Home-based Brainwave Entrainment Technology (hBET) for management of chronic pain and sleep disturbance: work in progress

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Background

Chronic pain is a global health crisis and one of the greatest sources of disability. In the UK alone it is estimated to affect around 28 million individuals. It also incurs substantial healthcare costs, with back pain alone costing UK society £12 billion each year.

Two-thirds of people with chronic pain also experience sleep disturbance. There is evidence for a bidirectional relationship between the two symptoms with sleep disturbance making pain perception worse and nocturnal pain causing sleep problems. There is evidence for common neurophysiological mechanisms involved in both symptoms.

Current pharmacological treatments for are poorly efficacious and risky. A single, low-cost intervention, managed by the individual in their own home and free of side-effects, tolerance or dependence has huge potential to improve individual wellbeing and wider society.

Brainwaves are the naturally occurring oscillations of coordinated cortical electrical activity detected on EEG, and vary in frequency depending on the mental state of the individual. Brainwave entrainment is a technique of using rhythmic sensory stimuli to induce desired brainwave frequencies for benefits such as analgesia and better sleep.

The smartphone app developed by our team delivers audio or visual stimulation at desired frequencies by using headphones to listen to specific tones (binaural beats) or wearing a headset with a slot for the smartphone to display flickering lights in front of the participant's closed eyes. Previous work by our team has demonstrated that stimulation at 10Hz can successfully entrain alpha brainwave activity and significantly reduce experimental pain intensity.

We have held two PPI workshops to guide the development of the hBET app and this study protocol.

Methods

The aim of this study is to test the feasibility of using hBET for individuals with chronic pain and sleep disturbance, and inform the design of a future trial to assess whether this intervention is effective.

The objectives are to:

- Assess whether individuals can use hBET independently in their homes
- Establish feasibility and speed of recruitment and estimate withdrawal rates
- Gather feedback on study design including acceptability of outcome measures
- Estimate variance in measures of pain and sleep and possible effect size related to the intervention, to inform sample size calculation

We will recruit 30 adult participants with chronic, non-cancer pain, who have sleep difficulties. Individuals with epilepsy, photosensitivity, severe sensory problems and those unable to consent would be excluded.

Following a week-long baseline data collection period, participants will self-administer hBET every night at bedtime for 4 weeks. They will have the choice of using the audio or visual programme at a given time. They will prepare their room for sleep and lie down in a comfortable position and use the hBET programme for a recommended time of at least 20 minutes.

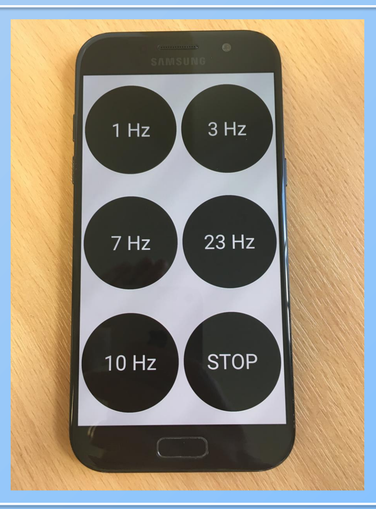

Figure 1. Smartphone app and example of headset

Participant identification

Publicity in:

- NHS clinics
- Primary care
- Support groups
- Potential participants screened

Participant recruitment

- N= 30
- Minimum 24 hours to consider
- Written consent

Initial appointment

- hBET training and setup
- Study outcomes training (actigraphy, diary)
- Baseline questionnaires

Home-based use

- 1 week baseline data
- 4 weeks use of hBET
- Weekly phone calls with researcher

Final appointment

- 1 hour interview
- Retrieve devices and forms

Figure 2. Participant flowchart

Results

The outcome measures selected to address pain, sleep, fatigue, mood and health related quality of life, and their timings are shown in Table 1.

A final in-depth interview with each participant will provide rich data on the perceived usefulness of hBET, feasibility and process issues with the trial and attitudes to pain and sleep. Qualitative data will be analysed using Template Analysis, an approach to thematic analysis involving the iterative development of a hierarchical coding template.

Data downloaded from the actigraphy watches will be summarised using the specific Actigraph software. Descriptive statistics will be used to meet the study objectives of informing the future trial. The presence and magnitude of a pre- and post-intervention difference will be examined using repeated paired sample T-tests (with Bonferroni adjustment for multiple comparisons) and the effect size will be explored using both ANOVA partial Eta squared and Cohen's d.

	Baseline		hBET use period		At completion	
	At initial appointment	Daily for 1 week prior to start	Daily for 4 weeks	Weekly for 4 weeks	After 4 week use period	At final appointment
Qualitative Interviews						X
Pain and sleep diary		X	X			
Actigraphy		X	X			
BPI	X			X	X	
PSQI	X				X	
HADS	X				X	
MFI	X				X	
EQ5D	X				X	

Table 1. Outcome measures

Discussion

This study has been assessed for HRA approval at REC 19/YH/0313.

Conclusion

This study will demonstrate the acceptability of hBET for chronic pain and sleep problems in a real world setting and provide valuable insights on feasibility to inform future RCTs.

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