmic auditory stimulation studies [13].

CUE1 utilizes somatosensory stimulation through cueing and vibration to alleviate Parkinson's symptoms. This report serves as an initial account of the Beta CUE1 testers' experience.

2. Methods

8 patients received a CUE1 device to test its effectiveness in symptom mitigation within their own homes. The study was conducted over a combined total of 13.5 months without altering any aspect of their medication. The testing was performed in a naturalistic setting in order to determine the extent of CUE1's influence on their daily routine. Due to the device still being in development, some malfunctions were present; however, those devices were either fixed or replaced without significant impact on duration of use. Each participant was sent a

questionnaire at the end of their testing period (see below), and invited to provide diary feedback as well as any other forms of objective data they collected over the course of the study.

3. Results

Patient	Testing Period	Improved Symptoms	Usage Habits	Request for additional devices	Reason for request	Experience without device
1	2 months	Gait, stiffness, posture, strength and pain	Entire day regardless of activity	Yes	Use on multiple areas	Rigidity
2	2 months	Movement, speed, fatigue, confidence	During exercise (running)	Yes	Spare	Fatigue
3	3 months	Falls, freezing, speed, fatigue, confidence	Entire day regardless of activity	Yes	Spare	Possible anxiety
4	2 months	Gait, posture, speed, balance, confidence	During exercise (walking)	Yes	Spare	Balance issues, irregular gait & cadence
5	2 months	Gait, movement control, tremor, stiffness, confidence	Entire day regardless of activity	Yes	Use on multiple areas	Decreased confidence
6	1 month	Tremor, stiffness, movement control	During activities and onset of tremor	Yes	Use on multiple areas	N/A
7	1 month	Freezing	N/A	N/A	N/A	N/A
8	<1 month	Movement, posture	N/A	N/A	N/A	N/A

Early testers, patients 1-5, reported notable improvements in gait, speed, stiffness, fatigue, tremor and confidence. Despite reporting improvements of a smaller degree, Patients 6-8 felt noticeable differences in their stiffness,

tremor, freezing, movement and posture. Users conveyed experiencing rigidity, fatigue, anxiety, balance issues, irregular gait and decreased confidence in the absence of CUE1 during repairs. The use behaviours displayed by testers may be split into two groups: those who used the CUE1 continuously throughout the day, and those who solely used it during set activities. Of the sample shown above, distribution across these two groups was roughly equal. At the time of writing this report, not everyone had answered if they would prefer additional devices. Those who had, expressed their desire to possess more than one. Reasons include interest in concurrently trying CUE1 on multiple areas as well as having a spare whilst the main unit charges or when it is not possible to charge one.

4. Discussion

The cueing phenomenon seen in patients with Parkinson's disease may be achieved by bypassing the internal rhythm deficit of the basal ganglia [17]. The defective basal ganglia - supplementary motor area circuit may be bypassed using alternative circuitry which enables movement preparation and initiation to take place [18]. Somatosensory cues, utilised by the CUE1 device, stimulate proprioceptive inputs, which help provide enhanced information on limb position and movement, both of which are believed to be deficient in patients with Parkinson's disease [19,20]. The positive effect of enhancing proprioception is also seen in the focused stimulation phenomenon, where oscillatory beta waves are attenuated in the basal ganglia [21]. This has also been observed in cueing studies where beta-band frequency oscillations in the subthalamic nucleus are significantly decreased in cued Parkinson's disease patients [13,22]. Vibratory stimuli produced by CUE1 is thought to activate muscle spindles which convey proprioceptive inputs to the central nervous system. Proprioceptive signals generated in the spindles are relayed to the primary somatosensory cortex via type IA afferent nerve fibres, which provide additional information on the state of the body [23]. The proprioceptive input, which is thought to be deficient in patients with Parkinson's disease, plays an important role in maintaining postural stability [24,25].

The difference between symptom improvement in earlier and later phase patients might be attributed to having used the CUE1 for a longer time, having malfunctions addressed earlier and having found their own optimal stimulation settings. Although cueing can produce instant effects, lasting benefits occur after an initial period of cueing [13-16]. Whether the patients who tested later will experience the same level of improvement is still being investigated. Patients have also described a perceptible difference in their symptoms while their unit was undergoing repairs. Whether this was purely due to the absence of the CUE1 device or increased anxiety without the device still remains under investigation.

Overall, feedback from this user testing has highlighted the potential benefits of cueing and vibrotactile stimulation on the symptoms of Parkinson's disease over a prolonged period in real life setting. Improvements on gait and movement were the most commonly reported areas of improvement. Improvement in postural stability led to increased confidence and a reduction in the frequency of falls.

The Beta CUE1 User Testing report is the first report on the effectiveness of the CUE1 over a prolonged period of use in a naturalistic setting. The report offers insight into the relief provided by the device in characteristic symptoms such as gait, stiffness and tremors. The observations should continue to be monitored in further studies to determine if similar results can be reproduced in a clinical trial setting.

5. References

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6. Appendix

List of questions included in questionnaire.

Name

Email

You are the ...

Do you consent to being contacted by email for further questions?

Packaging

Did the CUE1 arrive intact and without damage?

Was the packaging easy to open? If not, let us know why!

Information Booklet

Was the information ... [Sufficient?]

Was the information ... [Easy to read?]

Was the information ... [Easy to understand?]

If insufficient, what other information would you like to be included?

Would you have liked a video guide?

Adhesives

Was the adhesive ... [Easy to take out of the case]

Was the adhesive ... [Easy to apply]

Was the adhesive ... [Comfortable during wear]

Was the adhesive ... [Comfortable during removal]

Was the adhesive ... [Case drawer easy to rotate]

Was the adhesive ... [Drawer easier to rotate over time]

If the adhesives were uncomfortable at any time, please feel free to describe when!

Let us know if you have any comments or if you'd like to see any improvements in the processes above.

How long were you wearing the adhesives for?

Could you easily attach CUE1 back on the adhesive after having removed it to charge?

If not, what would make it better?

Using the CUE1

Regarding CUE1 ... [It was easy to activate]

Regarding CUE1 ... [It was easy to use on your own]

Regarding CUE1 ... [The noise was at an acceptable level]

Regarding CUE1 ... [There was no pain while wearing CUE]

Regarding CUE1 ... [I was comfortable while wearing CUE]

Regarding CUE1 ... [Vibrations did not cause any soreness]

Please feel free to leave any comments you have regarding the processes above!

How often were you using the device on average?



We'd love to know what you use CUE for!

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Did not try other areas]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Neck]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Upper Back]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Lower Back]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Upper Arm]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Forearm]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Hand]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Thigh]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Calves]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Ankles]

Did you place the device on other areas of your body? If so, where, and what worked best/worst? [Other location]

If you have tried another location, do let us know where and how that worked out!

If you have any ideas on how it could've worked better we would like to know!

Did you experience any device malfunctions? If so, when and what happened?

Did the device/adhesive detach at any point?

If so, how did it detach and what were you doing at the time? How many times did the device detach?

Were the processes easy to do? [Opening the case]

Were the processes easy to do? [Removing the CUE device from the case]

Were the processes easy to do? [Using the CUE device]

Were the processes easy to do? [Removing the CUE device from your body]

Were the processes easy to do? [Charging the CUE device]

Are there any improvements you would like to see in the processes above?

How often do you charge the device?

How long has the device lasted on a charge?

Your Experience

How long have you been using CUE1?

How often did you fall on average BEFORE using CUE1?

How often did you fall on average WHILST using CUE1?

How have your symptoms improved/worsened? [Stiffness]

How have your symptoms improved/worsened? [Slowness]

How have your symptoms improved/worsened? [Tremors]

How have your symptoms improved/worsened? [Gait]

How have your symptoms improved/worsened? [Freeze of Gait]

How have your symptoms improved/worsened? [Balance]

How have your symptoms improved/worsened? [Posture]

How have your symptoms improved/worsened? [Speech]

How have your symptoms improved/worsened? [Writing/Typing]

How have your symptoms improved/worsened? [Sleep]

How have your symptoms improved/worsened? [Pain]

How have your symptoms improved/worsened? [Mood]

Please feel free to elaborate on how your symptoms improved/worsened.

Have any other symptoms improved/worsened? If so, how?



Were there any specific activities that you felt improved significantly?

Use of Resources

How many times over the year do you go to the GP? How much more/less would you need it with CUE1?

How many times over the year do you rely on nurses? How much more/less would you need them with CUE1?

How many times over the year do you rely on Parkinson's nurses? How much more/less would you need them with CUE1?

How many times over the year do you rely on health visitors? How much more/less would you need them with CUE1?

How many times over the year do you rely on social workers? How much more/less would you need them with CUE1?

How many times over the year do you rely on NHS physiotherapists? How much more/less would you need them with CUE1?

How many times over the year do you rely on occupational therapists? How much more/less would you need them with CUE1?

How many times over the year do you rely on speech therapists? How much more/less would you need them with CUE1?

How many times over the year do you visit the day hospital? How much more/less would you visit with CUE1?

How many times over the year do you visit the outpatient clinic? How much more/less would you visit with CUE1?

How many times over the year do you rely on home care? How much more/less would you need it with CUE1?

How many times over the year do you use Meals on Wheels? How much more/less would you use it with CUE1?

How many times over the year do you visit the day centre? How much more/less would you visit with CUE1?

How many times over the year do you visit the luncheon club? How much more/less would you visit with CUE1?

How many times over the year do you rely on sitting services? How much more/less would you need to with CUE1?

How many times over the year do you rely on night services? How much more/less would you need to with CUE1?

How do those resources help you? Do you feel that ... [The CUE1 has been helpful?]

Customer Service

What was your experience with us like? [Any issues were dealt with appropriately?]

What was your experience with us like? [Any issues were dealt with in a timely fashion?]

What was your experience with us like? [The online shop was easy to navigate when buying adhesives?]

Please feel free to let us know how we can improve!

New Features

Would you like the device to have a timer function (control when it turns off)?

Would you have liked an additional CUE1 device?

If yes, why?

Is the range of stimulation settings sufficient, or would you want more options? [Sufficient]

Is the range of stimulation settings sufficient, or would you want more options? [Higher strength]

Is the range of stimulation settings sufficient, or would you want more options? [Lower strength]

Is the range of stimulation settings sufficient, or would you want more options? [Higher frequency]

Is the range of stimulation settings sufficient, or would you want more options? [Lower frequency]

Would you have any final suggestions?